CODEX, WTO-SPS, IPPC 2008년 채택기준
국제기준 협정관리 자료집

AGROS
농식품안전정보서비스

국제기준 협정관리 자료집
농림수산식품부
한국농림수산정보센터

발간등록번호
11-1541000-000088-11

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Agro-Food Safety Information Service

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## CODEX(2008)

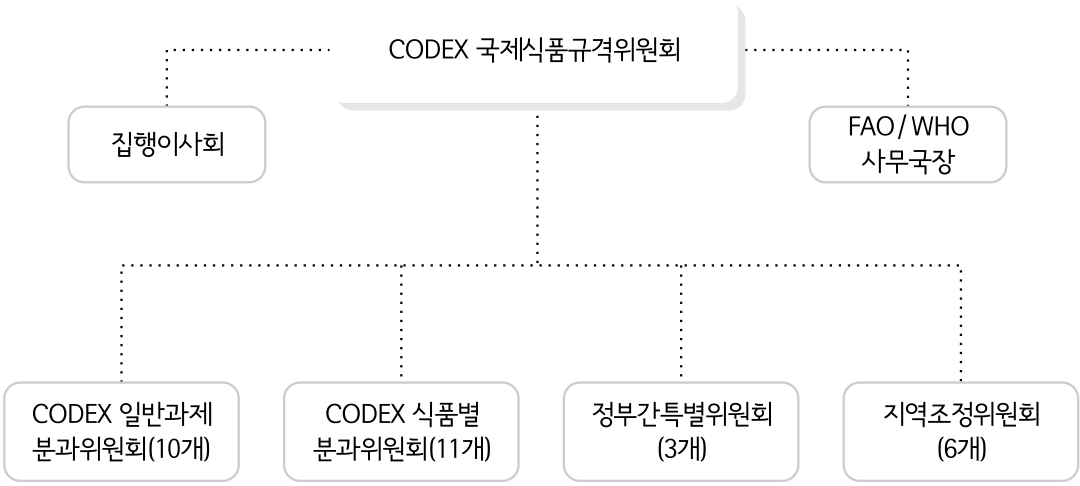
## WTO-SPS(2008)



## IPPC(2008)

# 1. CODEX

CODEX는 식품에 대해 전 세계적으로 통용될 수 있는 기준 및 규격 등을 규정한 식품법령이다. 지난 1962년 설립된 CODEX 국제식품규격위원회(Codex Alimentarius Commission)는 정부간 협의기구로 식품에 대한 규격(Standard), 지침(Guideline), 실행규범(Code of Practice) 및 최대 잔류허용기준(MRLs) 등의 설정을 통해 소비자의 건강보호와 식품 교역시 공정한 무역 행위의 확보를 목적으로 하고 있다.




현재 CODEX에 참여하고 있는 나라는 총 176개국입니다. 아시아에서는 우리나라와 북한을 포함해 총 22개 나라가 회원국으로 참여하고 있다. CODEX 조직은 크게 CODEX 위원회, 집행이사회, CODEX 하부조직(각 분과별 위원회)로 구성됩니다. CODEX 위원회는 1년 또는 2년에 한번씩 CODEX총회를 개최합니다. 집행이사회는 총회와 총회사이에 CODEX 위원회의 기본 방향과 작업계획을 제시하거나 협의하는 총회에서 인정한 사업의 집행을 담당하는 조직입니다. CODEX하부조직에는 크게 4개의 분과위원회가 있는데, CODEX 일반과제 분과위원회(10개), CODEX 식품별 분과위원회(11개), 정부간특별위원회(3개), 지역조정위원회(6개)가 활동 중에 있습니다.

## 2. WTO

GATT(General Agreement on Tariffs and Trade : 관세 및 무역에 관한 일반협정) 체제를 대신하여 세계무역질서를 세우고 UR(Uruguay Round of Multinational Trade Negotiation: 우루과이라운드) 협정의 이행을 감시하는 국제기구이다

설 립 연 도 : 1995년 1월 1일
목　　적 : 국제간 교역의 증진
주 요 활 동 : 국가간 경제분쟁에 대한 판결권과 그 판결의 강제집행권 이용, 규범에 따라 국가간 분쟁이나 마찰 조정
본부소재지 : 스위스 제네바

약칭은 WTO(World Trade Organization)이다. WTO 조직에는 총회·각료회의·무역위원회·사무국 등이 있으며 그밖에 분쟁해결기구와 무역정책검토기구가 있다. 분쟁해결기구는 법적 구속력과 감시기능을 갖추고 무역 관련 분쟁을 담당하며 무역정책검토기구는 각국 무역정책을 정기적으로 검토하여 정책을 투명하게 운영하도록 하고 사전에 분쟁을 예방하여 다자간 무역체제의 효율성을 높이는 역할을 하고 있다.

## 3. IPPC

식물병해충의 유입 및 만연의 방지를 위해 긴밀한 국제협력을 도모하기 위하여 설립된 FAO 산하기구이다. 우리나라는 1953.12.8 가입하였으며, 전체 회원국은 95개국임. 회원국의 임무는 식물병해충의 유입 및 만연의 방지를 위하여 협약에 규정된 입법, 기술 및 행정적 의무수행이며, 협약의 적용범위는 국제무역과 관련되는 검역대상병해충(Quarantine pest)에 주로 적용되고 있다.

세계 각국은 식물에 대한 검역과 식물위생증명서 발급을 담당하는 국립식물검역기관을 설치하여야 하며, 식물병해충의 유입방지를 위해 특정식물의 수입을 금지 또는 제한할 권한을 보유하며, 수입관련 검역법규의 제정 또는 개정시 FAO와 관련국가에 그 내용을 통보하고, 본 협약의 해석 또는 적용상 분쟁이 발생할 경우 FAO 사무총장에게 위원회 구성을 요청하여 해결하는 절차를 거쳐야 한다.

CODEX, WTO-SPS, IPPC 2008년 채택기준

국제기준 협정관리 자료집

# CODEX(2008)

농림수산식품부

한국농림수산정보센터

# CODEX STANDARD FOR TOMATOES
# (CODEX STAN 293-2008)

## 1. DEFINITION OF PRODUCE

This Standard applies to commercial varieties of tomatoes grown from *Lycopersicon esculentum* Mill, of the *Solanaceae* family, to be supplied fresh to the consumer, after preparation and packaging. Tomatoes for industrial processing are excluded.

Tomatoes may be classified into four commercial types :

- "Round" ;
- "Ribbed" ;
- "Oblong" or "Elongated" ;
- "Cherry" tomatoes and "Cocktail" tomatoes.

## 2. PROVISIONS CONCERNING QUALITY

### 2.1 MINIMUM REQUIREMENTS

In all classes, subject to the special provisions for each class and the tolerances allowed, the tomatoes must be :

- whole ;
- sound, produce affected by rotting or deterioration such as to make it unfit for consumption is excluded ;
- clean, practically free of any visible foreign matter;
- practically free of pests and damage caused by them affecting the general appearance of the produce ;
- free of abnormal external moisture, excluding condensation following removal from cold storage ;
- free of any foreign smell and/or taste.
- fresh in appearance.

In the case of trusses of tomatoes, the stalks must be fresh, healthy, clean and free of all leaves and any visible foreign matter.

#### 2.1.1 The development and condition of the tomatoes must be such as to enable them :

- to withstand transport and handling ; and
- to arrive in satisfactory condition at place of destination.

#### 2.1.2 Maturity Requirements

The tomatoes must be sufficiently developed and display satisfactory ripeness.

The development and state of maturity of the tomatoes must be such as to enable them to continue their ripening process and to reach the appropriate degree of ripeness.

### 2.2 CLASSIFICATION

Tomatoes are classified in three classes defined below :

#### 2.2.1 "Extra" Class

Tomatoes in this class must be of superior quality. They must have firm flesh and must be characteristic of the variety as regards shape, appearance and development.

They must be uniform in terms of size. Their colouring, according to their state of ripeness, must be such as to satisfy the requirements set out in Section 2.1.1 above.

They must be free of greenbacks and other defects, with the exception of very slight superficial defects, provided these do not affect the general appearance of the produce, the quality, the keeping quality and presentation in the package.

2.2.2 Class I

Tomatoes in this class must be of good quality. They must have reasonably firm flesh and must be characteristic of the variety as regards shape, appearance and development.

They must be uniform in terms of size. They must be free of cracks and visible greenback.

The following slight defects, however, may be allowed, provided these do not affect the general appearance of the produce, the quality, the keeping quality and presentation in the package :

- a slight defect in shape and development ;
- a slight defect in colouring ;
- slight skin defects ;
- very slight bruises.

Furthermore, "ribbed" tomatoes may show :

- shallow healed cracks not more than 1 cm long ;
- no excessive protuberances ;
- small umbilicus but not suberization ;
- suberization of the stigma up to 1 cm2
- a linear scar no longer than two thirds of the greatest diameter of the fruit.

2.2.3 Class ii

This class includes tomatoes which do not qualify for inclusion in the higher classes, but satisfy the minimum requirements specified in Section 2.1 above.

They must have reasonably firm flesh (but may be slightly less firm than in Class i ) and must not show unhealed cracks.

The following defects, however, may be allowed, provided the tomatoes retain their essential characteristics as regards the quality, the keeping quality and presentation :

- defects in shape, development and colouring;
- skin defects or bruises, provided the fruit is not seriously affected ;
- shallow healed cracks not more than 3 cm in length for round, ribbed or oblong tomatoes.

Furthermore, "ribbed" tomatoes may show :

- more pronounced protuberances than allowed under Class I, but without being misshapen ;
- one umbilicus ;
- suberization of the stigma up to 2 cm2
- fine blossom scar in elongated form (like a seam).

## 3. PROVISIONS CONCERNING SIZING

When sized by diameter, size is determined by the maximum diameter of the equatorial section.

Sizing does not apply to trusses of tomatoes.

Sizing is not compulsory for Class ii .

Tomatoes are sized with one of the following options :

(a) Tomatoes may be sized according to the following table :

| Size code | Diameter (mm) |
|---|---|
| 0 | 0 ≤ 20 |
| 1 | 1 〉 20 ≤ 25 |
| 2 | 2 〉 25 ≤ 30 |
| 3 | 3 〉 30 ≤ 35 |
| 4 | 4 〉 35 ≤ 40 |
| 5 | 5 〉 40 ≤ 47 |
| 6 | 6 〉 47 ≤ 57 |
| 7 | 7 〉 57 ≤ 67 |
| 8 | 8 〉 67 ≤ 82 |
| 9 | 9 〉 82 ≤ 102 |
| 10 | 10 〉 102 |

**or**

(b) Tomatoes may be sized according to the following uniformity provision :

The maximum difference in diameter between tomatoes in the same package shall be limited to :

- 10 mm, if the diameter of the smallest fruit (as indicated on the package) is under 50 mm,
- 15 mm, if the diameter of the smallest fruit (as indicated on the package) is 50 mm and over but under 70 mm,
- 20 mm, if the diameter of the smallest fruit (as indicated on the package) is 70 mm and over but under 100 mm,
- There is no limitation of difference in diameter for fruit equal or over 100 mm.

**or**

(c) Tomatoes may be sized by count, diameter or weight, according to the provisions of the legislation of the importing country.

## 4. PROVISIONS CONCERNING TOLERANCES

Tolerances in respect of quality and size shall be allowed in each package for produce not satisfying the requirements of the class indicated.

### 4.1 QUALITY TOLERANCES

#### 4.1.1 "xtra" Class

Five percent by number or weight of tomatoes not satisfying the requirements of the class, but meeting those of Class I or, exceptionally, coming within the tolerances of that class.

#### 4.1.2 Class I

Ten percent by number or weight of tomatoes not satisfying the requirements of the class, but meeting those of Class ii or, exceptionally, coming within the tolerances of that class.

In the case of trusses of tomatoes, 5% by number or weight of tomatoes detached from the stalk.

4.1.3 Class ii

Ten percent by number or weight of tomatoes satisfying neither the requirements of the class nor the minimum requirements, with the exception of produce affected by rotting, marked bruising or any other deterioration rendering it unfit for consumption.

In the case of trusses of tomatoes, 10% by number or weight of tomatoes detached from the stalk.

4.2 SIZE TOLERANCES

For all classes, 10 % by number or weight of tomatoes not satisfying the requirements as regards sizing but have a diameter greater or less than 10 mm of the size marked.

## 5. PROVISIONS CONCERNING PRESENTATION

5.1 UNIFORMITY

The contents of each package must be uniform and contain only tomatoes of the same origin, variety or commercial type, quality and size (if sized).

The ripeness and colouring of tomatoes in "Extra" Class and Class I must be practically uniform. In addition, the length of "oblong" tomatoes must be sufficiently uniform.

The visible part of the contents of the package must be representative of the entire contents.

5.2 PACKAGING

Tomatoes must be packed in such a way as to protect the produce properly. The materials used inside the package must be new[1], clean, and of a quality such as to avoid causing any external or internal damage to the produce. The use of materials, particularly of paper or stamps bearing trade specifications is allowed, provided the printing or labelling has been done with non-toxic ink or glue.

Tomatoes shall be packed in each container in compliance with the Recommended International Code of Practice for Packaging and Transport of Fresh Fruit and Vegetables (CAC/RCP 44-1995).

5.2.1 Description of Containers

The containers shall meet the quality, hygiene, ventilation and resistance characteristics to ensure suitable handling, shipping and preserving of the tomatoes. Packages must be free of all foreign matter and smell.

5.3 PRESENTATION

The tomatoes may be presented as follows:

(i) as individual tomatoes, with or without calyx and short stalk;

(ii) as trusses of tomatoes, in other words, in entire inflorescence or part of inflorescence, where each inflorescence or part of each inflorescence should comprise at least the following number of tomatoes.

- 3 (2 if prepackaged) or
- in the case of trusses of "cherry" tomatoes, 6 (4 if prepackaged).

## 6. MARKING OR LABELLING

6.1 CONSUMER PACKAGES

In addition to the requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), the following specific provisions apply:

1 For the purposes of this Standard, this includes recycled material of food-grade quality.

6.1.1 Nature of Produce

If the produce is not visible from the outside, each package shall be labelled as to the name of the produce and may be labelled as to the name of the variety and/or commercial type.

6.2 NON-RETAIL CONTAINERS

Each package must bear the following particulars, in letters grouped on the same side, legibly and indelibly marked, and visible from the outside, or in the documents accompanying the shipment.

6.2.1 Identification

Name and address of exporter, packer and/or dispatcher. Identification code (optional)[2].

6.2.2 Nature of Produce

- Name of the produce "tomatoes" or "trusses of tomatoes" and the commercial type if the contents are not visible from the outside. These details must always be provided for "cherry" and "cocktail" tomatoes, whether in trusses or not ;
- Name of the variety (optional).

6.2.3 Origin of Produce

Country of origin and, optionally, district where grown, or national, regional or local place name.

6.2.4 Commercial Identification

- Class ;
- Size expressed as minimum and maximum diameters (if sized).

6.2.5 Official Inspection Mark (optional)

## 7. CONTAMINANTS

7.1 PESTICIDE RESIDUES

Tomatoes shall comply with those maximum pesticide residue limits established by Codex Alimentarius Commission for this commodity.

7.2 OTHER CONTAMINANTS

Tomatoes shall comply with those maximum levels for contaminants established by the Codex Alimentarius Commission for this commodity.

## 8. HYGIENE

8.1 It is recommended that the produce covered by the provisions of this Standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969), Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

8.2 The produce should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

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2 The national legislation of a number of countries requires the explicit declaration of the name and address. However, in the case where a code mark is used, the reference "packer and/or dispatcher (or equivalent abbreviations)" has to be indicated in close connection with the code mark.

# CODEX STANDARD FOR CHEDDAR

## 1. SCOPE

This Standard applies to Cheddar intended for direct consumption or for further processing in conformity with the description in Section 2 of this Standard.

## 2. DESCRIPTION

Cheddar is a ripened hard cheese in conformity with the General Standard for Cheese (CODEX STAN 283-1978). The body has a near white or ivory through to light yellow or orange colour and a firm-textured (when pressed by thumb), smooth and waxy texture. Gas holes are absent, but a few openings and splits are acceptable. The cheese is manufactured and sold with or without[1] rind which may be coated.

For Cheddar ready for consumption, the ripening procedure to develop flavour and body characteristics is normally from 5 weeks at 7–15 ℃ depending on the extent of maturity required. Alternative ripening conditions (including the addition of ripening enhancing enzymes) may be used, provided the cheese exhibits similar physical, biochemical and sensory properties as those achieved by the previously stated ripening procedure. Cheddar intended for further processing need not exhibit the same extent of ripening when justified through technical and/or trade needs.

## 3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

### 3.1 Raw materials

Cows' milk or buffaloes' milk, or their mixtures, and products obtained from these milks.

### 3.2 Permitted ingredients

- Starter cultures of harmless lactic acid and / or flavour producing bacteria and cultures of other harmless microorganisms ;
- Rennet or other safe and suitable coagulating enzymes ;
- Sodium chloride and potassium chloride as a salt substitute ;
- Potable water ;
- Safe and suitable enzymes to enhance the ripening process ;
- Safe and suitable processing aids ;
- Rice, corn and potato flours and starches: Notwithstanding the provisions in the General Standard for Cheese (CODEX STAN 283-1978), these substances can be used in the same function as anti-caking agents for treatment of the surface of cut, sliced, and shredded products only, provided they are added only in amounts functionally necessary as governed by Good Manufacturing Practice, taking into account any use of the anti-caking agents listed in section 4.

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1 This is not to mean that the rind has been removed before sale, instead the cheese has been ripened and/or kept in such a way that no rind is developed(a "rindless" cheese). Ripening film is used in the manufacture of rindless cheese. Ripening film may also constitute the coating that protects the cheese. For rindless cheese see also the Appendix to the Codex General Standard for Cheese (CODEX STAN 283-1978).

3.3 Composition

| Milk constituent | Minimum content *(m/m)* | Maximum content *(m/m)* | Reference level *(m/m)* |
|---|---|---|---|
| Milkfat in dry matter : | 22% | Not restricted | 48% to 60% |
| Dry matter : | Depending on the fat in dry matter content, according to the table below. | | |
| | Fat in dry matter content (m/m) : | | Corresponding minimum dry matter content (m/m) : |
| | Equal to or above 22% but less than 30% : | | 49% |
| | Equal to or above 30% but less than 40% : | | 53% |
| | Equal to or above 40% but less than 48% : | | 57% |
| | Equal to or above 48% but less than 60% : | | 61% |
| | Equal to or above 60% : | | 66% |

Compositional modifications beyond the minima and maxima specified above for milkfat and dry matter are not considered to be in compliance with section 4.3.3 of the *Codex General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999).

## 4. FOOD ADDITIVES

Only those additives classes indicated as justified in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those food additives listed below may be used and only within the functions and limits specified.

| Additive functional class : | Justified use | |
|---|---|---|
| | Cheese mass | Surface/rind treatment |
| Colours : | X[1] | – |
| Bleaching agents : | – | – |
| Acids : | – | – |
| Acidity regulators : | X | – |
| Stabilizers : | – | – |
| Thickeners : | – | – |
| Emulsifiers : | – | – |
| Antioxidants : | – | – |
| Preservatives : | X | X |
| Foaming agents : | – | – |
| Anti-caking agents : | – | X[2] |

[1] Only to obtain the colour characteristics, as described in Section 2.

[2] For the surface of sliced, cut, shredded or grated cheese, only.

X = The use of additives belonging to the class is technologically justified.

– = The use of additives belonging to the class is not technologically justified.

| INS no. | Name of additive | Maximum level |
|---|---|---|
| Colours | | |
| 101( i ) | Riboflavin | 300 mg/kg |
| 140 | Chlorophyll | Limited by GMP |
| 160a( i ) | beta-Carotene (synthetic) | 35 mg/kg<br>Singly or in combination |
| 160a(iii) | beta-Carotene (Blakeslea trispora) | |
| 160e | beta-apo-8'-Carotenal | |
| 160f | beta-apo-8'-Carotenoic acid, methyl or ethyl ester | |
| 160a( ii ) | beta-Carotenes, vegetable | 600 mg/kg |
| 160b( ii ) | Annatto extracts –- norbixin-based | 25 mg/kg |
| Preservatives | | |
| 1105 | Lysozyme | Limited by GMP |
| 200 | Sorbic acid | 1 000 mg/kg based on sorbic acid.<br>Surface Treatment only * |
| 201 | Sodium sorbate | |
| 202 | Potassium sorbate | |
| 203 | Calcium sorbate | |
| 234 | Nisin | 12.5 mg/kg |
| 235 | Pimaricin (Natamycin) | 2 mg/dm2 Not present at a depth of 5 mm. Surface Treatment only * |
| 251 | Sodium nitrate | 37 mg/kg<br>Singly or in combination (expressed as nitrate ion) |
| 252 | Potassium nitrate | |
| 280 | Propionic acid | 3 000 mg/kg<br>Surface Treatment only * |
| 281 | Sodium propionate | |
| 282 | Potassium propionate | |
| Acidity regulators | | |
| 170( i ) | Calcium carbonate | Limited by GMP |
| 504 ( i ) | Magnesium carbonate | Limited by GMP |
| 575 | Glucono delta-lactone | Limited by GMP |
| Anticaking agents | | |
| 460( i ) | Microcrystalline cellulose | Limited by GMP |
| 460( ii ) | Powdered cellulose | Limited by GMP |
| 551 | Silicon dioxide, amorphous | 10 000 mg/kg<br>Singly or in combination<br>Silicates calculated as silicon dioxide |
| 552 | Calcium silicate | |
| 553( i ) | Magnesium silicate | |
| 553(iii) | Talc | |
| 554 | Sodium aluminosilicate | |
| 556 | Calcium aluminium silicate | |
| 559 | Aluminium silicate | |

* For the definition of cheese surface and rind see Appendix to the *Codex General Standard for Cheese* (Codex STAN 283-1978)

## 5. CONTAMINANTS

The products covered by this Standard shall comply with the Maximum Levels of the *Codex General Standard for Contaminants and Toxins in Foods* (CODEX STAN 193-1995) and the maximum residue limits for pesticides and veterinary drugs established by the CAC.

## 6. HYGIENE

It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969), the *Code of Hygienic Practice Milk and Milk Products* (CAC/RCP 57-2004) and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice. The products should comply with any microbiological criteria established in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

## 7. LABELLING

In addition to the provisions of the *Codex General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) and the *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999), the following specific provisions apply:

### 7.1 Name of the food

The name Cheddar may be applied in accordance with section 4.1 of the *Codex General Standard for the Labelling of Prepackaged Foods*, provided that the product is in conformity with this Standard. Where customary in the country of retail sale, alternative spelling may be used.

The use of the name is an option that may be chosen only if the cheese complies with this standard. Where the name is not used for a cheese that complies with this standard, the naming provisions of the *General Standard for Cheese* (CODEX STAN 283-1978) apply.

The designation of products in which the fat content is below or above the reference range but above the absolute minimum specified in section 3.3 of this Standard shall be accompanied by an appropriate qualification describing the modification made or the fat content (expressed as fat in dry matter or as percentage by mass, which ever is acceptable in the country of retail sale), either as part of the name or in a prominent position in the same field of vision. Suitable qualifiers are the appropriate characterizing terms specified in Section 7.2 of the *General Standard for Cheese* (CODEX STAN 283-1978) or a nutritional claim in accordance with the *Guidelines for the Use of Nutritional Claims* (CAC/GL 23-1997)[2].

The designation may also be used for cut, sliced, shredded or grated products made from cheese which cheese is in conformity with this Standard.

### 7.2 Country of origin

The country of origin (which means the country of manufacture, not the country in which the name originated) shall be declared. When the product undergoes substantial transformation[3] in a second country, the country in which the transformation is performed shall be considered to be the country of origin for the purpose of labelling.

### 7.3 Declaration of milkfat content

The milk fat content shall be declared in a manner found acceptable in the country of retail sale either (i) as a percentage by mass, (ii) as a percentage of fat in dry matter, or (iii) in grams per serving as quantified in the label, provided that the number of servings is stated.

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2 For the purpose of comparative nutritional claims, the minimum fat content of 48% fat in dry matter constitutes the reference.

3 For instance, repackaging, cutting, slicing, shredding and grating is not regarded as substantial transformation.

7.4 Date marking

Notwithstanding the provisions of Section 4.7.1 of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985), the date of manufacture may be declared instead of the minimum durability information, provided that the product is not intended to be purchased as such by the final consumer.

7.5 Labelling of non-retail containers

Information specified in Section 7 of this Standard and Sections 4.1 to 4.8 of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) and, if necessary, storage instructions, shall be given either on the container or in accompanying documents, except that the name of the product, lot identification, and the name of the manufacturer or packer shall appear on the container, and in the absence of such a container, on the product itself. However, lot identification and the name and address may be replaced by an identification mark, provided that such mark is clearly identifiable with the accompanying documents.

## 8. METHODS OF SAMPLING AND ANALYSIS

**See CODEX STAN 234-1999.**

## APPENDIXAPPENDIX

Information on usual patterns of manufacturing Cheddar

The information below is intended for voluntary application by commercial partners and not for application by governments.

### 1. Method of manufacture

1.1 Starter cultures consist of non-gas forming lactic acid producing bacteria.

1.2 After coagulation, the curd is cut and heated in its whey to a temperature above the coagulation temperature. The curd is separated from the whey and stirred or cheddared. In traditional manufacture the curd is cut into blocks which are turned and progressively piled, keeping the curd warm, which results in the curd becoming compressed, smooth and elastic. After cheddaring the curd is milled. When the desired acidity is reached the curd is salted. The curd and salt are then mixed and moulded. Other processing techniques, which give end products with the same physical, chemical and organoleptic characteristics may be applied.

# CODEX STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN CODEX STAN 110-1979

## 1. SCOPE

1.1 This standard applies to foods for special dietary uses that have been formulated, processed or prepared to meet the special dietary needs of people intolerant to gluten.

1.2 Foods for general consumption which by their nature are suitable for use by people with gluten intolerance may indicate such suitability in accordance with the provisions of Section 4.3.

## 2. DESCRIPTION

### 2.1 Definitions

The products covered by this standard are described as follows:

#### 2.1.1 Gluten-free foods

Gluten-free foods are dietary foods

(a) consisting of or made only from one or more ingredients which do not contain wheat (i.e., all *Triticum* species, such as durum wheat, spelt, and kamut), rye, barley, oats1 or their crossbred varieties, and the gluten level does not exceed 20 mg/kg in total, based on the food as sold or distributed to the consumer, and/or

(b) consisting of one or more ingredients from wheat (i.e., all *Triticum* species, such as durum wheat, spelt, and kamut), rye, barley, oats[1] or their crossbred varieties, which have been specially processed to remove gluten, and the gluten level does not exceed 20 mg/kg in total, based on the food as sold or distributed to the consumer.

#### 2.1.2 Foods specially processed to reduce gluten content to a level above 20 up to 100 mg/kg

These foods consist of one or more ingredients from wheat (i.e., all *Triticum* species, such as durum wheat, spelt, and kamut), rye, barley, oats1 or their crossbred varieties, which have been specially processed to reduce the gluten content to a level above 20 up to 100 mg/kg in total, based on the food as sold or distributed to the consumer.

Decisions on the marketing of products described in this section may be determined at the national level.

### 2.2 Subsidiary Definitions

#### 2.2.1 Gluten

For the purpose of this standard, "gluten" is defined as a protein fraction from wheat, rye, barley, oats1 or their crossbred varieties and derivatives thereof, to which some persons are intolerant and that is insoluble in water and 0.5M NaCl.

#### 2.2.2 Prolamins

Prolamins are defined as the fraction from gluten that can be extracted by 40-70% of ethanol. The prolamin from wheat is gliadin, from rye is secalin, from barley hordein and from oats[1] avenin.

It is however an established custom to speak of gluten sensitivity. The prolamin content of gluten

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1 Oats can be tolerated by most but not all people who are intolerant to gluten. Therefore, the allowance of oats that are not contaminated with wheat, rye or barley in foods covered by this standard may be determined at the national level.

is generally taken as 50%.

## 3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 For products referred to in 2.1.1 (a) and (b), the gluten content shall not exceed 20 mg/kg in the food as sold or distributed to the consumer.

3.2 For products referred to in 2.1.2 the gluten content shall not exceed 100 mg/kg in the food as sold or distributed to the consumer.

3.3. Products covered by this standard substituting important basic foods, should supply approximately the same amount of vitamins and minerals as the original foods they replace.

3.4 The products covered by this standard shall be prepared with special care under Good Manufacturing Practice (GMP) to avoid contamination with gluten.

## 4. LABELLING

In addition to the general labelling provisions contained in the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) and the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985), and any specific labelling provisions set out in a Codex standard applying to the particular food concerned, the following provisions for the labelling of "gluten-free foods" shall apply:

4.1 The term "gluten-free" shall be printed in the immediate proximity of the name of the product in the case of products described in section 2.1.1.

4.2 The labelling of products described in section 2.1.2 should be determined at the national level. However these products must not be called gluten-free. The labelling terms for such products should indicate the true nature of the food, and shall be printed in the immediate proximity of the name of the product.

4.3 A food which, by its nature, is suitable for use as part of a gluten-free diet, shall not be designated "special dietary", "special dietetic" or any other equivalent term. However, such a food may bear a statement on the label that "this food is by its nature gluten-free" provided that it complies with the essential composition provisions for gluten-free as set out in section 3.1 and provided that such a statement does not mislead the consumer. More detailed rules in order to ensure that the consumer is not misled may be determined at the national level.

## 5. METHODS OF ANALYSIS AND SAMPLING

### 5.1 General outline of the methods

- The quantitative determination of gluten in foods and ingredients shall be based on an immunologic method or other method providing at least equal sensitivity and specificity.
- The antibody used should react with the cereal protein fractions that are toxic for persons intolerant to gluten and should not cross-react with other cereal proteins or other constituents of the foods or ingredients.
- Methods used for determination should be validated and calibrated against a certified reference material, if available.
- The detection limit has to be appropriate according to the state of the art and the technical standard. It should be 10 mg gluten/kg or below.
- The qualitative analysis that indicates the presence of gluten shall be based on relevant methods (e.g. ELISA-based methods, DNA methods).

### 5.2 Method for determination of gluten

Enzyme-linked Immunoassay (ELISA) R5 Mendez Method.

# PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF FOOD SAFETY CONTROL MEASURES CAC/GL 69 - 2008

## 1. INTRODUCTION

The control of hazards potentially associated with foods typically involves the application of control measures in the food chain, from primary production, through processing, to consumption. In the current environment of systems-based food safety controls that provide flexibility with the selection of control measures, validation of these control measures acquires increased importance. It is through the validation process that one demonstrates that the selected control measures are actually capable, on a consistent basis, of achieving the intended level of hazard control.

It is important to make a clear distinction between the role of industry[1] and the role of the competent authority in validating control measures. Industry is responsible for validation of control measures, while the competent authority ensures that industry has effective systems for validation and that control measures are appropriately validated. Governments may provide guidance to industry on how to conduct validation studies and how validated control measures may be implemented. Governments or international organizations may also conduct validation studies in support of risk management decisions or provide information on control measures considered to be validated, especially where the resources are not available to conduct such studies (e.g. small and less-developed businesses).

These guidelines present information on the concept and nature of validation, tasks prior to validation, the validation process, and the need for re-validation. These guidelines also address the difference between validation, monitoring and verification. Annex I provides examples of validation scenarios which are for purpose of illustration only and which do not represent actual validation of control measures and which do not have global application.

## 2. SCOPE

These guidelines apply to validation of control measures at any stage of the food chain[2]. These guidelines are intended as guidance to industry and governments on the validation of individual control measures, a limited combination of control measures, or sets of control measure combinations forming a food safety control system (e.g. HACCP, GHP).

The tools, techniques, and statistical principles that would be used to validate specific food safety control measures are beyond the scope of the current document. Advice on specific applications should be acquired from scientific organizations, competent authorities, process control experts or related sources of scientific expertise that can provide the specific principles and best practices upon which the validation of a specific control measure should be based.

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1 For the purposes of this document, it is understood that industry includes all relevant sectors associated with the production, storage and handling of food, from primary production through retail and food service level (adapted from *Working Principles for Risk Analysis for Application in the Framework of Codex Alimentarius* and taken from *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007).

2 The focus of this document is the validation of elements of a food safety control system; however, the recommendations in this document also may be applied in the validation of other food hygiene measures.

## 3. DEFINITIONS[3]

Control Measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.[4]

Food Safety Control System : The combination of control measures that, when taken as whole, ensures that food is safe for its intended use.

Monitoring : The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.[5]

Validation : Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.[6]

Verification : The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.[7]

## 4. CONCEPT AND NATURE OF VALIDATION

Validation focuses on the collection and evaluation of scientific, technical and observational information to determine whether control measures are capable of achieving their specified purpose in terms of hazard control. Validation involves measuring performance against a desired food safety outcome or target, in respect of a required level of hazard control.[8]

Validation is performed at the time a control measure or a food safety control system is designed, or when changes indicate the need for re-validation (see section 7). Validation of control measures is, whenever possible, performed before their full implementation.

### Interrelationships among Validation, Monitoring and Verification

There is often confusion among the concepts of validation, monitoring and verification. Validation of control measures as described in this document is different from monitoring and verification, which both take place after the validated control measures have been implemented. Monitoring and verification are the tools used to check whether the control measures are being adhered to and to demonstrate that they are operating as intended.

- Monitoring of control measures is the on-going collection of information at the step the control measure is applied. The information establishes that the measure is functioning as intended, i.e., within established limits. Monitoring activities are typically focused on "real-time" measurements and on the performance of a specific control measure.
- Verification is an ongoing activity used to determine that the control measures have been implemented as intended. Verification occurs during or after operation of a control measure through a variety of activities, including observation of monitoring activities and review of records to confirm that implementation of control measures is according to design.

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3 In many cases, existing definitions such as those contained in the SPS Agreement, the General Principles of Food Hygiene, HACCP Annex and the CCFH Risk Management document, were suitable for use in this document. In other cases, where a definition was too limiting outside of its original context (e.g. some HACCP Annex definitions), another definition was developed that was more suitable for use within the context of these guidelines.

4 International Recommended Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969), HACCP Annex.

5 Derived from *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969), HACCP Annex, but was modified to apply to all control measures, whether or not a HACCP system is employed.

6 Ibid.

7 Ibid.

8 See *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007) and *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

The following example for uncooked fermented sausages illustrates the interrelationship of validation, verification and monitoring :

- Validation : The competent authority established the need for control measure(s) that achieve a specified log reduction in pathogenic *Escherichia coli.* The validation process indicated that industry could consistently achieve a specified log reduction through ensuring a specific decrease in pH during fermentation and a specific decrease in water activity during maturation, coupled with ensuring that the raw materials have less than a specified level of pathogenic *E. coli* based on statistically-based microbiological testing.
- Monitoring : Measuring pH drop during fermentation and weight loss (or water activity) during maturation.
- Verification : Periodic process control testing for pathogenic *E. coli* to verify that incoming levels in the raw materials are within specification and that fermentation and maturation achieve the intended outcome in the semi-finished or finished product. Examination of monitoring records to check for continuous control over time.

## 5. TASKS PRIOR TO VALIDATION OF CONTROL MEASURES

Prior to the validation of control measures by the food establishment, it is important to complete certain tasks so that validation can be accomplished effectively and efficiently. The following tasks could be carried out either independently or in conjunction with the establishment of GHPs, HACCP, etc.

Tasks prior to validation include :

(a) Identify the hazards that are intended to be controlled in the commodity and/or environment concerned, taking into account all relevant information, including information from a risk assessment if available.

(b) Identify the food safety outcome required.

The food safety outcome can be determined in a number of ways. Industry should determine if there are existing food safety outcomes or targets, established by the competent authority, relevant to the intended use of the food. In the absence of food safety outcomes or targets established by the competent authority, targets should be identified by industry, as appropriate. Industry may also set stricter targets than those set by the competent authority.

(c) Identify the measures that are to be validated, taking into account :

- The importance of the control measure in achieving control of the hazard to a specified outcome. Examples might include :
  - ○ Heat treatment step in a canning process
  - ○ Cooling to a specified temperature within a specific timeframe
- Whether the control measure has already been validated

Identify whether the control measure has previously been validated in a way that is applicable and appropriate to the food business (e.g. a control measure required by a competent authority or validated by a competent authority or other national or international organization) or whether its performance is so well established for the application under consideration that further validation is not necessary. In either case, a food business operator must ensure that the conditions (e.g. raw materials, relevant hazards, combinations of control measures, intended use, and distribution and consumption patterns) in their particular operation do not differ from the conditions under which the control measure was previously validated.

- Priority of validation

Considering that food safety outcomes are often dependent on multiple control measures, prioritization of validation activities may be necessary and may take into account :

- Adverse health effect : The higher the potential for an adverse health effect from a hazard, the more attention should be paid to assuring that the set of control measures selected is effective. Consideration should be given to the size of the population and the age/sex of groups most at risk.
- Historical experience : For many food production and processing scenarios, there is extensive history that specific measures used to control food borne hazards are effective. If little or no experience exists with respect to the performance of a control measure in controlling a particular hazard within a specified context, it becomes more important that validation be undertaken.

  In certain instances, these historical data may obviate the need to conduct validations. However, it is important to avoid assuming that a food production or processing system is safe based solely on historical experience. All relevant current information should be considered when evaluating the adequacy of historical information, as it may be outdated. For example, sampling and testing procedures used to obtain the original data may be insufficient in the context of current operating procedures. New strains of microbial pathogens may now exist that do not behave in the same manner as the strains of pathogens or surrogate microorganisms used for determining early food control processes. New epidemiological and/or clinical information may indicate that the control measures used in the past were less effective than previously thought.
- Other factors/constraints

  ■ Ability to monitor and verify the control measure

  - In prioritizing control measures for validation, consideration should be given to the amenability of the control measure to monitoring and/or verification after implementation.
  - Control measures that are of such a nature that it is not feasible to determine their quantitative effect on specific hazards may not always be considered priority for validation. Examples of such control measures include air locks to minimize cross contamination, hand washing procedures, and several other basic hygiene practices described in the International Recommended Code of Practice : General Principles of Food Hygiene (CAC/RCP 1-1969).

  ■ Scientific and technical feasibility

  - In prioritizing control measures for validation, consideration should be given to any scientific and/or technical challenges to validating the measure. This would include consideration of the variability associated with the control measure being validated, the food being considered, and the hazards being controlled.

  ■ Resource

  - Validation activities may be resource intensive. Particular validation activities, such as experimental trials, process capability studies, surveys, mathematical modelling, product or environmental sampling and analytical testing, particularly when applied in an appropriate statistical fashion, require significant resources. The extent to which sufficient resources are available and such activities can be undertaken will place limits on the ability to develop and validate food safety control measures. Necessary assistance (e.g. development of guidelines for industry, training and technical assistance), particularly to small and less-developed businesses, provided by national and international organizations could help to perform validation of food safety control measures.

## 6. THE VALIDATION PROCESS

A range of approaches to validation are available. The precise approach will depend, among other things, on the nature of the hazard, the nature of the raw ingredients and product, the type of control measures or food safety control system selected to control the hazard, and the intended stringency of control of the hazard.

### Approaches for validating control measures

The following approaches to validation may be used individually or in combination, as appropriate. These are presented in no particular order.

- **Reference to scientific or technical literature, previous validation studies or historical knowledge of the performance of the control measure.** Scientific or technical information needed to validate control measures may, in many instances, be available from many sources. These include scientific literature, government guidance, guidelines on GHP and HACCP control measures with a known history of good performance validated by competent authorities or independent scientific authorities, international standards or guidelines (e.g. Codex Alimentarius), and validation studies from industry and/or equipment manufacturers. However, if relying on such knowledge, care should be taken to ensure that the conditions of application in a food safety control system are consistent with those identified in the scientific information examined. For certain well-established processes (e.g. time and temperature combinations for milk pasteurization), it may be sufficient to acquire only the data on the conditions or attributes specific for the operation in question.

- Scientifically valid experimental data that demonstrate the adequacy of the control measure. Laboratory challenge testing designed to mimic process conditions and industrial or pilot plant trials of particular aspects of a food processing system are validation techniques that are used commonly, particularly in food processing unit operations. Quantitative demonstration and documentation of appropriate log reduction of a specified pathogen by a specific microbiocidal process is an example of validation of a control measure by experimental trials. If the risk from a hazard is associated with growth of the pathogen to unacceptable numbers, then the conditions (e.g. product formulation, processing parameters, packaging or conditions of storage and distribution) that prevent the growth of the pathogen may need to be validated and documented using appropriately designed experimental trials. For example, if water activity must be controlled in a product to prevent growth of *Staphylococcus aureus*, then validation can be achieved by demonstrating that the water activity of the product under expected conditions of storage and distribution will be equal to or less than the specified water activity.

  Scale up of laboratory-based experimental trials in a pilot plant is helpful in ensuring that the trials properly reflect actual processing parameters and conditions. However, this almost always requires the availability of appropriate non-pathogenic surrogate microorganisms, as viable pathogenic microorganisms should not be purposefully introduced into a food production facility. When surrogate microorganisms are used, validation should cover the appropriateness of the surrogates. Validation may have to be limited to a laboratory/pilot plant if there are no appropriate surrogate microorganisms available that can be used to acquire data under actual production conditions.

  Additional safety margins may be required to account for the uncertainty or variability of the control measure or combination of control measures in achieving the desired level of control when implemented in a full scale operation.

- **Collection of data during operating conditions in the whole food operation.** When this approach is used, biological, chemical or physical data relating to the hazards of concern are collected for a specified period (e.g. 3-6 weeks of full scale production) during operating conditions representative of the whole food operation, including periods where production is increased, e.g. holiday rush. For example, when the food safety control system is contingent upon the use of good veterinary or agricultural practices in the field or good hygienic practices in the processing establishment, it may be necessary to validate these measures through the use of intermediate/finished product

and/or environmental sampling and testing. Sampling should be based on the use of appropriate sampling techniques, sampling plans and testing methodology. Data collected should be sufficient for the statistical analyses required.

- **Mathematical modelling.** Mathematical modelling is a means of mathematically integrating scientific data on how factors affecting the performance of a control measure or combination of control measures affect their ability to achieve the intended food safety outcome. Mathematical models, such as pathogen growth models to assess the impact of changes in pH and water activity on the control of pathogen growth or the use of z-value models to determine alternative thermal processing conditions, are used extensively by industry. This can also include the use of risk-based models that examine the impact of a control measure or combination of control measures further along the food chain. Effective use of mathematical modelling typically requires that a model be appropriately validated for a specific food application. This may require additional testing. Validation based on the use of mathematical modelling should take into consideration the uncertainty/variability limits associated with the models' predictions.
- **Surveys.** Surveys can be used to validate control measures, as appropriate, in conjunction with other approaches to demonstrate the expected level of control of hazards can be achieved. For example, an evaluation of consumers' understanding of information on the label prior to or during the design of a label can be considered a validation approach for labelling as a control measure.[9] Care should be taken to ensure that statistically valid surveys or other activity provide data that are accurate and appropriate for use by an individual food business operator or competent authority.

## Steps Involved in the Validation Process

After completing the tasks needed prior to validation, the process of validating control measures includes the following steps :

- Decide on the approach or combination of approaches.
- Define the parameters and decision criteria[10] that will demonstrate that a control measure or combination of control measures, if properly implemented, is capable of consistently controlling the hazard to the specified outcome.
- Assemble relevant validation information and conduct the studies where needed.
- Analyze the results.
- Document and review the validation.

Results of a validation will either demonstrate that a control measure or combination of control measures,

- is capable of controlling the hazard to the specified outcome if properly implemented, and thus, could be implemented, or
- is not capable of controlling the hazard to the specified outcome and should not be implemented.

The latter may lead to re-evaluation of product formulation, process parameters, or other appropriate decisions/actions.

Information gained in the validation process may be useful in designing verification and monitoring procedures. For example, if a control measure or combination of control measures produces a reduction of a pathogen well in excess of the reduction needed for hazard control, it may be possible to decrease the frequency of verification e.g. frequency of microbiological testing of end

9 Note that surveys carried out after the product is in the market place to assess whether consumers are following the instructions is a verification activity.

10 Decision criteria should take into account the uncertainty and variability associated with the validation methodology and the performance of the control measure or combination of control measures.

product.

## 7. NEED FOR RE-VALIDATION

There are many changes that could lead to a need to re-validate a control measure or combination of control measures. Examples include :

- System failure : If monitoring or verification identifies failures for which a process deviation cause cannot be identified, re-validation may be needed. Non-compliance with monitoring or verification criteria may indicate a need for a change in the parameters (i.e., the selection and specification of the control measures) on which the design of the food safety control system is based. A system failure may also result from an inadequate hazard analysis and may require re-validation.
- Process changes : The introduction in the food safety control system of a new control measure, technology or a piece of equipment that is likely to have a decisive impact on the control of the hazard may necessitate that the system or parts of it be re-validated. Similarly, changes made in product formulation or the application of current control measures (e.g. time/temperature changes) may result in the need for re-validation of control measures.
- New scientific or regulatory information : Re-validation may be needed if the hazard associated with a food or ingredient changes as a result of (i) higher concentrations of hazards than originally encountered and accounted for in the design, (ii) a change in response of a hazard to control (e.g. adaptation), (iii) emergence of a previously unidentified hazard, (iv) new information indicating that the hazard is not being controlled to the level specified (e.g. new epidemiological findings or new validated and internationally accepted analytical technologies ) or (v) a new food safety outcome.

## ANNEX I

## EXAMPLES OF VALIDATION OF FOOD SAFETY CONTROL MEASURES

This Annex contains examples of several approaches to validating control measures or combinations of control measures. All of the examples described below are for purposes of illustration only, do not represent actual validation scenarios in a global sense and should not be replicated as presented. . Also, the examples below are presented in a specific format only for consistency and this format is not intended to be a general model for validation.

In the examples below, it is assumed that the control measures have not been previously validated, that they have a decisive impact on the control of the specific hazard, and that they have been prioritized for validation.

### EXAMPLE ONE : VALIDATION OF POST-HARVEST DEHYDRATION TO PREVENT AFLATOXIN CONTAMINATION OF TREE NUTS[11]

1. Pre-validation Tasks.

   a. Hazard : Aflatoxin contamination has been identified as a hazard that is reasonably likely to occur in tree nuts. Its control requires applications of measures both pre-harvest and postharvest. Post-harvest measures are focused on rendering the tree nuts incapable of supporting continued aflatoxin production by *Aspergillus* spp.

   b. Food safety outcome required : The recognized international standard for aflatoxin $B_1$ is 20 $\mu$g/kg. However, to take into account process and analytical uncertainties, the food safety outcome is set at 10 $\mu$g/kg

   c. Control measure to be validated : Post-harvest dehydration of tree nuts

2. Approach : There are sufficient scientific data in the literature to allow the control measure to be validated without the need for additional studies.

3. Parameters and Decision Criteria :

   a. Parameters :

   i. Aflatoxin-producing *Aspergillus* spp. cannot grow and synthesize the toxins when the water activity of the product falls below 0.70.[12]

   ii. The amount of aflatoxin that is produced post-harvest is dependent on the speed that tree nuts can be dehydrated and the rate at which the mold can grow. The scientific literature suggests that germination of the spores and initiation of toxin synthesis can occur with 24 to 48 hours of exposure of post-harvest tree nuts to a moist environment.

   iii. The level of aflatoxin B1 present in post-harvest tree nuts will also be dependent on the levels present prior to the initiation of dehydration.

   b. Decision Criteria :

   i. A post-harvest dehydration control measure will be validated if

      1. The water activity in lots of tree nuts being treated can be consistently reduced to $< 0.70$ within 24 hours,

      2. After dehydration there is an absence of "wet spots" that have a water activity $\geq 0.70$ in the lot.

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11 Ongoing discussion is taking place in the Codex Committee on Contaminants in Foods regarding maximum levels for aflatoxin in tree nuts. The values used in the example are for illustration purposes only and shall not be considered as guidance in any way.

12 *Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts* (CAC/RCP 59-2005).

3. The level of aflatoxin B1 in the tree nuts after a water activity < 0.70 has been attained does not exceed 10 μg/kg.

4. The treatment includes appropriate packaging/storage of the dried tree nuts

4. Assemble relevant validation information and conduct the studies where needed.

a. Confirm incoming level of aflatoxin under a variety of harvest conditions

b. Obtain scientific references documenting that aflatoxin-producing *Aspergillus* spp. cannot synthesize the toxins when the water activity of the product falls below 0. 70.

c. Obtain information to support that toxin production is not likely to occur if tree nuts are dried to this water activity in 24 to 48 hours; this may include use of mathematical models for the rate of growth and toxin production by *Aspergillus* species.

d. Determine that the technology to be used will consistently produce tree nuts that have water activity levels < 0.70 within 24 h.

The available scientific literature and related scientific data relating water activity levels to aflatoxin production in tree nuts should be reviewed to determine their pertinence to the specific procedures being employed by the business operator. If there is uncertainty about the applicability of the scientific literature, acquisition of additional analytical data may be required. At a minimum, data on the water activity of tree nuts after 24 hours drying should be obtained.

5. Analyze the results.

a. Data acquired by the business operator on the ability of the dehydration technology employed by the operator to consistently achieve the dehydration outcomes should be analyzed to ensure key operating parameters of the equipment are being followed and are achieving the expected water activity within the expected timeframe in this specific operation.

b. As appropriate, statistical analyses should be performed to assess the variability in the processes.

6. Document and review the validation.

All analyses, data, and decisions should be documented.

7. Conclusion

a. Data indicate that if the incoming level of aflatoxin $B_1$ in the untreated tree nuts is < 1 μg/kg, then the levels after dehydration can be appropriately controlled and thus the control measure can be implemented.

b. Storage/packaging conditions must be adequate to maintain the desired water activity of the dried tree nuts.

c. These data can be used to establish a program of monitoring for water activity levels, and periodic analysis of the dehydrated tree nuts for aflatoxin $B_1$.

EXAMPLE TWO : MEETING A PERFORMANCE OBJECTIVE FOR VERO-TOXIN PRODUCING *ESCHERICHIA COLI* IN A HARD RAW MILK CHEESE

1. Pre-validation Tasks :

a. Hazard : Vero-toxin producing *Escherichia coli* (VTEC) in hard raw milk cheese.

b. Food Safety Outcome : A performance objective (PO) of < 0.001 cfu VTEC/g at the end of production.

c. Control Measure : A combination of control measures (level of the pathogen in the raw milk, time/temperature during processing, pH, water activity) contribute to the level of VTEC at the end of production, which includes a defined ripening period under specified conditions.

2. Approach : Use of scientifically valid experimental data to demonstrate the adequacy of the control measures

3. Parameters and Decision Criteria : The combination of control measures will be considered validated as achieving the PO[13] if the calculated geometric mean (x) + 3 standard deviations ($\sigma$) level of VTEC at the end of production (ripening) is 〈 0.001 cfu/g (-3 log10(cfu/g))

4. Assemble relevant validation information :

   a. the level (e.g. geometric mean (x) + 3$\sigma$) of the pathogen in the raw milk is estimated, using microbiological testing of the milk

   b. a model of the manufacturing process (time, temperature, pH, water activity) based on data collected from production (e.g. experimental production), including the possible variation in the process

   c. growth/reduction rates during the manufacturing process are identified from literature, other sources, or from experimental trials if necessary

   d. the changes in hazard levels that are reasonably likely to occur during processing steps (i.e. those steps that are technologically needed to manufacture the product)

   e. Initial selection of the manufacturing process that is likely to simultaneously yield the desired level of VTEC control and the desired product quality—his will identify the control measures required (time, temperature, pH, water activity).

5. Design an experimental study that mimics the selected process :

   a. Raw milk of the same status as intended for production is spiked with levels of VTEC (mixture of relevant strains, isolated from milk) that can be measured throughout the process

   b. The cheese is manufactured (pilot scale) and samples are taken for analysis at relevant points needed to validate the initial model.

   c. All parameters specifying the process are monitored during the trial to ensure comparability with full scale production

*6. Analyze the results*

   a. Data on the end product

   b. Data relating to the model and the process used

7. Document and review the validation

   Documentation should include :

   a. result of literature research

   b. results of the experimental study

   c. statistical analysis of raw data and analytical results

   d. description of the various models

   e. rationale for selecting the scenario for experimental trial (control measures and processing steps)

   f. data on VTEC strains used for spiking

   g. documentation of the variability in process

8. Conclusion

   The PO can be met under the following conditions :

   a. That the process parameters (time, temperature and pH profiles during cheese making) are within tolerance under monitoring and are not changed

   b. That the raw milk does not exceed xx cfu/g

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13 Ibid

c. That the cheese is ripened for a minimum of yy days prior to release.

EXAMPLE THREE : VALIDATION OF CLEANING AND DISINFECTING PROTOCOLS (Sanitation Standard Operating Procedures, SSOPs)

1. Pre-validation Tasks

   a. Hazard(s) : Generic microbial contaminants

   b. Food Safety Outcome: Effective sanitation of food-contact surfaces as demonstrated by compliance with microbiological criteria.

   c. Control Measure(s) : Cleaning and disinfection protocols (SSOPs) within a facility

2. Approach : Collection of scientific data.

3. Parameters and Decision Criteria : SSOPs will be considered to be validated if, after implementation of cleaning and disinfection protocols, food contact surfaces meet microbiological criteria established for aerobic plate counts or other indicator microorganisms as appropriate.

4. Assemble the relevant validation information

   a. SSOPs will be implemented as intended for 3-4 weeks of operation.

   b. Microbiological testing of food contact surfaces will be conducted after cleaning and disinfection protocols have been used at the end of each day's production.

5. Analyze the results

   a. Compare results obtained at the end of each day's production to the established microbiological criteria.

   b. Conduct appropriate statistical analyses to determine the variability in efficacy of the cleaning and disinfection procedures.

6. Document and review the validation

   a. Data from implementation of SSOPs should be documented.

   b. All data from food contact surface testing should be documented.

7. Conclusion

   If review and analysis of the validation results indicate that the SSOPs are capable of consistently delivering results that comply with the established microbiological criteria during 3-4 weeks of the validation period, then the cleaning and disinfection protocols can be considered validated.

   This same protocol with a reduced rate of testing can be used as an ongoing verification activity that the SSOPs are being implemented properly.

EXAMPLE FOUR : CONTROL OF METAL FRAGMENTS

1. Pre-validation Tasks :

   a. Hazard : Metal fragments

   b. Food Safety Outcome : Less than 1 metal fragment over 2 mm in 100,000 kg of product.

   c. Control Measure : Introduction of a sieve into a production line

2. Approach : Collection of data during normal operation.

3. Parameters and Decision Criteria :

   Control measure will be considered validated if a metal detector indicates that production with the sieve will allow $< 1$ metal fragment $\geq 2$ mm in 100,000 kg of final product. Operational data will be collected for one month and reviewed to determine the size of any metal pieces in products

rejected by the metal detector.

4. Assemble relevant validation information.

   a. Determine the size of metal fragments in products rejected by the metal detector.

   b. Ensure that the metal detector is sensitive enough and calibrated to detect metal pieces of 2 mm or more in the specific product.

   c. Ensure that the sieve remains intact during normal operations.

5. Analyze the results

   Determine the rate at which the sieve allowed fragments of 2 mm or more in the final product.

6. Document and review the validation

   a. Document all findings from the metal detector.

   b. Document the integrity of the sieve and the sensitivity and calibration of the metal detector.

7. Conclusion

   a. Control measure can be implemented if data indicate that production with the sieve will allow < 1 metal fragment ≥ 2 mm in 100,000 kg of final product.

   b. Validation will likely provide information on monitoring needed to ensure that sieve remains intact.

   c. The metal detector can be used after the validation as an ongoing verification activity to ensure that the sieve is controlling the hazard as intended.

EXAMPLE FIVE : VALIDATION BY A COMPETENT AUTHORITY (NEW ZEALAND) OF MEAT INSPECTION PROCEDURES FOR *TAENIA SAGINATA*[14]

1. Pre-validation Tasks :

   a. Hazard : Cysts of Taenia saginata in slaughtered cattle.

   b. Food safety outcome : No increase in risks to consumers

   c. Control Measure : A new post-mortem inspection procedure for the identification and removal of cysts. Post mortem inspection is the only available control measure. Traditional inspection involves slicing of a large number of tissues (and also results in a high degree of microbiological crosscontamination). The new inspection package would limit slicing to a minimum.

2. Approach : Experimental trial and mathematical modelling

3. Parameters and Decision Criteria

   a. The food safety outcome is no decrease in the current level of consumer protection, i.e. mean rate of 1.1 cases of infection per year in the total population per year.

   b. The decision criterion for validation is that any difference in non-detection rate at post mortem inspection does not result in a decrease in the current level of consumer protection.

   c. The decision criteria included consideration of probability distributions generated by the model.

4. Assemble information and conduct studies

   Detailed experimental trials to determine non-detection rates for the traditional and the alternative inspection measures, and mathematical modelling to determine impact on the chosen food safety outcome

5. Analyze the results

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14 This example is documented in Van der Logt, P., Hathaway, S. C. and Vose, D. (1997) : Risk assessment model for human infection with the cestode *Taenia saginata*. Journal of Food Protection 60:1110-1119.

The food safety outcome of the new control measure was presented as a frequency distribution and a mean value was chosen for purposes of comparison. The level of consumer protection was estimated to be a mean rate of 1.3 cases of infection in the total New Zealand population per year. Given the uncertainty in the biological system, primarily related to the very low sensitivity of any type of post mortem inspection (less than 25%) and the extremely low prevalence of *Taenia saginata* in New Zealand, this result met the decision criteria for validation.

Note : This validation process would likely not give the same result in a country with a moderate to high level of infection in the slaughter population.

6. Document and review

a. Document the methodology for the experimental trials and the results

b. Document the development of the mathematical model and its validation.

c. Document the results of the modelling.

7. Conclusion : The new inspection package results in the same level of consumer protection as the old inspection package that involved considerably more slicing.

EXAMPLE SIX : VALIDATION OF A SAFE-HANDLING LABEL FOR TABLE EGGS

1. Pre-validation Tasks :

a. Hazard : *Salmonella* Enteritidis (SE) in table eggs (shell eggs).

b. Food Safety Outcome: Reduced frequency of consumption of eggs contaminated with SE.

c. Control Measure: Labelling (one control measure among several beginning at primary production (on-farm practices) through consumer use (cooking, storage temperatures)). The label will state : "To avoid illness, refrigerate eggs at 5℃ (41°F) and cook eggs until the yolk is firm."

2. Approach: A representative survey of consumers

3. Parameters and Decision Criteria :

a. A risk assessment has shown that, in concert with control measures elsewhere in the food chain, the number of servings of eggs contaminated with SE will be significantly reduced if there is a 25% increase in the number of consumers that store table eggs at 5℃ (41°F) and cook eggs until the yolks are firm.

b. The control measure (label) will be considered validated if a specified percentage of the population understands the label (i.e., having read it, they can state what they would do if following the label instructions) and indicates that they plan to follow the instructions.

4. Assemble relevant validation information :

a. Identify target demographic for survey

b. Design a statistically-valid survey to determine

- Current consumer practices
- Whether the label is understandable
- Whether consumers plan to change their current practices, if necessary, based on the label instructions.

5. Analyze the results :

a. Determine the percentage of the population that is not currently following the practices described on the label.

b. Determine the percentage of the population that understands the label instructions.

c. Determine the percentage of the population that indicates that they plan to change their current practice and follow the label instructions.

6. Document and review the validation:

   a. Document the development of the survey

   b. Document the identification of the target demographics for the survey

   c. Document the survey results

7. Conclusion

   The control measure can be implemented because data indicated that because of the label instructions more than 25% of the population plan to change their current practice and begin refrigerating eggs at 5℃ (41℉) and, when appropriate, cooking eggs until the yolk is firm.

# MODEL EXPORT CERTIFICATE FOR MILK AND MILK PRODUCTS CAC/GL 67 - 2008

## INTRODUCTION

1. Certification is one method that can be utilized by regulatory agencies of importing and exporting countries to complement the control of their inspection systems for milk and milk products. This model certificate recognizes that importing country authorities may, as a condition of clearance of consignments, require importers to present official certificates issued by, or with the authority of, exporting country authorities. To help facilitate international trade, the numbers and types of certificates should be limited. Harmonisation efforts could be promoted through the use of international (Codex) model certificates such as this Model Export Certificate which should be considered when developing an official or officially recognised certificate for milk and milk products.

2. This Model Export Certificate does not deal with matters of animal and plant health unless directly related to food safety or suitability. However it is recognised that in practice a single certificate may contain information relevant to several matters. Where attestation on animal health matters is required, reference should be made to the OIE Terrestrial Animal Health Code.

3. The Model Export Certificate for Milk and Milk Products does not mandate the use of such certification. Alternatives to the use of official and officially recognized certificates should be considered wherever possible, in particular where the inspection system and requirements of an exporting country are assessed as being equivalent to those of the importing country.

4. The Model Export Certificate for Milk and Milk Products does not in any way diminish the trade facilitation role of commercial or other types of certificates, including third party certificates, not issued by, or with the authority of, exporting country authorities.

## OBJECTIVES

5. The certificate should contain essential information relating to the protection of the health of consumers and ensuring fair practices in the food trade.

6. The certificate should clearly describe the dairy product and the consignment to which it uniquely relates. The certificate should contain a clear reference to the hygiene requirements to which the certified dairy product needs to conform. This statement is based on the inspection system of the competent authority.

7. The level of information required should be adequate for the importing country's purpose and not impose unnecessary burdens on the exporting country or exporter, nor should there be a requirement for the disclosure of information that is commercial-in-confidence unless it is of relevance to public health.

8. The establishment of bilateral or multilateral agreements, such as equivalence agreements may provide the basis for dispensing with the issuance of certificates.

## SCOPE

9. The Model Export Certificate for Milk and Milk Products only relates to official certificates. It applies to milk, milk products and composite milk products as defined in *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999) presented for international trade that meet food safety and suitability requirements. The Model Export Certificate does not deal with matters of animal and plant health unless directly related to food safety or suitability.

10. Where administratively and economically feasible, certificates may be issued in an electronic format provided that the principles for electronic certification[1] are met.

## GENERAL REMARKS CONCERNING THE PRODUCTION AND ISSUANCE OF CERTIFICATES

11. The production and issuance of certificates for milk and milk products should be carried out in accordance with the principles and appropriate sections of the following Codex texts:

- *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* (CAC/GL 38-2001);
- *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995);
- *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997);
- *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999);
- *Code of Ethics for International Trade in Foods* (CAC/RCP 20-1979).

12. Certificates should be in a language or languages fully understood by the certifying officer in the exporting country, in transit countries where appropriate, by the receiving authority in the importing country or those countries in which the inspection of food takes place, whilst minimizing unnecessary burden on the exporting country. Where required the certificate can be accompanied by official translations.

## DEFINITIONS

***Certificates*** are those paper or electronic documents, which describe and attest to attributes of consignments of food moving in international trade.

***Certification*** is the procedure by which official certification bodies or officially recognized certification bodies provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products.

***Certifying bodies*** are official certification bodies and officially recognized certification bodies[2].

***Certifying officers*** are officers authorized or recognized, by the exporting country's competent authority, to complete and issue official certificates.

***Consignment*** means a defined collection of food products normally covered by a single certificate.

***Identification*** means a description of the commodity and consignment to which the certificate uniquely relates, e.g., lot identifier or date coding, facilitating the traceability/product tracing of the product in the event of public health investigations and/or recalls.

***Inspection*** is the examination of food or systems for control of food, raw materials, processing, and distribution including in-process and finished product testing, in order to verify that they conform to requirements.

***Official Certificates*** are certificates issued by, or under the control of the exporting country's competent authority, including by a certifying body recognized by the competent authority to issue such certificates.

***Official inspection systems and official certification systems*** are systems administered by a

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1 *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* (CAC/GL 38-2001)

2 Recognition of certification bodies is addressed under Section 8 – Official Accreditation of the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997).

government agency having jurisdiction empowered to perform a regulatory or enforcement function or both.

***Officially recognized inspection systems and officially recognized certification systems*** are systems which have been formally approved or recognized by a government agency having jurisdiction.

***Requirements*** are the criteria set down by the competent authorities relating to trade in foodstuffs covering the protection of public health, the protection of consumers and condition of fair trading,

## USE OF MODEL EXPORT CERTIFICATES FOR MILK AND MILK PRODUCTS

13. The model certificate consists of a series of fields. Each field of the Model Export Certificate for Milk and Milk Products must be filled in or else marked in a manner that would prevent alteration of the certificate. All fields that are necessary to support the validity of the attestation must be filled in.

14. The format and method of transmission of the certificate should respect the principles set by the *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* (CAC/GL 38-2001).

***Original Certificate*** should be identifiable and this status should be displayed appropriately with the mark "ORIGINAL" or if a copy is necessary, this certificate should be clearly marked "COPY". The term "REPLACEMENT" is reserved for use on certificates where, for any good and sufficient reason (such as loss of or damage to the certificate in transit), a replacement certificate is issued by a certifying officer.

***Page numbering*** should be used where the certificate occupies more than one sheet of paper. For multiple page certificates the certifying officer should ensure that it is clear that the pages constitute a single certificate including official translation(s) when appropriate (e.g., each page is numbered with the same unique certificate number certificate number so as to indicate it is a particular page in a finite sequence).

***Signature and appropriate means to ensure security of this document*** (for example use of seal, watermark paper, unique identification numbers or other security measures) should be applied in a manner that minimizes the risk of fraud. The official signature should appear at the end of the certificate. The official stamp should be applied at the end of the certificate, or at the end of each page in the case of multiple page certificates.

***Certificate number (No)*** is unique for each certificate and is authorized by the competent authority of the exporting country. This certificate number should appear on each page of the certificate. If there is an addendum, it must be clearly marked as such and must have the same identification number as the primary certificate and the signature of a certifying officer signing the sanitary certificate.

***Competent authority*** For the purposes of the Model Export Certificate for Milk and Milk Products, the competent authority is the official organisation empowered to execute various functions. Its responsibility may include the management of official systems of inspection or certification at the regional or local level.

## 1. DETAILS IDENTIFYING MILK AND MILK PRODUCTS

***Nature of food*** - Definition of the product according to Section 2.1, 2.2, 2.3 of the *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999).

***Name of product*** - The information appearing in this section should replicate what is presented on the label i.e. the name of the food and the trade name (where one is used) and should be sufficient to identify the food. Where a certificate for trade samples is required a consignment consisting of a food sample intended for evaluation, testing or research, in the importing country may be described using a term such as "trade samples". It should be clearly indicated on the

certificate or the package that the sample is not intended for retail sale and has no commercial value.

*Number of units* - refers to the number of packages as e.g. cartons, boxes, bags, barrels, pallets, etc.

*Lot*[3]*(s) identification number(s) / Date code* - is the lot identification system developed by a processor to account for their production of milk and milk products thereby facilitating the traceability/product tracing of the product in the event of public health investigations and/or recalls.

*Manufacturing establishment or Factory approval / Identity Number* - is the number assigned by the competent authority to the manufacturing establishment or factory where the milk product was produced. In case the consignment encompasses products from several manufacturing establishments or factories the approval number of each manufacturing establishment and/or factory should be mentioned.

## 2. PROVENANCE OF MILK AND MILK PRODUCTS

*Country of Dispatch* - For the purposes of the Model Export Certificate for Milk and Milk Products, the country of dispatch designates the name of the country of the competent authority which has the competence to verify and certify the conformity to the attestations. The relevant part of the country may be mentioned where this relates to specific attestations.

*Means of transport* - Describes the way the product is transported, including, if appropriate, identification of the shipping container and a seal number.

*Specific transportation and handling requirements* - If appropriate refer to the necessary information on how to handle the product in order to prevent it from perishing. This may include the indication of any storage temperature specified by the manufacturer.

## 3. DESTINATION OF MILK AND MILK PRODUCTS

The country of destination and name of the importer may change during transport. Importing countries may accept the provision of supplementary information in such cases.

## 4. ATTESTATION

*Public health attestation* statement confirming that the product or batches of products originate from an establishment that is in good regulatory standing with the Competent Authority in that country and that the products were processed and otherwise handled under a HACCP System, where appropriate, and that the food complies with the hygiene requirements of the country (to be agreed upon with the importing country) and/or the hygienic provisions of the *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004). The importing country should provide the exporting country with its provisions by precise and complete documents in a language agreed between the importing and exporting countries when it is required to meet the requirements of the importing country.

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3 Lot means a definitive quantity of a commodity produced essentially under the same conditions (*General Standard for the Labelling of Prepackaged Foods* - CODEX STAN 1-1985)

Logo/ letterhead of certifying body : _____ Certificate No : _____

## MODEL EXPORT CERTIFICATE FOR MILK AND MILK PRODUCTS

Competent authority responsible for Certification :

_____

### 1. Details identifying milk and milk products

Nature of Food : _____

Name of the Product (s) : _____

Number of units : _____ Weight per unit : _____

Total Net weight : _____

Lot(s) identification number(s) : _____

Date(s) of manufacture[4] : _____

Date(s) of minimum durability[5] : _____

Manufacturing Establishment or Factory Approval or Identity Number, or Name and Address of Manufacturer : _____

### 2. Provenance of milk and milk products

Country of dispatch : _____

Means of transport : _____

Specific transportation and handling requirements (if appropriate) : _____

Exporter or Consignor : _____

Name and Address : _____

Export Licence No (if required) :

_____

### 3. Destination of milk and milk products[6]

Country of destination : _____

Importer/Consignee Name and Address : _____

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4 When required by the importing country

5 When required by the importing country and expressed as provided in Section 4.7.1 of the *General Standard for the Labelling of Prepackaged Food (CODEX STAN 1-1995)*

6 The country of destination and name of the importer may change during transport. Importing countries may accept the provision of supplementary information in such cases

## 4. Attestation

The undersigned certifying officer hereby certifies that :

1. The products described above were manufactured at (an) establishment(s) that has/have been approved by, or otherwise determined to be in good regulatory standing with the competent authority in the exporting country and that
2. The product(s) (please tick the appropriate box(es). Where this is not possible the non-selected option may be deleted) ;

   has/have been prepared, packed, held and transported prior to export under good hygienic practice and an effective food safety control system, implemented within the context of HACCP systems where appropriate and in accordance with the provisions of the Codex *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004).

   was/were produced in accordance with the public health requirements of..... (specify the country)

Date and Place of issue : _____

Certifying officer (Name : _____

official stamp and signature) : _____

# GUIDELINES FOR THE USE OF FLAVOURINGS
# CAC/GL 66 - 2008

## 1.0 SCOPE

This guideline provides principles for the safe use of the components of flavourings evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and determined to present no safety concern at estimated levels of intake, or that have established JECFA acceptable daily intakes (ADIs), and for which corresponding specifications of identity and purity have been established and adopted by Codex.[1] In addition, the guideline provides principles for the establishment of practices that do not mislead the consumer.

## 2.0 DEFINITIONS

2.1 **Flavour** is the sum of those characteristics of any material taken in the mouth, perceived principally by the senses of taste and smell, and also the general pain and tactile receptors in the mouth, as received and interpreted by the brain. The perception of flavour is a property of flavourings.

2.2 **Flavourings** are products that are added to food to impart, modify, or enhance the flavour of food (with the exception of flavour enhancers considered as food additives under the Codex Class Names and the International Numbering System for Food Additives - CAC/GL 36-1989). Flavourings do not include substances that have an exclusively sweet, sour, or salty taste (e.g. sugar, vinegar, and table salt). Flavourings may consist of flavouring substances, natural flavouring complexes, thermal process flavourings or smoke flavourings and mixtures of them and may contain non-flavouring food ingredients (Section 2.3) within the conditions as referred to in 3.5. They are not intended to be consumed as such.

2.2.1 **Flavouring substances** are chemically-defined substances either formed by chemical synthesis, or obtained from materials of plant or animal origin.

2.2.1.1 **Natural flavouring substances** are flavouring substances obtained by physical processes that may result in unavoidable but unintentional changes in the chemical structure of the components of the flavouring (e.g. distillation and solvent extraction), or by enzymatic or microbiological processes, from material of plant or animal origin. Such material may be unprocessed, or processed for human consumption by traditional food-preparation processes (e.g. drying, torrefaction (roasting) and fermentation). This means substances that have been identified / detected in a natural material of animal or vegetable origin.

2.2.1.2 **Synthetic flavouring substances** are flavouring substances formed by chemical synthesis.

2.2.2 Natural flavouring complexes are preparations that contain flavouring substances obtained by physical processes that may result in unavoidable but unintentional changes in the chemical structure of the flavouring (e.g. distillation and solvent extraction), or by enzymatic or microbiological processes, from material of plant or animal origin. Such material may be unprocessed, or processed for human consumption by traditional food-preparation processes (e.g. drying, torrefaction (roasting) and fermentation). Natural flavouring complexes include the essential oil, essence, or extractive, protein hydrolysate, distillate, or any product of roasting, heating, or enzymolysis.

2.2.3 **Smoke flavourings** are complex mixtures of components of smoke obtained by subjecting untreated wood to pyrolysis in a limited and controlled amount of air, dry distillation, or superheated steam, then subjecting the wood smoke to an aqueous extraction system or to distillation, condensation,

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1 This guideline does not imply that the uses of flavouring components that have not yet been evaluated by JECFA are unsafe or otherwise unacceptable for use in food.

and separation for collection of the aqueous phase. The major flavouring principles of smoke flavourings are carboxylic acids, compounds with carbonyl groups and phenolic compounds.[2]

2.3 Non-flavouring food ingredients are food ingredients, such as food additives and foodstuffs that can be added to flavourings and are necessary for dissolving, dispersing, or diluting flavourings, or are necessary for the production, storage, handling and use of flavourings.

## 3.0 GENERAL PRINCIPLES FOR THE USE OF FLAVOURINGS

3.1 The use of flavourings in food should not lead to unsafe levels of their intake.

3.2 Flavourings should be of a purity suitable for use in food. Unavoidable impurities should not be present in the final food at levels that would pose an unacceptable risk to health.

3.3 The use of flavourings is justified only where they impart or modify flavour to food, provided that such use does not mislead the consumer about the nature or quality of food.

3.4 Flavourings should be used under conditions of good manufacturing practice, which includes limiting the quantity used in food to the lowest level necessary to accomplish the desired flavouring effect.

3.5 Flavourings may contain non-flavouring food ingredients, including food additives and foodstuffs, necessary for their production, storage, handling, and use. Such ingredients may also be used to facilitate the dilution, dissolution, or dispersion of flavourings in food. Non-flavouring food ingredients should be:

(a) Limited to the lowest level required to ensure the safety and quality of the flavourings, and to facilitate their storage and ease of use ;

(b) Reduced to the lowest level reasonably possible when not intended to accomplish a technological function in the food itself ; and,

(c) used in accordance with the provisions of the Codex General Standard for Food Additives (GSFA ; CODEX STAN 192) whenever they are intended to provide a technological function in the finished food.

## 4.0 FLAVOURING SUBSTANCES AND COMPONENTS OF NATURAL FLAVOURING COMPLEXES THAT MAY REQUIRE SOME RISK MANAGEMENT MEASURES

4.1 Some flavourings substances, and substances that may be components of natural flavouring complexes, or of food ingredients with flavourings properties (e.g. herbs and spices) may be identified by Codex members to be of potential health concern. Based on the evaluations by the JECFA, the Codex Alimentarius may consider proposals for specific risk management measures for certain flavouring substances or components of natural flavouring complexes to ensure consumer protection.

4.2 It may be appropriate in certain cases for Members to establish risk management measures to minimize specific risks. To avoid potential conflicts in risk management decisions between Codex and its members, any risk management measures selected by Members should complement existing Codex risk management guidance and take into account relevant JECFA evaluations.

4.3 When establishing risk management measures to reduce the risk to human health from such flavouring substances whether added as such or as components of natural flavouring complexes or as naturally occurring components of food, the following criteria should be considered.

(a) An appropriate risk assessment of the flavouring substance, component of a natural flavouring complex or a naturally occurring component of food has been conducted.

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2 FAO JECFA Monographs 1 (Volume 3) 2005 FAO Rome.

(b) The risk assessment has identified a specific human health risk associated with the presence of the substance in food as a result of its use as a flavouring substance, as a component of a natural flavouring complex or as a naturally occurring component of food.

(c) Acceptable maximum levels for substances of concern in specific foods have been established based on an assessment of dietary exposure using an appropriate method to ensure that the intake of the substance from all sources does not present a safety concern.

(d) A reference to a validated analytical method for the determination of the substance in food should be available. Methods of analysis should comply with the Principles for the Establishment of Codex Methods of Analysis (CAC Procedure Manual.).

## 5.0 HYGIENE

5.1 It is recommended that flavourings covered by the provisions of these guidelines be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

5.2 Flavourings should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

## 6.0 LABELLING

Labelling of flavourings should be in accordance with the requirements of the Codex *General Standard for the Labelling of Food Additives when sold as such* (CODEX STAN 107-1981). Labelling of foods containing added flavourings should be in accordance with the requirements of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985).

## 7.0 JECFA EVALUATIONS OF FLAVOURINGS AND THEIR SPECIFICATIONS

The flavourings for which JECFA has completed its safety evaluation are available from the WHO JECFA website (http://www.who.int/ipcs/publications/jecfa/en/index.html), through the link *Database of evaluation summaries,* or by contacting the WHO JECFA Secretariat. Specifications for flavouring substances evaluated by JECFA are available, in an on-line searchable database at the FAO JECFA website (http://apps3.fao.org/jecfa/flav_agents/flavag-q.jsp), or by contacting the FAO JECFA Secretariat.

# CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF OCHRATOXIN A CONTAMINATION IN WINE CAC/RCP 63 - 2007

## 1. PREAMBLE

Mycotoxins, in particular ochratoxin A (OTA), are secondary metabolites produced by filamentous fungi found in soil and organic matter, which spread and thrive on grapes during the berry ripening phase.

The formation of OTA in grapes is mainly due to berry contamination by certain mould species, and particular strains thereof, belonging essentially to the *Aspergillus* species (in particular *A. carbonarius* strains and to a lesser extent *A. niger*).

The presence and spread of such fungi in vineyards are influenced by environmental and climatic factors, nocturnal dampening condition of grapes, grape bunch shape, susceptibility of vine varieties, aeration level of the grape bunches, health status of grapes and berry injuries which are the main entry points for ochratoxigenic fungi.

## 2. CULTIVATION PRACTICES IN THE VINEYARDS

Application of the following preventive measures is recommended, in viticulture regions in which the climatic conditions are favourable to the formation of OTA in vine products in order to reduce endemic risk which favours the onset of the most damaging vine diseases :

### 2.1 REGIONAL RISK INFORMATION

- Ensure that regional authorities and grower organisations :

– analyse and identify the species and strains of toxigenic fungi present in their region ;

– combine this information with regional risk factors including meteorological data and viticultural techniques and propose appropriate management;

– communicate this information to growers.

### 2.2 TRAINING OF PRODUCERS

- Ensure training of producers with regards to :

– risk of mould and mycotoxins ;

– the identification of ochratoxigenic fungi or the presence of mould spoilage, especially black mould, and period of infection ;

– knowledge of preventive measures to be applied to vineyards and wineries.

### 2.3 VINEYARD ESTABLISHMENT

- Favour vine establishment in well aerated areas while avoiding very humid areas.
- Draw up plots of land with adequate planting disposition, and vegetation architecture (trellising system) to :

– facilitate planting operations,

– avoid direct contact of grapes bunches with the soil,

– ensure good pest and disease control,

– minimise the risk of grapes sun burn,

– promote the uniform ripening of the grape.

### 2.4 PLANT MATERIAL

- Choose vigorous rootstock and varieties which are less prone to developing mould and grape rot.
- Choose clones or biotypes within a variety which are better adapted to climatic and soil conditions in the specific cultivation areas and less sensitive to mould and rot development, which are often characterised by less compact grape bunches.
- Lay out homogeneous plots of land (varieties, clones) to facilitate growing operations and to ensure better crop and disease control and to obtain uniform ripening of the grapes.

### 2.5 GROWING TECHNIQUES

- Apply management practices which favour leaf/fruit balance for vines and which reduce excess vigour, in particular, avoiding inappropriate nitrogenous fertilizer applications.
- Favour vegetation or organic cover of soils and avoid working the soil between the beginning of the grape ripening and grape harvest period in order to limit the transfer of soil particles and the associated fungi to the grapes.
- Favour placing grape bunches in an orderly manner to avoid overcrowding.
- If water input is necessary, irrigate as regularly as possible in order to avoid berry splitting and the onset of cracks on the skin which are sources of mould penetration and development, especially in warm regions.
- Avoid using marc containing toxigenic fungi as a fertilizer in the vineyards.

### 2.6 PEST AND DISEASE CONTROL

- Carry out leaf removal in the grape cluster zone while recognising the need to limit the risk of sun burn. This must enable the aeration of clusters. This is particularly necessary under hot and humid weather conditions while the grapes are ripening.
- Avoid lesions on the berries and skin damage caused by diseases, insects, phytotoxicity and sun burn.
- Remove shriveled/desiccated berries.
- Apply vine protection plans in order to control dangerous fungal diseases affecting grape quality (oïdium disease, acidic rot).
- Prevent attacks of grape berry moths, grape mealybugs and grape leafhoppers, which favour mould development on damaged berries; pest control needs to be carried out according to biological and epidemic risk ; under high risk conditions preventive treatments must be applied by using specific products and taking into account the warnings of plant protection regional services.
- Apply appropriate and registered protective programmes against grape rot and mould using appropriate management to avoid fungal resistance. Appropriate treatments are recommended in all situations which are favourable to the development of toxin producing species.

## 3. PRACTICES AT HARVEST

Only a healthy grape harvest can ensure optimal quality and safety of vitivinicultural products. Consequently, only a healthy grape harvest can be used for human consumption without the risk of quality loss and without food safety problems for consumers.

The date of harvest must be decided taking into account grape ripeness, sanitary level, and forecasted climatic changes and endemic risk. In high risk OTA areas, it is recommended to advance the harvest date.

When grapes are extensively contaminated by mould :

– the grapes can not be used for making concentrated musts or wine;

– the grapes can only be used for distillation.

3.1 PRODUCTION OF RAISINED GRAPES FOR WINE PRODUCTION

For production used to obtain raisined grapes for wine production (sweet wine), the following actions are recommended :

- Ensure the hygiene of containers to be used for the harvest and/or the drying of grapes.
- Use only grapes not damaged by insects and not contaminated by mould.
- Sort grapes by eliminating damaged or contaminated grapes.
- Place grapes to be dried or raisined in a single layer and avoid overstacking.
- Favour progressive and uniform drying of all parts of the grape bunch.
- Take the necessary measures to avoid development of fruit fly infestation.
- For particular conditions of drying in open air, it is recommended to dry in well ventilated conditions and to cover the grapes at night to prevent condensation and humidity.

3.2 PRODUCTION OF WINE GRAPES

The following actions are recommended if the harvest is moderately contaminated with toxigenic moulds and is to be used in wine production :

- Grapes damaged by insects, mould, or contaminated by dirt particles must be eliminated before harvest or at harvest time depending on harvesting technique.
- Grapes need to be sorted, in order to separate the grape bunches or the damaged parts of bunches. It is important to discard grapes with black mould.
- Harvested grapes must be transported as quickly as possible to the winery in order to avoid extended waiting, especially for grapes with a high proportion of juice.
- It is important to clean containers after each load, especially in the case of harvests where the containers may have been used to harvest grapes that may be rotten.

## 4. TREATMENT AT THE WINERY

Under conditions with a risk of OTA contamination, it is recommended to measure the level of OTA in the musts to be used in winemaking.

4.1 PRE-FERMENTATION OPERATIONS AND TREATMENTS

- Avoid skin maceration in the case of OTA high-risk harvests or carry out short maceration.
- In the case of a significant contamination of red grapes, evaluate possibility of carrying out rosé winemaking.
- Adapt pressing rate to the health status of the grape; in case of contamination, carry out small volume, low pressure quick pressings. Avoid continuous press.
- In the case of contaminated grapes, avoid using pectolytic enzymes for racking must or maceration. Quick clarifications with must filtration, centrifugation and flotation are preferable.
- Avoid post-harvest heating treatments and aggressive and prolonged macerations.
- In the case of contamination by OTA, it is preferable to treat the grapes and the musts with the lowest possible and most effective doses of oenological charcoal in order to avoid possible loss of aromatic and polyphenolic compounds when the treatment is carried out on wine.

4.2 FERMENTATION TREATMENTS

- Carry out, as far as possible, fermentation and maturing in smooth walled containers to avoid sources of contamination linked to previous fermentations or maturing and in order to facilitate

cleaning.

- Dry active yeasts or inactive yeasts can help reduce the OTA level.
- For alcoholic or malolactic fermentations, use yeasts or bacteria which have adsorbent properties for OTA ; ensure that these characteristics are guaranteed by the supplier. Note that the usage of these products only enables a partial reduction of OTA.
- It is recommended to introduce, as quickly as possible, following fermentation treatments.

### 4.3 MATURING AND CLARIFICATION TREATMENTS

- Maturing on lees can help in reducing the OTA level. The risks of this technique related to the organoleptic quality of wine must be evaluated.
- Current clarification products (organic or inorganic fining agents) have variable levels of efficiency for reducing the level of OTA :

– Oenological charcoal is the most effective.

– Certain cellulose and silica gels associated with fining with gelatine only enable a partial reduction Before use :

– Become informed of effectiveness of product used and application technology,

– Carry out trials with different dosages to ascertain sensory repercussions and application rate.

## 5. GENERAL CONDITIONS FOR FOOD CONTACT MATERIALS

Food contact materials used during harvesting, transport and production in the winery should not give rise to contaminant migration or cross-contamination which can endanger human health.

## 6. CONCLUSION

These recommendations are based on current knowledge and can be updated according to the findings of research to be pursued.

Preventive measures are essentially carried out in vineyards and treatments undertaken at the wineries are solely corrective measures.

# CODE OF HYGIENIC PRACTICE FOR FRESH FRUITS AND VEGETABLES
# CAC / RCP 53 - 2003

## INTRODUCTION

Scientific research over the last decades has shown that a diet rich in fruits and vegetables is protective against many cancers and lowers the occurrence of coronary heart disease. This recognition of the importance of routine consumption of fresh fruits and vegetables, together with a marked increase in the year-round availability of fresh fruits and vegetables from a global market, has contributed to the substantial increase in consumption of fresh fruits and vegetables over the past two decades. However, the recent increase in reports of food borne illness associated with fresh fruits and vegetables has raised concerns from public health agencies and consumers about the safety of these products.

## 1. OBJECTIVES OF THE CODE

This code addresses Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) that will help control microbial, chemical and physical hazards associated with all stages of the production of fresh fruits and vegetables from primary production to packing. Particular attention is given to minimizing microbial hazards. The code provides a general framework of recommendations to allow uniform adoption by this sector rather than providing detailed recommendations for specific agricultural practices, operations or commodities. The fresh fruit and vegetable industry is very complex. Fresh fruits and vegetables are produced and packed under diverse environmental conditions. It is recognized that some of the provisions in this code may be difficult to implement in areas where primary production is conducted in small holdings, in both developed and developing countries and also in areas where traditional farming is practised. Therefore, the code is, of necessity, a flexible one to allow for different systems of control and prevention of contamination for different groups of commodities.

## 2. SCOPE, USE AND DEFINITIONS

### 2.1 SCOPE

This code of practice covers general hygienic practices for the primary production and packing of fresh fruits and vegetables cultivated for human consumption in order to produce a safe and wholesome product : particularly for those intended to be consumed raw. Specifically, this code is applicable to fresh fruits and vegetables grown in the field (with or without cover) or in protected facilities (hydroponic systems, greenhouses). It concentrates on microbial hazards and addresses physical and chemical hazards only in so far as these relate to GAPs and GMPs.

The *Annex for Ready -to-eat Fresh Pre-cut Fruits and Vegetables* (Annex I) and the *Annex for Sprout Production* (Annex II) are supplements to this code and include additional recommendations to cover, respectively, the hygienic practices for the processing of ready-to-eat fresh pre-cut fruits and vegetables, and the hygienic practices that are specific for the primary production of seeds for sprouting and the production of sprouts for human consumption.

The code does not provide recommendations for handling practices to maintain the safety of fresh fruits and vegetables at wholesale, retail, food services or in the home. It excludes food products for which there is a specific Codex Alimentarius Code of Hygienic Practices.

## 2.2 USE

This code follows the format of the Codex *Recommended International Code of Practice - General Principles of Food Hygiene* - CAC/RCP 1-1969, Rev 3 (1997) and should be used in conjunction with it.

This code focuses upon hygienic issues that are specific to the primary production and packing of fresh fruits and vegetables. The major issues are covered in Section 3. In other sections, the *General Principles of Food Hygiene* have been expanded where there are issues specific to primary production and packing. The *Annex for Ready-to-Eat Fresh Pre-Cut Fruits and Vegetables* provides additional recommendations specific for the processing of ready-to-eat fresh pre-cut fruits and vegetables and the *Annex for Sprout Production* provides additional recommendations specific for the primary production of seeds for sprouting and the production of sprouts for human consumption.

## 2.3 DEFINITIONS

Definitions of general expressions are included in the General Principles of Food Hygiene. For the purpose of this code, the following terms have the definition stated:

***Agricultural inputs*** - any incoming material (e.g. seeds, fertilizers, water, agricultural chemicals, plant support, etc.) used for the primary production of fresh fruits and vegetables.

***Agricultural worker*** - any person that undertakes one or more of the following: cultivation, harvesting and packing of fresh fruits and vegetables.

Antimicrobial agents - any substance of natural, synthetic or semi-synthetic origin which at low concentrations kills or inhibits the growth of microorganisms but causes little or no host damage.

***Biological control*** - the use of competing biologicals (such as insects, microorganisms and/or microbial metabolites) for the control of mites, pests, plant pathogens and spoilage organisms.

***Biosolids*** - Sludge and other residue deposits obtained from sewage treatment plants and from treatment applied to urban and industrial wastes (food industries or other types of industry).

***Composting*** - a managed process in which organic materials are digested aerobically or anaerobically by microbial action.

***Cultivation*** - any agricultural action or practise used by growers to allow and improve the growing conditions of fresh fruits or vegetables grown in the field (with of without cover) or in protected facilities (hydroponic systems, greenhouses).

***Farm*** - any premise or establishment in which fresh fruits and/or vegetables are grown and harvested and the surroundings under the control of the same management.

***Grower*** - the person responsible for the management of the primary production of fresh fruits and vegetables.

***Harvester*** - the person responsible for the management of the harvesting of fresh fruits and vegetables.

***Hazard*** - a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

***Hazardous material*** - any compound which, at specific levels, has the potential to cause adverse health effects.

***Hydroponics*** - a general term for the production of plants without soil in a water medium.

***Manure*** - Animal excrement which may be mixed with litter or other material, and which may be fermented or otherwise treated.

***Microorganisms*** - include yeasts, moulds, bacteria, viruses and parasites. When used as an adjective, the term "microbial" is used.

*Packer* - the person responsible for the management of post-harvest processing and packing of fresh fruits and vegetables.

*Packing* - the action of putting fresh fruits and vegetables in a package. This may take place in a field or in an establishment.

*Packing establishment* - any indoor establishment in which fresh fruits and vegetables receive postharvest treatment and are packaged.

*Primary production* - those steps involved in the growing and harvesting of fresh fruits and vegetables such as planting, irrigation, application of fertilizers, application of agricultural chemicals, etc.

Types of Water :

*Clean water* - water that does not compromise food safety in the circumstances of its use.

*Potable water* - water which meets the quality standards of drinking water such as described in the WHO Guidelines for Drinking Water Quality.

## 3. PRIMARY PRODUCTION

Fresh fruits and vegetables are grown and harvested under a wide range of climatic and diverse geographical conditions, using various agricultural inputs and technologies, and on farms of varying sizes. Biological, chemical and physical hazards may therefore vary significantly from one type of production to another. In each primary production area, it is necessary to consider the particular agricultural practices that promote the production of safe fresh fruits and vegetables, taking into account the conditions specific to the primary production area, type of products, and methods used. Procedures associated with primary production should be conducted under good hygienic conditions and should minimize potential hazards to health due to the contamination of fresh fruits and vegetables.

### 3.1 ENVIRONMENTAL HYGIENE

Where possible, potential sources of contamination from the environment should be identified. In particular, primary production should not be carried out in areas where the presence of potentially harmful substances would lead to an unacceptable level of such substances in or on fresh fruits and vegetables after harvest.

Where possible, growers should evaluate the previous uses of the sites (indoor and outdoor) as well as adjoining sites in order to identify potential microbial, chemical and physical hazards. The potential for other types of contamination (e.g., from agricultural chemicals, hazardous wastes, etc.) should also be considered. The evaluation process should include the following :

- Previous and present usage of the primary production area and the adjoining sites (e.g. crop grown, feed lot, animal production, hazardous waste site, sewage treatment site, mining extraction site) to identify potential microbial hazards including faecal contamination and contamination by organic waste and potential environmental hazards that could be carried to the growing site.
- The access of farm and wild animals to the site and to water sources used in primary production to identify potential faecal contamination of the soils and water and the likelihood of contaminating crop. Existing practices should be reviewed to assess the prevalence and likelihood of uncontrolled deposits of animal faeces coming into contact with crops. Considering this potential source of contamination, efforts should be made to protect fresh produce growing areas from animals. As far as possible, domestic and wild animal should be excluded from the area.
- Potential for contaminating produce fields from leaking, leaching or overflowing manure storage sites and flooding from polluted surface waters.

If previous uses cannot be identified, or the examination of the growing or adjoining sites leads to the conclusion that potential hazards exist, the sites should be analysed for contaminants of

concern. If the contaminants are at excessive levels and corrective or preventative actions have not been taken to minimize potential hazards, the sites should not be used until correction/control measures are applied.

## 3.2 HYGIENIC PRIMARY PRODUCTION OF FRESH FRUITS AND VEGETABLES

### 3.2.1 Agricultural input requirements

Agricultural inputs should not contain microbial or chemical contaminants (as defined under the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 3 (1997) at levels that may adversely affect the safety of fresh fruits and vegetables and taking into consideration the WHO guidelines on the safe use of wastewater and excreta in agriculture and aquaculture as appropriate.

#### 3.2.1.1 Water for primary production

- Growers should identify the sources of water used on the farm (municipality, re-used irrigation water, well, open canal, reservoir, rivers, lakes, farm ponds etc.). They should assess its microbial and chemical quality, and its suitability for intended use, and identify corrective actions to prevent or minimize contamination (e.g. from livestock, sewage treatment, human habitation).
- Where necessary, growers should have the water they use tested for microbial and chemical contaminants. The frequency of testing will depend on the water source and the risks of environmental contamination including intermittent or temporary contamination (e.g. heavy rain, flooding, etc.). If the water source is found to be contaminated corrective actions should be taken to ensure that the water is suitable for its intended use.

##### 3.2.1.1.1 Water for irrigation and harvesting

Water used for agricultural purposes should be of suitable quality for its intended use. Special attention to water quality should be considered for the following situations :

- Irrigation by water delivery techniques that expose the edible portion of fresh fruits and vegetables directly to water (e.g. sprayers) especially close to harvest time.
- Irrigation of fruits and vegetables that have physical characteristics such as leaves and rough surfaces which can trap water.
- Irrigation of fruits and vegetables that will receive little or no post-harvest wash treatments prior to packing, such as field-packed produce.

##### 3.2.1.1.2 Water for fertilizers, pest control and other agricultural chemicals

Water used for the application of water-soluble fertilizers and agricultural chemicals in the field and indoors should not contain microbial contaminants at levels that may adversely affect the safety of fresh fruits and vegetables. Special attention to the water quality should be considered when using fertilizer and agricultural chemical delivery techniques (e.g. sprayers) that expose the edible portion of fresh fruits and vegetables directly to water especially close to harvest time.

##### 3.2.1.1.3 Hydroponic water

Plants grown in hydroponic systems absorb nutrients and water at varying rates, constantly changing the composition of the re-circulated nutrient solution. Because of this :

- Water used in hydroponic culture should be changed frequently, or if recycled, should be treated to minimize microbial and chemical contamination.
- Water delivery systems should be maintained and cleaned, as appropriate, to prevent microbial contamination of water.

#### 3.2.1.2 Manure, biosolids and other natural fertilizers

The use of manure, biosolids and other natural fertilizers in the production of fresh fruits

and vegetables should be managed to limit the potential for microbial, chemical and physical contamination. Manure, biosolids and other natural fertilizers contaminated with heavy metals or other chemicals at levels that may affect the safety of fresh fruits and vegetables should not be used. Where necessary, in order to minimize microbial contamination the following practices should be considered :

- Adopt proper treatment procedures (e.g. composting, pasteurization, heat drying, UV irradiation, alkali digestion, sun drying or combinations of these) that are designed to reduce or eliminate pathogens in manure, biosolids and other natural fertilizers. The level of pathogen reduction achieved by different treatments should be taken into account when considering suitability for different applications.
- Manure, biosolids and other natural fertilizers which are untreated or partially treated may be used only if appropriate corrective actions are being adopted to reduce microbial contaminants such as maximizing the time between application and harvest of fresh fruits and vegetables.
- Growers who are purchasing manure, biosolids and other natural fertilizers that have been treated to reduce microbial or chemical contaminants, should, where possible, obtain documentation from the supplier that identifies the origin, treatment used, tests performed and the results thereof.
- Minimize direct or indirect contact between manure, biosolids and other natural fertilizers, and fresh fruits and vegetables, especially close to harvest.
- Minimize contamination by manure, biosolids and other natural fertilizers from adjoining fields. If the potential for contamination from the adjoining fields is identified, preventative actions (e.g. care during application and run-off controls) should be implemented to minimize the risk.
- Avoid locating treatment or storage sites in proximity to fresh fruit and vegetable production areas. Prevent cross-contamination from runoff or leaching by securing areas where manure, biosolids and other natural fertilizers are treated and stored.

3.2.1.3 Soil

Soils should be evaluated for hazards. If the evaluation concludes that such hazards are at levels that may compromise the safety of crops, control measures should be implemented to reduce hazards to acceptable levels. If this cannot be achieved by available control measures, growers should not use these soils for primary production.

3.2.1.4 Agricultural chemicals

- Growers should use only agricultural chemicals which are authorized for the cultivation of the specific fruit or vegetable and should use them according to the manufacturer's instructions for the intended purpose. Residues should not exceed levels as established by the Codex Alimentarius Commission.
- In order to minimize and contain the emergence of microbial resistance:
- the use of antimicrobial agents significant to human and animal therapy should be avoided.
- Antimicrobial agents not significant to human and animal therapy should be used only when unavoidable and in accordance with good agricultural practices and in a manner that achieves this objective.
- Agricultural workers who apply agricultural chemicals should be trained in proper application procedures.
- Growers should keep records of agricultural chemical applications. Records should include information on the date of application, the chemical used, the crop sprayed, the

pest or disease against which it was used, the concentration, method and frequency of application, and records on harvesting to verify that the time between application and harvesting is appropriate.

- Agricultural chemical sprayers should be calibrated, as necessary, to control the accuracy of the rate of application.
- The mixing of agricultural chemicals should be carried out in such a way as to avoid contamination of water and land in the surrounding areas and to protect employees involved in this activity from potential hazards.
- Sprayers and mixing containers should be thoroughly washed after use, especially when used with different agricultural chemicals on different crops, to avoid contaminating fruits and vegetables.
- Agricultural chemicals should be kept in their original containers, labelled with the name of the chemical and the instructions for application. Agricultural chemicals should be stored in a safe, well ventilated place, away from production areas, living areas and harvested fruits or vegetables, and disposed of in a manner that does not pose a risk of contaminating crops, the inhabitants of the area, or the environment of the primary production.
- Empty containers should be disposed of as indicated by the manufacturer. They should not be used for other food-related purposes.

3.2.1.5 Biological control

Environmental and consumer safety should be considered when using competing biological organisms and/or their metabolites applied for the control of pests, mites, plant pathogens and spoilage organisms in fresh fruits and vegetables.

Growers should use only biological controls which are authorized for the cultivation of the specific fruit or vegetable and should use them according to the manufacturer's instructions for the intended purpose.

### 3.2.2 Indoor facilities associated with growing and harvesting

For operations where fresh fruits and vegetables are grown indoors (greenhouses, hydroponic culture, etc.) suitable premises should be used.

3.2.2.1 Location, design and layout

- Premises and structures should be located, designed and constructed to avoid contaminating fresh fruits and vegetables and harboring pests such as insects, rodents and birds.
- Where appropriate, the internal design and layout should permit compliance with good hygienic practices for the primary production of fresh fruits and vegetables indoors, including protection against cross-contamination between and during operations. Each establishment should be evaluated individually in order to identify specific hygienic requirements for each product.

3.2.2.2 Water supply

Where appropriate an adequate supply of potable or clean water with appropriate facilities for its storage and distribution should be available in indoor primary production facilities. Non-potable water should have a separate system. Non-potable water systems should be identified and should not connect with, or allow reflux into, potable water systems.

- Avoid contaminating potable and clean water supplies by exposure to agricultural inputs used for growing fresh produce.
- Clean and disinfect potable and clean water storage facilities on a regular basis.
- Control the quality of the water supply.

3.2.2.3 Drainage and waste disposal

Adequate drainage and waste disposal systems and facilities should be provided. These systems should be designed and constructed so that the potential for contamination of fresh fruits and vegetables, agricultural inputs or the potable water supply is avoided.

### 3.2.3 Personnel health, hygiene and sanitary facilities

Hygiene and health requirements should be followed to ensure that personnel who come directly into contact with fresh fruits and vegetables during or after harvesting are not likely to contaminate them.

Visitors should, where appropriate, wear protective clothing and adhere to the other personal hygiene provisions in this section.

3.2.3.1 Personnel hygiene and sanitary facilities

Hygienic and sanitary facilities should be available to ensure that an appropriate degree of personal hygiene can be maintained. As far as possible, such facilities should :

- Be located in close proximity to the fields and indoor premises, and in sufficient number to accommodate personnel.
- Be of appropriate design to ensure hygienic removal of wastes and avoid contamination of growing sites, fresh fruits and vegetables or agricultural inputs.
- Have adequate means of hygienically washing and drying hands.
- Be maintained under sanitary conditions and good repair.

3.2.3.2 Health status

People known, or suspected, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through fresh fruits and vegetables, should not be allowed to enter any food handling area if there is a likelihood of their contaminating fresh fruits and vegetables. Any person so affected should immediately report illness or symptoms of illness to the management.

3.2.3.3 Personal cleanliness

Agricultural workers who have direct contact with fresh fruits and vegetables should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing and footwear. Cuts and wounds should be covered by suitable waterproof dressings when personnel are permitted to continue working.

Personnel should wash their hands when handling fresh fruits and vegetables or other material that comes in contact with them. Personnel should wash their hands before starting work involving the handling of fruits and vegetables, each time they return to handling areas after a break, immediately after using the toilet or after handling any contaminated material where this could result in contamination of fresh fruits and vegetables.

3.2.3.4 Personal behaviour

Agricultural workers should refrain from behaviour which could result in the contamination of food, for example: smoking, spitting, chewing gum or eating, or sneezing or coughing over unprotected fresh fruits and vegetables.

Personal effects such as jewellery, watches, or other items should not be worn or brought into fresh fruit and vegetable production areas if they pose a threat to the safety and suitability of the food.

### 3.2.4 Equipment associated with growing and harvesting

As required, growers and harvesters should follow the technical specifications recommended by the equipment manufacturers for their proper usage and maintenance. Growers and harvesters should

adopt the following sanitary practices:

- Equipment and containers coming into contact with fresh fruits and vegetables should be made of materials that are non-toxic. They should be designed and constructed to ensure that, when necessary, they can be cleaned, disinfected and maintained to avoid the contamination of fresh fruit and vegetables. Specific hygienic and maintenance requirements should be identified for each piece of equipment that is used and the type of fruit or vegetable associated with it.
- Containers for waste, by-products and inedible or dangerous substances, should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material. Where appropriate, such containers should be lockable to prevent malicious or accidental contamination of fresh fruits and vegetables or agricultural inputs. Such containers should be segregated or otherwise identified to prevent their use as harvesting containers.
- Containers that can no longer be kept in a hygienic condition should be discarded.
- Equipment and tools should function according to the use for which they are designed without damaging the produce. Such equipment should be maintained in good order.

## 3.3 ANDLING, STORAGE AND TRANSPORT

### 3.3.1 Prevention of cross-contamination

During the primary production and post-harvest activities, effective measures should be taken to prevent cross-contamination of fresh fruits and vegetables from agricultural inputs or personnel who come directly or indirectly into contact with fresh fruits and vegetables. To prevent the potential of crosscontaminating fresh fruits and vegetables, growers, harvesters and their employees should adhere to the recommendations presented elsewhere in section 3 of this code and the following :

- At the time of harvest, consideration should be given to the need for additional management action where any local factor, for example adverse weather conditions, may increase the opportunity for contamination of the crop.
- Fresh fruits and vegetables unfit for human consumption should be segregated during harvesting. Those which cannot be made safe by further processing should be disposed of properly to avoid contamination of fresh fruits and vegetables or agricultural inputs.
- Agricultural workers should not use harvesting containers for carrying materials (e.g. lunches, tools, fuel, etc.) other than harvested fruits and vegetables.
- Equipment and containers previously used for potentially hazardous materials (e.g. garbage, manure, etc.) should not be used for holding fresh fruits or vegetables or have contact with packaging material that is used for fresh fruits and vegetables without adequate cleaning and disinfecting.
- Care must be taken when packing fresh fruits and vegetables in the field to avoid contaminating containers or bins by exposure to , manure or animal/human faeces.

### 3.3.2 Storage and transport from the field to the packing facility

Fresh fruits and vegetables should be stored and transported under conditions which will minimize the potential for microbial, chemical or physical contamination. The following practices should be adopted :

- Storage facilities and vehicles for transporting the harvested crops should be built in a manner to minimize damage to fresh fruits and vegetables and to avoid access by pests. They should be made of non-toxic materials that permit easy and thorough cleaning. They should be constructed in a manner to reduce the opportunity for potential contamination from physical objects such as glass, wood, plastic, etc.
- Fresh fruits and vegetables unfit for human consumption should be segregated before storage or transport. Those which cannot be made safe by further processing should be disposed of properly to avoid contamination of fresh fruits and vegetables or agricultural inputs.

- Agricultural workers should remove as much soil as possible from fresh fruits and vegetables before they are stored or transported. Care should be taken to minimize physical damage to crop during this process.
- Transport vehicles should not be used for the transport of hazardous substances unless they are adequately cleaned, and where necessary disinfected, to avoid cross-contamination.

### 3.4 CLEANING, MAINTENANCE AND SANITATION

Premises and harvesting equipment should be kept in an appropriate state of repair and condition to facilitate cleaning and disinfection. Equipment should function as intended to prevent contamination of fresh fruits and vegetables. Cleaning materials and hazardous substances such as agricultural chemicals should be specifically identifiable and kept or stored separately in secure storage facilities. Cleaning materials and agricultural chemicals should be used according to manufacturer's instructions for their intended purpose.

#### 3.4.1 Cleaning programs

Cleaning and disinfection programs should be in place to ensure that any necessary cleaning and maintenance is carried out effectively and appropriately. Cleaning and disinfection systems should be monitored for effectiveness and should be regularly reviewed and adapted to reflect changing circumstances. Specific recommendations are as follows :

- Harvesting equipment and re-usable containers that come in contact with fresh fruits and vegetables should be cleaned, and, where appropriate, disinfected on a regular basis.
- Harvesting equipment and re-usable containers used for fresh fruits and vegetables that are not washed prior to packing should be cleaned and disinfected as necessary.

#### 3.4.2 Cleaning procedures and methods

The appropriate cleaning methods and materials will depend on the type of equipment and the nature of the fruit or vegetable. The following procedure should be adopted :

- Cleaning procedures should include the removal of debris from equipment surfaces, application of a detergent solution, rinsing with water, and, where appropriate, disinfection.

#### 3.4.3 Pest control systems

When primary production is carried out in indoor establishments (e.g. greenhouses), the recommendations of the *General Principles of Food Hygiene*, section 6.3 should be followed with respect to pest control.

#### 3.4.4 Waste management

Suitable provision must be made for the storage and removal of waste. Waste must not be allowed to accumulate in fresh fruit and vegetable handling and storage areas or the adjoining environment. Storage areas for waste should be kept clean.

## 4. PACKING ESTABLISHMENT: DESIGN AND FACILITIES

Refer to the General Principles of Food Hygiene.

## 5. CONTROL OF OPERATION

### 5.1 CONTROL OF FOOD HAZARDS

Refer to the General Principles of Food Hygiene.

### 5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

#### 5.2.1 Time and temperature control

Refer to the General Principles of Food Hygiene.

### 5.2.2 Specific process steps

#### 5.2.2.1 Post-harvest water use

Water quality management will vary throughout all operations. Packers should follow GMPs to prevent or minimize the potential for the introduction or spread of pathogens in processing water. The quality of water used should be dependent on the stage of the operation. For example, clean water could be used for initial washing stages, whereas water used for final rinses should be of potable quality.

- Post-harvest systems that use water should be designed in a manner to minimize places where product lodges and dirt builds up.
- Antimicrobial agents should only be used where absolutely necessary to minimize crosscontamination during post-harvest and where their use is in line with good hygienic practices. The antimicrobial agents levels should be monitored and controlled to ensure that they are maintained at effective concentrations. Application of antimicrobial agents, followed by a wash as necessary, should be done to ensure that chemical residues do not exceed levels as recommended by the Codex Alimentarius Commission.
- Where appropriate, the temperature of the post-harvest water should be controlled and monitored.
- Recycled water should be treated and maintained in conditions that do not constitute a risk to the safety of fresh fruits and vegetables. The treatment process should be effectively monitored and controlled.
- Recycled water may be used with no further treatment provided its use does not constitute a risk to the safety of fresh fruits and vegetables (e.g. use of water recovered from the final wash for the first wash).
- Ice should be made from potable water. Ice should be produced, handled and stored to protect it from contamination.

#### 5.2.2.2 Chemical treatments

- Packers should only use chemicals for post-harvest treatments (e.g. waxes, fungicides) in accordance with the General Standards on Food Additives or with the Codex Pesticide Guidelines. These treatments should be carried out in accordance with the manufacturer's instructions for the intended purpose.
- Sprayers for post-harvest treatments should be calibrated regularly to control the accuracy of the rate of application. They should be thoroughly washed in safe areas when used with different chemicals and on different fruits or vegetables to avoid contaminating the produce.

#### 5.2.2.3 Cooling of fresh fruits and vegetables

- Condensate and defrost water from evaporator type cooling systems (e.g. vacuum cooling, cold rooms) should not drip onto fresh fruits and vegetables. The inside of the cooling systems should be maintained clean.
- Potable water should be used in cooling systems where water or ice is in direct contact with fresh fruits and vegetables (e.g. hydro cooling, ice cooling). The water quality in these systems should be controlled and maintained.
- Forced-air cooling is the use of rapid movement of refrigerated air over fresh fruits and vegetables in cold rooms. Air cooling systems should be appropriately designed and maintained to avoid contaminating fresh produce.

#### 5.2.2.4 Cold storage

- When appropriate, fresh fruits and vegetables should be maintained at low temperatures

after cooling to minimize microbial growth. The temperature of the cold storage should be controlled and monitored.

- Condensate and defrost water from the cooling system in cold storage areas should not drip on to fresh fruits and vegetables. The inside of the cooling systems should be maintained in a clean and sanitary condition.

5.2.3 Microbiological and other specifications

Refer to the General Principles of Food Hygiene.

5.2.4 Microbial cross-contamination

Refer to the General Principles of Food Hygiene.

5.2.5 Physical and chemical contamination

Refer to the General Principles of Food Hygiene.

5.3 INCOMING MATERIAL REQUIREMENTS

Refer to the General Principles of Food Hygiene.

5.4 PACKING

Refer to the General Principles of Food Hygiene.

5.5 WATER USED IN THE PACKING ESTABLISHMENT

Refer to the General Principles of Food Hygiene.

5.6 MANAGEMENT AND SUPERVISION

Refer to the General Principles of Food Hygiene.

5.7 DOCUMENTATION AND RECORDS

Where appropriate, records of processing, production and distribution should be kept long enough to facilitate a recall and food borne illness investigation, if required. This period could be much longer than the shelf life of fresh fruits and vegetables. Documentation can enhance the credibility and effectiveness of the food safety control system.

- Growers should keep current all relevant information on agricultural activities such as the site of production, suppliers' information on agricultural inputs, lot numbers of agricultural inputs, irrigation practices, use of agricultural chemicals, water quality data, pest control and cleaning schedules for indoor establishments, premises, facilities, equipment and containers.
- Packers should keep current all information concerning each lot such as information on incoming materials (e.g. information from growers, lot numbers), data on the quality of processing water, pest control programmes, cooling and storage temperatures, chemicals used in post-harvest treatments, and cleaning schedules for premises, facilities, equipment and containers, etc.

5.8 RECALL PROCEDURES

Refer to the General Principles of Food Hygiene.

In addition, where appropriate :

- Growers and packers should have programs to ensure effective lot identification. These programs should be able to trace the sites and agricultural inputs involved in primary production and the origin of incoming material at the packing establishment in case of suspected contamination.
- Growers' information should be linked with packers'information so that the system can trace products from the distributor to the field. Information that should be included are the date of harvest, farm identification, and, where possible, the persons who handled the fresh fruits or vegetables from the primary production site to the packing establishment.

## 6. PACKING ESTABLISHMENT : MAINTENANCE AND SANITATION

Refer to the General principles of Food Hygiene.

## 7. PACKING ESTABLISHMENT: PERSONAL HYGIENE

Refer to the General Principles of Food Hygiene.

## 8. TRANSPORTATION

Refer to the General Principles of Food Hygiene and to the Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food.

## 9. PRODUCT INFORMATION AND CONSUMER AWARENESS

Refer to the General Principles of Food Hygiene.

## 10. TRAINING

Refer to the General Principles of Food Hygiene except for section 10.1 and 10.2.

### 10.1 AWARENESS AND RESPONSIBILITIES

Personnel associated with growing and harvesting should be aware of GAPs, good hygienic practices and their role and responsibility in protecting fresh fruits and vegetables from contamination or deterioration. Agricultural workers should have the necessary knowledge and skills to enable them to carry out agricultural activities and to handle fresh fruits and vegetables and agricultural inputs hygienically.

Personnel associated with packing should be aware of GMPs, good hygienic practices and their role and responsibility in protecting fresh fruits and vegetables from contamination or deterioration. Packers should have the necessary knowledge and skills to enable them to perform packing operations and to handle fresh fruits and vegetables in a way that minimizes the potential for microbial, chemical, or physical contamination.

All personnel who handle cleaning chemicals or other potentially hazardous chemicals should be instructed in safe handling techniques. They should be aware of their role and responsibility in protecting fresh fruit and vegetables from contamination during cleaning and maintenance.

### 10.2 TRAINING PROGRAMMES

Factors to take into account in assessing the level of training required in growing, harvesting and packing activities include:

- The nature of the fruit or vegetable, in particular its ability to sustain growth of pathogenic microorganisms.
- The agricultural techniques and the agricultural inputs used in the primary production including the probability of microbial, chemical and physical contamination.
- The task the employee is likely to perform and the hazards and controls associated with those tasks.
- The manner in which fresh fruits and vegetables are processed and packaged including the probability of contamination or microbial growth.
- The conditions under which fresh fruits and vegetables will be stored.
- The extent and nature of processing or further preparation by the consumer before final consumption.

Topics to be considered for training programmes include, but are not limited to, the following :

- The importance of good health and hygiene for personal health and food safety.
- The importance of hand washing for food safety and the importance of proper hand washing techniques.
- The importance of using sanitary facilities to reduce the potential for contaminating fields, produce, other workers, and water supplies.
- Techniques for hygienic handling and storage of fresh fruits and vegetables by transporters, distributers, storage handlers and consumer.

**ANNEX I**

## ANNEX FOR READY-TO-EAT FRESH PRE-CUT FRUITS AND VEGETABLES

### INTRODUCTION

The health benefits associated with fresh fruits and vegetables combined with the on-going consumer interest in the availability of a variety of ready-to-eat foods have contributed to a substantial increase in the popularity of pre-cut fruits and vegetables. Because of the increased convenience and consumption of pre-cut fruits and vegetables in and away from the home, the preparation of these products has moved from the point of consumption to the food processor or retailer. The processing of fresh produce without proper sanitation procedures in place in the manufacturing environment may enhance the potential for contamination by microbiological pathogens. The potential for pathogens to survive or grow may be enhanced by the high moisture and nutrient content of fresh-cut fruits and vegetables, the absence of a lethal process to eliminate them, and the potential for temperature abuse during processing, storage, transport, and retail display.

Some of the microbiological pathogens associated with fresh fruits and vegetables include *Salmonella* spp., *Shigella* spp., pathogenic strains of *Escherichia coli, Listeria monocytogenes*, Norwalk-like virus and hepatitis A virus and parasites such as Cyclospora. Some of these pathogens are associated with the agricultural environment, whereas others are associated with infected workers or contaminated water. Because of the ability for pathogens to survive and grow on fresh produce, it is important for the pre-cut industry to follow good hygienic practices to ensure the microbiological safety of its products.

### 1. OBJECTIVE

Hygienic recommendations for the primary production of fresh fruits and vegetables are covered under the *Code of Practice for Fresh Fruits and Vegetables*. This Annex recommends the application of Good Manufacturing Practices (GMPs) for all stages involved in the production of ready-to-eat fresh pre-cut fruits and vegetables, from receipt of raw materials to distribution of finished products.

The primary objective of this Annex is to identify GMPs that will help control microbiological, physical, and chemical hazards associated with the processing of fresh pre-cut fruits and vegetables. Particular attention is given to minimizing microbiological hazards. This Annex provides elements that should be taken into account in the production, processing and distribution of these foods.

### 2. SCOPE, USE AND DEFINITIONS

#### 2.1 SCOPE

This Annex specifically applies to ready-to-eat fresh fruit and vegetables that have been peeled, cut or otherwise physically altered from their original form but remain in the fresh state and particularly those that are intended to be consumed raw. This Annex applies irrespective of where the operations take place (e.g. in the field, at the farm, at the retailer, at the wholesaler, at the processing establishment, etc.).

For some establishments that process fresh pre-cut fruit and vegetables, this Annex will cover all operations from receipt of raw material to the distribution of the final product. For other establishments, (e.g. those that use ready-to-eat pre-cut fresh fruit and vegetables in combination with other products, such as sauces, meat, cheese, etc.) only the specific sections that relate to the processing of the fresh precut fruit and vegetable components will apply.

This Annex does not directly apply to fresh fruit and vegetables that have been trimmed leaving the food intact. Nor does it apply to other fresh fruit and vegetables that are pre-cut but are

destined for further processing that would be expected to eliminate any pathogen that may be present (e.g. cooking, juice processing, fermentation) nor to fresh fruit or vegetable juices. However, some of the basic principles of the Annex could still be applicable to such products. Packaging includes single serving containers (e.g., sealed pouches or plastic trays), larger consumer or institutional size packages and bulk containers. This Annex concentrates on microbial hazards and addresses physical and chemical hazards only in so far as these relate to GMPs.

2.2 USE

This document follows the format of the Recommended International Code of Practice - General Principles of Food Hygiene CAC/RCP 1-1969, Rev 3 (1997) and should be used in conjunction with the General Principles of Food Hygiene and the Code of Hygienic Practice for Fresh Fruits and Vegetables.

2.3 DEFINITIONS

*Processor* - the person responsible for the management of the activities associated with the production of ready-to-eat fresh pre-cut fruits and vegetables.

## 3. PRIMARY PRODUCTION

Refer to the Code of Hygienic Practice for Fresh Fruits and Vegetables.

## 4. ESTABLISHMENT : DESIGN AND FACILITIES

Refer to the General Principles of Food Hygiene. In addition:

4.4 FACILITIES

4.4.2 Drainage and Waste Disposal

The processing of products covered by this Annex generates a large quantity of waste that can serve as food and shelter for pests. It is therefore very important to plan an effective waste disposal system. This system should always be maintained in good condition so it does not become a source of product contamination.

## 5. CONTROL OF OPERATIONS

Refer to the Code of Hygienic Practice for Fresh Fruits and Vegetables. In addition :

5.1 CONTROL OF FOOD HAZARDS

For the products covered by this Annex it should be recognised that while processing may reduce the level of contamination initially present on the raw materials, it will not be able to guarantee elimination of such contamination. Consequently, the processor should ensure that steps are taken by their suppliers

(growers, harvesters, packers and distributors) to minimise contamination of the raw materials during primary production. It is recommended that processors ensure that their suppliers have adopted the principles outlined in the *Code of Hygienic Practice for Fresh Fruits and Vegetables*.

There are certain pathogens, *Listeria monocytogenes* and *Clostridium botulinum*, which present specific concern in relation to ready to eat fresh pre-cut vegetables packaged in a modified atmosphere. Processors should ensure that they have addressed all relevant safety issues relating to the use of such packaging.

5.2 KEY ASPECTS OF CONTROL SYSTEMS

5.2.2 Specific Process Steps

5.2.2.1 Receipt and inspection of raw materials

During unloading of raw material, verify the cleanliness of the food transportation unit and

raw materials for evidence of contamination and deterioration

5.2.2.2 Preparation of raw material before processing

Physical hazards (such as the presence of animal and plant debris, metal, and other foreign material) should be removed through manual sorting or the use of detectors, such as metal detectors. Raw materials should be trimmed to remove any damaged, rotten or mouldy material.

5.2.2.3 Washing and microbiological decontamination

Refer to section 5.2.2.1 of the Code of Hygienic Practice for Fresh Fruits and Vegetables. In addition :

- Water used for final rinses should be of potable quality, particularly for these products as they are not likely to be washed before consumption.

5.2.2.4 Pre-cooling Fresh Fruits and Vegetables

Refer to section 5.2.2.3 of the Code of Hygienic Practice for Fresh Fruits and Vegetables.

5.2.2.5 Cutting, slicing, shredding, and similar pre-cut processes

Procedures should be in place to minimize contamination with physical (e.g. metal) and microbiological contaminants during cutting, slicing, shredding or similar pre-cut processes.

5.2.2.6 Washing after cutting, slicing, shredding, and similar pre-cut processes

Washing cut produce with potable water may reduce microbiological contamination. In addition, it removes some of the cellular fluids that were released during the cutting process thereby reducing the level of available nutrients for microbiological growth. The following should be considered :

- Water should be replaced at sufficient frequency to prevent the build-up of organic material and prevent cross-contamination.
- Antimicrobial agents should be used, where necessary, to minimize cross-contamination during washing and where their use is in line with good hygienic practices. The antimicrobial agents levels should be monitored and controlled to ensure that they are maintained at effective concentrations. Application of antimicrobial agents, followed by a wash as necessary, should be done to ensure that chemical residues do not exceed levels as recommended by the Codex Alimentarius Commission.
- Drying or draining to remove water after washing is important to minimize microbiological growth.

5.2.2.7 Cold Storage

Refer to section 5.2.2.4 of the Code of Hygienic Practice for Fresh Fruits and Vegetables. In addition :

- Pre-cut fresh fruits and vegetables should be maintained at low temperatures at all stages, from cutting through distribution to minimise microbiological growth.

## 5.7 DOCUMENTATION AND RECORDS

Where appropriate, records should be maintained to adequately reflect product information, such as product formulations or specifications and operational controls. Maintaining adequate documentation and records of processing operations is important in the event of recall of with fresh pre-cut fruits and vegetables. Records should be kept long enough to facilitate recalls and foodborne illness investigations, if required. This period will likely be much longer than the shelf life of the product. Some examples of records to keep are the following :

- Fresh fruit and vegetable supplier records
- Water quality and supply records

- Equipment monitoring and maintenance records
- Equipment calibration records
- Sanitation records
- Product processing records
- Pest control records
- Distribution records

5.8 RECALL PROCEDURES

Refer to the General Principles of Food Hygiene.

## 6. ESTABLISHMENT : MAINTENANCE AND SANITATION

Refer to the General Principles of Food Hygiene.

## 7. ESTABLISHMENT : PERSONAL HYGIENE

Refer to the General Principles of Food Hygiene.

## 8. TRANSPORTATION

Refer to the General Principles of Food Hygiene and the Code of Hygienic Practice for Fresh Fruits and Vegetables.

## 9. PRODUCT INFORMATION AND CONSUMER AWARENESS

Refer to the General Principles of Food Hygiene.

## 10. TRAINING

Refer to the General Principles of Food Hygiene and the Code of Hygienic Practice for Fresh Fruits and Vegetables. In addition :

10.2 TRAINING PROGRAMS

To evaluate the level of training required of persons responsible for the production of fresh pre-cut fruits and vegetables, the additional following factors should be taken into account :

- the packaging systems used for fresh pre-cut fruits and vegetables, including the risks of contamination or microbiological growth involved in this method;
- the importance of temperature control and GMPs.

## ANNEX FOR SPROUT PRODUCTION

### INTRODUCTION

In recent years the popularity of sprouted seeds has increased dramatically and are favoured by many for their nutritional value. However, the recent increase in reports of food borne illness associated with raw sprouts has raised concerns from public health agencies and consumers about the safety of these products.

The microbial pathogens associated with sprouted seeds are for example *Salmonella* spp, pathogenic *E. coli, Listeria monocytogenes*, and *Shigella* spp. Outbreak investigations have indicated that microorganisms found on sprouts most likely originate from the seeds. Most seeds supplied to sprout producers are produced primarily for forage or animal grazing where the Good Agricultural Practices (GAPs) necessary to prevent microbial contamination of seeds intended for sprouting are not followed, especially through the misuse of natural fertilizers or contaminated irrigation water. As a result, the seeds may be contaminated in the field or during harvesting, storage or transportation. Typically, the germination process in sprout production involves keeping seeds warm and moist for two to ten days. In these conditions, if low levels of microbial contaminants are present on seeds, they can quickly reach levels high enough to cause illness.

The scientific literature proposes microbiological decontamination of seeds treatments which can achieve different levels of pathogen reduction. There is currently no treatment available that can guarantee pathogen free seeds. Research is in progress to find efficient microbiological decontamination treatments which would provide sufficient pathogen reduction on seeds especially if pathogens are internalized.

### 1. OBJECTIVES

This annex recommends control measures to occur in two areas: during seed production and during sprout production. During seed production, conditioning and storage, the application of Good Agricultural Practices (GAPs) and Good Hygienic Practices (GHPs) are aimed at preventing microbial pathogen contamination of seeds. During sprout production, the microbiological decontamination of seeds step is aimed at reducing potential contaminants and the good hygienic practices at preventing the introduction of microbial pathogens and minimizing their potential growth. The degree of control in these two areas has a significant impact on the safety of sprouts.

### 2. SCOPE, USE AND DEFINITION

#### 2.1 SCOPE

This annex covers the hygienic practices that are specific for the primary production of seeds for sprouting and the production of sprouts for human consumption in order to produce a safe and wholesome product.

#### 2.2 USE

This annex follows the format of the Recommended International Code of Practice – General Principles of Food Hygiene CAC/RCP 1-1969, Rev 3 (1997) and should be used in conjunction with the General Principles of Food Hygiene and the Code of Hygienic Practice for Fresh Fruit and Vegetables.

#### 2.3 DEFINITIONS

***Seed producer*** - any person responsible for the management of activities associated with the primary production of seeds including post-harvest practices.

***Seed distributor*** - any person responsible for the distribution of seeds (handling, storage and transportation) to sprout producers. Seed distributors may deal with single or multiple seed producers and can be producers themselves.

***Sprout producer*** - any person responsible for the management of the activities associated with the production of sprouted seeds.

***Spent irrigation water*** - water that has been in contact with sprouts during the sprouting process.

## 3. PRIMARY PRODUCTION OF SEEDS

Refer to the Code of Hygienic Practice for Fresh Fruits and Vegetables. In addition :

### 3.2 HYGIENIC PRODUCTION OF SEEDS

3.2.1.2 Manure and biosolids

When seeds are destined for the production of sprouts for human consumption, wild or domestic animals should not be allowed to graze in the fields where seeds are grown (e.g., employing sheep for spring clip back of alfalfa).

It is particularly important to prevent microbial contamination during the production of seeds which will be used to produce sprouts for human consumption because of the potential for pathogens to grow during the sprouting process. Consequently, manure, biosolids and other natural fertilizers should only be used when they have undergone treatments which achieve a high level of pathogen reduction.

3.2.1.4 Agricultural chemicals

Seed producers should only use chemicals (e.g., pesticides, desiccants) which are acceptable for seeds intended for the production of sprouts for human consumption.

3.2.4 Equipment associated with growing and harvesting

Prior to harvest, harvesting equipment should be adjusted to minimize soil intake and seed damage and should be cleaned from any debris or earth. Diseased or damaged seeds, which could be susceptible to microbial contamination, should not be used for the production of sprouts for human consumption.

### 3.3 HANDLING, STORAGE AND TRANSPORT

Seeds produced for the production of sprouts for human consumption should be segregated from product to be seeded or planted for animal feed (e.g., for forage or animal grazing) and clearly labelled.

Recognising that seeds are vulnerable to microbial pathogens during thrashing and drying, adequate care is needed to maintain sanitation in drying yards, and exposure of seeds to mist, high humidity and fog should be avoided.

### 3.4 ANALYSES

Seed producers, distributors, and sprout producers should test lots of seeds for microbial pathogens using internationally accepted analytical methods. Sprouting seeds before testing increases the possibility of finding pathogens that may be present. If lots of seeds are found to be contaminated, they should not be sold or used for the production of sprouts for human consumption. Because of the limitations associated with sampling methods and analytical tests, failure to find contamination does not guarantee that the seeds are pathogen free. However, if contamination is found at this stage, it allows seeds to be diverted or destroyed before entering sprout production for human consumption. Seed producers, distributors and sprout producers should refer to the *Principles for the Establishment and Application of Microbiological Criteria for Foods,* CAC/GL 21-1977, for guidance on establishing a sampling plan.

### 3.5 RECALL PROCEDURES

Seed producers for the production of sprouts for human consumption should ensure that records and recall procedures are in place to effectively respond to health risk situations. Procedures should enable the complete and rapid recall of any implicated seed. The procedures should also assist in providing detailed information for the identification and investigation of any contaminated seeds and sprouts. The following should be adopted:

- Seed production and distribution practices should be in place to minimize the quantity of seed identified as a single lot and avoid the mixing of multiple lots that would complicate recalls and provide greater opportunity for cross-contamination. Seed producers and distributors and sprout producers should maintain records for each lot. The lot number, producer and country of origin should be indicated on each container.
- Seed producers should have a system to: effectively identify lots, trace the production sites and agricultural inputs associated with the lots, and allow physical retrieval of the seeds in case of a suspected hazard.
- Where a lot has been recalled because of a health hazard, other lots that were produced under similar conditions (e.g., on the same production sites or with the same agricultural inputs) and which may present a similar hazard should be evaluated for safety. Any lot presenting a similar risk should be recalled. Blends containing potentially contaminated seeds must also be recalled.
- Seeds which may present a hazard must be held and detained until they are disposed of properly.

## 4. ESTABLISHMENT FOR SPROUT PRODUCTION

Refer to the General Principles of Food Hygiene. In addition:

### 4.2.1 Design and layout

Where appropriate, the internal design and layout of sprout establishments should permit Good Hygiene Practices, including protection against cross-contamination between and during operations. Storage, seed rinsing and microbiological decontamination, germination and packaging areas should be physically separated from each other.

## 5. CONTROL OF OPERATION

Refer to the General Principles of Food Hygiene. In addition:

### 5.2.2 Specific process steps in sprout production

#### 5.2.2.1 Water use during sprout production

Water quality management will vary throughout all operations. Sprout producers should follow GMPs to minimize the potential for the introduction or spread of pathogens in processing water. The quality of water used should be dependent on the stage of the operation. Because of the potential for pathogen proliferation during the sprouting process, clean water could be used for initial washing stages, whereas water used later in the sprout production process (i.e., for the rinse following the microbiological decontamination of seed, and subsequent operations) should be preferably of potable quality or at least clean water.

#### 5.2.2.2 Initial rinse

The seeds should be rinsed thoroughly before the microbiological decontamination treatment to remove dirt and increase the efficiency of this treatment.

- Seeds should be rinsed and thoroughly agitated in large volumes of clean water, in such a way to maximize surface contact. The process should be repeated until most of the dirt is removed and rinse water remains clear.

5.2.2.3 Microbiological decontamination of seeds

Due to the difficulty of obtaining seeds which can be guaranteed as pathogen free, it is recommended that seeds be treated prior to the sprouting process. Although there are other options like the use of lactic acid bacteria, liquid microbiological decontamination treatment is generally used. During this treatment sprout producers should adhere to the following :

- All containers used for microbiological decontamination of seeds should be cleaned and disinfected prior to use.
- Seeds should be well agitated in large volumes of antimicrobial agent to maximise surface contact.
- The duration of treatment and the concentration of antimicrobial agent used should be accurately measured and recorded.
- Strict measures should be in place to prevent re-contamination of seeds after the microbiological decontamination treatment.
- Antimicrobial agent should be used according to manufacturer's instructions for their intended use.

5.2.2.4 Rinse after seed treatment

As appropriate, seeds should be thoroughly rinsed after the microbiological decontamination treatment with potable water or at least clean water. Rinsing should be repeated sufficiently to eliminate antimicrobial agent.

5.2.2.5 Pre-germination soak

Soaking is often necessary to improve germination. When soaking, the sprout producer should adhere to the following :

- All containers used for soaking should be cleaned and disinfected prior to use.
- Seeds should be soaked in cleaned water for the shortest possible time to minimize microbial growth.
- This step may also employ antimicrobial agents.
- After soaking, seeds should be rinsed thoroughly with potable water or at least clean water.

5.2.2.6 Germination

During germination, keep the environment and equipment clean to avoid potential contamination. All equipment should be cleaned and disinfected before each new batch.

- Only potable water should be used.
- Where necessary and when used, soils or other matrices should be treated (e.g., pasteurized) to achieve a high degree of microbial reduction.

5.2.2.7 Harvesting

All equipment should be cleaned and disinfected before each new batch. Harvesting should be done with cleaned and disinfected tools dedicated for this use.

5.2.2.8 Final rinse and cooling

A final water rinse will remove hulls, cool product, and may reduce microbial contamination on sprouts. The following should be adopted :

- As appropriate, sprouts should be rinsed in cold potable water to lower sprout temperature and slow down microbial growth.
- Water should be changed, as needed (e.g., between batches), to prevent

crosscontamination.

- Sprouts should be drained using appropriate equipment (e.g. food grade centrifugal dryer) that is clean and disinfected prior to use.
- If additional cooling time is necessary, steps should be taken to facilitate rapid cooling (e.g., placed in smaller containers with adequate air flow between containers).

5.2.2.9 Storage of finished product

- Where appropriate, sprouts should be kept under cold temperature (e.g. 50C) that will minimize microbial growth for the intended shelf life of the product. Regular and effective monitoring of temperature of storage areas and transport vehicles should be carried out.

### 5.2.3 Microbiological and other specifications

It is recommended that seed and sprouts or spent irrigation water be tested for the presence of pathogens.

5.2.3.1 Testing of seed lots before entering production

It is recommended that each new lot of seeds received at the sprouting facility is tested before entering production (i.e. before the microbiological decontamination of seeds).

- The seed sample selected for testing should be sprouted prior to analysis to increase the potential to detect pathogens if present. Analysis may be performed on the sprouted seeds or the water used to sprout the sample.
- Seed samples for microbial analysis should not be subject to any microbiological decontamination treatment at the sprouting facility.

5.2.3.2 Testing of sprouts and/or spent irrigation water

Current seed treatments cannot guarantee total elimination of pathogens. Further, if even a few pathogens survive the microbiological decontamination treatment, they can grow to high numbers during sprouting. Therefore, producers should have in place a sampling/testing plan to regularly monitor for pathogens at one or more stages after the start of germination.

- Analyses can be performed during the germination process (e.g., spent irrigation water or sprouts) and/or finished product may be analysed after harvest.
- Testing spent irrigation water is a good indicator of microbial conditions of sprouts. It is homogeneous and is simpler to analyse. Further, sampling spent irrigation water (or sprouts) during germination allows earlier results compared to testing finished product.
- Because of the sporadic nature of seed contamination, it is recommended that producers test every production lot.

### 5.2.4 Microbiological cross-contamination

Sprout producers should adhere to the following :

- The traffic pattern of employees should prevent cross-contamination of sprouts. For example : the employees should avoid going back and forth to various areas of production. The employees should not go from a potentially contaminated area to the germination and/or packaging area unless they have washed their hands and changed to clean protective clothing.

## 5.3 INCOMING MATERIAL REQUIREMENTS

### 5.3.1 Specifications for incoming seeds

- Sprout producers should recommend that seed producers adopt good agricultural practices and provide evidence that the product was grown according to section 3 of this Annex and the *Code of Hygienic Practice for Fresh Fruits and Vegetables*.

- Seed and sprout producers should obtain assurance from seed producers or distributors that chemical residues of each incoming lot are within the limits established by the Codex Alimentarius Commission and, where appropriate, they should obtain certificates of analysis for microbial pathogens of concern.

#### 5.3.2 Control of incoming seeds

Seed containers should be examined at their arrival to minimize the potential for introducing obvious contaminants in the establishment.

- Seed containers should be examined for physical damage (e.g., holes from rodents) and signs of contamination (e.g., stains, rodent, insects, faeces, urine, foreign material, etc.). If found to be damaged, contaminated or potentially contaminated, its contents should not be used for the production of sprouts for human consumption.
- If seed lots are analysed for the presence of microbial pathogens of concern, these should not be used until results of analysis are available.

#### 5.3.3 Seed storage

Seeds should be handled and stored in a manner that will prevent damage and contamination.

- Seeds should be stored off the floor, away from walls and in proper storage conditions to prevent mould and bacterial growth and facilitate pest control inspection.
- Open containers should be stored in such a way that they are protected from pests and other sources of contamination.

### 5.7 DOCUMENTATION AND RECORDS

Refer to the Code of Hygienic Practice for Fresh Fruits and Vegetables. In addition :

Written records that accurately reflect product information and operational controls should be available to demonstrate the adequacy of the production activities.

- Upon receipt of seeds, records should be maintained of the seed supplier, the lot number and the country of origin to facilitate recall procedures.
- Records should be legible, permanent and accurate. Records should include written procedures, controls, limits, monitoring results and subsequent follow-up documents. Records must include : seed sources and lot numbers, water analysis results, sanitation checks, pest control monitoring, sprout lot codes, analysis results, production volumes, storage temperature monitoring, product distribution and consumer complaints.
- Records should be kept long enough to facilitate recalls and food borne illness investigation, if required. This period will likely be much longer than the shelf life of the product.

## 6. ESTABLISHMENT : MAINTENANCE AND SANITATION

Refer to the General Principles of Food Hygiene.

## 7. ESTABLISHMENT : PERSONAL HYGIENE

Refer to the General Principles of Food Hygiene.

## 8. TRANSPORTATION

Refer to the General Principles of Food Hygiene.

## 9. PRODUCT INFORMATION AND CONSUMER AWARENESS

Refer to the General Principles of Food Hygiene.

## 10. TRAINING

Refer to the General Principles of Food Hygiene. In addition:

### 10.1 AWARENESS AND RESPONSIBILITIES

Refer to the Code of Hygienic Practice for Fresh Fruits and Vegetables. In addition :

- The producer should have a written training program that is routinely reviewed and updated. Systems should be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety of sprouts.

# GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS[1]
# CAC / GL 53 - 2003

## SECTION 1 – PREAMBLE

1. It is often the case that importing and exporting countries operate different food inspection and certification systems. The reasons for such differences include differences in prevalence of particular food safety hazards, national choice about management of food safety risks and differences in the historical development of food control systems.

2. In such circumstances, and in order to facilitate trade while protecting the health of consumers, an exporting and an importing country may work together to consider the effectiveness of sanitary measures of the exporting country in achieving the appropriate level of sanitary protection of the importing country, consistent with the principle of equivalence as provided for in the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement).[2]

3. Application of the principle of equivalence has mutual benefits for both exporting and importing countries. While protecting the health of consumers, it serves to facilitate trade, and minimize the costs of regulation to governments, industry, producers, and consumers by allowing the exporting country to employ the most convenient means in its circumstances to achieve the appropriate level of protection of the importing country.[3]

4. Importing countries should avoid the application of unnecessary measures when they have already been carried out by the exporting country. Importing countries may be able to reduce the frequency and extent of verification measures following a judgment of equivalence of measures applied in the exporting country.

## SECTION 2 – SCOPE

5. This document provides guidelines on the judgement of the equivalence of sanitary measures associated with food inspection and certification systems. For the purpose of determining equivalence, these measures can be broadly characterized as infrastructure; programme design, implementation and monitoring; and/or specific requirements (refer paragraph 13).

## SECTION 3 – DEFINITIONS

6. The definitions presented in this document are derived from and consistent with those of the Codex Alimentarius Commission and the WTO SPS Agreement.

*Sanitary measure :* Any measure applied to protect human life or health within the territory of the

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1 These guidelines should be read in conjunction with other relevant Codex texts, including in particular the Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems – CAC/GL 34-1999.

2 Consistent with the definition of equivalence in Section 3, measures that are *equivalent* (i.e., are different from the measures used by the importing country but nonetheless achieve the importing country's appropriate level of protection) should be distinguished from measures that are the same as the measures of the importing country.

3 The benefits to an exporting country of application of the principle of equivalence would be offset or negated if a request for an equivalence determination were, by itself, used as a pretext for the disruption of established trade. Such action by an importing country would be contrary to the principles of international trade.

country from risks arising from additives, contaminants, toxins or disease-causing organisms in food or feedstuffs, or from risks arising from diseases carried by foods which are animals, plants or products thereof or from risks arising from any other hazards in foods.

Note : Sanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter* alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures ; provisions on relevant statistical methods, sampling procedures and methods of risk assessment ; and packaging and labeling requirements directly related to food safety.

***Hazard :*** A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.[4]

***Risk :*** A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.[4]

***Risk Assessment :*** A scientifically-based process consisting of the following steps : ( i ) hazard identification ; ( ii ) hazard characterization ; (iii) exposure assessment ; and (iv) risk characterisation.[4]

***Appropriate level of sanitary protection (ALOP) :*** The level of protection deemed appropriate by the country establishing a sanitary measure to protect human life or health within its territory. (This concept may otherwise be referred to as the "acceptable level of risk".)

***Equivalence of sanitary measures :*** [5] Equivalence is the state wherein sanitary measures applied in an exporting country, though different from the measures applied in an importing country, achieve, as demonstrated by the exporting country, the importing country's appropriate level of sanitary protection.

## SECTION 4 - GENERAL PRINCIPLES FOR THE DETERMINATION OF EQUIVALENCE

7. Determination of the equivalence of sanitary measures associated with food inspection and certification systems should be based on application of the following principles :

(a) An importing country has the right to set a level of sanitary protection it deems appropriate in relation to the protection of human life and health.[6] The ALOP may be expressed in qualitative or quantitative terms.

(b) The sanitary measure[7] applied in an importing country should in practice achieve the ALOP of the importing country and be applied consistent with article 2.3 of the SPS agreement.[8]

(c) An importing country should describe how its own sanitary measure achieves its ALOP.

(d) An importing country should recognize that sanitary measures different from its own may be capable of achieving its ALOP, and can therefore be found to be equivalent.

(e) The sanitary measure that the exporting country proposes as equivalent must be capable of achieving the importing country's ALOP.

(f) An importing country should, upon request by an exporting country, promptly enter into consultations with the aim of determining the equivalence of specified sanitary measures within

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4 Codex Alimentarius Commission: Procedural Manual (12th Edition), pages 43-44.

5 Equivalence is defined in CAC/GL 26-1997 as "the capability of different inspection and certification systems to meet the same objectives".

6 The SPS Agreement sets out the rights and obligations of WTO Members in relation to the determination of an appropriate level of sanitary protection.

7 Where this guideline refers to 'measure' in the singular it may also be taken to refer to 'measures' or 'a set of measures', as appropriate to the circumstances.

8 Equivalent measures may achieve the ALOP of the importing country or, in combination with other measures, they may contribute to the achievement of the importing country's ALOP. In the remainder of this guideline any reference to the former should be taken to include the latter possibility.

a reasonable period of time.[9]

(g) It is the responsibility of the exporting country to objectively demonstrate that its sanitary measure can achieve the importing country' s ALOP.

(h) The comparison of countries' sanitary measures should be carried out in an objective manner.

( i ) Where risk assessment is used in the demonstration of equivalence, countries should strive to achieve consistency in the techniques applied, using internationally accepted methodology where available and taking into account relevant Codex texts.

(j) The importing country should take into account any knowledge and past experience it has of the food inspection and certification systems in the exporting country to make the determination as efficiently and quickly as possible.

(k) The exporting country should provide access to enable the inspection and certification systems which are the subject of the equivalence determination to be examined and evaluated upon request of the food control authorities of the importing country.

(l) All judgments of equivalence should consider the means by which that equivalence will be maintained.

(m) Countries should ensure transparency in both the demonstration and judgment of equivalence, consulting all interested parties to the extent practicable and reasonable. The exporting and importing countries should approach an equivalence determination procedure in a cooperative way.

(n) An importing country should give positive consideration to a request by an exporting developing country for appropriate technical assistance that would facilitate the successful completion of an equivalency determination.

## SECTION 5 - THE CONTEXT OF AN EQUIVALENCE DETERMINATION

8. To facilitate judgement of equivalence between countries and promote harmonisation of food safety standards, Codex members should base their sanitary measures on Codex standards and related texts.[10]

9. An equivalence determination can be sought for any sanitary measure or set of measures relevant to a food product or group of food products. Relevant sanitary measures making up a food control system in the exporting country that are not the subject of an equivalence determination should meet importing country requirements.

10. The extent of the equivalence determination will depend on the prior experience, knowledge, and confidence that the importing country has regarding the food control measures of the exporting country.

11. When an importing country has prior experience, knowledge, and confidence in food control measures relevant to those being evaluated for equivalence and the countries agree that import requirements are being fully met, e.g. where trade experience exists, determination of the equivalence of sanitary measures may be made without further consideration of those other relevant measures making up the food control system.

12. When an importing country does not have prior experience, knowledge, and confidence in food control measures relevant to those being evaluated for equivalence and the countries have not

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9 Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems - CAC/GL 26- 1997.

10 Article 3 of the WTO SPS Agreement states, *inter alia*, that WTO Members may introduce or maintain sanitary measures which result in a higher level of sanitary protection than would be achieved based on Codex standards, if there is a scientific justification, or as a consequence of the member's chosen level of protection. Such measures must be based on a risk assessment appropriate to the circumstances.

determined that import requirements are being fully met, e.g., where trade in a food product or group of food products is being proposed for the first time, determination of the equivalence of sanitary measures will require further consideration of those other relevant measures making up the food control system.

13. For the purposes of determining equivalence, the sanitary measures associated with a food inspection and certification system can be broadly categorised as :

(a) infrastructure; including the legislative base (e.g., food and enforcement law), and administrative systems (e.g., organization of national and regional authorities, enforcement systems, etc.) ;

(b) programme design, implementation and monitoring; including documentation of systems, monitoring, performance, decision criteria and action, laboratory capability, transportation infrastructure and provisions for certification and audit ; and/or

(c) specific requirements; including requirements applicable to individual facilities (e.g., premises design), equipment (e.g., design of food contact machinery), processes (e.g., HACCP plans), procedures (e.g., ante- and post-mortem inspection), tests (e.g., laboratory tests for microbiological and chemical hazards) and methods of sampling and inspection.

14. Categorization in this manner is likely to facilitate agreement between countries on the basis for comparison of sanitary measures subject to an equivalence determination (see section 6). Further, allocation of measures to a particular category may assist countries in simplifying the extent of the equivalence determination relative to other sanitary measures making up the food control system.

## SECTION 6 - OBJECTIVE BASIS OF COMPARISON

15. Since the sanitary measures applied by an importing country have the purpose of achieving its ALOP, an exporting country may demonstrate achievement of the importing country's ALOP by demonstrating that the measures it proposes as equivalent have the same effect, relative to the achievement of the importing country's ALOP, as the corresponding sanitary measures applied by the importing country by using an objective basis of comparison.

16. The importing country should, at the request of the exporting country, specify as precisely as possible an objective basis for comparison of the sanitary measures proposed by the exporting country and its own measures.[11] Dialogue between the exporting and importing country will assist in the development of understanding and, desirably, agreement on the objective basis for comparison. Supporting information to be provided by the importing country may include :

(a) the reason/purpose for the sanitary measure, including identification of the specific risks that the measure is intended to address ;

(b) the relationship of the sanitary measure to the ALOP, i.e., how the sanitary measure achieves the ALOP ;

(c) where appropriate, an expression of the level of control of the hazard in a food that is achieved by the sanitary measure ;

(d) the scientific basis for the sanitary measure under consideration, including risk assessment where appropriate ;

(e) any additional information that may assist the exporting country in presenting an objective demonstration of equivalence.

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11 The objective basis for comparison of sanitary measures categorized as "Infrastructure" is likely to be of a qualitative nature, e.g., the ability of food control legislation to achieve broad food safety goals. The objective basis of comparison of sanitary measures categorized as "Specific Requirements" is likely to be quantitative in nature e.g., a comparison of levels of hazard control achieved by the measure. The objective basis of comparison of sanitary measures categorized as "Programme" is likely to contain a mixture of qualitative and quantitative elements e.g., correct application of principles, and establishment of appropriate critical limits, in HACCP food control systems.

## SECTION 7 - PROCEDURE FOR THE DETERMINATION OF EQUIVALENCE

17. The importing country should make available details of its sanitary measures to the exporting country on request. The exporting country should review all applicable sanitary measures of the importing country for the food involved and identify those it will meet and those for which it seeks determination of equivalence. The importing and exporting countries should then use an agreed process for exchange of the relevant information to facilitate the determination of equivalence. This information should be limited to that which is necessary for this purpose.

18. The determination of equivalence is facilitated by both exporting and importing countries following a sequence of steps, such as those described below and illustrated in Figure 1. The parties should work through these steps in a cooperative manner with the aim of reaching agreement:

(a) The exporting country identifies the sanitary measure of the importing country for which it wishes to apply a different measure, and requests the reason/purpose for the measure.

(b) The importing country provides the reason/purpose for the identified sanitary measure and other relevant information in accordance with section 6.

(c) In accordance with section 6 the importing country should specify as precisely as possible an objective basis for comparison of the sanitary measures proposed by the exporting country and its own measures. On the initiative of the exporting country, the importing and exporting countries should enter into a dialogue concerning this objective basis for comparison with a view to reaching agreement.

(d) The exporting country develops a submission using risk assessment or other relevant methodology as appropriate, to demonstrate that the application of the different sanitary measure achieves the ALOP of the importing country, and presents it to the importing country.

(e) The importing country reviews the submission and, if adequate, uses the submission to determine whether the exporting country's measure achieves the importing country's ALOP.

(f) If the importing country has any concerns with the submission as presented, it should notify them to the exporting country at the earliest opportunity and should detail the reasons for concern. If possible, the importing country should suggest how the concerns might be addressed.

(g) The exporting country should respond to such concerns by providing further information, modifying its proposal or taking other action as appropriate.

(h) The importing country notifies the exporting country of its judgement within a reasonable period of time and provides the reasoning for its decision, should the judgement be that the sanitary measure is not equivalent, i.e., does not achieve the importing country's ALOP.

(i) An attempt should be made to resolve any differences of opinion over judgement of a submission, either interim or final.

## SECTION 8 - JUDGEMENT

19. Judgement of equivalence by the importing country should be based on a transparent analytical process that is objective and consistent, and includes consultation with all interested parties to the extent practicable and reasonable.

20. Judgement of the equivalence of sanitary measures should take into account:

(a) experience, knowledge and confidence of an exporting country's food inspection and certification systems (see section 5);

(b) supporting data submitted by the exporting country;

(c) analysis of the strength of the relationship between the exporting country's specified sanitary measure, and the achievement of the ALOP of the importing country as reflected in the

objective basis for comparison (see section 6) ;

(d) that parameters should be stated in quantitative terms to the extent possible ;

(e) adequacy of qualitative descriptions where the level of control of hazards in foods in is not quantified ;

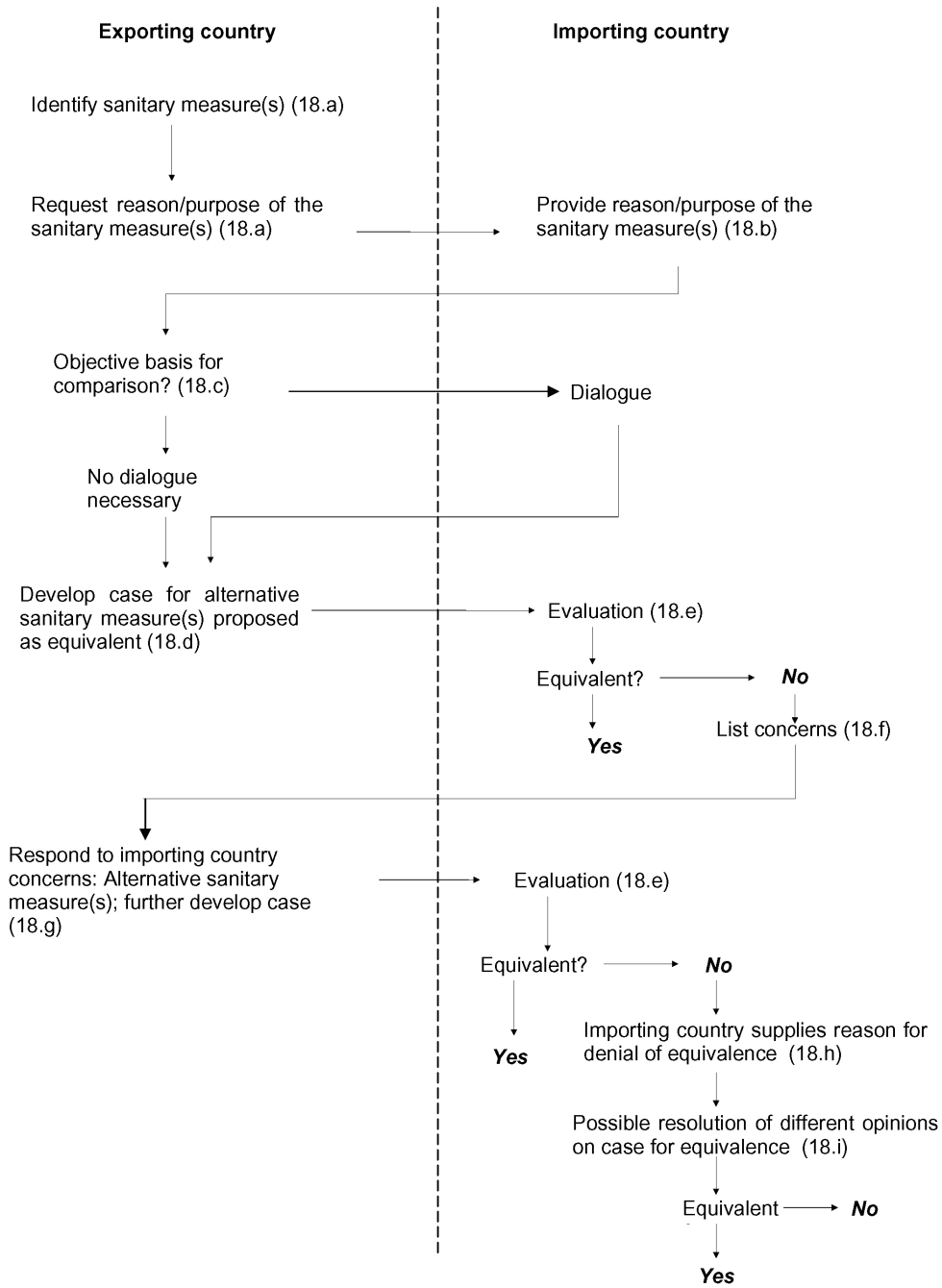
(f) consideration of variability and other sources of uncertainty in data ;

(g) consideration of all expected human health outcomes of the exporting country's identified sanitary measure ;

(h) those Codex texts relevant to the food safety matters under consideration.

21. Following any judgment of equivalence, exporting and importing countries should promptly advise each other of significant changes in their supporting programmes and infrastructure that may affect the original determination of equivalence.

**Figure I : Simplified flow chart for the determination of equivalence (individual steps may be iterated)**



# CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS
# CAC / RCP 52 - 2003

## INTRODUCTION

This Code of Practice for Fish and Fishery Products has been developed by the Codex Committee on Fish and Fishery Products from the merging of the individual codes listed in Appendix Xii* plus a section on aquaculture and a section on frozen surimi. These codes were primarily of a technological nature offering general advice on the production, storage and handling of fish and fishery products on board fishing vessels and on shore. It also deals with the distribution and retail display of fish and fishery products.

This combined Code of practice has been further modified to incorporate the Hazard Analysis Critical Control Point (HACCP) approach described in the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969), Annex : *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application.* A pre-requisite programme is described in the Code covering technological guidelines and the essential requirements of hygiene in the production of fish, shellfish and their products, which are safe for human consumption, and otherwise meets the requirements of the appropriate Codex product standards. The Code also contains guidance on the use of HACCP, which is recommended to ensure the hygienic production of fish and fishery products to meet health and safety requirements.

Within this Code a similar systematic approach has been applied to essential quality, composition and labelling provisions of the appropriate Codex product standards. Throughout the code this is referred to as "Defect Action Point (DAP) Analysis". However DAP analysis is optional.

The Codex Committee on Fish and Fishery Products recommended at its Twentieth Session that defects of a commercial nature, i.e. workmanship defects, which had been removed from Codex fish product standards, be transferred to the appropriate Codex code of practice for optional use between buyers and sellers during commercial transactions. The Committee further recommended that this detail should be described in a section on Final Product Specifications, which now appear as Appendices II-XI* of this document. A similar approach to HACCP has been incorporated into the Code as guidelines for the control of defects (DAP Analysis).

This Code will assist all those who are engaged in the handling and production of fish and fishery products, or are concerned with their storage, distribution, export, import and sale in attaining safe and wholesome products which can be sold on national or international markets and meet the requirements of the Codex Standards (see Appendix Xii*).

## HOW TO USE THIS CODE

The aim of this Code is to provide a user-friendly document as background information and guidance for the elaboration of fish and shellfish process management systems which would incorporate Good Manufacturing Practice (GMP) as well as the application of HACCP in countries where these, as yet, have not been developed. In addition, it could be used for training of fishermen and employees of the fish and shellfish processing industries.

The practical application of this *international* Code, with regard to *national* fisheries, would therefore require some modifications and amendments, taking into account local conditions and specific consumer requirements. This Code, therefore, is not intended to replace the advice or guidance of trained and experienced technologists regarding the complex technological and hygienic problems which might be unique to a specific geographical area or specific fishery and, in fact, is

* Under development

intended to be used as a supplement in such instances.

This Code is divided into separate, though interrelated, Sections. It is intended that in order to set up a HACCP or DAP programme these should be consulted as appropriate :

(a) *Section 2 - Definitions* – Being acquainted with the definitions is important and will aid the overall understanding of the Code.

(b) *Section 3 - Pre-requisite Programme* - Before HACCP or a similar approach can properly be applied to a process it is important that a solid foundation of good hygienic practice exists. This Section covers the groundwork which should be regarded as the minimum requirements for a facility prior to the application of hazard and defect analyses.

(c) *Section 4 - General Considerations for the Handling of Fresh Fish, Shellfish and Other Aquatic Invertebrates* - This Section provides an overall view of the potential hazards and defects which may have to be considered when building up a HACCP or DAP plan. This is not intended to be an exhaustive list but is designed to help a HACCP or DAP team to think about what hazards or defects should be considered in the fresh fish, shellfish and other aquatic invertebrates, and then it is up to the team to determine the significance of the hazard or defect in relation to the process.

(d) *Section 5 - Hazard Analysis Critical Control Point (HACCP) and Defect Action Point (DAP) Analysis* - Only when the groundwork in Section 3 has been satisfactorily achieved should the application of the principles outlined in *Section 5* be considered. This Section uses an example of the processing of a canned tuna product to help illustrate how the principles of HACCP should be applied to a process.

(e) *Sections 6 and 7 - Aquaculture Production and Live and Raw Bivalve Mollusc Production* deal with preharvest and primary production of fish, crustaceans and molluscan shellfish not caught in the wild*.

Although potential hazards and potential defects are listed for most steps in Sections 6 to 18, it should be noted that this is only for guidance and the consideration of other hazards and/or defects may be appropriate. Also, the format in these Sections has been designed for maximum 'ease of use' and therefore the **'potential hazards'** or **'potential defects'** are listed only where they may be introduced into a product or where they are controlled, rather than repeating them at all the intervening processing steps.

Additionally, it must be stressed that hazards and defects, and their subsequent control or action points, are product and line specific and therefore a full critical analysis based on *Section* 5 must be completed for each individual operation.

(f) *Section 8 - Processing of Fresh, Frozen and Minced Fish* - This Section forms the foundation for most of the subsequent processing Sections. It deals with the major process steps in the handling of raw fish through to cold storage and gives guidance and examples on the sort of hazards and defects to expect at the various steps. This Section should be used as the basis for all the other processing operations (Sections 9-16) which give additional guidance specific to the appropriate product sector*.

(g) *Sections 9 to 16 - Processing of Specific Fish and Shellfish Products* - Processors operating in particular sectors will need to consult the appropriate Section to find additional information specific to that sector*.

(h) *Sections 17 to 18 - Transportation and Retail* cover general transportation and retail issues. Transportation and retail apply to most if not all sections for processing of specific products. They should be considered with the same care as the other processing steps*.

( i ) Additional information will be found in the *Appendices**.

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* Under development.

## SECTION 1 - SCOPE

This Code of practice applies to the growing, harvesting, handling, production, processing, storage transportation and retail of fish, shellfish and aquatic invertebrates and products thereof from marine and freshwater sources, which are intended for human consumption.

## SECTION 2 - DEFINITIONS

For the purpose of this Code :

### 2.1 GENERAL DEFINITIONS

**Biotoxins** means poisonous substances naturally present in fish and fishery products or accumulated by the animals feeding on toxin producing algae, or in water containing toxins produced by such organisms.

**Chilling** is the process of cooling fish and shellfish to a temperature approaching that of melting ice.

**Clean Water** means water from any source where harmful microbiological contamination, substances and/or toxic plankton are not present in such quantities as may affect the health quality of fish, shellfish and their products.

**Cleaning** means the removal of soil, food residues, dirt, grease or other objectionable matter.

**Contaminant** means any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability.

**Contamination** the introduction or occurrence of a contaminant in fish, shellfish and their products.

**Control Measure** means any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level. For the purposes of this Code a control measure is also applied to a defect.

**Corrective Action** means any action to be taken when the results of monitoring at the CCP indicate a loss of control. For the purposes of this Code this also applies to a DAP.

**Critical Control Point (CCP)** a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

**Critical Limit** is a criterion, which separates acceptability from unacceptability. For the purpose of this Code this also applies to a DAP.

**Decision Tree** a sequence of questions applied to each process step with an identified hazard to identify which process steps are CCPs. For the purpose of this Code this also applies to a DAP.

**Decomposition** is the deterioration of fish, shellfish and their products including texture breakdown and causing a persistent and distinct objectionable odour or flavour.

**Defect** means a condition found in a product which fails to meet essential quality, composition and/or labelling provisions of the appropriate Codex product standards.

**Defect Action Point (DAP)** a step at which control can be applied and a quality (non-safety) defect can be prevented, eliminated or reduced to acceptable level, or a fraud risk eliminated.

**Disinfection** means the reduction, by means of chemical agents and/or physical methods, the number of micro-organisms in the environment, to a level that does not compromise food safety or suitability.

**Dressed** means that portion of fish remaining after heading and gutting.

**Facility** means any premises where fish and fishery products are prepared, processed, chilled, frozen, packaged or stored. For the purposes of this Code, premises also include vessels.

**Fish** means any of the cold-blooded (ectothermic) aquatic vertebrates. Amphibians and aquatic reptiles are not included.

**Hazard** a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

**Hazard Analysis** the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

**Hazard Analysis Critical Control Point (HACCP)** a system which identifies, evaluates, and controls hazards which are significant for food safety.

**Monitor** the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control. For the purpose of this Code this also applies to a DAP.

**Potable Water** is fresh water fit for human consumption. Standards of potability should not be lower than those contained in the latest edition of the "International Standards for Drinking Water", World Health Organisation.

**Pre-Requisite Programme** is a programme that is required prior to the application of the HACCP system to ensure that a fish and shellfish processing facility is operating according to the Codex Principles of Food Hygiene, the appropriate Code of Practice and appropriate food safety legislation.

**Raw Material** are fresh and frozen fish, shellfish and/or their parts which may be utilised to produce fish and shellfish products intended for human consumption.

**Refrigerated Water** is clean water cooled by a suitable refrigeration system.

**Shelf-Life** the period during which the product maintains its microbiological and chemical safety and sensory qualities at a specific storage temperature. It is based on identified hazards for the product, heat or other preservation treatments, packaging method and other hurdles or inhibiting factors that may be used.

**Shellfish** means those species of aquatic molluscs and crustaceans that are commonly used for food.

**Step** is a point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.

**Validation** means obtaining evidence that the elements of the HACCP plan are effective.

**Verification** the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan. For the purposes of this Code this also applies to a DAP.

**Whole Fish (or Round Fish)** are fish as captured, ungutted.

## 2.2 AQUACULTURE

**Aquaculture** means the farming during part or the whole of their life cycle of all aquatic animals, except mammalian species, aquatic reptiles and amphibians intended for human consumption, but excluding species covered in section 7 of this code. These aquatic animals are hereafter referred to as "fish" for ease of reference in section 2.2 and section6.

**Aquaculture Establishment** is any premises for the production of fish intended for human consumption, including the supporting inner infrastructure and surroundings under the control of the same management.

**Chemicals** includes any substance either natural or synthetic which can affect the live fish, its

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| | pathogens, the water, equipment used for production or the land within the aquaculture establishment. |
| **Colouring** | means obtaining specifically coloured feature (e.g. flesh/shell/gonad) of a targeted organism by incorporating into the fish food a natural or artificial substance or additive approved for this purpose by the agency having jurisdiction. |
| **Diseased Fish** | means a fish on or in which pathological changes or other abnormalities that affect safety and quality are apparent. |
| **Extensive farming** | means raising fish under conditions of little or incomplete control over the growing process and production conditions where their growth is dependent upon endogenously supplied nutrient inputs. |
| **Feed Additives** | means chemicals other than nutrients for fish which are approved for addition to their feed. |
| **Fish farm** | is an aquaculture production unit (either land-or water based) ; usually consisting of holding facilities (tanks, ponds, raceways, cages), plant (buildings, storage, processing), service equipment and stock. |
| **Fish Feed** | means fodder intended for fish in aquaculture establishments, in any form and of any composition. |
| **Good Aquaculture (or Good Fish Farming) Practices** | are defined as those practices of the aquaculture sector that are necessary to produce quality and safe food products conforming to food laws and regulations |
| **Harvesting** | Operations involving taking the fish from the water. |
| **Intensive farming** | means raising fish under controlled growing process and production conditions where their growth is completely dependent on externally supplied fish feed. |
| **Official Agency Having Jurisdiction** | means the official authority or authorities charged by the government with the control of food hygiene (sometimes referred to as the competent authority) as well as/or with sanitation in aquaculture. |
| **Pesticide** | means any substance intended for preventing, destroying, attracting, repelling or controlling any pest including unwanted species of plants or animals during the production, storage, transport, distribution and processing of food, agricultural commodities, or animal feeds or which may be administered to animals for the control of ectoparasites. The term normally excludes fertilisers, plant and animal nutrients, food additives, and veterinary drugs. |
| **Pesticide Residue** | means any specified substance in food, agricultural commodities, or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and impurities considered to be of toxicological significance. |
| **Residues** | means any foreign substances including their metabolites, which remain in fish prior to harvesting as a result of either application or accidental exposure. |
| **Semi-intensive farming** | means raising fish under conditions of partial control over the growing process and production conditions where their growth is dependent upon endogenously supplied nutrient inputs and externally supplied fish feed. |
| **Stocking density** | is the amount of fish stocked per unit of area or volume. |
| **Veterinary Drug** | means any substance applied or administered to any food-producing animal, such as meat or milk-producing animals, poultry, fish or bees, whether used for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behaviour. |
| **Withdrawal Time** | is the period of time necessary between the last administration of a veterinary drug to |

fish, or exposure of these animals to a veterinary drug, and harvesting of them to ensure that the concentration of the veterinary drug in their edible flesh intended for human consumption, complies with the maximum permitted residue limits.

## 2.3 LIVE AND RAW BIVALVE MOLLUSCS

**Accepted / Acceptable / Approved** means accepted by the official agency having jurisdiction;

**Conditioning** means placing live bivalve molluscs in tanks, floats or natural sites to remove sand, mud or slime and improve product acceptability;

**Distribution Centre** means any approved on-shore or off-shore installation or establishment for the reception, conditioning, washing, cleaning, grading and packaging of live bivalve molluscs fit for human consumption from which the bivalve molluscs are dispatched alive;

**Growing Areas** means all brackish and marine areas approved for the production or harvesting of bivalve molluscs either by natural growth or by aquaculture destined for human consumption. The growing areas may be approved as production or harvesting areas for bivalve molluscs for direct consumption, or they may be approved as production or harvesting areas for bivalve molluscs for either depuration or relaying

**Heat Shocking** means the process of subjecting bivalve molluscs in the shell to any form of heat treatment, such as steam, hot water, or dry heat for a short period of time, to facilitate rapid removal of meat from the shell for the purpose of shucking.

**Depuration** means the reduction of microorganisms to a level acceptable for direct consumption by the process of holding live bivalve molluscs for a period of time under approved, controlled conditions in natural or artificial sea water suitable for the process, which may be treated or untreated.,

**Depuration centre** means any approved establishment for the depuration of live bivalve molluscs.

**Relaying** means the removal of bivalve molluscs from microbiologically contaminated growing area to an acceptable growing or holding area under the supervision of the agency having jurisdiction and holding them there for the time necessary for the reduction of contamination to an acceptable level for human consumption.

## 2.4 FRESH, FROZEN AND MINCED FISH

**Candling** is passing fillets of fish over a translucent table illuminated from below to detect parasites and other defects.

**Dehydration** is the loss of moisture from frozen products through evaporation. This may occur if the products are not properly glazed, packaged or stored. Deep dehydration adversely affects the appearance and surface texture of the product and is commonly known as "freezer burn".

**Fillet** is a slice of fish of irregular size and shape removed from the carcase by cuts made parallel to the backbone.

**Freezer** is equipment designed for freezing fish and other food products, by quickly lowering the temperature so that after thermal stabilisation the temperature in the thermal centre of the product is the same as the storage temperature.

**Freezing Process** is a process which is carried out in appropriate equipment in such a way that the range of temperature of maximum crystallisation is passed quickly. The quick freezing process shall not be regarded as complete unless and until the product temperature has reached -18℃ (0°F) or lower at the thermal centre after thermal stabilisation.

**Frozen Storage Facility** a facility that is capable of maintaining the temperature of fish at -18℃.

**Fresh Fish** are fish or fishery products which have received no preserving treatment other than chilling.

**Frozen Fish** are fish which have been subjected to a freezing process sufficient to reduce the temperature of the whole product to a level low enough to preserve the inherent quality of the fish and which have been maintained at this low temperature, as specified in the Standard for Quick Frozen Finfish, Eviscerated and Uneviscerated during transportation, storage and distribution up to and including the time of final sale. For the purpose of this Code the terms "frozen", "deep frozen", "quick frozen", unless otherwise stated, shall be regarded as synonymous.

**Glazing** The application of a protective layer of ice formed at the surface of a frozen product by spraying it with, or dipping it into, clean sea water, potable water, or potable water with approved additives, as appropriate.

**Minced Fish** is comminuted flesh produced by separation from skin and bones.

**Modified Atmosphere Packaging (MAP)** means packaging in which the atmosphere surrounding the fish is different from the normal composition of air.

**Separation** is a mechanical process for producing minced fish whereby the skin and bone is substantially removed from the flesh.

**Separator** is a mechanical device used for separation.

**Steak** is a section of fish, removed by cutting approximately at right angle to the backbone.

## 2.5 FROZEN SURIMI

**De-Watering** means removal of excessive wash water from the minced fish flesh.

**Frozen Surimi** means the fish protein product for further processing, which has been processed by heading, gutting, cleaning fresh fish, and mechanically separating the edible muscle from the skin and bone. The minced fish muscle is then washed, refined, de-watered, mixed with cryoprotective food ingredients and frozen.

**Gel Forming Ability** means the ability of surimi to form an elastic gel when fish meat is comminuted with the addition of salt and then formed and heated. This elasticity is a function possessed by myosin as the primary component of myofibrillar protein.

**Myofibrillar Protein** is a generic term of skeletal muscle proteins such as myosin and actin.

**Refining** means a process of removing from washed meat by used of a strainer small bones, sinews, scales and bloody flesh of such sizes as may not be mixed in a final product, thereby concentrating myofibrillar protein.

**Surimi-Based Products** means a variety of products produced from surimi with addition of ingredients and flavour such as "urimi gel" and shellfish analogues.

**Water-Soluble Components** means any water-soluble proteins, organic substances and inorganic salts contained in fish meat.

**Washing** means a process of washing away blood and water soluble components from minced fish with cold water by the use of a rotary filter, thus increasing the level of myofibrillar proteins thereof.

**Washed meat** means fish meat that is washed and then drained of water.

## 2.6 QUICK-FROZEN COATED FISH PRODUCTS

**Batter** liquid preparation from ground cereals, spices, salt, sugar and other ingredients and/or additives for coating. Typical batter types are : non-leavened batter and leavened batter.

**Breading** dry breadcrumbs or other dry preparations mainly from cereals with colorants and other ingredients used for the final coating of fishery products. Typical breading types are : free-flowing breading, coarse breading, flour-type breading.

**Coating** covering the surface of a fishery product with batter and/or breading.

**Pre-frying** frying of breaded and battered fishery products in an oil bath in a way so that the core remains frozen.

**Sawing** cutting (by hand or fully mechanised) of regular shapes of fish blocks into pieces suitable for later coating.

## 2.7 SALTED AND DRIED SALTED FISH

**Barrel** a cylindrical container made from wood or plastic or other suitable food contact material with a lid for water-tight closure.

**Black membrane** Parietal peritoneum, the pigmented lining of the abdominal cavity.

**Brine** solution of salt in water.

**Brine Injection** is the process for injecting brine directly into the fish flesh.

**Brining** means the process of placing fish in brine for a period of sufficient length for the fish tissue to absorb a specific quantity of salt.

**Dry-Salting** is the process of mixing fish with suitable food grade salt and stacking the fish in such a manner that the resulting brine drains away.

**Dun** a discoloration and a development of the mould *Sporendonema epizoum* which affect the fish surface and make it look like peppered. The fish flesh is unaffected.

**Fatty Fish** is fish in which the main reserves of fat are in the body tissue and the fat content is more than 2%.

**Gibbing** the process of removing the gills, long gut and stomach from fatty fish, such as herring, by inserting a knife or using hands at the gills ; the milt or roe and some of the pyloric caeca are left in the fish.

**Lean Fish (White Fish)** is fish in which the main reserves of fat are in the liver and less than 2% fat in the body tissue.

**Maturing** the process from salting until the fish is salt-matured.

**Nobbing** removing the head and gut from fatty fish, such as herring, in one operation by partially severing the head and pulling the head away together with attached gut, the roe or milt is left in.

**Pickle** brine which may contain vinegar and spices.

**Pickling** is the process whereby primary fatty fish is mixed with suitable salt which may contain vinegar and spices and stored in watertight containers under the resultant pickle which forms by solution of salt in the water extracted from the fish tissue. Pickle may be added to the container. Pickled products will always remain in a brine solution.

**Pink a** discoloration caused by red halophilic bacteria which damages the fish flesh.

**Salt** is a crystalline product consisting predominantly of sodium chloride. It is obtained from the sea, from underground rock salt deposits or from vacuum processed and refined brine.

**Salt-Matured Fish** means salted fish that has an appearance, consistency and flavour characteristic of the final product.

**Salted Fish / Salted Fillet** fish / fillets which have been treated by either brining, brine injection, dry-salting, pickling or wet-salting or a combination of these.

**Saturated** the water phase of the fish muscle is saturated with salt (26,4 g salt/100g water phase).

**Split Fish** fish that have been cut open from throat or nape to the tail, with gills, guts, roe or milt removed. Head and whole or part of backbone may be left in or removed.

**Stacking (restacking)** laying fish in piles with salt spread evenly on the surface.

**Wet - Salting** is the process whereby primary lean fish is mixed with suitable food grade salt and stored in watertight containers under the resultant brine which forms by solution of salt in the water extracted from the fish tissue. Brine may be added to the container. The fish can be removed from the container and stacked so that the brine drains away.

2.10 SHRIMPS AND PRAWNS

**Dehead** means to remove the head from the entire shrimp or prawn

**De-veined shrimp** means all the shrimp which have been peeled, the back of the peeled segments of the shrimp have been open out and the gut ( "vein" ) removed.

**Fresh shrimp** are freshly caught shrimp which have received no preserving treatment or which have been preserved only by chilling. It does not include freshly cooked shrimp.

**Peeled shrimp** are shrimps with heads and all shell removed.

**Raw headless shrimp** are raw shrimps with heads removed and the shell on.

**Shrimp** the term shrimp (which includes the frequently used term "prawn") refers to the species covered by the most recent edition of the FAO listing of shrimps, FAO Fisheries Synopsis No. 125, Volume 1, Shrimps and Prawns of the World.

2.11 CEPHALOPODS

**Splitting** is the process of cutting cephalopods along the mantle to produce a single fillet.

2.12 CANNED FISH AND SHELLFISH

*For the purpose of this Code, only the definitions of the main terms related to canning industry and used in section 13 are given. For an overall set of definitions please refer to the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Food (CAC/RCP 23-1979)*

**Canned Food** means commercially sterile food in hermetically sealed containers.

**Commercial sterility of thermally processed food** means the condition achieved by application of heat, sufficient, alone or in combination with other appropriate treatments, to render the food free from micro-organisms capable of growing in the food at normal non-refrigerated conditions at which the food is likely to be held during distribution and storage.

**Hermetically Sealed Containers** are containers which are sealed to protect the content against the entry of microorganisms during and after heat treatment.

**Retort** means a pressure vessel designed for thermal processing of food packed in hermetically sealed containers.

**Scheduled Process (or Sterilisation schedule)** means the thermal process chosen by the processor for a given product and container size to achieve at least commercial sterility.

**Sterilisation Temperature** means the temperature maintained throughout the thermal process as specified in the scheduled process.

**Sterilisation Time** means the time between the moment sterilisation temperature is achieved and the moment cooling started.

**Thermal Process** means the heat treatment to achieve commercial sterility and is quantified in terms of time and temperature.

**Venting** means thorough removal of the air from steam retorts by steam prior to a scheduled process.

2.13 TRANSPORT

2.14 RETAIL

**Retail** means an operation that stores, prepares, packages, serves, or otherwise provides fish, shellfish and their products directly to the consumer for preparation by the consumer for human consumption. This may be free standing seafood markets, seafood sections in grocery or department stores, packaged chilled or frozen and / or full service.

**Packaged** means packaged in advance and displayed chilled or frozen for direct consumer pick up.

**Full Service Display** means a display of chilled fish, shellfish and their products to be weighed and wrapped by establishment personnel at the request of the consumer.

## SECTION 3 - PRE-REQUISITE PROGRAMME

Prior to the application of HACCP to any segment of the product processing chain, that segment must be supported by pre-requisite programmes based on good hygienic practice or as required by the competent authority.

The establishment of pre-requisite programmes will allow the HACCP team to focus on the HACCP application to food safety hazards which are directly applicable to the product and the process selected, without undue consideration and repetition of hazards from the surrounding environment. The pre-requisite programmes would be specific within an individual establishment or for an individual vessel and will require monitoring and evaluation to ensure their continued effectiveness.

Reference should be made to the International Recommended Code of Practice-General Principles of Food Hygiene (CAC/RCP 1-1969), Annex: Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application for further information to assist with the design of the pre-requisite programmes for a processing facility or vessel.

It should be noted that some of the issues listed below, e.g. those related to damage, are designed to maintain quality rather than food safety and are not always essential to a pre-requisite programme for a food safety oriented HACCP system.

HACCP principles can also be applied to defect action points.

### 3.1 FISHING AND HARVESTING VESSEL DESIGN AND CONSTRUCTION

There are many different types of fishing vessel used throughout the world which have evolved in particular regions to take account of the prevailing economics, environment and types of fish and shellfish caught or harvested. This Section attempts to highlight the basic requirements for cleanability, minimising damage, contamination and decomposition to which all vessels should have regard to the extent possible in order to ensure hygienic, high quality handling of fresh fish and shellfish intended for further processing and freezing.

The design and construction of a fishing vessel and vessels used to harvest farmed fish and shellfish should take into consideration the following :

### 3.1.1 For Ease of Cleaning and Disinfection

- vessels should be designed and constructed to minimise sharp inside corners and projections to avoid dirt traps ;
- construction should facilitate ample drainage ;
- a good supply of clean water or potable water[1] at adequate pressure.

### 3.1.2 To Minimise Contamination

- all surfaces in handling areas should be non-toxic, smooth impervious and in sound condition, to minimise the build-up of fish slime, blood, scales and guts and to reduce the risk of physical and microbial contamination ;
- where appropriate, adequate facilities should be provided for the handling and washing of fish and shellfish and should have an adequate supply of cold potable water or clean water for that purpose ;
- adequate facilities should be provided for washing and disinfecting equipment, where appropriate ;
- the intake for clean water should be located to avoid contamination ;
- all plumbing and waste lines should be capable of coping with peak demand ;
- non-potable water lines should be clearly identified and separated from potable water to avoid contamination ;
- objectionable substances, which could include bilge water, smoke, fuel oil, grease, drainage and other solid or semi-solid wastes should not contaminate the fish and shellfish ;
- where appropriate, containers for offal and waste material should be clearly identified, suitably constructed with a fitted lid and made of impervious material ;
- separate and adequate facilities should be provided to prevent the contamination of fish and shellfish and dry materials, such as packaging, by :

  − poisonous or harmful substances ;
  − dry storage of materials, packaging etc. ;
  − offal and waste materials ;

- adequate hand washing and toilet facilities, isolated from the fish and shellfish handling areas, should be available where appropriate ;
- prevent the entry of birds, insects, or other pests, animals and vermin, where appropriate.

### 3.1.3 To Minimise Damage to the Fish, Shellfish and Other Aquatic Invertebrates

- in handling areas, surfaces should have a minimum of sharp corners and projections ;
- in boxing and shelving storage areas, the design should preclude excessive pressure being exerted on the fish and shellfish ;
- chutes and conveyors should be designed to prevent physical damage caused by long drops or crushing ;
- the fishing gear and its usage should minimise damage and deterioration to the fish and shellfish.

### 3.1.4 To Minimise Damage during Harvesting of Aquacultured and Molluscan Shellfish

When aquacultured products and molluscan shellfish are harvested using seines or nets or other means and are transported live to facilities :

- seines, nets and traps should be carefully selected to ensure minimum damage during harvesting ;

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1 WHO Guidelines for Drinking Water Quality, Geneva

- harvesting areas and all equipment for harvesting, catching, sorting, grading, conveying and transporting of live products should be designed for their rapid and efficient handling without causing mechanical damage ; These should be easy cleanable and free from contamination ;
- conveying equipment for live and slaughtered products should be constructed of suitable corrosion-resistant material which does not transmit toxic substances and should not cause mechanical injuries to them ;
- where fish is transported live, care should be taken to avoid overcrowding and to minimise bruising ;
- where fish are held or transported live, care should be taken to maintain factors that affect fish health (e.g. $CO_2$, $O_2$, temperature, nitrogenous wastes, etc).

## 3.2 FACILITY DESIGN AND CONSTRUCTION

The facility should include a product flow-through pattern that is designed to prevent potential sources of contamination, minimise process delays which could result in further reduction in essential quality, and prevent cross-contamination of finished product from raw materials. Fish, shellfish and other aquatic invertebrates are highly perishable foods and should be handled carefully and chilled without undue delay. The facility, therefore, should be designed to facilitate rapid processing and subsequent storage.

The design and construction of a facility should take into consideration the following :

### 3.2.1 For Ease of Cleaning and Disinfection

- the surfaces of walls, partitions and floors should be made of impervious, non-toxic materials ;
- all surfaces with which fish, shellfish and their products might come in contact should be of corrosion resistant, impervious material which is light-coloured, smooth and easily cleanable ;
- walls and partitions should have a smooth surface up to a height appropriate to the operation ;
- floors should be constructed to allow adequate drainage ;
- ceilings and overhead fixtures should be constructed and finished to minimise the build-up of dirt and condensation, and the shedding of particles ;
- windows should be constructed to minimise the build-up of dirt and, where necessary, be fitted with removable and cleanable insect-proof screens. Where necessary, windows should be fixed ;
- doors should have smooth, non-absorbent surfaces ;
- joints between floors and walls should be constructed for ease of cleaning (round joints).

### 3.2.2 To Minimise Contamination

- facility layout should be designed to minimise cross-contamination and may be accomplished by physical or time separation ;
- all surfaces in handling areas should be non-toxic, smooth impervious and in sound condition, to minimise the build-up of fish slime, blood, scales and guts and to reduce the risk of physical contamination ;
- working surfaces that come into direct contact with fish, shellfish and their products should be in sound condition, durable and easy to maintain. They should be made of smooth, nonabsorbent and non-toxic materials, and inert to fish, shellfish and their products, detergents and

disinfectants under normal operating conditions ;

- adequate facilities should be provided for the handling and washing of products and should have an adequate supply of cold potable water for that purpose ;
- suitable and adequate facilities should be provided for storage and/or production of ice ;

- ceiling lights should be covered or otherwise suitably protected to prevent contamination by glass or other materials ;
- ventilation should be sufficient to remove excess steam, smoke and objectionable odours and cross contamination through aerosols should be avoided ;
- adequate facilities should be provided for washing and disinfecting equipment, where appropriate ;
- non-potable water lines should be clearly identified and separated from potable water to avoid contamination ;
- all plumbing and waste lines should be capable of coping with peak demands ;
- accumulation of solid, semi-solid or liquid wastes should be minimised to prevent contamination ;
- where appropriate, containers for offal and waste material should be clearly identified, suitably constructed with a fitted lid and made of impervious material ;
- separate and adequate facilities should be provided to prevent the contamination by :

– poisonous or harmful substances ;
– dry storage of materials, packaging etc. ;
– offal and waste materials ;

- adequate hand washing and toilet facilities, isolated from handling area, should be available ;
- prevent the entry of birds, insects, or other pests and animals ;
- water supply lines should be fitted with back flow devices, where appropriate.

### 3.2.3 To Provide Adequate Lighting

- to all work surfaces.

## 3.3 DESIGN AND CONSTRUCTION OF EQUIPMENT AND UTENSILS

The equipment and utensils used for the handling of fishery products on a vessel or in a facility will vary greatly depending on the nature and type of operation involved. During use, they are constantly in contact with fish, shellfish and their products. The condition of the equipment and utensils should be such that it minimises the build-up of residues and prevents them becoming a source of contamination.

The design and construction equipment and utensils should take into consideration the following :

### 3.3.1 For Ease of Cleaning and Disinfection

- equipment should be durable and movable and/or capable of being disassembled to allow for maintenance, cleaning, disinfection and monitoring ;
- equipment, containers and utensils coming into contact with fish, shellfish and their products should be designed to provide for adequate drainage and constructed to ensure that they can be adequately cleaned, disinfected and maintained to avoid contamination ;
- equipment and utensils should be designed and constructed to minimise sharp inside corners and projections and tiny crevices or gaps to avoid dirt traps ;
- a suitable and adequate supply of cleaning utensils and cleaning agents, approved by the official agency having jurisdiction, should be provided.

### 3.3.2 To Minimise Contamination

- all surfaces of equipment in handling areas should be non-toxic, smooth, impervious and in sound condition, to minimise the build-up of fish slime, blood, scales and guts and to reduce the risk of physical contamination ;
- accumulation of solid, semi-solid or liquid wastes should be minimised to prevent contamination of fish ;

- adequate drainage should be provided in storage containers and equipment ;
- drainage should not be permitted to contaminate products.

### 3.3.3 To Minimise Damage

- surfaces should have a minimum of sharp corners and projections;
- chutes and conveyors should be designed to prevent physical damage caused by long drops or crushing ;
- storage equipment should be fit for the purpose and not lead to crushing of the product.

## 3.4 HYGIENE CONTROL PROGRAMME

The potential effects of harvesting and handling of products, on-board vessel handling or in-plant production activities on the safety and suitability of fish, shellfish and their products should be considered at all times. In particular this includes all points where contamination may exist and taking specific measures to ensure the production of a safe and wholesome product. The type of control and supervision needed will depend on the size of the operation and the nature of its activities.

Schedules should be implemented to :

- prevent the build up of waste and debris ;
- protect the fish, shellfish and their products from contamination ;
- dispose of any rejected material in a hygienic manner ;
- monitor personal hygiene and health standards ;
- monitor the pest control programme ;
- monitor cleaning and disinfecting programmes ;
- monitor the quality and safety of water and ice supplies.

The hygiene control programme should take into consideration the following :

### 3.4.1 A Permanent Cleaning and Disinfection Schedule

A permanent cleaning and disinfection schedule should be drawn up to ensure that all parts of the vessel, processing facility and equipment therein are cleaned appropriately and regularly. The schedule should be reassessed whenever changes occur to the vessel, processing facility and/or equipment. Part of this schedule should include a 'clean as you go' policy.

A typical cleaning and disinfecting process may involve as many as seven separate steps :

**Pre-cleaning** Preparation of area and equipment for cleaning. Involves steps such as removal of all fish, shellfish and their products from area, protection of sensitive components and packaging materials from water, removal by hand or squeegee of fish scraps, etc.

**Pre-rinse** A rinsing with water to remove remaining large pieces of loose soil.

**Cleaning** means the removal of soil, food residues, dirt, grease or other objectionable matter.

**Rinse** A rinsing with potable water or clean water, as appropriate, to remove all soil and detergent residues.

**Disinfection** Application of chemicals, approved by the official agency having jurisdiction and/or heat to destroy most microorganisms on surface.

**Post-rinse** As appropriate a final rinse with potable water or clean water to remove all disinfectant residues.

**Storage** Cleaned and disinfected equipment, container and utensils should be stored in a fashion which would prevent its contamination.

**Check of the efficiency of the cleaning** The efficiency of the cleaning should be controlled as appropriate.

Handlers or cleaning personnel as appropriate should be well trained in the use of special cleaning tools and chemicals, methods of dismantling equipment for cleaning and should be knowledgeable in the significance of contamination and the hazards involved.

### 3.4.2 Designation of Personnel for Cleaning

- In each processing plant or vessel a trained individual should be designated to be responsible for the sanitation of the processing facility or vessel and the equipment within.

### 3.4.3 Maintenance of Premises, Equipment and Utensils

- buildings, materials, utensils and all equipment in the establishment - including drainage systems - should be maintained in a good state and order ;
- equipment, utensils and other physical facilities of the plant or vessel should be kept clean and in good repair ;
- procedures for the maintenance, repair, adjustment and calibration, as appropriate, of apparatus should be established. These procedures should specify for each equipment, the methods used, the persons in charge of their application, and their frequency.

### 3.4.4 Pest Control Systems

- good hygienic practices should be employed to avoid creating an environment conducive to pests ;
- pest control programmes could include preventing access, eliminating harbourage and infestations, and establishing monitoring detection and eradication systems ;
- physical, chemical and biological agents should be properly applied by appropriately qualified personnel.

### 3.4.5 Supply of Water, Ice and Steam

#### 3.4.5.1 Water

- an ample supply of cold and hot potable water[2] and/or clean water under adequate pressure should be provided where appropriate ;
- potable water2 should be used wherever necessary to avoid contamination.

#### 3.4.5.2 Ice

- ice should be manufactured using potable water[2] or clean water ;
- ice should be protected from contamination.

#### 3.4.5.3 Steam

- for operations which require steam, an adequate supply at sufficient pressure should be maintained ;
- steam used in direct contact with fish or shellfish or food contact surfaces should not constitute a threat to the safety or suitability of the food.

### 3.4.6 Waste Management

- offal and other waste materials should be removed from the premises of a processing facility or vessel on a regular basis ;
- facilities for the containment of offal and waste material should be properly maintained ;
- vessel waste discharge should not contaminate vessel water intake system or incoming product.

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2 WHO Guidelines for Drinking Water Quality, Geneva

## 3.5 PERSONAL HYGIENE AND HEALTH

Personal hygiene and facilities should be such to ensure that an appropriate degree of personal hygiene can be maintained to avoid contamination.

### 3.5.1 Facilities and Equipment

Facilities and equipment should include :

- adequate means of hygienically washing and drying hands ;
- adequate toilet and changing facilities for personnel should be suitably located and designated.

### 3.5.2 Personnel Hygiene

- no person who is known to be suffering from, or who is a carrier of any communicable disease or has an infected wound or open lesion should be engaged in the preparation, handling or transportation ;
- where necessary, adequate and appropriate protective clothing, headcovering and footwear should be worn ;
- all persons working in a facility should maintain a high degree of personal cleanliness and should take all necessary precautions to prevent the contamination ;
- hand-washing should be carried out by all personnel working in a processing area :
  - at the start of fish or shellfish handling activities and upon re-entering a processing area ;
  - immediately after using the toilet ;
- the following should not be permitted in handling and processing areas :
  - smoking
  - spitting
  - chewing or eating
  - sneezing or coughing over unprotected food
  - the adornment of personal effects such as jewellery, watches, pins or other items that, if dislodged, may pose a threat to the safety and suitability of the products.

## 3.6 TRANSPORTATION

Vehicles should be designed and constructed :

- such that walls, floors and ceilings, where appropriate, are made of a suitable corrosion-resistant material with smooth non-absorbent surfaces. Floors should be adequately drained ;
- where appropriate with chilling equipment to maintain chilled fish or shellfish during transport to a temperature as close as possible to 0℃ or, for frozen fish, shellfish and their products, to maintain a temperature of -18℃ or colder (except for brine frozen fish intended for canning which may be transported at -9℃ or colder) ;
- live fish and shellfish are to be transported at temperature tolerant to species ;
- to provide the fish or shellfish with protection against contamination, exposure to extreme temperatures and the drying effects of the sun or wind ;
- to permit the free flow of chilled air around the load when fitted with mechanical refrigeration means.

## 3.7 PRODUCT TRACING AND RECALL PROCEDURES

Experience has demonstrated that a system for recall of product is a necessary component of a pre-requisite programme because no process is fail-safe. Product tracing, which includes lot identification, is essential to an effective recall procedure.

- managers should ensure effective procedures are in place to effect the complete product tracing and rapid recall of any lot of fishery product from the market ;
- appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf-life of the product ;
- each container of fish, shellfish and their products intended for the final consumer or for further processing should be clearly marked to ensure the identification of the producer and of the lot ;
- where there is an health hazard, products produced under similar conditions, and likely to present a similar hazard to public health, may be withdrawn. The need for public warnings should be considered ;
- recalled products should be held under supervision until they are destroyed, used for purposes other than human consumption, or reprocessed in a manner to ensure their safety.

### 3.8 TRAINING

Fish or shellfish hygiene training is fundamentally important. All personnel should be aware of their role and responsibility in protecting fish or shellfish from contamination and deterioration. Handlers should have the necessary knowledge and skill to enable them to handle fish or shellfish hygienically. Those who handle strong cleaning chemicals or other potentially hazardous chemicals should be instructed in safe handling techniques.

Each fish and shellfish facility should ensure that individuals have received adequate and appropriate training in the design and proper application of a HACCP system and process control. Training of personnel in the use of HACCP is fundamental to the successful implementation and delivery of the programme in fish or shellfish processing establishments. The practical application of such systems will be enhanced when the individual responsible for HACCP has successfully completed a course. Managers should also arrange for adequate and periodic training of relevant employee in the facility so that they understand the principles involved in HACCP.

## SECTION 4 - GENERAL CONSIDERATIONS FOR THE HANDLING OF FRESH FISH, SHELLFISH AND OTHER AQUATIC INVERTEBRATES

Unless they can be reduced to an acceptable level by normal sorting and/or processing, no fish, shellfish and other aquatic invertebrates should be accepted if it is known to contain parasites, undesirable microorganisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances known to be harmful to human health. When fish and shellfish determined as unfit for human consumption are found they should be removed and stored separately from the catch and either reworked and/or disposed of in a proper manner. All fish and shellfish deemed fit for human consumption should be handled properly with particular attention being paid to time and temperature control.

### 4.1 TIME AND TEMPERATURE CONTROL

Temperature is the single most important factor affecting the rate of fish and shellfish deterioration and multiplication of micro-organisms. For species prone to scombrotoxin production, time and temperature control may be the most effective method in controlling food safety. It is therefore essential that fresh fish, fillets, shellfish and their products which are to be chilled should be held at a temperature as close as possible to 0℃.

#### 4.1.1 Minimise the Deterioration - Time

To minimise the deterioration, it is important that :

- chilling should commence as soon as possible ;
- fresh fish, shellfish and other aquatic invertebrates should be kept chilled, processed and distributed with care and minimum delay.

### 4.1.2 Minimise the Deterioration - Temperature Control

Where temperature control is concerned:

- sufficient and adequate icing, or chilled or refrigerated water systems where appropriate, should be employed to ensure that fish, shellfish and other aquatic invertebrates are kept chilled at a temperature as close as possible to 0℃;
- fish, shellfish and other aquatic invertebrates should be stored in shallow layers and surrounded by finely divided melting ice;
- live fish and shellfish are to be transported at temperature tolerant to species.
- chilled or refrigerated water systems and/or cold storage systems should be designed and maintained to provide adequate cooling and/or freezing capacities during peak loads;
- fish should not be stored in refrigerated water systems to a density which impairs its working efficiency;
- monitoring and controlling the time and temperature and homogeneity of chilling should be performed regularly.

### 4.2 MINIMISE THE DETERIORATION - HANDLING

Poor handling practices can lead to damage of fresh fish, shellfish and other aquatic invertebrates which can accelerate the rate of decomposition and increase unnecessary post-harvest losses. Handling damage can be minimised by:

- fish and shellfish should be handled and conveyed with care particularly during transfer and sorting in order to avoid physical damage such as puncture, mutilation, etc.;
- where fish and shellfish are held or transported live, care should be taken to maintain factors that can influence fish health (e.g. $CO_2$, $O_2$, temperature, nitrogenous wastes, etc.);
- fish and shellfish should not be trampled or stood upon;
- where boxes are used for storage of fish and shellfish they should not be overfilled or stacked too deeply;
- while fish and shellfish are on deck, exposure to the adverse effects of the elements should be kept to a minimum in order to prevent unnecessary dehydration;
- finely divided ice should be used where possible, which can help minimise damage to fish and shellfish and maximise cooling capacity;
- in refrigerated water storage areas, the density of the fish should be controlled to prevent damage.

## SECTION 5 - HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) AND DEFECT ACTION POINT (DAP) ANALYSIS

The Hazard Analysis Critical Control Point (HACCP) is a science-based system which is aimed to prevent food safety problems from occurring rather than reacting to non-compliance of the finished product. The HACCP system accomplishes this by the identification of specific hazards and the implementation of control measures. An effective HACCP system should reduce the reliance on traditional end-product testing. Section 5 explains the principles of HACCP as it applies aquaculture and molluscan shellfish production and to the handling and processing, but the Code can only provide guidance on how to use these principles and offer suggestions as to the type of hazards which may occur in the various fishery products. The HACCP plan, which should be incorporated into the food management plan should be well documented and be as simple as possible. This section will demonstrate one format, which may be considered in the development of the HACCP plan.

Section 5 also explains how a similar approach involving many of the principles can apply to the broader application covering the essential quality, composition and labelling provisions of Codex standards or other non-safety requirements which in this case are referred to as **Defect Action Point Analysis.** This approach for defect analysis is optional and other techniques, which achieve the same objective, may be considered.

Figure 5.1 summarises how to develop a HACCP and Defect Analysis system.

## 5.1 HACCP PRINCIPLES

The HACCP System consists of seven principles[3], which are

**PRINCIPLE 1 -** Conduct a hazard analysis.

**PRINCIPLE 2 -** Determine the Critical Control Points (CCPs).

**PRINCIPLE 3 -** Establish critical limit (s).

**PRINCIPLE 4 -** Establish a system to monitor control of the CCP.

**PRINCIPLE 5 -** Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

**PRINCIPLE 6 -** Establish procedures for verification to confirm that the HACCP system is working effectively.

**PRINCIPLE 7 -** Establish documentation concerning all procedures and records appropriate to these principles and their application

3 *International Recommended Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969), Annex : *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application*

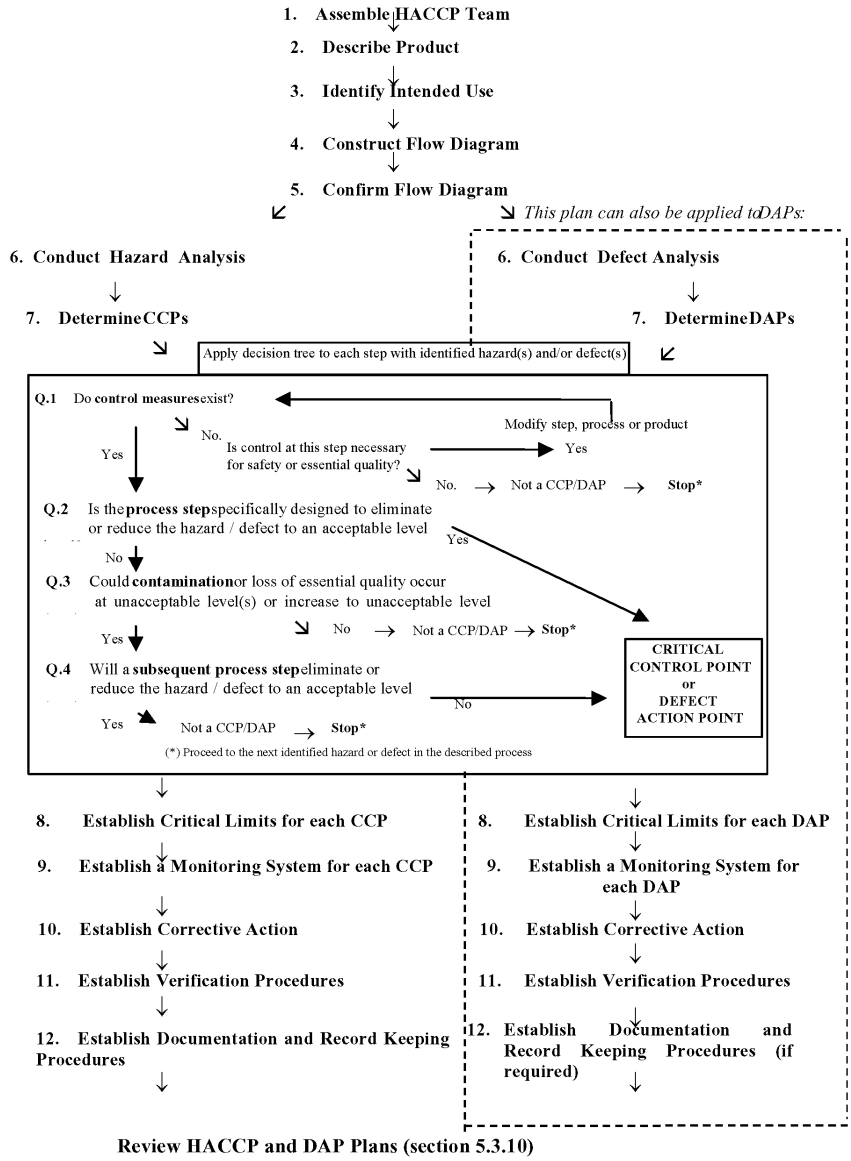


**Figure 5.1 Summary of how to implement a HACCP and Defect Analysis**

These principles have to be followed in any consideration of HACCP.

HACCP is an important management tool, which can be used by operators for ensuring safe, efficient processing. It must also be recognised that personnel training is essential in order that HACCP will be effective. In following HACCP principles, users are requested to list all of the hazards that may be reasonably expected to occur for each product type at each step or procedure in the process from point of harvest, during unloading, transport, storage or during processing, as appropriate to the process defined. It is important that HACCP principles be considered on a specific basis to reflect the risks of the operation.

## 5.2 DEFECT ACTION POINT ANALYSIS

Since the Code is intended to cover not only those hazards associated with safety but to include other aspects of production including the essential product quality, composition and labelling provisions as described in product standards developed by the Codex Alimentarius Commission, not only are critical control points (CCP) described but also defect action points (DAP) are included in the Code. The HACCP principles may be applied to the determination of a DAP, with quality instead of safety parameters being considered at the various steps.

## 5.3 APPLICATION

Each aquaculture, molluscan shellfish, shellfish and fish facility should ensure that the provisions of the appropriate Codex standards are met. To accomplish this, each facility should implement a food safety management system based on HACCP principles and should at least consider a similar approach to defects, both of which are described in this code. Prior to the application of HACCP to any segment of the growing, handling and processing chain, that segment must be supported by a pre-requisite programme based on good hygienic practice (see Section 3). It should be noted that parts of the pre-requisite programme may be classified as a CCP or DAP within a particular process.

The food management system developed should indicate responsibility, authority and the interrelationships of all personnel who manage, perform and verify work affecting the performance of such systems. It is important that the collection, collation and evaluation of scientific and technical data should be carried out by a multi-disciplinary team. Ideally, a team should consist of people with the appropriate level of expertise together with those having a detailed knowledge of the process and product under review. Examples of the type of personnel to include on the team are the processing facility manager, a microbiologist, a quality assurance/quality control specialist, and others such as buyers, operators, etc., as necessary. For small-scale operations, it may not be possible to establish such a team and therefore external advice should be sought.

The scope of the HACCP plan should be identified and should describe which segments of the food chain are involved and the general classes of hazards to be addressed.

The design of this programme should identify critical control points in the operation where the processing facility or product will be controlled, the specification or standard to be met, the monitoring frequency and sampling plan used at the critical control point, the monitoring system used to record the results of these inspections and any corrective action when required. A record for each critical control point that demonstrates that the monitoring procedures and corrective actions are being followed should be provided. The records should be maintained as verification and evidence of the plant's quality assurance programme. Similar records and procedures may be applied to DAPs with the necessary degree of record keeping. A method to identify, describe and locate the records associated with HACCP programmes should be established as part of the HACCP programme.

Verification activities include the application of methods; procedures (review/audit) and tests in addition to those used in monitoring to determine :

- the effectiveness of the HACCP or DAP plan in delivering expected outcomes i.e. validation ;
- compliance with the HACCP or DAP plan, e.g. audit/review ;
- whether the HACCP or DAP plan or its method of application need modification or revalidation.

Table 5.1 A product description for Canned Tuna in Salted Water

| | Objective | Example |
|---|---|---|
| Product name(s) | Identify the species and method of processing. | Canned tuna in salted water |
| Source of raw material | Describe the origin of the fish | Yellowfin tuna caught by purse seine in the Gulf of Guinea Whole brine frozen |
| Important final product characteristics | List characteristics that affect product safety and essential quality, especially those that influence microbial flora. | Compliance with Codex Standard Canned Tuna and Bonito ; 'low-acid' food ; can seal integrity. |
| Ingredients | List every substance added during processing. Only ingredients approved by the official agency having jurisdiction may be used. | water, salt |
| Packaging | List all packaging materials. Only materials approved by the official agency having jurisdiction may be used. | Container in coated chromium steel, capacity : 212 ml, total net weight : 185 g, fish weight : 150 g Traditional opening |
| How the end product is to be used | State how the final product is to be prepared for serving, especially whether it is ready to eat. | Ready to eat |
| Shelf life (if applicable) | State the date when the product can be expected to begin to deteriorate if stored according to instructions. | 3 years |
| Where the product will be sold | Indicate the intended market. This information will facilitate compliance with target market regulations and standards. | Domestic retail market. |
| Special labelling instructions | List all instructions for safe storage and preparation | "Best before the date shown on label." |
| Special distribution control | List all instructions for safe product distribution. | None |

The implementation of HACCP principles is better identified in the Logic Sequence for implementation of HACCP (Figure 5.1).

*This flow chart is for illustrative purposes only. For in-factory HACCP implementation a complete and comprehensive flow chart has to be drawn up for each process*

*References correspond to relevant Sections of the Code.*

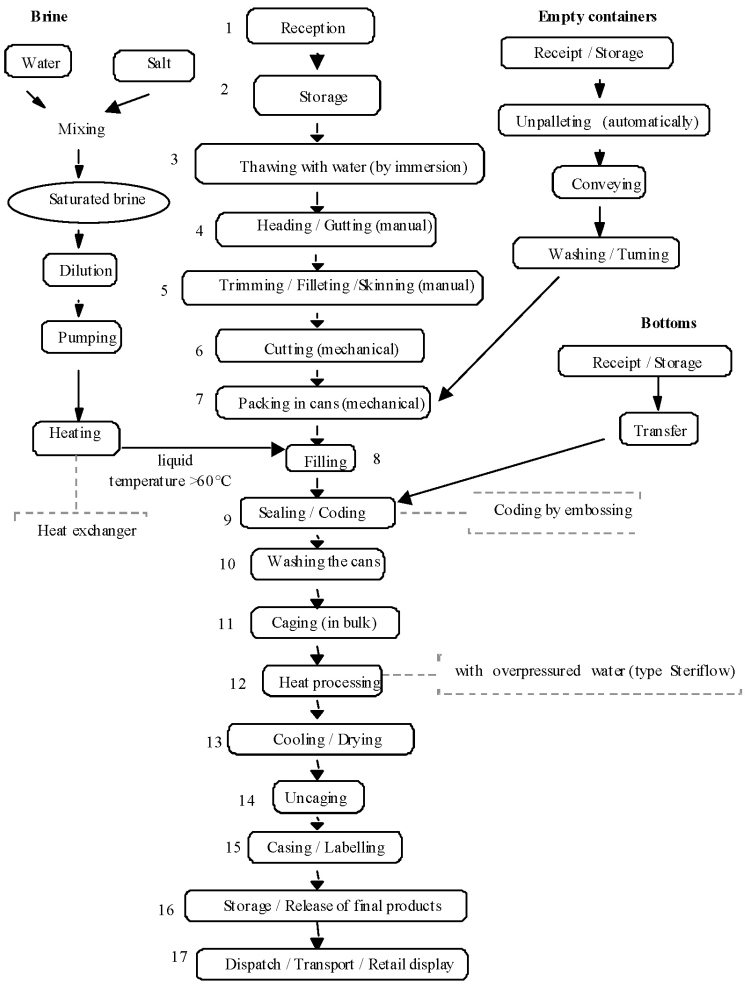


**Figure 5.2 Example of a flow diagram for a processing line of canned tuna fish in brine**

### 5.3.1 Describe Product

In order to gain a greater understanding and knowledge of the product under review, a thorough product description evaluation should be carried out. This exercise will facilitate in the identification of potential hazards or defects. An example of the type of information used in describing a product is given in Table 5.1.

### 5.3.2 Flow Diagram

For Hazard and Defect Analysis, it is necessary to carefully examine both the product and the process and produce a flow diagram(s). Any flow diagram should be as simple as possible. Each step in the process, including process delays from the selection of raw materials through to the processing, distribution, sale and customer handling, should be clearly outlined in sequence with sufficient technical data to avoid ambiguity. If a process is too complex to be easily represented by a single flow diagram, then it can be sub-divided into constituent parts, provided the relationship between each of the parts is clearly defined. It is helpful to number and label each processing step for ease of reference. An accurate and properly constructed flow diagram will provide the multi-disciplinary team with a clear vision of the process sequence. Once CCPs and DAPs have been identified they can be incorporated into the flow diagram specific for each processing facility. Figure 5.2 represents an example of a flow diagram for a canned tuna fish processing line. For examples of different processes see Figures 8.1 to 10.1 in the individual processing sections of the code.

### 5.3.3 Conduct Hazard and Defect Analysis

The purposes of hazard analysis are to identify all such food safety hazards at each Step, to determine their significance and to assess whether control measures for those hazards are available at each Step. Defect analysis serves the same purpose for potential quality defects.

#### 5.3.3.1 Identification of Hazards and Defects

It cannot be stressed enough that where practical and feasible each individual facility should gather sound scientific and technical data relevant to the businesses for each step, from primary production, processing, manufacture, storage and distribution until the point of consumption. The assembly and nature of this information should be such to ensure that the multi-disciplinary team is able to identify and list, at each step of the process, all of the hazards that may reasonably likely to occur and defects that, in the absence of control measure(s), may likely result in the production of an unacceptable food. Potential hazards, which have been known to be associated with fresh fish and shellfish, are described in Annex 1. Table 5.2 summarises possible pre-harvest and harvest safety hazards in incoming fish and shellfish and Table 5.3 summarises possible safety hazards introduced in the post harvest and further processing of fish and shellfish.

It is important to identify potential hazards and defects in the operation from the point of view of plant construction, equipment used in the plant and hygienic practices, including those which may be associated with the use of ice and water. This is covered by the pre-requisite programme and is used to denote hazards that are common to almost any point in the process.

Table 5.2 Examples of Pre-harvest and Harvest Hazards in Incoming Fish & Shellfish

| Biological | | Chemical | | Physical | |
|---|---|---|---|---|---|
| Parasites : | Parasites of public health significance : Trematodes, Nematodes, Cestodes | Chemicals: | Pesticides, herbicides, algicides, fungicides, anti-oxidants (added in feeds) ; | Foreign Matter | fish hooks |
| Pathogenic bacteria : | *Salmonella, Shigella, E. coli, Vibrio cholerae, Vibrio parahaemolyticus, Vibrio vulnificus* | Veterinary drug residues : | Antibiotics, growth promoters (hormones), other veterinary drugs and feed additives | | |
| Enteric Viruses : | Norwalk virus | Heavy metals : | Metals leached from marine sediments and soil, from industrial wastes, from sewage or animal manures | | |
| Biotoxins : | Biotoxins, Scombrotoxin | | | | |
| | | Miscellaneous : | Petroleum | | |

Table 5.3 Examples of Hazards Introduced in the Post Harvest and Further Processing of Fish & Shellfish*

| Biological | | Chemical | | Physical | |
|---|---|---|---|---|---|
| Pathogenic bacteria : | *Listeria monocytogenes, Clostridium botulinum, Staphylococcus aureus* | Chemicals: | Disinfectants, Sanitizers or Lubricants (Misapplication) | Foreign Matter | Metal fragments ; hard or sharp objects |
| Enteric Viruses : | Hepatitis A, Rotovirus | | Disinfectants, Sanitizers or Lubricants (nonapproved) | | |
| Biotoxins : | Scombrotoxin, Staph. Enterotoxin, botulinum toxin | | | | |
| | | Ingredients and Additives : | Misapplication and non-approved | | |

*Note* : For biological hazards, environmental factors (for example: temperature, oxygen availability, pH and Aw) play a major role in their activity and growth, therefore the type of processing the fish or shellfish will undergo, and its subsequent storage, will determine their risk to human health and inclusion in a food safety operation through their existence and manifestation into the water supply.

* For hazards relating to specific products see the relevant processing section.

For the example on canned tuna developed in this section, the following essential potential hazards can be identified :

Table 5.4 : An example of potential hazards for canned tuna

| | In raw materials (frozen tuna) | During processing or storage or transportation |
|---|---|---|
| Biological | Presence of *C. botulinum,* Presence of scombrotoxin | Contamination by *C. botulinum,* Growth of *C. botulinum,* Survival of spores of *C. botulinum,* Contamination and growth of *Staphylococcus aureus* Microbial recontamination after heat processing Production of scombrotoxin during processing, Production of staphylotoxin |
| Chemical | Presence of heavy metals | Recontamination by metals coming from the cans Recontamination by cleaning agents, by the brine, by mechanical grease, …… |
| Physical | Presence of foreign material | Recontamination during processing (pieces of knives, by the cans, ……) |

For the example on canned tuna developed in this section, the following potential defects can be identified :

Table 5.5 An example of potential defects of canned tuna

| | In raw materials (frozen tuna) | During processing or storage or transportation |
|---|---|---|
| Biological | Decomposition | Decomposition, survival of micro-organisms responsible for decomposition, …… |
| Chemical | | oxidation during storage, …… |
| Physical | | Objectionable matters (viscera, scales, skin, ……), formation of struvite crystals, container defects (panelled container, ……) |
| Others | species substitution | abnormal flavours, incorrect weight, incorrect coding, incorrect labelling |

5.3.3.1.1Hazards

It is equally important to consider, naturally occurring food safety hazards in the environment from which fish or shellfish are harvested. In general, risks to consumer health from seafood captured in unpolluted marine environments are low, provided these products are handled in line with principles of Good Manufacturing Practice. However, as with all foods, there are some health risks associated with the consumption of certain products, which may be increased when the catch is mishandled after harvest. Fish from some marine environments, such as tropical reef fish, can pose a consumer risk from natural marine toxins, such as ciguatera. The risk of adverse health effects from certain hazards might be increased under certain circumstances in products from aquaculture when compared with fish and crustacean from the marine environment. The risks of foodborne disease associated with products from aquaculture are related to inland and coastal ecosystems, where the potential of environmental contamination is greater when compared to capture fisheries. In some parts of the world, where fish or shellfish are consumed either raw or partially cooked, there is an increased risk of foodborne parasitic or bacterial disease. In order to perform a hazard analysis as part of the process of developing a HACCP plan, processors must have scientific information on potential hazards associated with raw material and products for further processing.

5.3.3.1.2 Defects

Potential defects are outlined in the essential quality, labelling and composition requirements described in the Codex Standards listed in Appendix X ii *. Where no Codex Standard exists regard should be made to national regulations and/or commercial specifications.

End product specifications outlined in Appendices ii – XI*, describe optional requirements which are intended to assist buyers and sellers in describing those provisions which are often used in commercial transactions or in designing specifications for final products. These requirements are intended for voluntary application by commercial partners and not necessarily for application by governments.

5.3.3.2 Significance of Hazards and Defects

One of the most important activities, which must be performed in a processing facility as part of the food safety management system is to determine if an identified hazard or defect is significant. The two primary factors that determine whether a hazard or defect is significant for HACCP purposes are probability of occurrence of an adverse health effect and the severity of the effect. A hazard that has a high severity of effect, such as death from *Clostridium botulinum* toxin, may impose a socially unacceptable risk at very low probability of occurrence, and thus warrant the application of HACCP controls (i.e., be a significant hazard for purposes of HACCP). Thus, in the processed canned tuna, *Clostridium botulinum* should be considered a significant hazard to be controlled through the application of a validated thermal process schedule. On the other hand, a hazard with a relatively low severity, such as mild gastroenteritis, might not warrant the HACCP controls at the same very low probability of occurrence, and thus not be significant for purposes of HACCP.

Information gathered during the product description exercise (refer to Section 5.3.1 – Describe Product) could also help facilitate the determination of significance since the likelihood of occurrence of hazard or defect can be affected by factors such as how the consumer will likely use the product (e.g., to consumed or cooked raw); the types of consumers who will likely consume it (e.g., immuno-compromised, elderly, children, etc.) and the method of storage and distribution (e.g., refrigerated or frozen).

Once significant hazard and defects have been identified, consideration needs to be given to assess their potential to be introduced or controlled at each step of the process. The use of a flow diagram (refer to Section 5.3.2 – Flow Diagram) is beneficial for this purpose. Control measures must be considered for significant hazard(s) or defect(s) associated with each step with the aim of eliminating its possible occurrence or to reduce it to an acceptable level. A hazard or defect may be controlled by more that one control measure. For illustrative purposes, tables 5.6 and 5.7 demonstrate an approach to listing significant hazards and defects and the related control measures for the processing step, "Heat Processing".

Table 5.6 An example of the significant hazard survival of C. botulinum at the step of heat processing for canned tuna

| Processing step | Potential hazard | Is the potential hazard significant? | Justification | Control measures |
|---|---|---|---|---|
| 12. Heat processing | *C. botulinum* viable spores | Yes | An insufficient heat processing may result in survival of *C. botulinum* spores and therefore, possibility of toxin production. A product must be commercially sterile | Ensure adequate heat applied for proper time at retort |

* Under elaboration.

Table 5.7 An example of the significant defect rancidity during the storage of frozen tuna for canned tuna

| Processing step | Potential defect | Is the potential defect significant? | Justification | Control measures |
|---|---|---|---|---|
| 2. Storage of frozen tuna | Persistent and distinct objectionable odours or flavours indicative of rancidity | Yes | Product does not meet quality or customer requirements | Controlled temperature in the storage premises<br>Stock management procedure<br>Maintenance procedure of the refrigeration system<br>Personnel training and qualification |

Table 5.8 A schematic example of a hazard analysis with corresponding control measures and the application of the Codex decision tree for the determination of a critical control point at processing step 12 of the example process as set out in Figure 5.2.

| Processing Step N° 12 Heat processing | | Application of Codex Decision Tree | | | |
|---|---|---|---|---|---|
| Potential Hazards | Control Measures | | | | |
| *C. botulinum* viable spores | Ensure adequate heat applied for proper time at retort | Q1 : Do control measures exist?<br><br>If yes – go to Q2.<br><br>If no – consider whether control measures are available or necessary within the process.<br><br>Proceed to next identified hazard. | Q2 : Is the step specifically designed to eliminate or reduce the likely occurrence of *C. botulinum* to an acceptable level?<br><br>If yes – this step is a CCP.<br><br>If no – go to Q3. | Q3 : Could contamination occur in excess of acceptable levels or could this increase to unacceptable levels?<br><br>If yes – go to Q4.<br><br>If no – not a CCP. | Q4 : Will a subsequent step eliminate or reduce the hazard to an acceptable level?<br><br>If yes – not a CCP.<br><br>If no – CCP. *What about consideration of a previous step?* |
| | | A : Yes : a heat processing procedure (schedule, method) is clearly defined. | A : Yes, this step was specifically designed to eliminate spores. | | |
| | | Decision : Processing step N° 12 « Heat processing » is a **Critical Control Point** | | | |

### 5.3.4 Determine Critical Control Points and Defect Action Points

A thorough and concise determination of Critical Control Points and Defect Action Points in a process is important in ensuring food safety and compliance with elements related to essential quality, composition and labelling provisions of the appropriate Codex standard. The Codex decision tree (Figure 5.1, step 7) is a tool, which can be applied, to the determination of CCPs and

a similar approach may be used for DAPs. Using this decision tree, a significant hazard or defect at a step can be assessed through a logical sequence of questions. Where CCPs and DAPs have been identified at a step, that point in the process must be controlled to prevent, reduce or eliminate the likely occurrence of the hazard or defect to an acceptable level. For illustrative purposes, an example of the application of the Codex decision tree to a hazard and defect using the canned tuna fish processing line, are shown in Tables 5.8 & 5.9, respectively.

Table 5.9 A schematic example of a defect analysis with corresponding control measures and the application of the Codex decision tree for the determination of a defect action point at processing step 2 of the example process as set out in Figure 5.2.

| Processing Steps N° 2 Storage of frozen tuna | | Application of Codex Decision Tree | | | |
|---|---|---|---|---|---|
| Potential Defects | Control Measures | | | | |
| Persistent and distinct objectionable odours or flavours indicative of rancidity | Controlled temperature in storage premises.<br><br>Stock management procedure. | Q1 : Do control measures exist?<br><br>If yes – go to Q2.<br><br>If no – consider whether control measures are available or necessary within the process.<br><br>Proceed to next identified hazard. | Q2 : Is the step specifically designed to eliminate or reduce the likely occurrence of rancidity to an acceptable level?<br><br>If yes – this step is a DAP.<br><br>If no – go to Q3. | Q3 : Could rancidity occur in excess of acceptable levels or could it increase to unacceptable levels?<br><br>If yes – go to Q4.<br><br>If no – not a DAP. | Q4 : Will a subsequent step eliminate rancidity or reduce its likely occurrence to acceptable level?<br><br>If yes – not a DAP.<br><br>If no – DAP. *What about consideration of a previous step?* |
| | | A : Yes, the storage temperature is controlled, procedures exist | A : No | A : Yes, if the storage time is too long and/or the storage temperature is too high | A : No |
| | | Decision : Processing Step N° 2 « Storage of frozen tuna » is a **Defect Action Point** | | | |

### 5.3.5 Establish Critical Limits

For each CCP and DAP, critical limits for the control of the hazard or defect must be specified. For any given hazard or defect, it may be necessary to have more than one critical limit designated for each control measure. The establishment of critical limits should be based on scientific evidence and validated by appropriate technical experts to ensure its effectiveness in controlling the hazard or defect to the determined level. Table 5.10 illustrates critical limits for a CCP and a DAP using a canned tuna fish processing line as an example.

### 5.3.6 Establish Monitoring Procedures

Any monitoring system developed by the multi-disciplinary team should be designed to detect loss of control at a CCP or DAP relative to its critical limit. The monitoring activity of a CCP or DAP should be documented in a concise fashion providing details regarding the individual responsible for the observation or measurement, the methodology used, the parameter(s) being monitored and the frequency of the inspections. The complexity of the monitoring procedure should also be carefully considered. Considerations include optimising the number of individuals performing the

measurement and selection of appropriate methods, which will produce rapid results (for example : time, temperature, pH). For CCPs, records of monitoring should be acknowledged and dated by a responsible person for verification.

Because each process is unique for each product, it is possible only to present, for illustrative purposes, an example of a monitoring approach for a CCP and DAP using the canned tuna fish processing line. This example is shown in Table 5.10.

### 5.3.7 Establish Corrective Action

An effective HACCP or DAP plan is anticipatory by nature and it is recognised that corrective action may be necessary from time to time. A documented corrective action programme should be established to deal with instances where the critical limit has been exceeded and loss of control has occurred at a CCP or DAP. The goal of this plan is to ensure that comprehensive and specific controls are in place and can be implemented to prevent the affected lot(s) from reaching the consumer. For example, fish and shellfish should be held and rejected if they are known to contain harmful substances and/or defects which would not be eliminated or reduced to an acceptable level by normal procedures of sorting or preparation. Of equal importance, is an assessment by plant management and other appropriate personnel to determine the underlying reason(s) why control was lost. For the latter, a modification to HACCP and DAP plans may be necessary. A record of investigation results and actions taken should be documented by a responsible person for each instance where loss of control occurred at a CCP or DAP. The record should demonstrate that control of the process has been re-established, that appropriate product disposition has occurred and that preventative action has been initiated. An example of a corrective action approach for a CCP and DAP using a canned tuna fish processing line is illustrated in Table 5.10.

### 5.3.8 Establish Verification Procedures

A processing facility should establish a verification procedure carried out by qualified individuals, to periodically assess if the HACCP and DAP plans are adequate, implemented and working properly. This step will help determine if CCPs and DAPs are under control. Examples of verification activities include : validation of all components of the HACCP plan including : a paper review of HACCP system, its procedures and records ; review of corrective actions and product disposition actions when critical limits are not met and validation of established critical limits. The latter is particularly important when an unexplained system failure has occurred, when a significant change to the process, product or packaging is planned or when new hazards or defects have been identified. Observation, measurement and inspection activities within the processing facility should also be incorporated as a part of the verification procedure, where applicable. Verification activities should be carried out by qualified competent individuals. The verification frequency of the HACCP and DAP plans should be sufficient to provide assurance that their design and implementation will prevent food safety problems as well as issues associated with essential quality, composition and labelling provisions of the appropriate Codex standard to enable problems to be detected and dealt with in a timely manner. For illustration purposes, an example of a verification procedure approach for a CCP and DAP using the canned tuna fish processing line is shown in Table 5.10.

### 5.3.9 Establish Documentation and Record Keeping Procedures

Documentation may include Hazard Analysis, CCP determination, critical limit determination, and procedures for monitoring, corrective action and verification.

A current, accurate and concise record keeping system will greatly enhance the effectiveness of a HACCP programme and facilitate in the verification process. Examples of the elements of a HACCP plan that should be documented have been provided in this section for illustrative purposes. Inspection and corrective action records should be practical and collect all the appropriate data necessary to demonstrate "real-time" control or deviation control of a CCP. Records are recommended but not required for a DAP except where a loss of control occurred. For illustration purposes, an example of a record keeping approach for a CCP and DAP using the canned tuna fish processing line is shown in Table 5.10.

### 5.3.10 Review of HACCP and DAP Plans

Upon completion of all the steps for the development of HACCP and DAP plans as outlined in Figure 1 a full review of all components should be conducted. The purpose of these reviews is to verify that the plans are capable of meeting their objectives.

Table 5.10 An example of the results of the application of HACCP principles to the two specific steps in the canned tuna process (Tables 5.8 & 5.9), for a CCP & a DAP, respectively.

| CCP | | | | |
|---|---|---|---|---|
| Processing Step No. 12 : Heat Processing<br>Hazard : *Clostridium botulinum* viable spores | | | | |
| Critical Limit | Monitoring Procedure | Corrective Action | Records | Verification |
| Those specific parameters associated with heat processing. | Who : Qualified person assigned to heat processing<br><br>What : All parameters<br><br>Frequency : every batch<br><br>How : Checks of sterilisation schedule and other factors | Who : qualified personnel<br>What : Personnel retraining<br><br>New heat processing or batch destruction<br><br>Corrective maintenance of equipment<br><br>Hold product until safety can be evaluated.<br><br>Who : Appropriate trained personnel | Monitoring records, corrective action records, product evaluation records, calibration records, validation records, audit records, HACCP plan review record Validation, finished | product evaluation, internal audit, review of records, calibration of machinery (may be a prerequisite), review of HACCP plan, external audit |

| DAP | | | | |
|---|---|---|---|---|
| Processing Step No. 2 : Storage of frozen tuna<br>Defect : Persistent and distinct objectionable odours or flavours indicative of rancidity | | | | |
| Critical Limit : | Monitoring Procedure | Corrective Action | Records | Verification |
| Number of rancid sample units cannot exceed acceptance number of established sampling plan.<br><br>Storage temperature and time. | Who : Appropriate trained personnel<br><br>How : Organoleptic examination<br><br>Chemical tests<br><br>Checking of the storage premise temperature<br>Checking of stock forms<br><br>What : fish quality and acceptability based on product Codex standard.<br><br>Frequency : as required | What : Application of an intensified monitoring<br><br>According to the results of this intensified inspection, immediate processing, sorting or reject of frozen tuna exceeding the critical limits.<br><br>Adjust storage temperature.<br><br>Personnel retraining<br><br>Who : Appropriate trained personnel | Analysis results<br><br>Stock forms<br><br>Temperature records | On-site audit<br><br>Review of monitoring and corrective action reports |

## 5.4 Conclusion

Section 5 has demonstrated the principles of HACCP and how they should be applied to a process to ensure safe product. The same principles can be used to determine the points in a process where it is necessary to control defects. Since every facility and each processing line is different it is possible within this Code only to demonstrate the types of potential hazards and defects that must be considered. Furthermore, because of the nature of the significance of hazards and defects it is not possible to categorically determine which steps in a process will be CCPs and/or DAPs without actually assessing the process, the objectives of the process, its environment and expected outcomes. The example of the canned tuna processing line is intended to illustrate how to apply the principles, given the outcome of a commercially sterile product, and why a HACCP and DAP plan will be unique to each operation.

The remaining Sections in the Code concentrate on aquaculture and molluscan shellfish production and to the handling and processing of fish, shellfish and their products and attempt to illustrate the potential hazards and defects at the various stages in a wide range of processes. In developing a HACCP or DAP plan it will be necessary to consult Sections 3 & 5 before turning to the appropriate processing section for specific advice. It should also be noted that Section 8 refers to processing of fresh, frozen and minced fish and will provide useful guidance for most of the other processing operations.

# SECTION 6 - AQUACULTURE PRODUCTION

## Preamble

Aquaculture establishments should operate in a responsible way such that they comply with the recommendations of the Code of Conduct for Responsible Fisheries (FAO, Rome, 1995) in order to minimize any adverse impact on human health and environment including any potential ecological changes.

Fish farms should operate effective fish health and welfare management. Fry and fingerlings should be disease free and should comply with the OIE Codes of Practice (International Aquatic Animal Health Code, 6th Edition, 2003). Growing fish should be monitored for disease. When using chemicals at fish farms, special care should be exercised so that these substances are not released into the surrounding environment.

Whilst the fish health, environment, and ecological aspects are important considerations in aquaculture activities, this section focuses on food safety and quality aspects.

This Section of the Code applies to industrialised and commercial aquaculture production, producing all aquatic animals, except mammalian species, aquatic reptiles and amphibians for direct human consumption, but excluding bivalve molluscs covered in section 7 of the code, hereafter referred to as "fish that are intended for direct human consumption. Such intensive or semi-intensive aquaculture systems use higher stocking densities, stock from hatcheries, use mainly formulated feeds and may utilise medication and vaccines. This Code is not intended to cover extensive fish farming systems that prevail in many developing countries or integrated livestock and fish culture systems. This section of the code covers the feeding, growing, harvesting and transport stages of aquaculture production. Further handling and processing of fish are covered elsewhere in the code.

In the context of recognising controls at individual processing steps, this section provides examples of potential hazards and defects and describes technological guidelines, which can be used to develop control measures and corrective action. At a particular step only the hazards and defects, which are likely to be introduced or controlled at that step, are listed. It should be recognised that in preparing a HACCP and/or DAP plan it is essential to consult Section 5 which provides guidance for the application of the principles of HACCP and DAP analysis. However, within the scope of this Code of Practice it is not possible to give details of critical limits, monitoring, record keeping and verification for each of the steps since these are specific to particular hazards and defects.

The Example flow diagram will provide guidance to some of the common steps in aquaculture production.

*This flow chart is for illustrative purpose only. For implementation of HACCP principles, a complete and comprehensive flow chart has to be drawn up for each product.*
*References correspond to relevant Sections of the Code.*

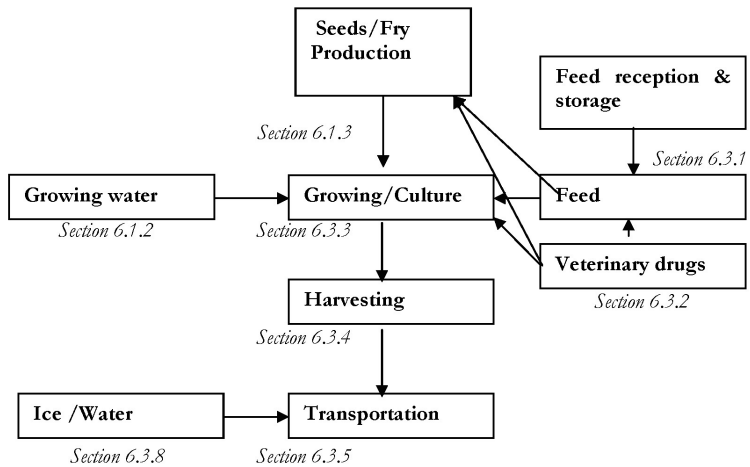


**Figure 6.1 Example of a flow chart for aquaculture production**

## 6.1 GENERAL

The general principles in Section 3 apply to aquaculture production, in addition to the following:

### 6.1.1 Site selection

- The siting, design and construction of fish farms should follow principles of good aquaculture practice, appropriate to species;
- The physical environment with regard to temperature, current, salinity and depth should also be considered since different species have different environmental requirements. Closed recirculation systems should be able to adapt the physical environment to the environment

requirements of the farmed fish species;

- Fish farms should be located in areas where the risk of contamination by chemical, physical or microbiological hazards is minimal and where sources of pollution can be controlled;
- Soil for the construction of earthen ponds should not contain such concentrations of chemicals and other substances, which may lead to the presence of unacceptable levels of contamination in fish;
- Ponds should have separated inlets and discharge canals, so that water supplies and effluent are not mixed;
- Adequate facility for treatment of effluent should be provided to allow sufficient time for sediments and organic load settlement before used water is discharged into the public water body

- Water inlets and outlets to ponds should be screened to prevent the entrance of unwanted species ;
- Fertilizers, liming materials or other chemicals and biological materials, should be used in accordance with good aquaculture practice ;
- All sites should be operated so as to not adversely impact human health from the consumption of the fish in farm.

### 6.1.2 Growing Water Quality

- The water in which fish are raised should be suitable for the production of products which are safe for human consumption ;
- The water quality should be monitored regularly such that the health and sanitation of the fish is continuously maintained to ensure aquaculture products are safe for human consumption ;
- Fish farms should not be sited where there is a risk of contamination of the water in which fish are reared ;
- Appropriate design and construction of fish farms should be adopted to ensure control of hazards and prevention of water contamination.

### 6.1.3 Source of Fry and Fingerlings

- The source of post-larvae, fries and fingerlings should be such to avoid the carryover of potential hazards into the growing stocks.

## 6.2 IDENTIFICATION OF HAZARDS AND DEFECTS

Consumption of fish and fishery products can be associated with a variety of human health hazards. Broadly the same hazards are present in aquaculture products as in corresponding varieties caught in the wild (Section 4.1). The risk of harm from a particular hazard might be increased, under some circumstances, in aquaculture products compared with fish caught in the wild - for instance if the withdrawal time for residues of veterinary drugs has not been observed. High stocking densities, compared with the natural situation, might increase the risk of cross-infection of pathogens within a population of fish and might lead to deterioration of water quality. On the other hand, farmed fish can also present a lower risk of harm. In systems where the fish receive formulated feeds, the risks associated with transmission of hazards through the food consumed by the fish could be reduced. For example, infection with nematode parasites is absent from, or very much reduced in, farmed salmon compared with salmon caught in the wild. Raising fish in cages in the marine environment poses few hazards and low risks. In closed recirculation systems hazards are even further reduced. In those systems, the water is constantly refreshed and reused and water quality is controlled within safe measures.

### 6.2.1 Hazards

Aquaculture products possess broadly the same hazards that are present in corresponding varieties caught in the wild (Section 5.3.3.1). Potential hazards that are specific to aquaculture products include : residues of veterinary drugs in excess of recommended guidelines and other chemicals used in aquaculture production, contamination of faecal origin where the facilities are close to human habitation or animal husbandry.

### 6.2.2 Defects

The same defects are present in aquaculture products as in corresponding varieties caught in the wild (Section 5.3.3.1). A defect which may occur is objectionable odours/flavours. During transport of live fish, it is important to reduce stress, as stressing fish can lead to deterioration in quality. Also, care should be taken to minimise physical damage to fish as this can lead to bruising.

## 6.3 PRODUCTION OPERATIONS

### 6.3.1 Feed Supply

Feeds used in aquaculture production should comply with the Codex Recommended Code of Practice on Good Animal Feeding (CAC/RCP 54 – 2004).

*Potential Hazards :* *Chemical contamination, mycotoxins and microbiological contamination.*

*Potential Defects :* *Decomposed feeds, fungal spoilage*

*Technical Guidance :*

- Feed and fresh stocks should be purchased and rotated and used prior to the expiry of their shelf life ;
- Dry fish feeds should be stored in cool and dry areas to prevent spoilage, mould growth and contamination. Moist feed should be properly refrigerated according to manufacturers instructions ;
- Feed ingredients should not contain unsafe levels of pesticides, chemical contaminants, microbial toxins, or other adulterating substances ;
- Industrially produced complete feeds and industrially produced feed ingredients should be properly labelled. Their composition must fit the declaration on the label and they should be hygienically acceptable ;
- Ingredients should meet acceptable, and if applicable, statutory standards for levels of pathogens, mycotoxins, herbicides, pesticides and other contaminants which may give rise to human health hazards ;
- Only approved colours of the correct concentration should be included in the feed ;
- Moist feed or feed ingredients should be fresh and of adequate chemical and microbiological quality ;
- Fresh or frozen fish should reach the fish farm in an adequate state of freshness ;
- Fish silage and offal from fish, if used, should be properly cooked or treated to eliminate potential hazards to human health ;
- Feed which is compounded industrially or at the fish farm, should contain only such additives, growth promoting substances, fish flesh colouring agents; anti-oxidising agents, caking agents or veterinary drugs which are permitted for fish by the official agency having jurisdictional ;
- Products should be registered with the relevant national authority as appropriate ;
- Storage and transport conditions should conform to the specifications on the label ;
- Veterinary drug and other chemical treatments should be administered in accordance with recommended practices and comply with national regulations ;
- Medicated feeds should be clearly identified in the package and stored separately, in order to avoid errors ;
- Farmers should follow manufacturers' instructions on the use of medicated feeds ;
- Product tracing of all feed ingredients should be assured by proper record keeping.

### 6.3.2 Veterinary Drugs

*Potential Hazards :* *Residues of veterinary drugs*

*Potential Defects :* *Unlikely*

*Technical Guidance :*

- All veterinary drugs for use in fish farming should comply with national regulations and international guidelines (in accordance with the Recommended International Code of Practice for

Control of the Use of Veterinary Drugs (CAC/RCP 38-1993) and the Codex Guidelines for the Establishment of a regulatory programme for control of veterinary drugs residues in foods (CAC/GL 16-1993).

- Prior to administering veterinary drugs, a system should be in place to monitor the application of the drug to ensure that the withdrawal time for the batch of treated fish can be verified.
- Veterinary drugs or medicated feeds should be used according to manufacturers' instructions, with particular attention to withdrawal periods.
- Products should be registered with the appropriate national authority.
- Products should only be prescribed or distributed by personnel authorised under national regulations.
- Storage and transport conditions should conform to the specifications on the label.
- Control of diseases with drugs should be carried out only on the basis of an accurate diagnosis
- Records should be maintained for the use of veterinary drugs in aquaculture production.
- For those fish which tested with drug residue concentrations above the MRL (or in some countries, by an industry imposed lower level), harvest of the batch should be postponed until the batch complies with the MRL. After an assessment of the Good Aquaculture Practices regarding pre-harvest measures, appropriate steps should be taken to modify the drug residue control system.
- A post harvest control should reject all fish that do not comply with the requirements set for veterinary drug residues by the relevant national authority.

### 6.3.3 Growing

*Potential Hazards :* *Microbiological and chemical contamination*

*Potential Defects :* *Abnormal colour, muddy flavour, physical damage*

*Technical Guidance :*

- Source of post-larvae, fries and fingerlings should be controlled to assure healthy stock.
- Stocking densities should be based on culture techniques, fish species, size and age, carrying capacity of the fish farm, anticipated survival and desired size at harvesting.
- Diseased fish should be quarantined when necessary and appropriate and dead fish should be disposed immediately in a sanitary manner that will discourage the spread of disease and the cause of death should be investigated.
- Good water quality should be maintained by using stocking and feeding rates that do not exceed the carrying capacity of the culture system.
- Growing water quality should be monitored regularly, so as to identify potential hazards and defects.
- The fish farm should have a management plan that includes a sanitation programme, monitoring and corrective actions, defined fallowing periods, appropriate use of agrochemicals, verification procedures for fish farming operations and systematic records.
- Equipment such as cages and nets should be designed and constructed to ensure minimum physical damage of the fish during the growing stage.
- All equipment and holding facilities should be easy to clean and to disinfect and should be cleaned and disinfected regularly and as appropriate.

### 6.3.4 Harvesting

*Potential Hazards :* *Unlikely*

*Potential Defects :* *Physical damage, physical/biochemical change due to stress of live fish*

*Technical Guidance :*

- Appropriate harvesting techniques should be applied to minimise physical damage and stress.
- Live fish should not be subjected to extremes of heat or cold or sudden variations in temperature and salinity.
- Fish should be free from excessive mud and weed soon after being harvested by washing it with clean seawater or fresh water under suitable pressure.
- Fish should be purged, where necessary, to reduce gut contents and pollution of fish during further processing.
- Fish should be handled in a sanitary manner according to the guidelines in Section 4 of the Code.
- Harvesting should be rapid so that fish are not exposed unduly to high temperatures.
- All equipment and holding facilities should be easy to clean and to disinfect and should be cleaned and disinfected regularly and as appropriate.

### 6.3.5 Holding and Transportation

*Potential Hazards :* *microbiological and chemical contamination*

*Potential Defects :* *physical damage, physical/biochemical change due to stress of live fish*

*Technical Guidance :*

- Fish should be handled in such a way as to avoid unnecessary stress.
- Fish should be transported without undue delay.
- Equipment for the transport of live fish should be designed for rapid and efficient handling without causing physical damage or stress.
- All equipment and holding facilities should be easy to clean and to disinfect and should be cleaned and disinfected regularly and as appropriate.
- Records for transport of fish should be maintained to ensure full product tracing.
- Fish should not be transported with other products which might contaminate them.

### 6.3.6 Storage and transport of live fish

This section is designed for the storage and transportation of live fish originating from aquaculture or capture.

*Potential Hazards :* *microbiological contamination, biotoxins, chemical contamination (e.g. oil, cleaning and disinfecting agents)*

*Potential Defects :* *Dead fish, physical damage, off flavours, physical/biochemical change due to stress of live fish*

*Technical Guidance :*

- Only healthy and undamaged fish should be chosen for live storage and transport. Damaged sick and dead fish should be removed before introduction to the holding or conditioning tanks.
- Holding tanks should be checked regularly during storage and transportation. Damaged, sick and dead fish should be removed immediately when found.
- Clean water utilised to fill holding tanks, or to pump fish between holding tanks, or for conditioning fish, should be similar in properties and composition to the water from where the fish was originally taken to reduce fish stress.
- Water should not be contaminated with either human sewage or industrial pollution. Holding tanks and transportation systems should be designed and operated in a hygienic way to prevent

contamination of water and equipment.

- Water in holding and conditioning tanks should be well aerated before fish is transferred into them.
- Where seawater is used in holding or conditioning tanks, for species prone to toxic algae contamination, seawater containing high level of cell concentrations should be avoided or filtered properly.
- No fish feeding should occur during storage and transport of live fish. Feeding will pollute water of holding tanks very quickly and, in general, fish should not be fed 24 hours before transporting.
- Material of holding and conditioning tanks, pumps, filters, piping, temperature control system, intermediate and final packaging or containers should not be harmful to fish or present hazards to humans.
- All equipment and facilities should be cleaned and disinfected regularly and as needed.

6.3.6.1 Live fish stored and transported at ambient temperature

*Potential Hazards :* *microbiological contamination, biotoxins, chemical contamination (e.g. oil, cleaning and disinfecting agents)*

*Potential Defects :* *Dead fish, physical damage, off flavours , physical/biochemical change due to stress of live fish*

*Technical Guidance :*

- Depending on the source of water, requirements of the species and time of storage and/or transport, it could be necessary to re-circulate the water and filter it through mechanical and/or biofilters.
- Water intake of holding tanks on board of vessels should be located so as to avoid contamination from vessel's sewage, waste and engine cooling discharge. Pumping of water should be avoided when the vessel comes into harbour or sailing through waters near sewage or industrial discharges. Equivalent precautions should be adopted for water intake on land.
- Facilities for storing and transportation (holding tanks) of live fish should be capable to :

– maintain the oxygenation of water in the holding tanks through either, continuous water flow, direct oxygenation (with oxygen or air bubbling), or regularly and as needed changing of the water of the holding tank ;

– maintain the temperature of storage and transport, for species sensitive to temperature fluctuations. It may be necessary to insulate the holding tanks and install a temperature control system ;

– keep water in reserve which might be needed in case the holding tank should drain. The volume in fixed facilities (storage) should be at least of the same volume of the total holding tanks in operation. The volume in land transport facilities should be at least capable to compensate water for evaporation, leakage, purges, filter cleaning and eventual mixing of water for control purposes ;

- For species known to exhibit strong territoriality or cannibalism or hyperactivity when under stress, these fish should be separated in individual tanks or appropriately secured/banned to prevent damage (an alternative method is reduction of temperature).

6.3.6.2 Live fish stored and transported at low temperatures

*Potential Hazards :* *microbiological contamination, biotoxins, chemical contamination (e.g. oil, cleaning and disinfecting agents)*

*Potential Defects :* *Dead fish, physical damage, off flavours, physical/biochemical change due to stress of live fish*

*Technical Guidance :*

- Conditioning should aim at reducing the metabolic rate of fish in order to minimize the stress to them. Conditioning of the fish at low temperatures should be done according to the characteristics of the species (minimum temperature, cooling rate, water/humidity requirements, packaging conditions). Conditioning is a biological operation to reduce the metabolic rate of the fish minimising the stress to them.
- The level of temperature to be reached should be in accordance with the species, transport and packaging conditions. There is a range of temperature in which fish do not exhibit or have reduced physical activity. The limit is attained at the temperature at which the metabolic rate of the fish is minimised without causing adverse effects to them (basal metabolic rate).
- When performing conditioning, only approved anaesthetics and procedures accepted by the regulations should be used.
- Conditioned fish should be packed without delay in proper insulated containers.
- Remaining water or water for use with packaging material for conditioned fish should be clean, of similar composition and pH to the water the fish was taken from, but to the temperature of storage.
- Water absorbent pads, shredded wood, wood shavings or sawdust and tying material that may be utilised for packaging conditioned fish should be clean, first use, free of possible hazards and be wet right at the time of packaging.
- Conditioned and packed fish should be stored or transported under conditions that assure proper temperature control.

## SECTION 7 - LIVE AND RAW BIVALVE MOLLUSCS

In the context of recognising controls at individual processing steps, this section provides examples of potential hazards and defects and describes technological guidelines, which can be used to develop control measures and corrective action. At a particular step only the hazards and defects, which are likely to be introduced or controlled at that step, are listed. It should be recognised that in preparing a HACCP and/or DAP plan it is essential to consult Section 5 which provides guidance for the application of the principles of HACCP and DAP analysis. However, within the scope of this Code of Practice it is not possible to give details of critical limits, monitoring, record keeping and verification for each of the steps since these are specific to particular hazards and defects.

*This flow chart is for illustrative purposes only. For implementation of HACCP principles, a complete and comprehensive flow chart has to be drawn up for each product.*

*References correspond to relevant Sections of the Code.*

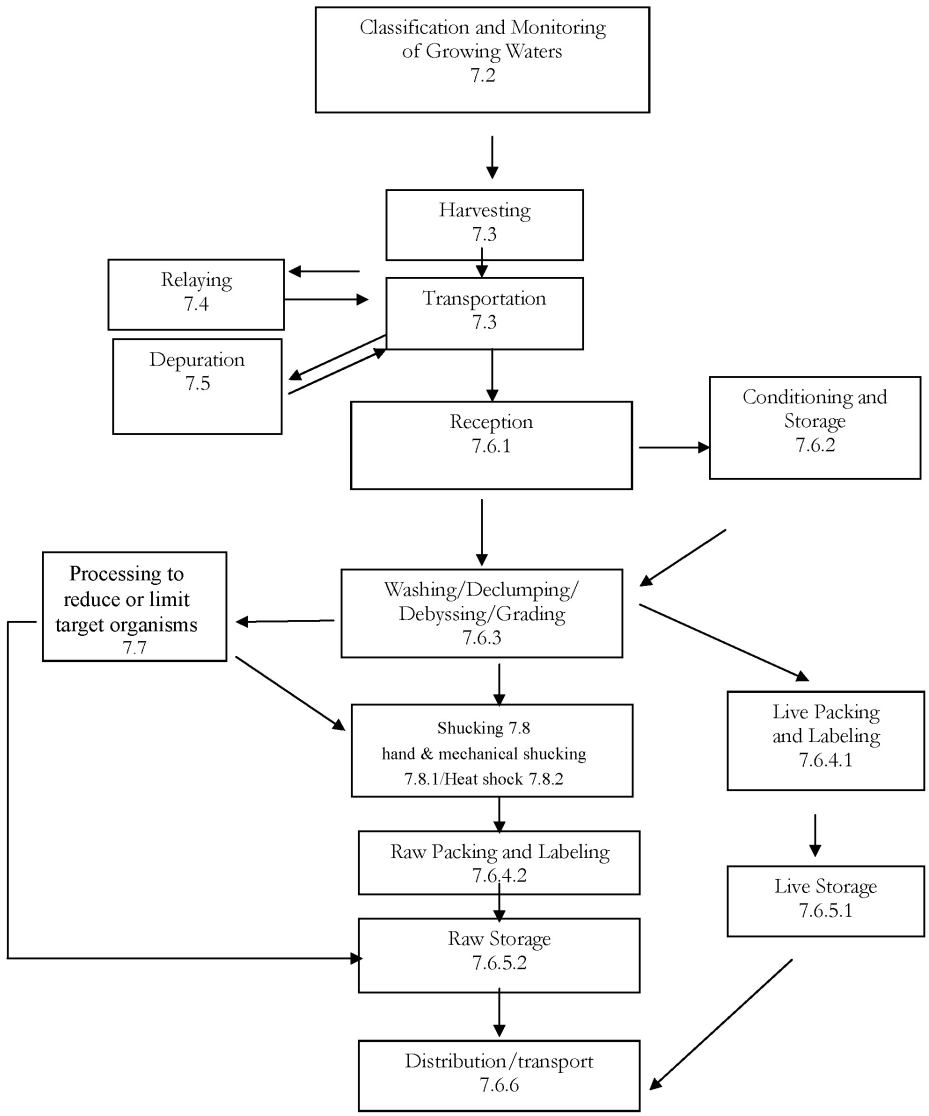


**Fig. 7.1 Example of a simplified flow diagram for production of live and raw bivalve molluscs**

## 7.1 GENERAL REMARKS, ADDITION TO THE PRE-REQUISITE PROGRAMME

Bivalve molluscs species like oysters, mussels, manilla and hard shell clams can survive for extended periods out of water and can be traded for human consumption as live animals. Other species like cockles can be traded live if carefully handled, but are normally processed. Species not adapted to dry conditions soon die out of water and are best handled as chilled products or processed.

When spawning (following "gonad ripening") occurs, it becomes undesirable and in many instances impracticable to trade them as live animals. Stress can induce spawning.

The main hazard known for the production of bivalve molluscs is microbiological contamination of waters in which they grow, especially when the bivalve molluscs are intended to be eaten live or raw. Since molluscs are filter feeders they concentrate contaminants to a much higher concentration than the surrounding sea water. The contamination with bacteria and viruses in the growing area is therefore critical for the end product specification and determines the process requirements for further processing. Gastro-enteritis and other serious diseases such as hepatitis can occur as a result from agricultural run-off and/or sewage contamination like enteric bacterial and/or viral pathogens (Norovirus, viruses causing hepatitis) or from natural occurring bacterial pathogens (*Vibrio* spp.). Another hazard is formed by biotoxins. Biotoxins produced by some algae can cause various forms of serious poisoning like diarrhetic shellfish poisoning (DSP), paralytic shellfish poisoning (PSP), neurotoxic shellfish poisoning (NSP), amnesic shellfish poisoning (ASP) or poisoning caused by Azaspiracid (AZP). Chemical substances, such as heavy metals, pesticides, organochlorides, petro-chemical substances may also form a hazard in certain areas.

To control the hazards, identification and monitoring of growing areas is very important for bivalve molluscs safety. The identification, classification and monitoring of these areas is a responsibility for competent authorities in cooperation with fishermen and primary producers. *E. coli*/faecal coliforms or total coliforms may be used as an indicator for the possibility of faecal contamination. If biotoxins are found in the bivalve molluscs flesh in hazardous amounts the growing area must be closed for harvesting bivalve molluscs until toxicological investigation has made clear that the bivalve mollusc meat is free from hazardous amount of biotoxins. Harmful chemical substances should not be present in the edible part in such amounts that the calculated dietary intake exceeds the permissible daily intake.

Bivalve molluscs from waters subject to microbiological contamination, as determined by the authority having jurisdiction, can be made safe by relaying in a suitable area or a depuration process to reduce the level of bacteria if the process is continued long enough, or by processing to reduce or limit target organisms. Depuration is a short-term process commonly used to reduce low levels of bacterial contamination, but long term relaying is required if there is a greater risk of contamination.

Especially when the bivalve molluscs need to undergo relaying or depuration to be eaten live or raw, stress and excessive shocks of the bivalve molluscs must be avoided. This is important because these bivalve molluscs should be able to function again during depuration, relaying or conditioning.

## 7.2 Classification and monitoring of growing areas

*Potential Hazards :* *Microbiological contamination, biotoxins, chemical contamination*

*Potential Defects :* *unlikely*

*Technical Guidance :*

There are 5 different types of important hazards coming from the bivalve molluscs growing environment :

- enteric bacterial pathogens (e.g. *Salmonella* spp.) ;
- enteric viral pathogens (e.g. Norovirus, viruses causing hepatitis) ;
- naturally occurring bacterial pathogens (e.g. *Vibrio* spp.) ;

- biotoxins (e.g. okadaic acid group (DSP), saxitoxin group (PSP), brevetoxin group (NSP), domoic acid group (ASP), azaspiracid group (AZP) ;
- chemical contaminants (e.g. heavy metals such lead, cadmium and mercury).

### 7.2.1 Classification of growing areas

Surveys of the growing area, shoreline and land catchment should be conducted to determine sources of both domestic and industrial pollution which may affect the quality of the growing area water and bivalve molluscs. Sources may include municipal sewage outputs, industrial outputs, mine wastes, geophysical contaminants, domestic animal holding pens, nuclear power plants, refineries or other sources. The need to reschedule hygiene surveys will be determined by population shifts and changes in agricultural and industrial activities in the coastal area. Resurveys should be conducted at an acceptable frequency and known pollution sources should be re-evaluated on a regular basis to determine any changes to their impact on the growing area.

When pollution sources have been identified and evaluated, sampling stations for water and/or bivalve molluscs and/or sediments should be established and studies conducted to determine the effects of the pollutants on water and bivalve molluscs quality. The data should be evaluated by the official agency having jurisdiction and growing areas should be classified according to official standards and criteria.

When interpreting growing area data, the official agency having jurisdiction should take into account variations which may affect the level of pollution during the most unfavourable hydrographic and climatic conditions as influenced by rainfall, tides, winds, methods of sewage treatment, population variations and other local factors, since bivalve molluscs respond rapidly to an increase in the number of bacteria or viruses in their environment by accumulating these agents. The agency should also consider that bivalve molluscs have the ability to accumulate toxic chemicals in their tissue in concentrations greater than the levels found in the surrounding water. FAO, WHO, or other international or national food standards may be used as a guide to acceptable levels.

The official agency having jurisdiction should immediately announce decisions concerning the classification of growing areas to the affected producers and depuration and distribution centres.

When sampling shellfish meats for classification purposes, if the limits of any biological or chemical hazard set in the end product specification are exceeded, appropriate measures must be taken under the responsibility of the official agency having jurisdiction.

Classified growing areas should be clearly defined by the official agency having jurisdiction as either :

- suitable for harvesting for direct human consumption, relaying in acceptable water or depuration in an approved depuration centre or approved processing to reduce or limit target organisms ; or
- non-suitable for growing or harvesting bivalve molluscs.

### 7.2.2 Monitoring of growing areas

Growing areas should be routinely monitored for changes in water quality and/or bivalve molluscs quality, and sub-standard areas patrolled to prevent harvesting for purposes other than that established by the official agency.

Biotoxins in bivalve molluscs can be caused by plankton containing toxins. For early warning purposes, where appropriate, it is recommended to have a programme present to monitor growing areas for the species of plankton that can produce toxins and to recognize other environmental signals that a toxic event may be developing.

Harmful chemical substances within bivalve molluscs should not be present in amounts so that the calculated dietary intake exceeds the permissible daily intake. A monitoring system should be present for harmful chemical substances.

When routine monitoring programmes or resurveys show that the growing area no longer meets the classification criteria, the area should be reclassified or closed for harvesting immediately by the

official agency having jurisdiction.

In determining the public health suitability of bivalve molluscs classified growing areas the official agency having jurisdiction should consider the following actions :

- Classification/reclassification of growing areas by sanitary survey, monitoring of *E.coli*/faecal coliforms or total coliforms at an appropriate frequency based on the risk of contamination, and other sanitary control measures as applicable.
- Classification/reclassification of growing areas by monitoring of pathogens at an appropriate frequency based on the probability of contamination in bivalve mollusc meat (see 7.2.2.2).
- Closure/Reopening of growing areas by the monitoring of biotoxins in bivalve molluscs alone or in combination with the monitoring of phytoplankton in seawater at an appropriate frequency based on the probability of contamination (see 7.2.2.3).
- Control of chemical contaminants.

Under the responsibility of the official agency having jurisdiction the growing areas providing bivalve molluscs for direct human consumption meet the following requirements at time of harvest :

- The area is not subject to contamination that may present an actual or potential hazard to human health ;
- The bivalve molluscs harvested meet the end product specification. This can be determined by examination of mollusc's flesh or through adequate monitoring of the water, as appropriate.

Growing areas providing bivalve molluscs for indirect human consumption should be defined in relation to the further procedure of the lot.

### 7.2.2.1 *E. Coli*/faecal coliforms/total coliforms

All growing water and/or molluscan flesh should be monitored for the presence of *E. coli*/faecal coliforms or total coliforms at an appropriate frequency based on the probability and degree of faecal contamination.

Tests for suitable indicator bacteria such as faecal coliforms or *Escherichia coli* or total coliforms should be used to determine the degree of faecal contamination. The effectiveness of indicator bacteria used should be kept under constant review for their reliability as measures for the degree of faecal contamination. If faecal agency having jurisdiction may be allowed.

*E. coli*/faecal coliforms or total coliforms may be used as an indicator for the presence of faecal contamination. Because these indicators do not correlate well with the presence of viruses, other controls such as shoreline surveys should always be employed.

Other methods such as bacteriophage and viral detection could also be used as indicators when validated analytical methods become available in the future.

### 7.2.2.2 Pathogen Monitoring

Shellfish sanitation programs rely upon the use of indicator organisms for the presence of contamination rather than upon attempts to monitor for specific pathogens. However, where there has been a shellfish borne outbreak caused by an identified pathogen such as *Salmonella* and others (*Vibrio* and viruses), monitoring the bivalve molluscs may be appropriate as part of the process of closure/reopening the affected harvest area. The species, and typically the actual strain, should be known to ensure that monitoring is addressing the source of the pathogen. Predetermined acceptance/rejection levels for the pathogen should have been established in order to use such monitoring results for decision making. Other conditions including the sanitary survey requirements should also have been satisfied as a condition of reopening this area.

### 7.2.2.3 Marine biotoxin control

Phytoplankton monitoring is a valuable complementary tool that can be used, in combination with the required monitoring of marine biotoxins in shellfish tissue, to optimize program management and resources. Growing areas should also be monitored for environmental signals that a toxin event

maybe occurring, e.g, dead or dying birds, mammals, or fish. The risk of blooms of toxic algae may show seasonal variability and areas may also be affected by toxic algae previously unknown in the surrounding sea or coastal waters. These risks should be recognised when drawing up monitoring schedules.

It is important to note that in using indicator shellfish species, the absence of toxicity in indicated species is assumed to imply the absence of toxicity in other species in the growing area. This implication must be verified for each shellfish species and for each group of toxins before defining a particular shellfish species as an indicator for that growing area.

The official agency having jurisdiction should close immediately and effectively patrol affected areas when acceptable levels are exceeded in edible portions of bivalve molluscs meats. These areas should not be opened before toxicological investigation has made clear that the bivalve molluscs meat is free from hazardous amounts of biotoxins.

The official agency having jurisdiction should immediately announce these decisions to the affected producers and depuration and distribution centres.

In establishing sampling programme over space and time, consideration should be given to assuring adequate location and number of sampling sites. Testing for a particular biotoxin may not be appropriate when it has been demonstrated that this biotoxin has not been associated with bivalve molluscs in the growing and harvesting areas. Sampling frequency must be sufficient to address spatial-temporal changes in micro-algae, toxins in shellfish and to cover the risks of rapid rises in shellfish toxicity.

*Spatial Representational Sampling*

The selection of sampling stations for both benthic and suspended culture should be based on sites which have historically presented toxicity in the early stages of a toxic event. It is recognised that sampling, generally, cannot be carried out in a statistically valid way without excessive cost. In order to protect public health, the selection of sampling stations should give appropriate coverage of the extent of a toxic event or the likely "worst case scenario" in a growing area. This should be based on expert judgment using the following factors :

- Hydrography, known upwellings, fronts, current patterns and tidal effects.
- Access to sampling stations in all weather conditions during harvesting.
- Desirability of toxin and micro-algal sampling at the same sampling station.
- In addition to primary (routine) stations, the need for secondary (complementary) and offshore stations.
- Existence of *in-situ* growth (for example, toxic micro-algae from cyst beds).
- The advection of offshore toxic micro-algal blooms into growing areas.

Routine sampling for micro-algae will generally mean taking an integrated sample from the water column. When a toxic event is in progress or developing, targeted, depth-specific sampling should be considered.

Sampling for shellfish grown in suspension, should at least involve an integrated sample composed of shellfish taken from the top, middle and bottom of the lines.

*Temporal Representational Sampling*

Minimum weekly sampling frequencies are adopted by most monitoring programmes in areas where toxicity is prevalent and where harvesting is taking place or about to take place. Decisions on the frequency of sampling should be based on risk evaluation. Inputs into the decision may include factors such as seasonality (toxicity and / or harvesting), accessibility, historical baseline information, including toxin and micro-algal data, and the effects of environmental factors such as wind, tide and currents.

Sampling frequency and the factors that may lead to it being changed should be described in a "Marine Biotoxin Action Plan" for the growing area.

*Shellfish Sample Size*

There is no internationally agreed sample size for different shellfish species. There may be high variability of toxicity among individual shellfish. The number of shellfish sampled should be sufficient to address this variability. For this reason, the number of shellfish in the sample, rather than the mass of the shellfish flesh should be the determining factor for the sample size. Additionally, the size of the sample should be sufficient to allow the test or tests for which the sample is being taken to be carried out, and the shellfish sampled should be of the size marketed.

7.2.2.4 Marine biotoxin test methods

Methods suitable for the determination of marine biotoxins are listed in the draft Standard for Live and Raw Bivalve Molluscs. Any methods may be deemed suitable for screening purposes provided they are approved by a country's competent authority.

7.2.2.5 Chemical contaminants

Growing areas should be monitored for chemical contaminants on a sufficiently frequent basis to provide confidence that any identified sources of chemical contamination are not contaminating the shellfish. Shellfish growing areas where there are no known point sources of likely chemical contamination should only require occasional checks every few years. However, where there are known point sources of specific contamination shellfish may need to be checked more frequently on a routine basis. There should also be the capacity to sample shellfish reactively if a defined event occurs – for example a spillage of anti-fouling paint.

## 7.3 HARVESTING AND TRANSPORTATION OF LIVE BIVALVE MOLLUSCS

Refer also to Sections 3.1, 3.3, 3.4 and 3.5

This section applies to the transportation of bivalve molluscs for the purpose of direct human consumption, relaying, depuration, processing to reduce or limit target organisms, or further processing.

Appropriate handling procedures depend on different species, growing area and season.

*Potential Hazards:* *Microbiological contamination, biotoxins, chemical contamination*

*Potential Defects:* *Physical damage*

*Technical Guidance:*

- Dredges and other harvesting equipment, decks, holds and containers, which are contaminated from use in a polluted area, should be cleaned and if applicable disinfected (sanitised) before being used for bivalve molluscs from an unpolluted area.
- Holds in which bivalve molluscs are held or containers should be so constructed that the bivalve molluscs are held above the floor level and drained so that the bivalve molluscs is not in contact with wash-down or bilge water, or shell fluid. Where necessary a bilge pumping system must be provided.
- Suitable precautions should be taken to protect bivalve molluscs from being contaminated by polluted water, droppings from sea birds, footwear which may have been in contact with faecal matter or by other polluted material. No overboard discharge of waste, including human faecal material, should occur from harvest vessels around shellfish growing areas. No animals should be allowed on harvest vessels.
- Wash-down pumps should draw water only from non-contaminated seawater.
- Bivalve molluscs should be harvested from and stored in a growing area or relaying area acceptable to the official agency having jurisdiction.

- On removal from water or during handling and transportation, bivalve molluscs should not be subjected to extremes of heat or cold or sudden variations in temperature. Temperature control is critical in handling live bivalve molluscs. Special equipment, such as insulated containers and refrigeration equipment should be used if prevailing temperatures and the time involved so require. Bivalve molluscs should not be exposed to full sun or surfaces heated by the sun or come into direct contact with ice and other freezing surfaces, nor should it be held in closed containers with solid carbon dioxide. In most cases storage above 10℃ (50°F) or below 2℃ (35°F) should be avoided.
- Bivalve molluscs should be freed from excessive mud and weed soon after being harvested by washing it with clean seawater or potable water under suitable pressure. Wash water should not be allowed to flow over bivalve molluscs already cleaned. The water could be re-circulated if it meets the definition for clean water.
- The interval between harvesting and immersion in water for relaying, storage, conditioning or depuration should be kept as short as possible. This also applies to the interval between final harvesting and handling in a distribution centre.
- If bivalve molluscs are to be re-immersed after harvest they should be re-immersed in clean seawater.
- Appropriate documentation should be maintained for harvesting and transportation activities.

## 7.4 RELAYING

The requirements for classification and monitoring of growing areas also apply to Relaying areas.

Relaying is intended to reduce the level of biological contaminants that may be present in bivalve molluscs which have been harvested from contaminated areas to such levels that the bivalve molluscs will be acceptable for human consumption without further processing. Bivalve molluscs harvested for relaying should only be harvested from areas that are so designated/classified by the official agency having jurisdiction. Relaying methods vary worldwide. Bivalve molluscs may be placed in floats, rafts or directly on the bottom.

*Potential Hazards:* *Microbiological contamination, biotoxins, chemical contamination*

*Potential Defects:* *Physical damage*

*Technical Guidance:*

- Relaying operations should be strictly supervised by the official agency having jurisdiction to prevent contaminated bivalve molluscs from being diverted directly to the consumer market or from cross contamination of other bivalve molluscs. Boundaries of relaying areas should be clearly identified by buoys, poles or other fixed means. These areas should be adequately separated from the bivalve molluscs in adjacent waters and suitable control systems should be in place to prevent cross contamination and commingling.
- Holding time and minimum temperature in the accepted area prior to harvest will be determined by the official agency having jurisdiction according to the degree of contamination before relaying, the temperature of the water, the bivalve molluscs species involved and local geographic or hydrographic conditions to ensure that contamination levels have been adequately reduced.
- Relaying sites could become biotoxic from a bloom, or could become an unexpected a source of environmental pathogens such as *Vibrio* bacteria, and should therefore be monitored as appropriate while they are being used for relaying.
- Bivalve molluscs should be laid out at a density which will permit them to open and undergo natural depuration.
- Appropriate documentation should be maintained for relaying operations.

## 7.5 DEPURATION

Refer also to Sections : 3.2, 3.3, 3.4 and 3.5

Depuration is intended to reduce the number of pathogenic micro-organisms that may be present in bivalve molluscs which have been harvested from moderately polluted areas to such levels that the bivalve molluscs will be acceptable for human consumption without further processing. Depuration alone is not suitable for cleansing bivalve molluscs from more heavily contaminated areas or areas subject to contamination by hydro-carbons, heavy metals, pesticides, viruses, vibrios or biotoxins. Bivalve molluscs harvested for depuration should only be harvested from areas that are so designated/classified by the official agency having jurisdiction.

The required conditions vary according to the species of molluscs and the design of the depuration system.

For natural functioning and therefore depuration to occur it is essential that the molluscs have not been overstressed or damaged during harvesting or handling prior to depuration and should not be in a seasonally weak or spawning condition.

Depuration centres should maintain the same hygiene standards as sections 3.2, 3.3, 3.4, 3.5.

*Potential Hazards : Microbiological contamination*

*Potential Defects : physical damage*

*Technical Guidance :*

Depuration centres and tanks should be approved by the official agency having jurisdiction.

- Bivalve molluscs subjected to the depuration process should not contain metallic ions, pesticides, industrial wastes or marine biotoxins in such quantities that it presents a health hazard to the consumer.
- Use only shellstock designated as acceptable by the official agency having jurisdiction.
- The process and the equipment, e.g. tanks, used for depuration should be acceptable to the official agency having jurisdiction.
- Dead or damaged bivalve molluscs should be removed before the depuration process, when practicable. Surfaces of shells should be free from mud and soft commensal organisms. If necessary the bivalve molluscs should be washed with clean sea water before the depuration

process.

- The length of the period of depuration should be adapted to the water temperature and physical water quality parameters (clean sea water, salinity, dissolved oxygen and pH levels suitable to permit the bivalve molluscs to function normally), the degree of contamination before depuration and the bivalve molluscs species. Microbiological investigation of process water and of bivalve molluscs meat should be used to assess depuration parameters. It should be taken into account that viruses and *Vibrio* spp. are more persistent during depuration than the indicator bacteria mostly used for microbiological monitoring and that the reducing of the number of indicator bacteria does not always reflect the real situation as regards contamination by viruses and *Vibrio*.
- Water used in depuration tanks should be changed continuously or at suitable intervals or if recirculated be treated properly. The flow of water per hour should be sufficient to the amount of bivalve molluscs treated and should depend on the degree of contamination of the bivalve molluscs.
- Bivalve molluscs undergoing depuration should remain immersed in clean sea water until it satisfies the sanitary requirements of the official agency having jurisdiction.
- Bivalve molluscs should be laid out at a density which will permit them to open and undergo natural depuration.

- During the process of depuration, the water temperature should not be allowed to fall below the minimum at which bivalve molluscs remain physiologically active ; high water temperatures which adversely affect the pumping rate and the depuration process should be avoided; tanks should be protected from the direct rays of the sun when necessary.
- Equipment in contact with water, i.e. tanks, pumps, pipes or piping, and other equipment should be constructed of non-porous, non-toxic materials. Copper, zinc, lead and their alloys should preferably not be used in tanks, pumps or piping systems used in depuration processing.
- To avoid recontamination of bivalve molluscs undergoing depuration, unpurified bivalve molluscs should not be placed in the same tank as bivalve molluscs which are already undergoing depuration.
- On removal from the depuration system, bivalve molluscs should be washed with running potable water or clean sea water, and handled in the same manner as living bivalve molluscs taken directly from a non-polluted area. Dead, with broken shells or otherwise unwholesome bivalve molluscs should be removed.
- Before removing the bivalve molluscs form the tanks drain the water from the system to avoid resuspension and reingestion. The tanks should be cleaned after each use and disinfected at suitable intervals.
- After depuration the bivalve molluscs should meet the end product specification.
- Appropriate documentation should be maintained for depuration.

## 7.6 PROCESSING OF BIVALVE MOLLUSCS IN A DISTRIBUTION CENTRE OR AN ESTABLISHMENT

Some countries require that bivalve molluscs that are to be frozen and/or shucked, and/or processed to reduce or limit target organisms must first pass through a "distribution centre" from which they exit alive. Other countries allow freezing, shucking, and processing to reduce or limit target organisms to occur in establishments that perform the functions of a "distribution centre." Both practices are legitimate and the products from each one should be equally permitted in international trade. Where "distribution centre" activities and processing activities occur under the same roof, care must be taken to ensure adequate separation of activities to prevent cross-contamination or commingling products.

Distribution centres that prepare live bivalve molluscs suitable for direct consumption and establishments that prepare live and raw bivalve molluscs suitable for direct consumption should maintain the same hygiene standards as sections 3.2, 3.3, 3.4, 3.5.

### 7.6.1 Reception

*Potential Hazards :* *Microbiological, chemical and physical contamination*

*Potential Defects :* *Viable parasites ,physical damage, foreign matter, dead or dying of bivalve molluscs*

*Technical Guidance :*

Stress and excessive shocks to bivalve molluscs that will be dispatched live from a distribution centre or other establishment must be avoided.

Distribution centres and other establishments that prepare live bivalve molluscs should only accept bivalve molluscs which meet the end product specification and which originate directly from approved growing areas or after relaying in an approved relaying area or after depuration in an approved depuration centre or tank.

### 7.6.2 Conditioning and storage of bivalve molluscs

Refer also to Sections 3.2, 3.3, 3.4 and 3.5

*Potential Hazards :* *Microbiological contamination, chemical contamination, biotoxins*

*Potential Defects :* *Physical damage, foreign matter, dead or dying of bivalve molluscs*

*Technical Guidance :*

Conditioning means storage of bivalve molluscs in sea water tanks, basins, floats, rafts or natural sites with the intention to remove mud, sand and slime.

The process of storing bivalve molluscs in sea water tanks, basins, floats, natural sites or rafts can be used if it is acceptable to the official agency having jurisdiction.

Only clean sea water should be used in the tanks, floats, natural sites or rafts and should be of an adequate salinity and adequate physical water quality parameters to permit the bivalve molluscs to function normally. Optimum salinity will vary with bivalve molluscs species and with the harvesting area. Water condition has to be satisfactory adequate for the process. Where natural sites are used for conditioning these should be classified by the official agency having jurisdiction.

Before conditioning or storage bivalve molluscs should be washed to remove mud and soft commensal organisms and dead or damaged bivalve molluscs should be removed when practicable.

During storage bivalve molluscs should be laid out at a density and under such conditions that will permit them to open and function normally.

The oxygen content in the seawater should be maintained at an adequate level at all times.

The temperature of the water in storage tanks should not be allowed to rise to such levels as to cause weakness of the bivalve molluscs. If ambient temperatures are excessively high, tanks should be placed in a well-ventilated building or away from the direct rays of the sun. The length of the period of conditioning should be adapted to the water temperature.

Bivalve molluscs should be stored in clean sea water only for such time as they remain sound and active.

Tanks should be drained, cleaned and disinfected at suitable intervals.

Recirculating wet storage systems must contain approved water treatment systems.

### 7.6.3 Washing, declumping, debyssing and grading

Refer also to Sections 3.2, 3.3, 3.4 and 3.5

*Potential Hazards : Microbiological contamination, chemical and physical contamination*

*Potential Defects : Mechanical damage*

*Technical Guidance :*

- All steps in the process, including packaging, should be performed without unnecessary delay and under conditions which will prevent the possibility of contamination, deterioration and the growth of pathogenic and spoilage micro-organisms.
- Damage to shells and stress will shorten the shelf life of bivalve molluscs and increase the risk of contamination and deterioration. So bivalve molluscs have to be handled carefully :
- The number of handlings with bivalve molluscs should be minimised;
- Excessive shocks should be avoided.
- The different process steps should be supervised by technically competent personnel.
- The outsides of the shells should be washed free of mud, and all soft adhering organisms should be removed. Hard adhering organisms should also be removed when possible, care being taken not to chip lips of shells by vigorous washing. Washing should be carried out using pressurised clean (sea) water.

Bivalve molluscs having formed clumps should be declumped and debyssed as appropriate. The equipment used should be designed and adjusted to minimise the risk of damage to the shells.

## 7.6.4 Packing and Labelling

Refer also to Sections: 3.2, 3.3, 3.4 and 3.5

All steps in the process of packaging should be performed without unnecessary delay and under conditions that will prevent the possibility of contamination, deterioration and the growth of pathogenic and spoilage micro-organisms.

The packaging material should be appropriate for the product to be packed and for the expected conditions of storage and should not transmit to the product harmful or other objectionable substances or odours and tastes.

The packaging material should be sound and should provide appropriate protection from damage and contamination.

### 7.6.4.1 Packing and Labelling of Live Bivalve Molluscs

*Potential Hazards :* *Microbiological contamination, physical contamination, chemical contamination*

*Potential Defects :* *Incorrect labelling, presence of damaged or dead bivalve molluscs, foreign matter*

*Technical Guidance :*

- Before packing bivalve molluscs should undergo visual inspection. Bivalve molluscs which are dead, with broken shells, with adhering soil or otherwise unwholesome, should be rejected for human consumption.
- The packaging material should avoid contamination and should be drained.
- Labels should be clearly printed and must comply with the labelling laws of the country where the product is marketed. The packaging material may be used to bear an indication as to how the bivalve molluscs should be kept from the time they were bought at the retailer. It is recommended to include the date of packaging.
- All packaging material should be stored in a clean and sanitary manner. Product containers should not have been used for any purpose, which may lead to contamination of the product. Packaging material should be inspected immediately before use to ensure that they are in a satisfactory condition and where necessary disposed of or cleaned and/or disinfected ; when washed they should be well drained before filling. Only packaging material required for immediate use should be kept in the packing or filling area.

### 7.6.4.2 Packing and Labelling of Raw Bivalve Molluscs

*Potential Hazards : Microbiological and physical contamination*

*Potential Defects : objectionable matter such as shell pieces; incorrect labelling*

*Technical Guidance :*

- Labels should be clearly printed and must comply with the labelling laws of the country where the product is marketed. The packaging material or label may be used as a means to convey appropriate storage instructions to the consumer after retail purchase. It is recommended to include the date of packaging
- All packaging material should be stored in a clean and sanitary manner. Only packaging material required for immediate use should be kept in the packing or filling area.
- Shucked and post harvest treated product should be packed and chilled or frozen as soon as possible.
- Freezing should take place quickly (see section 8.3). Slow freezing will damage meat.
- If labels on post harvest treated raw bivalve molluscs make safety claims relating to the post harvest treatment, the claims should be specific to the target hazard that has been eliminated or reduced.

### 7.6.5 Storage

#### 7.6.5.1 Storage of Live Bivalve Molluscs

*Potential Hazards :* *Microbiological contamination, chemical and physical contamination*

*Potential Defects :* *physical damage*

*Technical Guidance :*

- The end product should be stored under such conditions as will preclude the contamination with and/or proliferation of micro-organisms. The packaging material of the end product should not have direct contact with the floor but should be placed on a clean, raised surface.
- Storage periods should be kept as short as possible.
- Re-immersion in or spraying with water of live bivalve molluscs must not take place after they have been packed and have left the distribution centre or establishment except in the case of retail sale at the distribution centre.

#### 7.6.5.2 Storage of Raw Bivalve Molluscs

*Potential Hazards :* *Microbiological contamination, chemical and physical contamination*

*Potential Defects :* *physical damage*

*Technical Guidance :*

- Storage periods should be kept as short as possible
- Damage to packaging of frozen product should be avoided.

### 7.6.6 Distribution / Transport

#### 7.6.6.1 Distribution of Live Bivalve Molluscs

Refer also to Sections 3.6 and 17

*Potential Hazards :* *Microbiological contamination*

*Potential Defects :* *Physical damage*

*Technical Guidance :*

- The product should be dispatched in the sequence of the lot numbers.
- Temperature should be maintained during distribution to control microbial growth.
- Bivalve molluscs intended for human consumption should only be distributed in closed packaging.
- The means of transport should provide sufficient protection of the bivalve molluscs against damage to the shells from shocks. The bivalve molluscs should not be transported with other products which might contaminate them.

#### 7.6.6.2 Distribution of Raw Bivalve Molluscs

*Potential Hazards :* *Microbiological contamination*

*Potential Defects :* *unlikely*

*Technical Guidance :*

- Temperature should be maintained during distribution to control microbial growth.
- The product should be dispatched in the sequence of the lot numbers.
- Transportation should be able to maintain chilled or frozen product for safety and quality.

## 7.7. PROCESSING TO REDUCE OR LIMIT TARGET ORGANISMS

Refer also to Sections 3.2, 3.3, 3.4, and 3.5.

Bivalve molluscs processed to reduce or limit target organisms are products prepared from live or raw bivalve molluscs that have been processed after harvest to reduce or limit specified target organisms within the product to levels that are satisfactory to the official agency having jurisdiction. Processing to reduce or limit target microorganisms is intended to retain the sensory qualities of a live bivalve mollusc. As with all live and raw bivalve molluscs, these bivalve molluscs must meet all microbiological criteria associated with traditional harvest water controls designed to prevent faecal contamination and resulting introduction of enteric pathogens as well as toxins and other contaminants. However, these growing area controls are not designed for control of pathogens that are independent from faecal contamination.

*Potential Hazards:* *Microbiological contamination*

*Potential Defects:* *Coagulation of meat, defective meat texture, hydrostatic medium forced into the flesh.*

*Technical Guidance:*

- Any treatment developed to eliminate or reduce pathogens should be thoroughly validated scientifically to ensure that the process is effective (see the Draft Guidelines for the Validation of Food Safety Control Measures).
- The control treatments (heat, pressure, etc.) should be closely monitored to ensure that the product does not undergo textural changes in the flesh that are unacceptable to the consumer.
- The treatment parameters established to reduce or limit pathogens should be approved by the official agency having jurisdiction.
- Each establishment which purifies bivalve molluscs with a heat treatment must develop a heat treatment process schedule, acceptable to the official agency having jurisdiction, which addresses such critical factors as the species and size of bivalve molluscs, time of exposure to heat, internal bivalve molluscs temperature, type of heat process used, water/steam to bivalve molluscs ratios, nature of heat equipment, measurement devices and their calibration, post heating chilling operations, cleaning and sanitising of heat process equipment.

## 7.8 SHUCKING

Shucking is the processing step that removes the edible portion of the mollusc from the shell. It is usually done by hand, mechanically or through heat shock with steam or hot water. This step may expose the product to microbiological or physical contamination.

### 7.8.1 Hand and Mechanical Shucking and Washing,

Physical removal of shellfish meat from the shell will often expose the product to dirt, mud and detritus that should be removed before further processing through washing or other means.

*Potential Hazards:* *Physical contamination, microbiological contamination*

*Potential Defects:* *Cuts and tears of the flesh, presence of sand and mud*

*Technical Guidance:*

- Care should be taken to eliminate excess mud, detritus and sand from the shucking tables.
- The product should be examined to ensure that cuts and tears are minimized.
- Shucked molluscs should be rinsed or washed to further eliminate mud, sand, detritus and reduce the microbiological level of the products.

### 7.8.2 Heat shocking of bivalve molluscs followed by packing

Heat shocking is a method to remove shells from the bivalve molluscs.

Refer also to Sections 3.2, 3.3, 3.4 and 3.5

*Potential Hazards:* *Physical contamination*

*Potential Defects :* *unlikely*

*Technical Guidance :*

- The bivalve molluscs must come from approved growing areas and/or after relaying in an approved relaying area or depuration in an approved depuration centre or tank. Each establishment which heat shucks bivalve molluscs should develop a heat shuck process schedule, acceptable to the official agency having jurisdiction, which addresses such critical factors as the species and size of bivalve molluscs, time of exposure to heat, internal bivalve molluscs temperature, type of heat process used, water/steam to bivalve molluscs ratios, nature of heat equipment, measurement devices and their calibration, post heating chilling operations, cleaning and sanitising of heat process equipment.
- All bivalve molluscs should be washed with pressurised potable water or clean sea water and culled for damaged and dead bivalve molluscs prior to heat treatment.
- Before heat shocking the bivalve molluscs should be inspected to determine whether the bivalve molluscs are alive and not badly damaged
- Heat shocked bivalve molluscs should be cooled to 7℃ or less within two hours of being heat treated (this time includes the shucking process). This temperature should be maintained during transport, storage and distribution.
- The heat shocked bivalve molluscs should be packed as soon as possible. Before packing the bivalve molluscs should be examined for objectionable matter such as shell pieces.

## 7.9 DOCUMENTATION

The transport of live bivalve molluscs from a growing area to a distribution centre, depuration centre, relaying area or establishment should be accompanied by documentation for the identification of batches of live bivalve molluscs.

Storage and transport temperatures should be indicated.

Permanent, legible and dated records of relaying and depuration should be kept concerning each lot. These records should be retained for a period of minimal one year.

Depuration centres or tanks and distribution centres and establishments should only accept lots of live bivalve molluscs with documentation issued by or accepted by the official agency having jurisdiction. Where appropriate, his document should contain the following information

- the gatherer's identity and signature ;
- the date of harvesting;
- common and/or scientific name and quantity of bivalve molluscs ;
- the location of the growing area and the status of this area (suitable for harvesting for direct human consumption, suitable for relaying, suitable for depuration, suitable for approved processing to reduce or limit target organisms).
- for distribution centres and establishments, if appropriate, the date and duration of depuration and the responsible's identity and signature.
- for distribution centres and establishments, if appropriate, the date and duration of relaying, the location of the relaying area and the responsible's identity and signature Complete records of harvest area and date of harvest and length of time of relaying or depuration of each lot should be maintained by the distribution centre or establishment for a period designated by the official agency having jurisdiction.

## 7.10 LOT IDENTIFICATION AND RECALL PROCEDURES

Refer also to Section 3.7

- "Each product should have an easy identifiable lot number. This lot number must include an identification code, the number of the establishment that distributes the product, the country of

origin and day and month of packing, in order to facilitate the traceability/product tracing of the product. A record keeping system should be based on these lot numbers so that individual lots of bivalve molluscs can be traced from the growing area to the end user.

## SECTION 8 - PROCESSING OF FRESH, FROZEN AND MINCED FISH

In the context of recognising controls at individual processing steps, this section provides examples of potential hazards and defects and describes technological guidelines, which can be used to develop control measures and corrective action. At a particular step only the hazards and defects, which are likely to be introduced or controlled at that step, are listed. It should be recognised that in preparing a HACCP and/or DAP plan it is essential to consult Section 5 which provides guidance for the application of the principles of HACCP and DAP analysis. However, within the scope of this Code of Practice it is not possible to give details of critical limits, monitoring, record keeping and verification for each of the steps since these are specific to particular hazards and defects.

In general, the processing of fresh, frozen fish and minced fish, will range in sophistication. In its simplest form, the processing of fresh and frozen fish may be presented in a raw state such as dressed, fillets, and minced to be distributed in markets and institutions or used in processing facilities. For the latter, the processing of fresh, frozen and minced fish is often an intermediate step to the production of value added products (for example, smoked fish as described in section 12, canned fish as described in section 16, frozen breaded or battered fish as described in section 15). Traditional methods often prevail in the design of a process. However, modern scientific food technology is having an increasingly important role in enhancing the preservation and shelf-stability of a product. Regardless of the complexity of a particular process, the fabrication of the desired product relies on the consecutive execution of individual steps. As stressed by this Code, the application of appropriate elements of the pre-requisite programme (Section 3) and HACCP principles (Section 5) at these steps will provide the processor with reasonable assurance that the essential quality, composition and labelling provisions of the appropriate Codex standard will be maintained and food safety issues controlled.

The example of the flow diagram (Figure 8.1) will provide guidance to some of the common steps involved in a fish fillet preparation line, and three examples of final product types: modified atmosphere packaging (MAP), minced and frozen fish. As in the further processing of fresh fish in a MAP product, or minced or frozen fish, the section labelled "Fish Preparation" is used as the basis for all the other fish processing operations (Sections 9-16)[4], where appropriate.

4 Sections 12 - 13 under elaboration

*This flow chart is for illustrative purposes only. For in-factory HACCP implementation a complete and comprehensive flow chart has to be drawn up for each process.*

*References correspond to relevant Sections of the Code.*

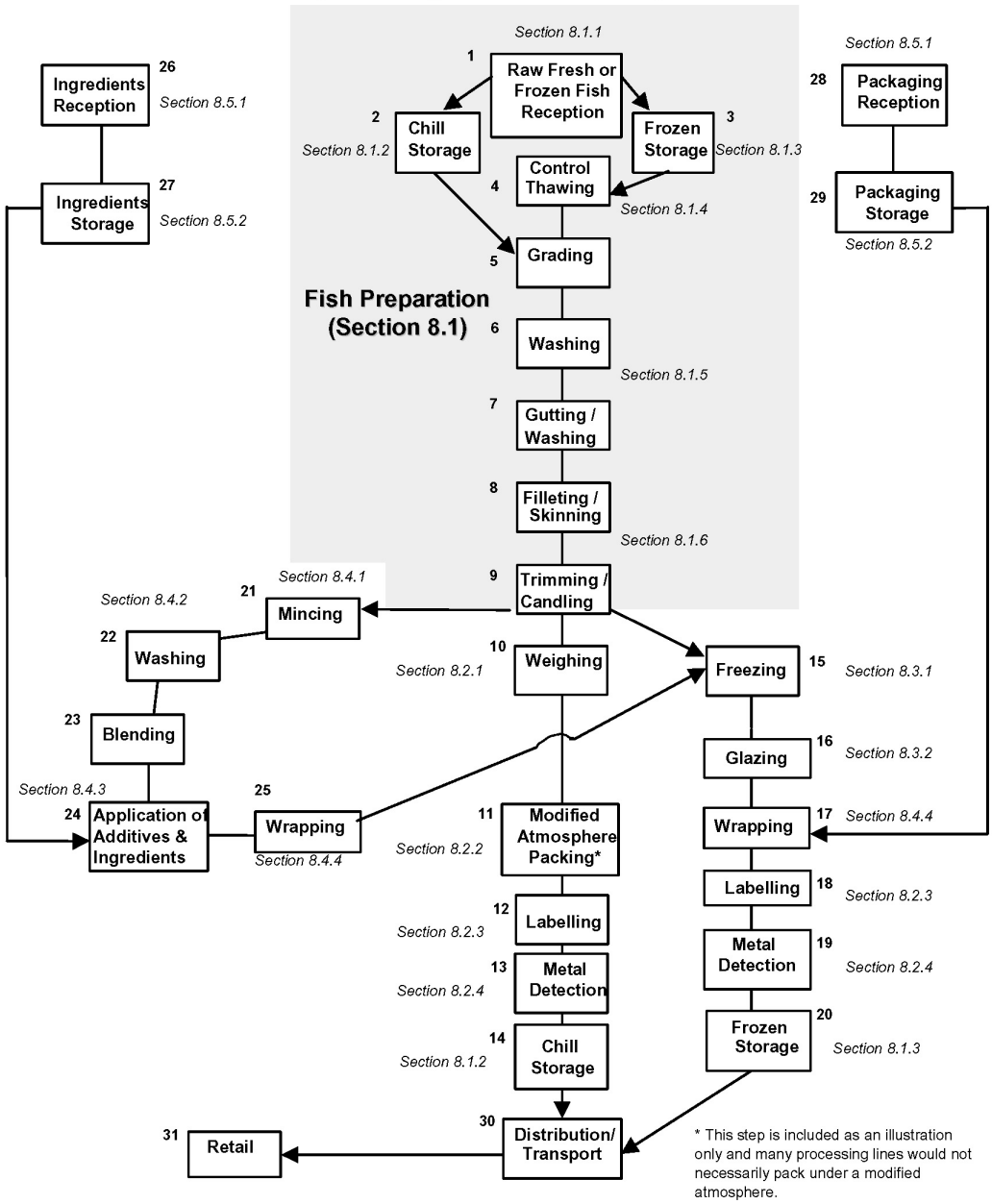


**Figure 8.1 Example of a flow chart of a fish fillet preparation line, including MAP, mincing and freezing operations**

## 8.1 FINFISH PREPARATION

The hygienic conditions and technical manner in which fish are prepared is similar and is not influenced greatly by its intended purpose (for direct distribution or for further processing). However, variations will exist in the form in which the fresh fish flesh is to be utilised. The forms may include, but not limited to, dressed, fillets or steaks.

### 8.1.1 Raw, Fresh or Frozen Fish Reception (Processing Steps 1)

*Potential Hazards :* *Microbiological pathogens, viable parasites, biotoxins, scombrotoxin, chemicals (including veterinary drug residues) and physical contamination.*

*Potential Defects :* *Decomposition, parasites, physical contamination*

*Technical Guidance :*

- for raw fish material, product specifications could include the following characteristics :
  - organoleptic characteristics such as appearance, odour, texture, etc;
  - chemical indicators of decomposition and/or contamination, for example, TVBN, histamine, heavy metals, pesticide residues, nitrates etc ;
  - microbiological criteria, in particular for intermediate raw materials, to prevent the processing of raw material containing microbial toxins ;
  - foreign matter ;
  - physical characteristics such as size of fish ;
  - species homogeneity.
- training in species identification and communication in product specification should be provided to fish handlers and appropriate personnel to ensure a safe source of incoming fish where written protocols exist. Of special consideration, are the reception and sorting of fish species that poses a risk of biotoxins such as ciguatoxin in large carnivorous tropical and sub-tropical reef fish or scombrotoxin in scombroid species or parasites ;
- skills should be acquired by fish handlers and appropriate personnel in sensory evaluation techniques to ensure raw fish meet essential quality provisions of the appropriate Codex standard;
- fish requiring gutting on arrival at the processing facility should be gutted efficiently, without undue delay and with care to avoid contamination (see Section 8.1.5 - Washing & Gutting) ;
- fish should be rejected if it is known to contain harmful, decomposed or extraneous substances, which will not be reduced or eliminated to an acceptable level by normal procedures of sorting or preparation ;
- information about the harvesting area.

#### 8.1.1.1 Sensory Evaluation of Fish

The best method of assessing the freshness or spoilage of fish is by sensory evaluation techniques[5]. It is recommended that appropriate sensory evaluation criteria be used to evaluate the acceptability of fish and to eliminate fish showing loss of essential quality provisions of the appropriate Codex standards. As an example, fresh white fish species are considered unacceptable when showing the following characteristics :

| | |
|---|---|
| Skin / Slime | dull, gritty colours with yellow brown dotting slime |
| Eyes | Concave, opaque, sunken discoloured |
| Gills | grey – brown or bleached, slime opaque yellow, thick or clotting |
| Odour | flesh odour amines, ammonia, milky lactic, sulphide, faecal, putrid, rancid |

5 *Guidelines for Sensory Evaluation of Fish and Shellfish in Laboratories* (CAC/GL 31-1999)

8.1.2 Chilled Storage (Processing Steps 2 & 14)

*Potential Hazards :* *Microbiological pathogens, biotoxin, and scombrotoxin.*

*Potential Defects :* *Decomposition, physical damage.*

*Technical Guidance :*

- fish should be moved to the chill storage facility without undue delay ;
- the facility should be capable of maintaining the temperature of the fish between 0℃ - +4℃ ;
- the chill room should be equipped with a calibrated indicating thermometer. Fitting of a recording thermometer is strongly recommended ;
- stock rotation plans should ensure proper utilisation of the fish ;
- the fish should be stored in shallow layers and surrounded by sufficient finely divided ice or with a mixture of ice and of water before processing ;
- fish should be stored such that damage will be prevented from over-stacking or over-filling of boxes ;
- where appropriate replenish ice supply on the fish or alter temperature of the room.

8.1.3 Frozen Storage (Processing Steps 3 & 20)

*Potential Hazards :* *Microbiological pathogens, toxins, viable parasites*

*Potential Defects :* *Dehydration, rancidity, loss of nutritional quality*

*Technical Guidance :*

- the facility should be capable of maintaining the temperature of the fish at or colder than -18℃, and with minimal temperature fluctuations ;
- the store should be equipped with a calibrated indicating thermometer. Fitting of a recording thermometer is strongly recommended ;
- a systematic stock rotation plan should be developed and maintained ;
- product should be glazed and/or wrapped to protect it from dehydration ;
- fish should be rejected if known to contain defects, which subsequently cannot be reduced or eliminated to an acceptable level by re-working. An appropriate assessment should be carried out to determine the reason(s) for loss of control and the DAP plan modified where necessary
- for killing of parasites harmful to human health, the freezing temperature and monitoring of duration of freezing should be combined with good inventory control to ensure sufficient cold treatment.

8.1.4 Control Thawing (Processing Step 4)

*Potential Hazards :* *Microbiological pathogens, biotoxins and scombrotoxin*

*Potential Defects :* *Decomposition*

*Technical Guidance :*

- the thawing method should be clearly defined and should address the time and temperature of thawing, temperature measuring instrument used and placement of device for measurement. The thawing schedule (time and temperature parameters) should be carefully monitored. Selection of the thawing method should take into account in particular the thickness and uniformity of size of the products to be thawed ;
- thawing time and temperature and fish temperature critical limits should be selected so as to control the development of micro-organisms, histamine, where high risk species are concerned or persistent and distinctive objectionable odours or flavours indicative of decomposition or rancidity ;

- where water is used as the thawing medium, it should be of potable quality ;
- where recycling of water is used, care should be taken to avoid the build up of microorganisms ;
- where water is used, circulation should be sufficient to produce even thawing ;
- during thawing, according to the method used, products should not be exposed to excessively high temperatures ;
- particular attention should be paid to controlling condensation and drip from the fish. An effective drainage should be made ;
- after thawing, fish should be immediately processed or refrigerated and kept at the adequate temperature (temperature of melting ice) ;
- the thawing schedule should be reviewed as appropriate and amended where necessary.

8.1.5 Washing and Gutting (Processing Steps 6 & 7)

*Potential Hazards :* *Microbiological pathogens, biotoxins and scombrotoxin*

*Potential Defects :* *Presence of viscera, bruising, off-flavours, cutting faults.*

*Technical Guidance :*

- gutting is considered complete when the intestinal tract and internal organs have been removed ;
- an adequate supply of clean sea water or potable water should be available for washing of :
  - whole fish to remove foreign debris and reduce bacterial load prior to gutting ;
  - gutted fish to remove blood and viscera from the belly cavity ;
  - surface of fish to remove any loose scales ;
  - gutting equipment and utensils to minimise build-up of slime and blood and offal ;
- depending on the vessel or processing facility product flow pattern and where a prescribed critical limit for staging time and temperature regime has been established for the control of histamine or a defect, the gutted fish should be drained and well iced or appropriately chilled in clean containers and stored in specially designated and appropriate areas within the processing facility ;
- separate and adequate storage facilities should be provided for the fish roe, milt and livers, if these are saved for later utilisation.

8.1.6 Filleting, Skinning, Trimming and Candling (Processing Steps 8 & 9)

*Potential Hazards :* *Viable parasites, microbiological pathogens, biotoxins and scombrotoxin, presence of bones.*

*Potential Defects :* *Parasites, presence of bones, objectionable matter (e.g. skin, scales, etc.), decomposition.*

*Technical Guidance :*

- to minimise time delays, the design of the filleting line and candling line, where applicable, should be continuous and sequential to permit the uniform flow without stoppages or slowdowns and removal of waste ;
- an adequate supply of clean sea water or potable water should be available for washing of :
  - fish prior to filleting or cutting especially fish that have been scaled ;
  - fillets after filleting or skinning or trimming to remove any signs of blood, scales or viscera ;
  - filleting equipment and utensils to minimise build-up of slime and blood and offal ;
  - for fillets to be marketed and designated as boneless, fish handlers should employ appropriate inspection techniques and use the necessary tools to remove bones not meeting Codex

standards[6,7] or commercial specifications;

- The candling of skinless fillets by skilled personnel, in a suitable location which optimises the illuminating effect, is an effective technique in controlling parasites (in fresh fish) and should be employed when implicated fish species are being used;
- the candling table should be frequently cleaned during operation in order to minimise the microbial activity of contact surfaces and the drying of fish residue due to heat generated from the lamp;
- where a prescribed critical limit for staging time and temperature regime has been established for the control of histamine or a defect, the fish fillets should be well iced or appropriately chilled in clean containers, protected from dehydration and stored in appropriate areas within the processing facility.

## 8.2 PROCESSING OF VACUUM OR MODIFIED ATMOSPHERE PACKED FISH

This section is designed to augment the processing of fresh fish section with additional operation steps pertaining specifically to the modified atmosphere packing of fish (see also Appendix i).

### 8.2.1 Weighing (Processing Step 10)

*Potential Hazards:* *Unlikely*

*PotentialDefects:* *Incorrect net weight*

*Technical Guidance:*

- weigh scales should be periodically calibrated with a standardised mass to ensure accuracy.

### 8.2.2 Vacuum or Modified Atmosphere Packaging (Processing Step 11)

*Potential Hazards:* *Subsequent microbiological pathogens and biotoxins, physical contamination (metal).*

*Potential Defects:* *Subsequent decomposition*

*Technical Guidance:*

The extent to which the shelf-life of the product can be extended by vacuum or MAP will depend on the species, fat content, initial bacterial load, gas mixture, type of packaging material and, especially important, the temperature of storage. Refer to Appendix I for process control issues in modified atmosphere packaging.

- modified atmosphere packaging should be strictly controlled by:
  - monitoring the gas to product ratio;
  - types and ratio of gas mixtures used;
  - type of film used;
  - type and integrity of the seal;
  - temperature control of product during storage;
- occurrence of adequate vacuum and package;
- fish flesh should be clear of the seam area;
- packaging material should be inspected prior to use to ensure that it is not damaged or contaminated;
- packaging integrity of the finished product should be inspected at regular intervals by an appropriately trained personnel to verify the effectiveness of the seal and the proper operation of

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6 Codex Standard for Quick Frozen Blocks of Fish Fillet, Minced Fish Flesh and Mixtures of Fillets and Minced Fish Flesh (CODEX STAN 165-1989)

7 Codex Standard for Quick Frozen Fish Fillets (CODEX STAN 190-1995)

the packaging machine ;

- following sealing, MAP or vacuumed products should be transferred carefully and without undue delay to chilled storage ;
- Ensure that adequate vacuum is attained, and the package seals are intact.

### 8.2.3 Labelling (Processing Steps 12 & 18)

*Potential Hazards :* *Unlikely*

*Potential Defects :* *Incorrect labelling*

*Technical Guidance :*

- prior to their application, labels should be verified to ensure that all information declared meet, where applicable, the Codex General Standard for the Labelling of Pre-packaged Foods[8], labelling provisions of the appropriate Codex Standard for products and/or other relevant national legislative requirements ;
- in many cases it will be possible to re-label incorrectly labelled products. An appropriate assessment should be carried out to determine the reason(s) for incorrect labelling and the DAP plan should be modified where necessary ;

### 8.2.4 Metal Detection (Processing Steps 13 & 19)

*Potential Hazards :* *Metal contamination*

*Potential Defects :* *Unlikely*

*Technical Guidance :*

- it is important that line speeds are adjusted to allow for the proper functioning of a metal detector ;
- routine procedures should be initiated to ensure product rejected by the detector is investigated as to the cause of the rejection ;
- metal detectors, if used, should be periodically calibrated with a known standard to ensure proper operation ;

## 8.3 PROCESSING OF FROZEN FISH

This section is designed to augment the processing of fresh fish section with additional operation steps pertaining specifically to the processing of frozen fish.

### 8.3.1 Freezing Process (Processing Step 15)

*Potential Hazards :* *Viable parasites.*

*Potential Defects :* *Texture deterioration, development of rancid odours, freezer burn*

*Technical Guidance :*

The fish product should be subjected to a freezing process as quickly as possible since unnecessary delays before freezing will cause temperature of the fish products to rise, increasing the rate of quality deterioration and reducing shelf-life due to the action of micro-organisms and undesirable chemical reactions.

- a time and temperature regime for freezing should be established and should take into consideration the freezing equipment and capacity; the nature of the fish product including thermal conductivity, thickness, shape and temperature and the volume of production, to ensure that the range of temperature of maximum crystallisation is passed through as quickly as possible ;
- the thickness, shape and temperature of fish product entering the freezing process should be as

8 Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985)

uniform as possible ;

- processing facility production should be geared to the capacity of freezers ;
- frozen product should be moved to the cold storage facility as quickly as possible ;
- the core temperature of the frozen fish should be monitored regularly for completeness of the freezing process ;
- frequent checks should be made to ensure correct operation of freezing ;
- accurate records of all freezing operations should be kept
- for killing of parasites harmful to human health, the freezing temperature and monitoring of duration of freezing should be combined with good inventory control to ensure sufficient cold treatment.

8.3.2 Glazing (Processing Step 16)

*Potential Hazards :* *Microbiological pathogens*

*Potential Defects :* *Subsequent dehydration, incorrect net weight*

*Technical Guidance :*

- glazing is considered complete when the entire surface of the frozen fish product is covered with a suitable protective coating of ice and should be free of exposed areas where dehydration (freezer-burn) can occur ;
- if additives are used in the water for glazing, care should be taken to ensure its proper proportion and application with product specifications ;
- where the labelling of a product is concerned, information on the amount or proportion of glaze applied to a product or a production run should be kept and used in the determination of the net weight which is exclusive of the glaze ;
- where appropriate monitoring should ensure that spray nozzles do not become blocked ;
- where dips are used for glazing it is important to replace the glazing solution periodically to minimise the bacterial load and build-up of fish protein, which can hamper freezing performance.

8.4 PROCESSING OF MINCED FISH

This section is designed to augment the processing of fresh fish section (prior to mincing) and processing of frozen fish section (after mincing) with additional operation steps pertaining specifically to the processing of minced fish.

8.4.1 Mincing Fish Using Mechanical Separation Process (Processing Step 21)

*Potential Hazards :* *Microbiological pathogens, biotoxins and scombrotoxin, physical contamination (metal, bones, rubber from separator belt, etc).*

*Potential Defects :* *Incorrect separation (i.e. objectionable matter), decomposition, presence of defect bones, parasites.*

*Technical Guidance :*

- the separator should be fed continuously but not excessively ;
- candling is recommended for fish suspected of high infestation with parasites ;
- split fish or fillets should be fed to the separator so that the cut surface contacts the perforated surface ;
- fish should be fed to the separator in a size that it is able to handle ;
- in order to avoid time-consuming adjustments of the machinery and variations in quality of the finished product, raw materials of different species and types should be segregated and

processing of separate batches should be carefully planned ;

- the perforation sizes of the separator surface as well as the pressure on the raw material should be adjusted to the characteristics desired in the final product ;
- the separated residual material should be carefully removed on a continuous or near-continuous basis to the next processing stage ;
- temperature monitoring should ensure undue temperature rises of the product are avoided.

8.4.2 Washing of Minced Fish (Processing Step 22)

*Potential Hazards :* *Microbiological pathogens and scombrotoxin.*

*Potential Defects :* *Poor colour, poor texture, excess of water*

*Technical Guidance :*

- if necessary the mince should be washed and should be adequate for the type of product desired ;
- stirring during washing should be carried out with care, but it should be kept as gentle as possible in order to avoid excessive disintegration of the minced flesh which will reduce the yield due to the formation of fines ;
- the washed minced fish flesh may be partially de-watered by rotary sieves or centrifugal equipment and the process completed by pressing to appropriate moisture content ;
- if necessary, and depending on eventual end-use, the de-watered mince should be either strained or emulsified ;
- special attention should be taken to ensure mince being strained is kept cool ;
- the resulting waste water should be disposed of in a suitable manner.

8.4.3 Blending and Application of Additives and Ingredients to Minced Fish (Processing Steps 23 & 24)

*Potential Hazards :* *Physical contamination, non-approved additives and/or ingredients.*

*Potential Defects :* *Physical contamination, incorrect addition of additives.*

*Technical Guidance :*

- if fish, ingredients and /or additives are to be added, they should be blended in the proper proportions to achieve the desired sensory quality ;
- additives should comply with the requirements of the Codex General Standard for Food Additives ;
- the minced fish product should be packaged and frozen immediately after preparation; if it is not frozen or used immediately after preparation it should be chilled.

8.4.4 Wrapping and Packing (Processing Steps 17 & 25)

*Potential Hazards :* *Microbiological pathogens*

*Potential Defects :* *Subsequent dehydration, decomposition*

*Technical Guidance :*

- packaging material should be clean, sound, durable, sufficient for its intended use and of food grade material ;
- the packaging operation should be conducted to minimise the risk of contamination and decomposition ;
- products should meet appropriate standards for labelling and weights.

8.5 PACKAGING, LABELS & INGREDIENTS

8.5.1 Reception – Packaging, Labels & Ingredients (Processing Steps 26 & 28)

*Potential Hazards :* *Microbiological pathogens, chemical and physical contamination*

*Potential Defects :* *Misdescription*

*Technical Guidance :*

- only ingredients, packaging material and labels complying with the processors' specification should be accepted into the processing facility ;
- labels which are to be used in direct contact with the fish should be fabricated of a nonabsorbent material and the ink or dye used on that label should be approved by the official agency having jurisdiction ;
- ingredients and packaging material not approved by the official agency having jurisdiction should be investigated and refused at reception.

8.5.2 Storage - Packaging, Labels & Ingredients (Processing Steps 27 & 29)

*Potential Hazards :* *Microbiological pathogens, chemical and physical contamination.*

*Potential Defects :* *Loss of quality characteristics of packaging materials or ingredients.*

*Technical Guidance :*

- ingredients and packaging should be stored appropriately in terms of temperature and humidity ;
- a systematic stock rotation plan should be developed and maintained to avoid out of date materials ;
- ingredients and packaging should be properly protected and segregated to prevent crosscontamination ;
- defective ingredients and packaging should not be used.

## SECTION 9 - PROCESSING OF FROZEN SURIMI

In the context of recognising controls at individual processing steps, this section provides examples of potential hazards and defects and describes technological guidelines, which can be used to develop control measures and corrective action. At a particular step only the hazards and defects, which are likely to be introduced or controlled at that step, are listed. It should be recognised that in preparing a HACCP and/or DAP plan it is essential to consult Section 5 which provides guidance for the application of the principles of HACCP and DAP analysis. However, within the scope of this Code of Practice it is not possible to give details of critical limits, monitoring, record keeping and verification for each of the steps since these are specific to particular hazards and defects.

Frozen surimi is an intermediate food ingredient made from myofibrillar fish protein isolated from other constituent fish protein by repeated washing and de-watering of minced fish. Cryoprotectants are added so that the mince can be frozen and will retain the capacity to form gel when heat-treated after thawing. Frozen surimi is usually blended with other components and further processed into surimi-based products such as kamaboko or crab analogs (imitation crab) that utilise its gel forming ability.

The main emphasis of this section of the code is to give guidance to the manufacture of frozen surimi processed from amarine groundfish such as Alaska Pollock and Pacific Whiting by mechanised operations that are common in Japan, the United States and some other country in which there are processors under mechanised operation.

The vast majority of frozen surimi is processed from marine groundfish such as Alaska Pollock and Pacific Whiting. However, technological advances and the change of main raw fish species for frozen surimi production will necessitate revision of this section of the Code of Practice.

*Frozen surimi is manufactured using various methods, but this flow chart shows the most typical procedure.*

*This flow chart is for illustrative purpose only. For in-factory HACCP implementation a complete and comprehensive flow chart has to be draw up for each process.*

*References correspond to relevant Sections of the Code.*

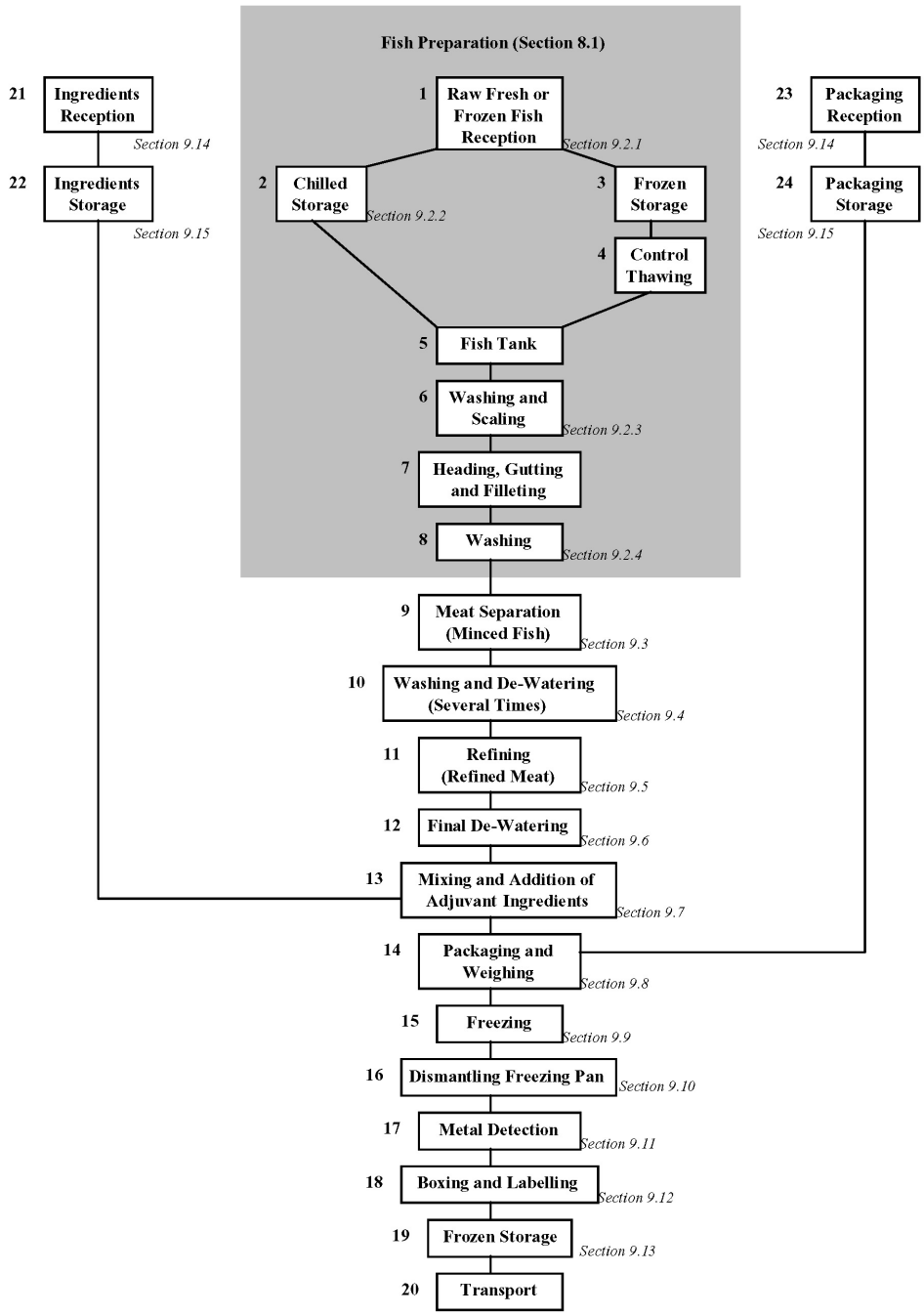


**Figure 9.1** Example of a flow chart of a frozen surimi production process.

## 9.1 GENERAL CONSIDERATIONS OF HAZARDS AND DEFECTS FOR FROZEN SURIMI PRODUCTION

### 9.1.1 Hazards

Frozen surimi is an intermediate ingredient that will be further processed into surimi-based products such as kamaboko and crab analogs. Many of the potential food safety hazards will be controlled during subsequent processing. For example, pathogenic bacteria such as *Listeria monocytogenes* and toxin formers such as *Clostridium botulinum* (that becomes a hazard due to modified atmosphere packaging of the end product) should be controlled during the cooking or pasteurising steps of final processing. Possible *Staphylococcus aureus* contamination that produces heat-stable enterotoxins should be adequately controlled by the prerequisite programme. Parasites will not be a hazard since the final product will be cooked or pasteurised.

If scombrotoxin-forming fish such as tuna or mackerel or tropical reef fish that may accumulate ciguatera toxin are utilised for surimi, appropriate controls for these hazards should be developed. Likewise, due to the highly mechanised nature of surimi processing, appropriate controls should be instituted to assure that metal fragments (e.g., bearings, bolts, washers, and nuts) are excluded or eliminated in the end product.

In countries that produce frozen surimi by traditional non-mechanised methods from locally available fish species for local consumption, extensive consideration should be given to pre-requisite programmes described in section 3.

### 9.1.2 Defects

Certain quality attributes of frozen surimi is important for the successful manufacture of surimi-based products such as kamaboko and crab analogs that meet consumer expectations of quality. Some of these important factors are colour, moisture content, pH or gel strength. These and others are described in more detail in Appendix X of the code entitled Optional Final Product Requirements for Frozen Surimi[9].

Myxosporidia is a parasite that is common in marine groundfish such as Pacific Whiting. This organism contains protease enzymes that chemically separate proteins that can ultimately affect the gel strength of surimi even at very low incidence. If species are used that are known to contain this parasite, a protease inhibitors such as beef plasma protein or egg whites may be needed as additives to attain the necessary gel strength capabilities for kamaboko or crab analogs production.

Decomposed fish should not be used as raw material for frozen surimi production. The sensory qualities will not be sufficient to produce acceptable kamaboko or crab analog end products. It also necessary to note that decomposed fish should not be used as raw material for production of frozen surimi, because proliferation of spoilage bacteria that cause decomposition of the end product will cause negative effect on the gel forming ability of frozen surimi by denaturing salt soluble protein.

The washing and de-watering cycle should be sufficient to achieve separation of the water-soluble protein from the myofibrillar proteins. If water-soluble proteins remain in the product it will negatively affect the gel forming ability and the long term frozen storage shelf life.

Objectionable matter such as small bones, scales and black belly lining should be minimised as it negatively affects the usability of frozen surimi for processing into end products.

Due to the comminuted nature of raw surimi, the use of food additive may be necessary to achieve the level of quality that is desired. These additives should be introduced to surimi in accordance to appropriate regulations and manufacturer's recommendation in order to avoid quality problems and regulatory actions.

Consideration should be given to the thermal stability of fish proteins. At normal room temperatures

9 Under elaboration

most fish proteins will undergo denaturing that will inhibit the gel forming ability of the product. Alaska Pollock and other cold water marine fish should not be subjected to temperatures above 10℃ during processing. Warm water fishes may denature at a slower rate and may not be as temperature sensitive.

In countries that produce frozen surimi by traditional non-mechanised methods from locally available fish species for local consumption, special consideration should be given to several defects. Since the growth of spoilage bacteria that cause decomposition and protein denaturation increases with temperature, the conditions that the raw and processed product is subjected to should be carefully monitored.

## 9.2 FISH PREPARATION (Processing Steps 1 to 8)

Refer to Section 8.1 steps 1 through 8 for information regarding preparation of fish for processing. For frozen surimi processing, consideration should be given to the following for each step :

### 9.2.1 Raw Fresh and Frozen Fish Reception (Processing Step 1)

*Potential Hazards :* *unlikely when using marine ground fish as the raw material*

*Potential Defects :* *decomposition, protein denaturation*

*Technical Guidance :*

- harvested fish intended for frozen surimi processing should preferably be kept at 4℃ or below ;
- consideration should be given to the age and condition of fish used for surimi processing as the factors will affect the final gel strength capability. Especially, care should be taken to raw fish received many hours after harvest. For example acceptable period after harvest should be as follows, but processing as fast as possible after harvest will better retain adequate quality of frozen surimi :

– round ; within 14 days of harvest, when stored at 4℃ or below ;

– dressed ; within 24 hours after dressing, when stored at 4℃ or below.

- date, time of harvesting, origin and harvester or vendor of products received should be properly recorded and identified ;
- presence of decomposition in raw product should not be allowed, as it will negatively affect the gel strength capability of the end product. Harvested fish in poor condition may not result in specified colour characteristics ;
- Fish that is used for frozen surimi processing should have a flesh for adequate gel strength capability. For example an aggregate flesh for Alaska Pollock (*Theragra chalcogramma*) should have pH of 7.0 ± 0.5
- fish that is crushed and suffocated due to abnormally big tow size and duration during harvesting should be deleted from the line in order to avoid negative effect to gel forming ability.

### 9.2.2 Chilled Storage (Processing Step 2)

*Potential Hazards :* *unlikely*

*Potential Defects :* *protein denaturation*

*Technical Guidance :*

- chilled storage at the processing facility should be minimised with prompt processing in order to minimise protein denaturation and loss of gel strength capability ;
- raw fish should be preferably stored at 4℃ or below and the dates of harvesting and the time of receipt of the fish should identify the lot of fish used for processing.

### 9.2.3 Washing and Scaling (Processing Step 6)

*Potential Hazards :* *unlikely*

*Potential Defects :* *protein denaturation, colour, objectionable matter*

*Technical Guidance :*

- the epidermis (slime layer), scales and loose pigment should be removed before heading and gutting. This will lessen the level of impurities and extraneous material that can negatively affect the gel strength capability and colour of the end product.

9.2.4 Washing (Processing Step 8)

*Potential Hazards :* *unlikely*

*Potential Defects :* *impurities, extraneous materials*

*Technical Guidance :*

- headed and gutted fish should be re-washed. This will lessen the level of impurities and extraneous material that can negatively affect the gel strength capability and colour of the end product.

9.3 MEAT SEPARATION PROCESS (Processing Step 9)

*Potential Hazards :* *metal fragments*

*Potential Defects :* *Impurities*

*Technical Guidance :*

- fish flesh is minced using mechanical separation process, therefore metal detection equipment that is capable of sensing product that has become contaminated with metal fragments of the size likely to cause human injury should be installed at the most appropriate place in the process to eliminate the hazard ;
- procedures should be established to assure that chemical contamination of the product is not likely ;
- separated minced meat should be immediately spread into water and transferred to the washing and de-watering step to prevent blood from congealing and causing loss of gel strength capability.

9.4 WASHING AND DE-WATERING PROCESS (Processing Step 10)

*Potential Hazards :* *pathogenic microbial growth*

*Potential Defects :* *decomposition, protein denaturation, residual water-soluble protein*

*Technical Guidance :*

- temperature of the water and minced fish flesh in the rotating sieve or wash water should be adequately controlled to prevent the growth of pathogenic microbes ;
- wash water should be 10℃ or below for adequate separation of water-soluble proteins. Wash water for Pacific Whiting should be lower than 5℃ since this species will usually have a high protease activity. Some warm water species may be processed at temperatures up to 15℃ ;
- product should be processed promptly to minimise possible pathogenic microbial growth ;
- minced fish should be spread uniformly in the water to assure dilution of the water-soluble components and effect proper separation from the myofibrillar protein ;
- consideration should be given to the specific design of the washing and de-watering step in regards to the desired yield, quality and fish species ;
- a sufficient amount of potable water should be available for washing ;
- the pH of wash water should be near 7.0. Wash water should preferably have a total hardness of 100mg/kg or below in terms of converted $CaCO_3$ ;

- salt or other de-watering aids can be added (less than 0.3% salt) in the final stage of washing to enhance dehydration efficiency ;
- food additives should be added in accordance with national regulations and manufacturer's instructions, if use in this process ;
- wastewater should be disposed of in a suitable manner ;
- wash water should not be recycled unless there are appropriate controls on its microbial quality.

9.5 REFINING PROCESS (Processing Step 11)

Potential Hazards : *pathogenic microbial growth, metal fragments*

*Potential Defects* : *objectionable matter, protein denaturation*

*Technical Guidance* :

- temperature of the minced fish flesh in the refining process should be adequately controlled to prevent the growth of pathogenic bacteria ;
- for preventing protein denaturation, temperature of minced fish flesh should not exceed 10℃ in the refining process ;
- product should be processed promptly to minimise possible pathogenic microbial growth ;
- metal detection equipment that is capable of sensing product that has become contaminated with metal fragments of the size likely to cause human injury should be installed at the most appropriate place in the process to eliminate the hazard ;
- objectionable matter such as small bones, black membranes, scales, bloody flesh and connective tissue should be removed from washed flesh with appropriate refining equipment before final de-watering ;
- equipment should be properly adjusted to effect efficient product throughput ;
- refined product should not be allowed to accumulate on sieve screens for long periods of time.

9.6 FINAL DE-WATERING PROCESS (Processing Step 12)

*Potential Hazards* : *pathogenic microbial growth*

*Potential Defects* : *decomposition, protein denaturation*

*Technical Guidance* :

- temperature of the refined fish flesh in the final de-watering process should be adequately controlled to prevent the growth of pathogenic bacteria ;
- temperature of refined fish flesh should not exceed 10℃ for cold water fish species, such asAlaska Pollock. For Pacific Whiting the temperature should not exceed 5℃, since this species usually will have a high protease activity. Some warm water species may be processed at temperatures up to 15℃ ;
- product should be processed promptly to minimise possible pathogenic microbial growth ;
- the moisture level of refined product should be controlled to specified levels with appropriate de-watering equipment (e.g., centrifuge, hydraulic press, screw press) ;
- consideration should be given to variations in moisture levels due to the age, condition or mode of capture of the raw fish. In some cases dehydration should be performed before refining.

9.7 MIXING AND ADDITION OF ADJUVANT INGREDIENTS PROCESS (Processing Step 13)

*Potential Hazards* : *pathogenic microbial growth, metal fragments*

*Potential Defects* : *improper use of food additives, protein denaturation*

*Technical Guidance* :

- temperature of the product in the mixing process should be adequately controlled to avoid the growth of pathogenic bacteria ;
- temperature of dehydrated fish flesh during mixing should not exceed 10℃ for cold water fish species such as Alaska Pollock. For Pacific Whiting the temperature should not exceed 5℃ since this species usually will have a high protease activity. Some warm water species may be processed at temperatures up to 15℃ ;
- product should be processed promptly to minimise possible pathogenic microbial growth ;
- metal detection equipment that is capable of sensing product that has become contaminated with metal fragments of the size likely to cause human injury should be installed at the most appropriate place in the process to eliminate the hazard ;
- food additives should be the same and comply with Codex General Standard for Food Additives ;
- food additives should be mixed homogeneously ;
- Cryoprotectants should be used in frozen surimi. Sugars and/or polyhydric alcohols are commonly used to prevent protein denaturation in the frozen state ;
- food grade enzyme inhibitors (e.g. egg white, beef protein plasma) should be used for species that exhibit high levels of proteolytic enzyme activity such as Pacific Whiting that reduce the gel forming ability of surimi during kamaboko or crab analogs processing. The use of protein plasma should be appropriately labelled.

9.8 PACKAGING AND WEIGHING (Processing Step 14)

*Potential hazards :* *pathogenic microbial growth*

*Potential defects :* *foreign matter (packaging), incorrect net weight, incomplete packaging, denaturation of protein*

*Technical Guidance :*

- temperature of the product should be adequately controlled during packaging to avoid the growth of pathogenic bacteria ;
- product should be packaged promptly to minimise possible pathogenic microbial growth ;
- the packaging operation should have procedures established that make possible cross contamination unlikely ;
- product should be stuffed into clean plastic bags or packaged into clean containers that have been properly stored ;
- product should be appropriately shaped ;
- packaging should be conducted rapidly to minimise the risk of contamination or decomposition ;
- packaged products should not contain voids ;
- the product should meet appropriate standards for net weight.

See also Section 8.2.1 "Weighing" and Section 8.4.4 "Wrapping and Packing".

9.9 FREEZING OPERATION (Processing Step 15)

Refer to Section 8.3.1 for general considerations for freezing fish and fishery products.

*Potential Hazards :* *unlikely*

*Potential Defects :* *protein denaturation, decomposition*

*Technical Guidance :*

- after packaging and weighing the product should be promptly frozen to maintain the quality of the product ;

- procedures should be established that specifies maximum time limits from packaging to freezing.

9.10 DISMANTLING FREEZING PAN (Processing Step 16)

*Potential Hazards :* *unlikely*

*Potential Defects :* *damage to plastic bag and product*

*Technical Guidance :*

- care should be taken to avoid breakage of plastic bag and the product itself in order to refrain from deep dehydration during long-term cold storage.

9.11 METAL DETECTION (Processing Step 17)

Refer to Section 8.2.4 "Metal Detection" for general information.

*Potential Hazards :* *metal fragments*

*Potential Defects :* *unlikely*

*Technical Guidance :*

- Metal detection equipment that is capable of sensing product that has become contaminated with metal fragments of the size likely to cause human injury should be installed at the most appropriate place in the process to eliminate the hazard.

9.12 BOXING AND LABELLING (Processing Step 18)

Refer to Section 8.2.3 "Labelling" and Section 8.4.4 "Wrapping and Packing".

*Potential Hazards :* *unlikely*

*Potential Defects :* *incorrect label, damage to packaging*

*Technical Guidance :*

- boxing should be clean, durable and suitable for the intended use ;
- the boxing operation should be conducted to avoid the damage of packaging materials ;
- product in damaged boxing should be re-boxed so that it is properly protected.

9.13 FROZEN STORAGE (Processing Step 19)

Refer to Section 8.1.3 "Frozen Storage" for general information concerning fish and fishery products.

*Potential Hazards :* *unlikely*

*Potential Defects :* *decomposition, protein denaturation*

*Technical Guidance :*

- frozen surimi should be stored at -20℃ or colder to prevent protein denaturation from taking place. Quality and shelf life will be maintained more adequately if the product is stored at -25℃ or colder ;
- stored frozen product should have adequate air circulation to assure that it remains properly frozen. This includes preventing product from being stored directly on the floor of the freezer.

9.14 RAW MATERIAL RECEPTION - PACKAGING AND INGREDIENTS (Processing Steps 21 and 22)

Refer to Section 8.5.1 "Raw Material Reception - Packaging, Labels and Ingredients".

9.15 RAW MATERIAL STORAGE - PACKAGING AND INGREDIENTS (Processing Steps 23 and 24)

Refer to Section 8.5.2 "Raw Material Storage - Packaging, Labels and Ingredients".

## SECTION 10 - PROCESSING OF QUICK-FROZEN COATED FISH PRODUCTS

In the context of recognising controls at individual processing steps, this section provides examples of potential hazards and defects and describes technological guidelines, which can be used to develop control measures and corrective action. At a particular step only the hazards and defects, which are likely to be introduced or controlled at that step, are listed. It should be recognised that in preparing a HACCP and/or DAP plan it is essential to consult Section 5 which provides guidance for the application of the principles of HACCP and DAP analysis. However, within the scope of this Code of Practice it is not possible to give details of critical limits, monitoring, record keeping and verification for each of the steps since these are specific to particular hazards and defects.

*This flow chart is for illustrative purposes only. For in-factory HACCP implementation a complete and comprehensive flow chart has to be drawn up for each process.*

*References correspond to relevant Sections of the Code.*

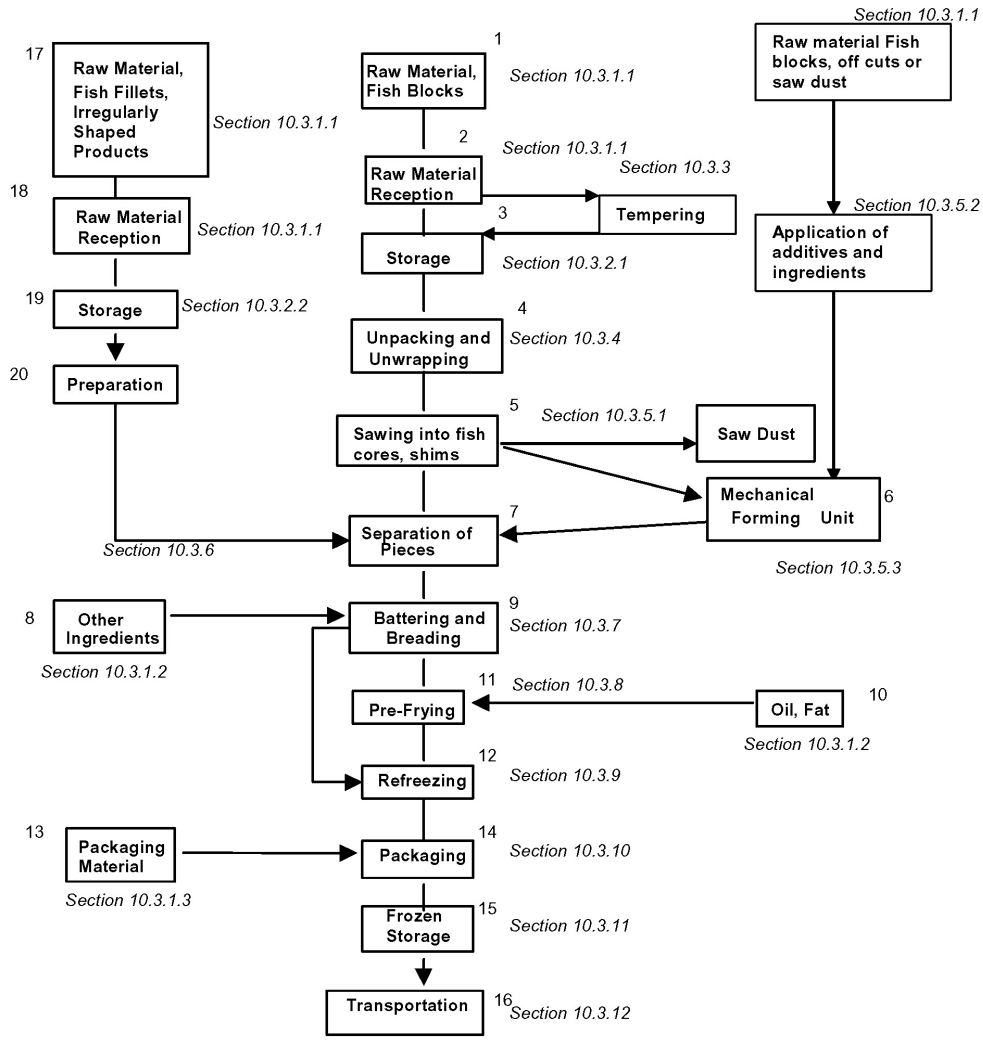


**Figure 10.1 Example of a flow chart for the processing of coated fish products**

## 10.1 GENERAL ADDITION TO PRE-REQUISITE PROGRAMME

- conveyor systems used to transport uncoated and coated fish should be designed and constructed to prevent damaging and contamination of the products ;
- shims sawn for formed fish production and held for tempering should be kept at temperatures that will prevent deterioration of the essential quality of the product ;
- if the whole process is run continuously an adequate number of processing lines should be available to avoid interruptions and batch-wise processing. If the process has to be interrupted, intermediate products have to be stored under deep-frozen conditions until being further processed ;
- pre-frying baths, freezing cabinets used for re-freezing should be equipped with permanent temperature and belt speed control device ;
- the proportion of sawdust should be minimised by using appropriate sawing equipment ;
- sawdust should be kept well separated from fish cores used for coated products, should be temperature controlled, not stay too long at ambient temperature and should be stored preferably in frozen state prior to further processing into suitable products.

## 10.2 IDENTIFICATION OF HAZARDS AND DEFECTS

Refer also to Section 5.3.3 and Appendix XI.

This Section describes the main hazards and defects specific to quick frozen coated fish and shellfish.

### 10.2.1 Hazards

Refer also to Section 5.3.3.1.

The production and storage of batter for application to fish portions, fillets, etc., may involve either rehydration of a commercial batter mix or preparation from raw ingredients. During the preparation of this batter and its use, the potential hazard for the possible growth and toxins production of *Staphylococcus aureus* and *Bacillus cereus* must be controlled.

### 10.2.2 Defects

Potential defects are outlined in the essential quality, labelling and composition requirements described in the relevant Codex Standard for Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets – Breaded or in Batter (CODEX STAN 166-1989).

End product specifications outlined in Appendix XI describe optional requirements specific to quick frozen coated fishery products.

## 10.3 PROCESSING OPERATIONS

Refer to figure 10.1 for an example of a flow chart for coated fish product processing.

### 10.3.1. Reception

10.3.1.1 Fish

*Potential Hazards :* *chemical and biochemical contamination, histamine ;*

*Potential Defects :* *tainting, block irregularities, water and air pockets, packaging material, foreign matter, parasites, dehydration, decomposition ;*

*Technical Guidance :*

- Temperatures of all incoming lots should be recorded ;
- Packaging material of frozen products should be examined for dirt, tearing and evidence of thawing ;

- Cleanliness and suitability of the transport vehicle to carry frozen fish products should be examined ;
- Use of temperature recording devices with the shipment is recommended ;
- Representative samples should be taken for further examination for possible hazards and defects ;

10.3.1.2 Other Ingredients

*Potential Hazards :* *chemical, biochemical and microbiological contamination*

*Potential Defects :* *mould , colour deviations, filth, sand*

*Technical Guidance :*

- breading and batter should be inspected for broken packaging material, signs of rodent and insect infestations and other damage such as dirt on packaging materials and wetness ;
- cleanliness and suitability of the transport vehicle to carry food products should be examined ;
- representative samples of the ingredients should be taken and examined to ensure that the product is not contaminated and meets specifications for use in the end product ;
- ingredients should be shipped on transportation vehicles that are suitable for handling food products and ingredients. Vehicles that have previously hauled potentially unsafe or hazardous material should not be used for hauling food products or ingredients.

10.3.1.3 Packaging Materials

*Potential Hazards :* *foreign matter*

*Potential Defects :* *tainting of products*

*Technical Guidance :*

- packaging material used should be clean, sound, durable, sufficient for its intended use and of food grade material ;
- for pre-fried products it should be impermeable for fat and oil ;
- cleanliness and suitability of the transport vehicle to carry food packaging material should be examined ;
- pre-printed labelling and packaging material should be examined for accuracy.

10.3.2 Storage of Raw Material, Other Ingredients and Packaging Materials

10.3.2.1 Fish (Frozen Storage)

Refer to Section 8.1.3

10.3.2.2 Fish (chilled storage)

For storage of non-frozen fish, refer to section 8.1.2.

10.3.2.3 Other Ingredients and Packaging Materials

*Potential Hazards :* *biological, physical and chemical contamination*

*Potential Defects :* *loss of quality and characteristics of ingredients, rancidity*

*Technical Guidance :*

- all other ingredients and packaging material should be stored in a dry and clean place under hygienic conditions ;
- all other ingredients and packaging material should be stored appropriately in terms of temperature and humidity ;
- a systematic stock rotation plan should be developed and maintained to avoid out of date materials ;
- ingredients should be protected from insects, rodents and other pests ;

- defective ingredients and packaging material should not be used.

10.3.3. Frozen Fish Block/Fillet tempering

*Potential Hazards :* *Unlikely*

*Potential Defects :* *Incorrect dimension due to sawing of over softened fish flesh (applies to fish sticks)*

*Technical Guidance :*

- Depending on the use of the fish, the tempering of frozen fish blocks/fillets should be carried out in a manner which will allow the temperature of the fish to rise without thawing ;
- Tempering block/fillets of frozen fish in chilled storage is a slow process that usually requires at least 12 hours or more ;
- Over softening of the outer layers is undesirable (poor performance during sawing) and should be avoided. It could be avoided if facilities used for tempering are maintained at a temperature of 0 -4℃ and if fish blocks/fillets are stacked in layers ;
- microwave tempering is an alternate method but should also be controlled to prevent softening of outer layers.

10.3.4 Unwrapping, Unpacking

*Potential Hazards :* *Microbiological contamination*

*Potential Defects :* *remaining undetected packaging material, contamination by filth*

*Technical Guidance :*

- during unwrapping and unpacking of fish blocks care should be given not to contaminate the fish ;
- special attention has to be given to cardboard and/or plastic material partly or fully embedded in the blocks ;
- all packaging material should be disposed of properly and promptly ;
- Protect wrapped, unwrapped and unpacked fish blocks when cleaning and sanitizing processing lines during breaks and between shifts if the production process is interrupted.

10.3.5 Production of Fish Core

10.3.5.1 Sawing

*Potential Hazards :* *foreign material (metal or plastic parts of saws)*

*Potential Defects :* *irregularly shaped pieces or portions*

*Technical Guidance :*

- sawing instruments should be kept in clean and hygienic conditions ;
- saw-blades must be inspected regularly, to avoid tearing of the product and breakage ;
- saw dust must not collect on the saw-table and must be collected in special containers if used for further processing ;
- sawn shims used to form irregularly shaped fish cores by mechanical pressure should be kept in clean, hygienic conditions until further manufacturing.

10.3.5.2. Application of additives and Ingredients

Also refer to Section 8.4.3

*Potential Hazards :* *foreign material, microbiological contamination*

*Potential Defects :* *Incorrect addition of additives*

*Technical Guidance :*

- The temperature of the product in the mixing process should be adequately controlled to avoid the growth of pathogenic bacteria.

10.3.5.3 Forming

*Potential Hazards :* *foreign material (metal or plastic from machine) and/or microbiological contamination (fish mixture only)*

*Potential Defects :* *poorly formed fish cores, cores subject to too much pressure (mushy, rancid)*

*Technical Guidance :*

Forming of fish cores is a highly mechanised method of producing fish cores for battering and breading. It utilises either hydraulic pressure to force shims (sawn portions of fish blocks) into moulds that are ejected onto the conveyor belt or mechanical forming of fish mixtures.

- forming machines should be kept in hygienic conditions ;
- formed fish cores should be examined closely for proper shape, weight and texture.

10.3.6 Separation of Pieces

*Potential Hazards :* *Unlikely*

*Potential Defects :* *adhering pieces or portions*

*Technical Guidance :*

- the fish flesh cores cut from the blocks or fish fillets or other irregular shaped QF fish material must be well separated from each other and should not adhere to each other ;
- fish cores that are touching each other going through the wet coating step should be removed and placed back on the conveyor in order to get a uniform batter coat and a uniform breading pick-up ;
- cored fish should be monitored for foreign material and other hazards and defects before coating ;
- Remove from production any broken, misshaped or out of specification pieces.

10.3.7 Coating

In industrial practice the order and the number of coating steps may differ and may therefore deviate considerably from this scheme.

10.3.7.1 Wet Coating

*Potential Hazards :* *Microbiological contamination*

*Potential Defects :* *Insufficient cover or excessive cover of coating*

*Technical Guidance :*

- fish pieces must be well coated from all sides ;
- surplus liquid, which should be reused, must be re-transported under clean and hygienic conditions ;
- surplus liquid on fish pieces should be removed by clean air ;
- viscosity and temperature of hydrated batter mixes should be monitored and controlled within certain parameters to effect the proper amount of breading pick-up ;
- to avoid microbiological contamination of the hydrated batter, appropriate means should be adopted to ensure that significant growth does not take place, such as temperature control, dumping liquid contents and regular or scheduled clean-ups and/or sanitation during the manufacturing shift.

10.3.7.2 Dry Coating

*Potential Hazards :* *microbiological contamination*

*Potential Defects :* *insufficient coating or excessive coating*

*Technical Guidance :*

- dry coating must cover the whole products and should stick well on the wet coating ;
- surplus coating is removed by blowing away with clean air and/or by vibration of conveyors and must be removed in a clean and hygienic way if further use is intended ;
- flow of breading from the application hopper should be free, even and continuous ;
- coating defects should be monitored and be in accordance to Codex Standard for Frozen Fish Fingers, Fish Portions and Fish Fillets – Breaded or in Batter (CODEX STAN 166-1989) ;
- the proportion of breading and fish core should be in accordance to Codex Standard for Frozen Fish Fingers, Fish Portions and Fish Fillets – Breaded or in Batter (CODEX STAN 166-1989).

10.3.8 Pre-Frying

There are some variations in industrial production for the frying process in so far that QF coated products are completely fried including fish core and re-frozen later. For this case alternative hazards and defects have to be described and not all statements in this section apply. In some regions it is common practice to manufacture raw (not pre-fried) coated fish products.

*Potential Hazards :* *Unlikely*

*Potential Defects :* *over-oxidised oil, insufficient frying, loosely adhering coating, burnt pieces and portions*

*Technical Guidance :*

- frying oil should have a temperature between approx. 160℃ and 195℃ ;
- coated fish pieces should remain in frying oil for sufficient time depending on the frying temperature to get a satisfying colour, flavour, and structure to adhere firmly to the fish core, but core should be kept frozen throughout the whole time ;
- frying oil has to be exchanged when colour becomes too dark or when concentration of fat degradation products exceeds certain limits ;
- remains from coating which concentrate at the bottom of the frying bath have to be removed regularly to avoid partial dark coloration on coated products caused by upwelling of oil ;
- excessive oil should be removed from coated products after pre-frying by a suitable device.

10.3.9 Re-freezing- Final Freezing

*Potential Hazards :* *foreign material*

*Potential Defects :* *Insufficient freezing leads to sticking of units together or to walls of freezing equipment and facilitates mechanical removal of breading/batter*

*Technical Guidance :*

- re-freezing to -18℃ or lower of the whole product should take place immediately after prefrying ;
- products should be allowed to stay sufficient time in freezer cabinet to assure core temperature of products of -18℃ or lower ;
- cryogenic freezers should have sufficient compressed gas flow to effect proper freezing of the product ;
- processors that utilise blast freezers may package the product in the consumer containers before freezing.

### 10.3.10 Packing and Labelling

Refer to Section 8.2.3 "Labelling", Section 8.4.4 "Wrapping and Packing" and Section 8.2.1. "Weighing".

*Potential Hazards :* *Microbiological contamination*

*Potential Defects :* *Under - or over-packing, improper sealed containers, wrong or misleading labelling*

*Technical Guidance :*

- packaging should be made without delay after refreezing under clean and hygienic conditions. If packaging is made later (e.g. batch processing) re-frozen products should be kept under deep frozen conditions until being packed ;
- packages should be checked regularly by weight control, end products should be checked by a metal detector and/or other detection methods if applicable ;
- packaging of cartons or plastic bags to master shipping containers should be done without delay and under hygienic conditions ;
- both consumer packages and shipping containers should be appropriately lot coded for product tracing in the event of a product recall.

### 10.3.11 Storage of End Products

Also refer to Section 8.1.3.

*Potential Hazards :* *Unlikely*

*Potential Defects :* *texture and Flavour deviations due to fluctuations in temperature, deep f reezer burn, cold store flavour, cardboard flavour*

*Technical Guidance :*

- all end products should be stored at frozen temperature in a clean, sound and hygienic environment ;
- severe fluctuations of storage temperature (greater than 3℃) has to be avoided ;
- too long storage time (depending on fat content of species used and type of coating) should be avoided ;
- products should be properly protected from dehydration, dirt and other forms of contamination ;
- all end products should be stored in the freezer to allow proper air circulation.

### 10.3.12 Transport of End Product

Also refer to Section 3.6. "Transportation" and Section 17 "Transport" under elaboration

*Potential Hazards :* *Unlikely*

*Potential Defects :* *thawing of frozen product*

*Technical Guidance :*

- during all transportation steps deep-frozen conditions should be maintained -18℃ (maximum fluctuation ±3℃) until final destination of product is reached ;
- cleanliness and suitability of the transport vehicle to carry frozen food products should be examined ;
- use of temperature recording devices with the shipment is recommended.

## 10.4 PROCESSING OPERATIONS – MOLLUSCAN SHELLFISH

Coated molluscan shellfish should be manufactured from safe and wholesome molluscs that were

subject to regulation and controls of a shellfish authority having jurisdiction of the harvesting, processing and handling that ensures that they are safe to consume. Shellfish can be cooked or raw prior to the coating process and should not contain significant defects such as sand, cuts, parasites or discoloration that may affect the consumer acceptability of the finished product. The methods depicted in this subsection are typical processing techniques applied to a wide variety of molluscan shellfish that are commonly used. It is assumed that the end product will be cooked thoroughly before consumption.

Refer to figure 10.2 for an example of a flow chart for coated molluscan shellfish processing.

*This flow chart is for illustrative purposes only. For in-factory HACCP implementation a complete and comprehensive flow chart has to be drawn up for each process.*

*References correspond to relevant Sections of the Code.*

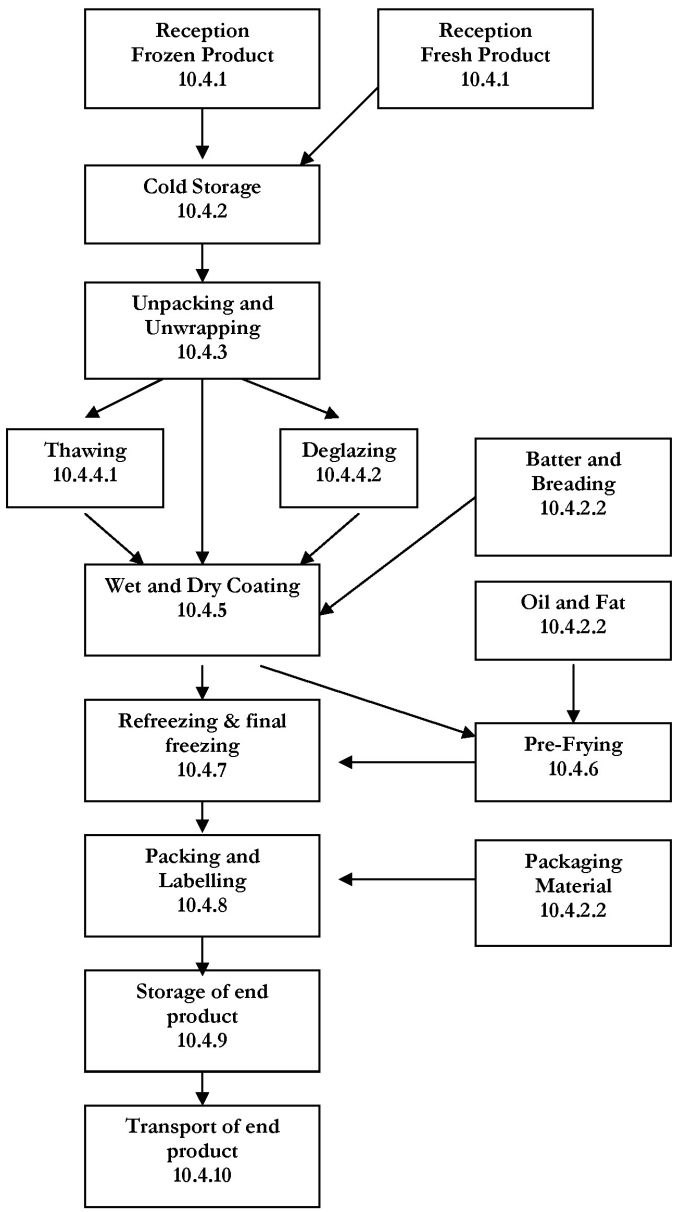


**Figure 10.2 Example of a flow chart of a coated molluscan shellfish processing line**

### 10.4.1 Reception

All incoming raw materials should be subject to an examination for food safety hazards and defects based on appropriate Codex Alimentarius sampling plans.

10.4.1.1 Molluscan Shellfish

*Potential Hazards :* *chemical contamination, biotoxins, microbiological contamination ;*

*Potential Defects :* *decomposition, oxidation, freezer burn, parasites, torn or damaged molluscs, packaging material, shells or pieces of shell ;*

*Technical Guidance :*

- Molluscan shellfish should be obtained from sources that are approved by a Shellfish Authority to ensure that marine biotoxins are properly controlled and that the product was handled and processed in accordance to hygienic standards and proper process control to control food safety hazards.
- Temperatures of all incoming lots should be recorded. Frozen product should be -18℃ or lower. Fresh product should not exceed 4℃.
- Packaging material of frozen products should be examined for dirt, tearing and evidence of thawing.
- Cleanliness and suitability of the transport vehicle to carry fresh and frozen molluscan shellfish products should be examined for each incoming shipment.
- Use of temperature recording devices with the shipment is recommended.
- Representative samples should be taken to assess the level of possible hazards and defects.

Refer also to Section 7 Live and Raw Bivalve Molluscs

10.4.1.2 Other Ingredients

See Section 10.3.1.2

10.4.1.3 Packaging Materials

See Section 10.3.1.3

### 10.4.2 Storage of Raw Material, Other Ingredients and Packaging Materials

10.4.2.1 Molluscan Shellfish (Frozen Storage)

See Section 10.3.2.1

10.4.2.2 Other Ingredients and Packaging Materials

See Section 10.3.2.3

10.4.2.3 Molluscan Shellfish (Refrigerated Storage)

*Potential Hazards :* *microbiological growth, physical and chemical*

*Potential Defects :* *decomposition*

*Technical Guidance :*

- raw fresh molluscan shellfish should be stored between 0º C and 4℃ ;
- raw fresh molluscan shellfish should be properly protected from contamination.

See Section 7.6.5

### 10.4.3 Unpacking and Unwrapping

See Section 10.3.4

### 10.4.4 Production of Coated Molluscan Shellfish

10.4.4.1 Thawing Frozen Product

*Potential Hazards :* *microbiological growth;*

*Potential Defects :* *decomposition, product damage*

*Technical Guidance :*

- molluscan shellfish that is frozen should be subjected to controlled conditions during the thawing process (below 4℃) that prevent the growth of pathogenic and spoilage bacteria ;
- sufficient controls should be instituted to ensure that the thawing product is not subject to conditions that are not hygienic or sanitary ;
- care should be taken to ensure that the raw thawed product is not subjected to conditions that cause tearing and breakage of the product ;

10.4.4.2 Deglazing

*Potential Hazards :* *contamination from dirty deglazing water*

*Potential Defects :* *thawing of product, contamination from dirty deglazing water;*

*Technical Guidance :*

- controls should be instituted to ensure that immersion to remove ice glaze is not too long to cause the individual molluscan shellfish to thaw ;
- thaw immersion water should be replaced at sufficient intervals to ensure that the product is not subject to dirt and other contaminants.

10.4.4.3 Separation of Individual Molluscan Shellfish

See Section 10.3.6

10.4.5 Coating

See Section 10.3.7

10.4.5.1 Wet Coating

See Section 10.3.7.1

10.4.5.2 Dry Coating

See Section 10.3.7.2

10.4.6 Pre-Frying

See Section 10.3.8

10.4.7 Re-Freezing－Final Freezing

See Section 10.3.9

10.4.8 Packing and Labelling

See Section 10.3.10

10.4.9 Storage of End Product

See Section 10.3.11

10.4.10 Transport of End Product

See Section 10.3.12

*This flow chart is for illustrative purposes only. For in-factory HACCP implementation a complete and comprehensive flow chart has to be drawn up for each process.*

*References correspond to relevant Sections of the Code.*

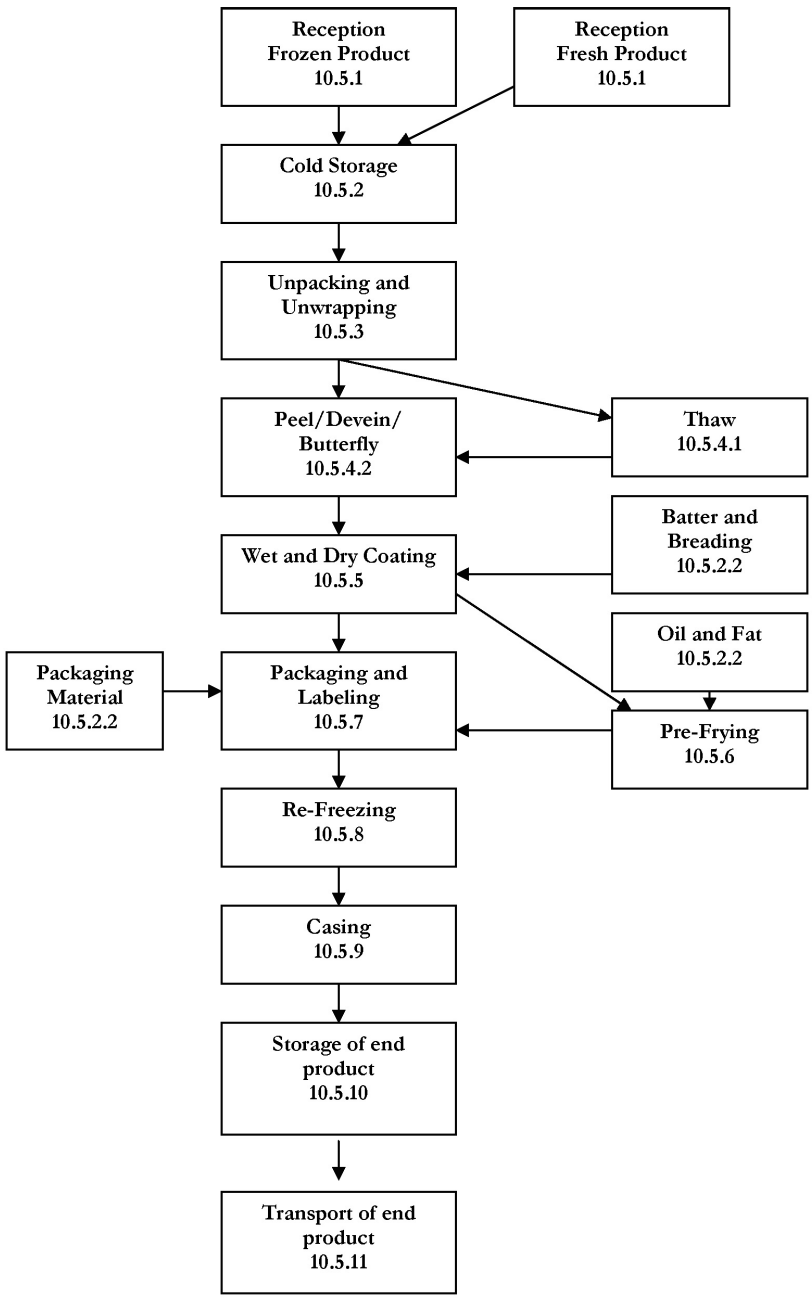


**Figure 10.3 Example of a flow chart of a coated shrimp processing line**

## 10.5 PROCESSING OPERATIONS – COATED SHRIMP

Coated or breaded shrimp should be manufactured from good quality shrimp that have been subjected to sanitary conditions and processed under conditions that properly control food safety hazards. Coated shrimp usually are removed from their shells with the exception of the tail (telson) and with the alimentary canal or "vein" removed. They are commonly either split (butterfly style) or are round then subjected to the wet and dry coating mixtures and further processed. Production methodology of coated shrimp varies widely. The methods depicted below are commonly applied to tropical and sub-tropical shrimp breading. It is assumed that the end product will be cooked thoroughly before consumption.

Refer to Figure 10.3 for an example of a flow chart for coated shrimp processing.

### 10.5.1 Reception

See Section 14 Processing of Shrimp and Prawns.

All incoming raw materials should be subject to an examination for food safety hazards and defects based on appropriate Codex sampling plans.

10.5.1.1 Shrimp

*Potential Hazards :* *sulphites*

*Potential Defects :* *black spot, soft flesh, inadequate head, viscera and leg removal, decomposition*

*Technical Guidance :*

- The presence of sulphites applied to the shrimp for the purpose of preventing black spot enzyme autolysis should be controlled to ensure that the product can be labelled as containing sulphites.
- Sulphites should be used in accordance with manufacturer's instructions and Good Manufacturing Practice.
- Raw shrimp with extensive black spot damage should be eliminated as an undesirable quality factor.
- Raw shrimp may exhibit soft flesh characteristics that result from bacterial infection that render it unsuitable for further processing. Incoming lots should be checked for this quality factor.
- Raw shrimp should not exhibit large amounts of viscera, head or leg material.
- Raw shrimp should be checked for signs of temperature abuse and decomposition that would be unsuitable in the finished product.
- Temperatures of all incoming lots should be recorded. Frozen product should be -18℃ or lower. Fresh product should not exceed 4℃.
- Packaging material of frozen products should be examined for dirt, tearing and evidence of thawing.
- Cleanliness and suitability of the transport vehicle to carry fresh and frozen shrimp products should be examined for each incoming shipment.
- Use of temperature recording devices with the shipment is recommended.
- Representative samples should be taken to assess the level of possible hazards and defects.

See Section 14.2.1

10.5.1.2 Other Ingredients

See Section 10.3.1.2

10.5.1.3 Packaging Material

See Section 10.3.1.3

### 10.5.2 Storage of Raw Material, Other Ingredients and Packaging Materials

10.5.2.1 Shrimp (Frozen Storage)

See Sections 10.3.2.1 and 14.2.2

10.5.2.2 Other Ingredients and Packaging Material

See Section 10.3.2.3

10.5.2.3 Shrimp (Refrigerated Storage)

*Potential Hazards :* *microbiological growth, physical and chemical contamination ;*

*Potential Defects :* *decomposition ;*

*Technical Guidance :*

- raw fresh shrimp should be stored between 0º C and 4℃ ;
- fresh shrimp should be properly protected from contamination ;

See Section 10.3.2.2

### 10.5.3 Unpacking and Unwrapping

See Section 10.3.4

### 10.5.4 Production of Coated Shrimp

10.5.4.1 Thawing Frozen Product

*Potential Hazards :* *microbiological growth;*

*Potential Defects :* *decomposition, product damage, physical contamination*

*Technical Guidance :*

- Shrimp that is frozen should be subjected to controlled conditions during the thawing process (below 4℃.) that prevent the growth of pathogenic and spoilage bacteria.
- Sufficient controls should be instituted to ensure that the thawing product is not subject to conditions that are not hygienic or sanitary.
- Care should be taken to ensure that the raw thawed product is not subjected to conditions that cause tearing and breakage of the product.

10.5.4.2 Peeling, Deveining, Butterflying

*Potential Hazards :* *microbiological contamination, chemical contamination, metal inclusion*

*Potential Defects :* *presence of shell, presence of vein, poor cut, damaged flesh*

*Technical Guidance :*

- Since peeling of larger shrimp usually used for coating is performed by hand, care should be taken to ensure that pathogenic bacteria are not transmitted from workers' hands. Careful compliance to Section 3.5 of the Codex Code of Practice on Fish and Fishery Products

should be carried out.

- Thawed shrimp should be adequately protected from contamination and processed quickly so that the raw flesh does not deteriorate.
- Sufficient amounts of water should be applied to peeled shrimp to ensure that all shell remnants and veins are washed away and removed from the shrimp.
- If veins are removed by hand with a knife the product should be regularly checked to ensure that the cuts are made to product specifications.
- If the shrimp is butterfly cut by hand the product should be regularly checked to ensure that the cuts are made to product specifications.
- If the shrimp is butterfly cut by machine the cutting blades should be regularly inspected so that the cut does not result in damaged shrimp or metal inclusion.

10.5.5 Coating

See Section 10.3.7

10.5.5.1 Wet Coating

*Potential Hazards :* *microbiological growth and toxin production in rehydrated batter, toxin formation*

*Potential Defects :* *improper batter viscosity, foreign material, defective coating*

*Technical Guidance :*

- batter ingredient powders should be checked against buying specification and ideally sieved before use to remove any packaging and extraneous materials ;
- liquid batter preparations should be properly refrigerated or discarded at regular intervals to prevent microbiological growth and toxin formation ;
- batter viscosity should be monitored to ensure the proper pick-up of dry coating material. Batter that is too thin or thick may result in a coating and flesh ratio that does not meet specifications and regulatory requirements;
- note that bacterial toxin formation is a possibility in batter mixes so that usage times and temperatures should be set and cleaning schedules of equipment defined and maintained
- bags of dry batter mix should be stripped of their outer layer before being emptied into batter tanks to prevent dust and other contaminants from entering the rehydrated batter mix and into the final product.
- tempura style batters may be used in which case additional crumb coatings will probably not be applied. However, frying temperatures and times will be critical to ensure correct texture
- where batter is for adherence of a crumb coating, formulation and viscosity will be different to tempura styles

See Section 10.3.7.1

10.5.5.2 Dry Coating

*Potential Hazards :* *unlikely*

*Potential Defects :* *defective coating, improper flesh/coating ratio, foreign material*

*Technical Guidance :*

- breadcrumb formulation and grist, or particle size will need to be checked against buying specification and stored according to supplier instructions to avoid staling ;
- individual shrimp should be well separated during the coating process to ensure complete coating of the product ;
- the total coating and flesh percentages should be regularly monitored using recognized methods to ensure that the specified flesh and coating ratio is attained ;
- air blowers that eliminate excess coating from the shrimp should be adjusted and regularly monitored to ensure that the proper coating level is maintained ;
- individual shrimp that exhibit incomplete or defective coating should be removed ;
- bags of dry coating mix should be stripped of their outer layer before being emptied into batter tanks to prevent dust and other contaminants from entering the rehydrated batter mix and into the final product ;

See Section 10.3.7.2

10.5.6 Pre-Frying

See Section 10.3.8

10.5.6.1 Frying

- whilst frying is necessary for tempura batter coatings, it may not always be used for crumb coating operations, although it may aid adhesion ;
- fryers should be operated by trained staff. Oil should be turned over on a regular basis to avoid oxidative rancidity ;
- oil temperatures should be controlled to avoid burning crumb or fire risk.

10.5.7 Packaging and Labeling

See Section 10.3.10

10.5.8 Re-Freezing - Final Freezing

*Potential Hazards :* *unlikely*

*Potential Defects :* *poor product texture, excessive moisture migration from flesh to coating*

*Technical Guidance :*

- blast freezing should be carried out quickly with the appropriate temperature and air flow parameters routinely monitored especially when the internal product temperature is between 0℃ and -4℃ C in order to minimize crystallization of the flesh and the moisture migration that will occur from the flesh to the coating.

10.5.9 Casing

*Potential Hazards :* *microbiological growth*

*Potential Defects :* *product thawing, moisture migration from flesh to coating*

*Technical Guidance :*

- casing of the frozen containers should be carried out quickly to prevent thawing and quality problems such as texture changes of the shrimp flesh and moisture migration from the flesh to the coating.

10.5.10 Frozen Storage of End Product

See Section 10.3.11

10.5.11 Transport of End Product

See Section 10.3.12

## SECTION 11 - PROCESSING OF SALTED AND DRIED SALTED FISH

In the context of recognising controls at individual processing steps, this section provides examples of potential hazards and defects and describes technological guidelines, which can be used to develop control measures and corrective action. At a particular step only the hazards and defects, which are likely to be introduced or controlled at that step, are listed. It should be recognised that in preparing a HACCP and/or DAP plan it is essential to consult Section 5 which provides guidance for the application of the principles of HACCP and DAP analysis. However, within the scope of this Code of Practice it is not possible to give details of critical limits, monitoring, record keeping and verification for each of the steps since these are specific to particular hazards and defects.

Salted fish and fish products and dried salted fish and fish products (i.e. klippfish) should be sound and wholesome, well prepared and packaged so that they will be protected from contamination and remain attractive and safe to eat. In order to maintain the quality of fish it is important to adopt quick, careful and efficient handling procedures.

## 11.1 GENERAL

Refer also to Section 8.1 for general handling prior to processing and figure 11.1 for an example flow chart of a salted and dried salted fish processing line.

- depending on the species for salting, fish should be completely bled as soon as practical ;
- where appropriate, fresh fish intended for processing salted fish should be checked for visible parasites ;
- frozen fish should not be salted before it is thoroughly thawed and inspected for suitability ;
- freezing, heating or adequate combination of salt content and storage time can be used as treatment procedures for killing living parasites ;
- the salt penetration will depend upon fat content, temperature, amount of salt, salt composition, brine concentration, etc. ;
- when fish that accumulate histamine are being salted, exposure to temperatures that would support toxin formation by bacteria should be limited at each step in the process ;
- to minimise time delays, the design of processing lines, where applicable, should be continuous and sequential to permit the uniform flow without stoppages or slow-downs and removal of waste.

*This flow chart is for illustrative purposes only. For in-factory HACCP implementation a complete and comprehensive flow chart has to be drawn up for each process.*
*References correspond to relevant Sections of the Code*

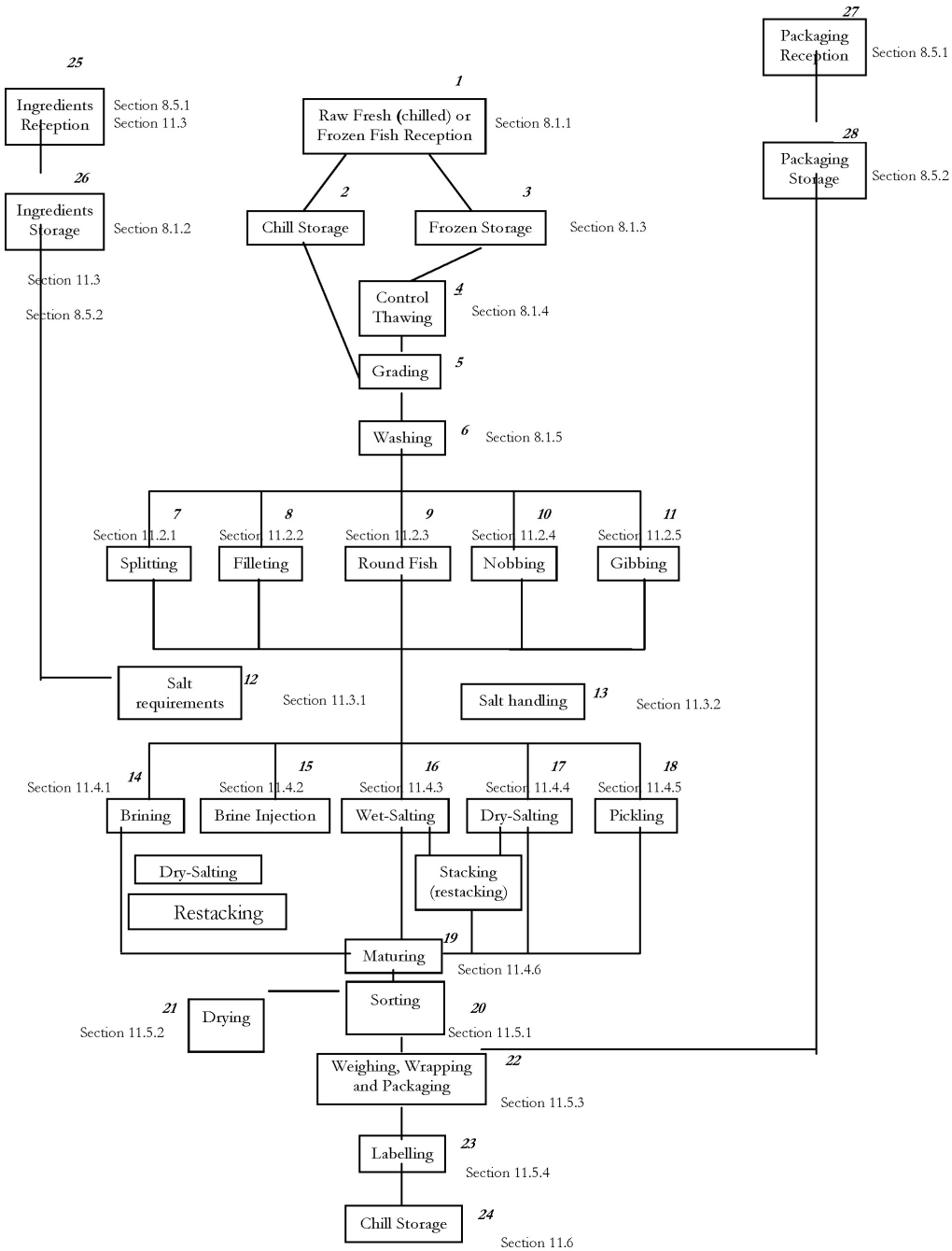


**Figure 11.1 Example of flow chart of a salted and dried salted fish processing line.**

## 11.2 PREPARING FOR SALTING

### 11.2.1 Splitting, Washing and Rinsing (Processing Steps 7)

*Potential Hazards :* *unlikely*

*Potential Defects :* *improper splitting*

*Technical Guidance :*

- fish should be split by a cut made parallel to the backbone straight down from the throat or nape to the tail and in such a way as to prevent uneven and ragged edges or a loss in recovery. If the backbone is to be removed, the fish should be split so deeply that the remains of the backbone (the tail-bone) lie free. It is important to cut the bone rather than to break it from the flesh ;
- splitting of fish should be carried out expertly so that blood in nape and blood clots are removed ;
- immediately after splitting, fish should be washed in plenty of running potable water or clean sea water, to remove all blood from the fish ;
- all impurities, blood and livers should be removed ;
- visible parasites should be removed ;
- if the black membrane has to be removed, then it should be done after the splitting step.

### 11.2.2 Filleting, Skinning and Trimming (Processing Steps 8)

Refer to Section 8.1.6.

### 11.2.3 Round Fish (Processing Steps 9)

Refer to Section 8.1.1 – 8.1.5.

### 11.2.4 Nobbing (Processing Steps 10)

*Potential Hazards :* *unlikely*

*Potential Defects :* *Remaining gut content and intestines other than roe or milt, decomposition*

*Technical Guidance :*

refer to section 11.2.1, 2nd bullet ;

- after nobbing fish should be checked for remaining intestines ;
- after nobbing fish should be thoroughly washed to remove blood, remaining intestines and scales if appropriate ;
- the nobbed fish should be drained and well iced or appropriately chilled in clean containers and stored in specially designated and appropriate areas within the processing facility.

### 11.2.5 Gibbing (Processing Steps 11)

*Potential Hazards :* *unlikely*

*Potential Defects :* *Remaining gut content, decomposition*

*Technical Guidance :*

refer to section 11.2.1, 2nd bullet ;

- after gibbing fish should be checked for correct gibbing ;
- fish with incorrect gibbing should be sorted out and used for other purposes ;
- after gibbing fish should be thoroughly washed to remove blood, remaining undesirable intestines, heart, etc. and scales if appropriate;

- the gibbed fish should be drained and well iced or appropriately chilled in clean containers and stored in specially designated and appropriate areas within the processing facility.

## 11.3 SALT HANDLING AND SALT REQUIREMENTS

### 11.3.1 Salt Requirements (Processing Steps 12)

*Potential Hazards :* *chemical and physical contamination*

*Potential Defects :* *incorrect composition*

*Technical Guidance :*

- the quality of salt used in salting of fish should possess an appropriate composition for the product ;
- the composition of salt differs according to the origin. Mine salt and solar salt of marine origin contain several other salts like calcium sulphate, magnesium sulphate and chloride as impurities. Vacuum processed and refined salt is almost pure sodium chloride ;
- a relatively pure salt is needed for the dry-salting of fatty fish but for some products the presence of small quantities of calcium salts will give the product a somewhat superior appearance. Too much calcium may reduce the rate of salt penetration to an extent that spoilage may occur ;
- magnesium salts if present at too high a concentration will give rise to unpleasant bitter flavours and may cause spoilage during the salting operation ;
- salt produced from marine sources may contain halophilic bacteria and mould which continue to live in the salt and dry salted fish and could contribute to spoilage ;
- salt used in salt fish should be inspected to ensure that it is clean, not used before, free from foreign matter and foreign crystals, show no visible sign of contamination with dirt, oil, bilge or other extraneous materials ;
- the size of the salt granules used should be carefully considered. The use of very fine salt granules could result in the formation of clusters which is not favourable for ensuring the uniform distribution of salt on the fish. The use of very coarse salt granule could result in damage to the fish flesh during salting and may reduce the rate of maturation ;
- small crystals of salt should be used for dry-salting of fatty fish and large crystals for lean fish ;
- Salt used as an ingredient needs to be of food grade.

### 11.3.2 Handling (Processing Steps 13)

*Potential Hazards :* *chemical and physical contamination*

*Potential Defects :* *Bacteria and mould*

*Technical Guidance :*

- salt for salting of fish should be transported and stored dry and hygienically covered in salt bins, storerooms, containers or in plastic sacks ;
- in order to minimise the presence and growth of bacteria and moulds in salted fish, such as pink and dun, the re-use of salt should be avoided ;

## 11.4 SALTING AND MATURING

Salted fish should be salt-matured, sound and wholesome. The salting process, including the temperature, should be sufficiently controlled to prevent the development of *Clostridium botulinum,* or the fish should be eviscerated prior to brining.

Salting of fish either by brining, brine injection, wet-salting, dry-salting or pickling should be carried out with full understanding of their effects on the quality of the final product and should be done under strict hygienic condition and temperature control.

Two particular conditions that can adversely affect the quality of salted fish are the occurrence of bacteria and mould. Both defects can be combated by maintaining a temperature lower than 8℃. Salt produced from marine sources may contain halophilic bacteria, which continue to live in the salt and salted fish. In order to minimise such microbial contamination of salted fish, previously used and/or contaminated salt should be removed from the plant.

Another adverse condition that can affect the quality of salted fish is brown (yellow) discolouration often due to rancidity caused by metal catalysts in the salt. The quality of the salt is important, low temperature should be maintained during the process and light and oxygen should be avoided.

### 11.4.1 Brining (Processing Steps 14)

*Potential Hazards :* *viable parasites, scombrotoxins, botulinum toxin*

*Potential Defects :* *decomposition*

*Technical Guidance :*

- only fresh stabilised brine should be used for the salting operations; water quality is important, potable water should be used for preparation of brine ;
- the ratio of brine to fish and the concentration of the brine should be adjusted to desired product ; time and temperature (〈4℃) control is important if the brine concentration is lower than saturated ;
- concentration of brine should be checked at regular intervals, incorrect concentration should be adjusted prior to use ;
- to assure proper salt penetration, fish should be of similar size.

### 11.4.2 Brine Injection (Processing Steps 15)

*Potential Hazards :* *viable parasites, scombrotoxins, injection needle fragment, botulinum toxin*

*Potential Defects :* *decomposition*

*Technical Guidance :*

- apparatuses used for brine injection should be cleaned and disinfected at regular intervals ;
- needles of apparatuses should be inspected daily for broken tips, for blocking and deflections of needles ;
- brine injection devices should be operated by trained personnel only ;
- conduct metal detection here or later in the process ;
- the reflux of injected brine into the reservoir should be avoided.

### 11.4.3 Wet-Salting (Processing Steps 16)

*Potential Hazards :* *viable parasites, scombrotoxins, botulinum toxin*

*Potential Defects :* *decomposition*

*Technical Guidance :*

- fish for wet-salting should be salted and carefully arranged in the curing container such that voids channels between the fish are minimised ;
- amount of salt, time and temperature should be controlled to obtain the desired product ;
- when salting the fish, the salt concentration of the brine should be checked periodically with a salinometer according to specifications ;
- after salting, the fish can be stacked. This should not be done before the proper salt/water balance is obtained. In case of stacking, adequate amounts of salt should be added and evenly distributed over the whole surface of the fish ;

- salted fish should be stored or maintained for a sufficient period under controlled temperatures, to ensure proper curing and to prevent deterioration of the product.

11.4.4 Dry-Salting (Processing Steps 17)

*Potential Hazards :* *viable parasites, scombrotoxins, botulinum toxin*

*Potential Defects :* *decomposition*

*Technical Guidance :*

- fish for dry salting should be carefully arranged such that voids or channels between fish are minimised and that drainage is adequate ;
- fish piles should never be placed directly on the floor or in direct contact with the wall ;
- amount of salt, time and temperature should be carefully controlled to obtain the desired product. Sufficient amount of salt is important for the quality of the product ;
- fish should be restacked periodically with the top of the pile going to the bottom of the new pile, and with the addition of fresh salt to ensure that sufficient salt will be present to complete the cure ;
- if the fish is restacked on pallets, the pallet should be clean ;
- fish should not be exposed to freezing temperatures during the salting process.

11.4.5 Pickling (Processing Steps 18)

*Potential Hazards :* *viable parasites, scombrotoxins, botulinum toxin*

*Potential Defects :* *decomposition,*

*Technical Guidance :*

- the amount of salt must be adjusted to the quality of the fatty (primary) fish (fat content). Salt, sugar and spices should be weighed/measured and be evenly distributed ;
- during the pickling operation all fish should be well immersed in the resulting pickle ;
- fish should be allowed to settle in containers and then salt or pickle added before the container is closed ;
- cured fatty fish should be kept in brine or pickle ;
- fatty fish should always be covered with pickle during curing ;
- pickling is primary used for fatty fish. Under certain conditions dry salting of small fatty fish, such as anchovy and small herring, may be used.

11.4.6 Maturing (Processing Steps 19)

*Potential Hazards :* *viable parasites, scombrotoxins, botulinum toxin*

*Potential Defects :* *decomposition, rancidity and discolouring of the flesh or surface bacteria and mould*

*Technical Guidance :*

- maturing time depends on the fish (species, size and quality), temperature and the amount of salt absorbed by the fish tissues ;
- the first part of curing period for fish that accumulate histamine should be done at temperatures between 0℃ and 5℃ to prevent development of histamine ;
- fatty fish such as herring may be kept in a temperature range of 5℃ to 10℃ under the maturing period. The length of this period will vary from weeks and up to several months depending of the specific products. If the containers are to be held at lower temperatures, the maturing period will increase ;

- when salting fish that accumulate histamine, regular checks should be made of histamine content of the end product.

## 11.5 SORTING, DRYING, WEIGHING, PACKAGING, WRAPPING AND LABELLING

Refer also to Sections 8.2.3 (labelling) and 8.4.4 (Wrapping and packaging)

### 11.5.1 Sorting (Processing Steps 20)

*Potential Hazards :* *Unlikely*

*Potential Defects :* *Incorrect sorting (quality, weight, size, species, etc.) bacteria and mould*

*Technical Guidance :*

- salted fish should be sorted into species, sizes and trade quality categories for the relevant market ;
- loose salt should be removed from the fish before sorting and new salt should be added before packaging.

### 11.5.2 Drying (Processing Steps 21)

*Potential Hazards :* *unlikely*

*Potential Defects :* *Decomposition, bacteria and mould*

*Technical Guidance :*

- the time and temperature used for drying will depend upon fish species, size and the handling and stacking of the fish ;
- to assure proper drying, the fish should be of similar size ;
- use of too high temperature can cause hard texture of the other layer of the muscle and should be avoided. This could stop the drying process.

### 11.5.3 Weighing, Wrapping and Packaging (Processing Steps 22)

*Potential Hazards :* *microbiological contamination*

*Potential Defects :* *unlikely*

*Technical Guidance :*

- packaging material should be clean, sound, durable, sufficient for its intended use and of food grade material ;
- barrels in which fatty fish are ready to be marketed should be clean, whole and hygienic ;
- the packaging operation should be conducted to minimise the risk of contamination and decomposition ;
- products should meet appropriate standards for labelling and weights.

### 11.5.4 Labelling (Processing Steps 23)

Refer to Section 8.2.3 and 8.5.

## 11.6 CHILL STORAGE (Processing Step 24)

*Potential Hazards :* *unlikely*

*Potential Defects :* *unlikely*

*Technical Guidance :*

- salt matured fish should be stored in chill storage ;
- the temperature in the chill storage should be between 1℃ to 4℃ ;

- temperature and storage time should be monitored and recorded at regular intervals ;
- the products should be handled carefully and not be over-stacked.

11.7 PACKAGING, LABELS & INGREDIENTS (Processing Steps 25, 26, 27 & 28)

Refer to Section 8.5.

## SECTION 14 - PROCESSING OF SHRIMPS AND PRAWNS

*Scope:* Shrimp frozen for further processing may be whole, head-off or deheaded or raw headless, peeled, peeled and de-veined or cooked on board harvest or processing vessels or at on shore processing plants.

In the context of recognising controls at individual processing steps, this section provides examples of potential hazards and defects and describes technological guidelines, which can be used to develop control measures and corrective action. At a particular step only the hazards and defects, which are likely to be introduced or controlled at that step, are listed. It should be recognised that in preparing a HACCP and/or DAP plan it is essential to consult Section 5 which provides guidance for the application of the principles of HACCP and DAP analysis. However, within the scope of this Code of Practice it is not possible to give details of critical limits, monitoring, record keeping and verification for each of the steps since these are specific to particular hazards and defects.

14.1 FROZEN SHRIMPS AND PRAWNS - GENERAL

- Shrimps for frozen product originate from a wide variety of sources as varied as deep cold seas to shallow tropical inshore waters and rivers through to aquaculture in tropical and semi tropical regions.
- The methods of catching, or harvesting and processing are as equally varied. Species in northern regions may be caught by freezer vessels, cooked, individually quick frozen and packed on board in their final marketing form. More often however, they will be raw IQF on board for further processing at on-shore plants, or even landed chilled on ice. Shrimps of these species are invariably pre-cooked at onshore plants through in-line integrated process lines, followed by mechanical peeling, cooking, freezing, glazing and packing. A much larger product line is produced in tropical and sub-tropical countries from wild caught and cultivated *Penaeus* species: whole, headless (head off), peeled, peeled and de-veined raw and/or cooked products presented in different marketing forms (easy-peel, tail-on, tail-off, butterfly, stretched, sushi shrimp). This wide range of products is prepared in shrimp processing plants that may be small and use manual techniques or large dimensions fully mechanised equipments. Cooked shrimp products are generally peeled after cooking.
- Warm water shrimps may also be subject to further added value processes such as marinating and batter and crumb coatings.
- Since some raw shrimp products, as well as cooked ones, may be consumed without further processing safety considerations are paramount.
- The processes described above are captured on the flow chart, but it must be appreciated that because of the diverse nature of production methods individual HACCP/DAP plans must be devised for each product.
- Other than the previous description of on-board cooking, there is no reference to processing of shrimps at sea or in farms. It is assumed that product will be correctly handled and processed in line with the relevant sections in the code of practice and that where appropriate some element of pre-preparation, such as de-heading, will have taken place prior to receipt at processing plants.

*This flow chart is for illustrative purposes only. For in-factory HACCP implementation a complete and comprehensive flow chart has to be drawn up for each process.*

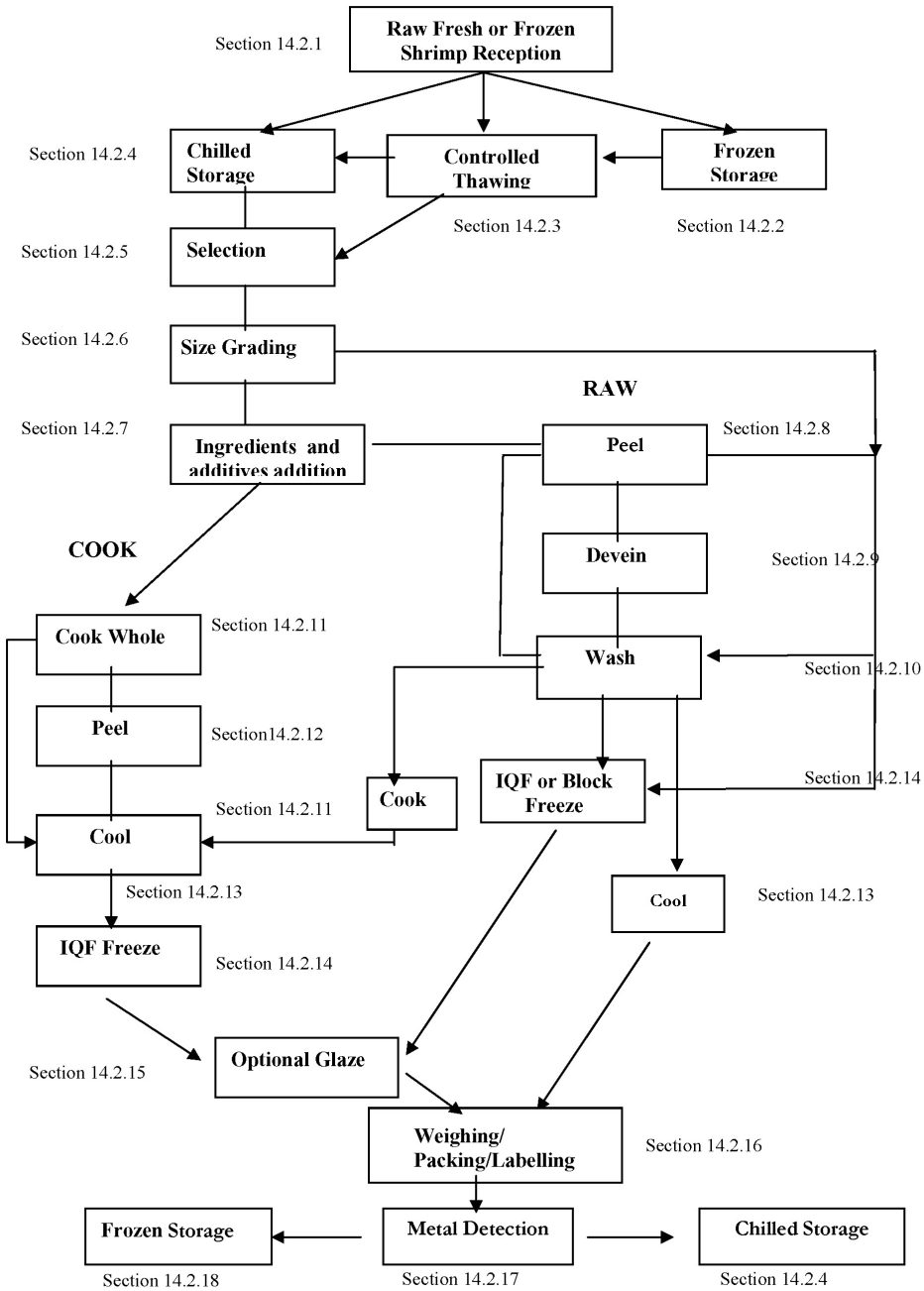


**Figure 14.2 Example of a flow chart of a shrimp and prawn processing line**

## 14.2 SHRIMP PREPARATION (PROCESSING STEPS 14.2.1 TO 14.2.18)

### 14.2.1 Raw Fresh and Frozen Shrimp Reception (Process Steps)

*Potential Hazards :* *phytotoxins (e.g. PSP)*
*microbiological contamination*
*antioxidants*
*sulphites*
*pesticides*
*fuel oil (chemical contamination)*

*Potential Defects :* *variable batch quality*
*mixed species*
*taints*
*blackspot*
*softening from head enzymes*
*decomposition*

*Technical Guidance :*

- inspection protocols should be devised to cover identified quality, HACCP and DAP plan parameters together with appropriate training for inspectors to undertake these tasks ;
- shrimps should be inspected upon receipt to ensure that they are well iced or deep frozen and properly documented to ensure product tracing ;
- the origin and previous known history will dictate the level of checking that may be necessary for, for example, phytotoxins in sea caught shrimps (specifically for head on products), for potential antibiotics presence in aquaculture shrimps, particularly if there is no supplier assurance certification. In addition, other chemical indicators for heavy metals, pesticides and indicators of decomposition such as TVBN's may be applied.
- shrimps should be stored in suitable facilities and allocated use-by times for processing to ensure quality parameters are met in end products ;
- incoming lots of shrimp should be monitored for sulphites at harvesting ;
- a sensory evaluation should be performed on incoming lots to ensure that the product is of acceptable quality and not decomposed ;
- it is necessary to wash fresh shrimps after receiving in an adequate equipment with a series of low velocity sprays with chilled clean water.

### 14.2.2 Frozen Storage

*Potential Hazards :* *unlikely*

*Potential Defects :* *protein denaturation, dehydration*

*Technical Guidance :*

- protective packaging should be undamaged, otherwise repacking to exclude possibilities of contamination and dehydration.
- cold storage temperatures to be suitable for storage with minimum fluctuation.
- product to be processed within the best before time on the packaging, or before as dictated at reception.
- the cold storage facility should have a temperature monitoring device preferably a continuous

recording unit to properly monitor and record ambient temperature.

### 14.2.3 Controlled Thawing

*Potential Hazards :* *microbiological contamination*

*contamination from wrapping*

*Potential Defects :* *decomposition*

*Technical Guidance :*

- thawing processes may be undertaken from block frozen or IQF shrimps depending on the raw material source. The outer and inner packaging should be removed prior to defrosting to prevent contamination and extra care should be taken on block frozen prawns where inner wax or polyethylene packaging may be entrapped with blocks ;
- thawing tanks should be purpose designed and allow for 'counter current' water defrosting where necessary to maintain lowest temperatures possible. However water re-use is discouraged ;
- Clean sea water or water and ice of potable quality should be used for thawing with a water temperature no higher than 20℃ (68°F) by use of additional ice to achieve a defrosted product at a temperature cooler than 4℃.
- thawing should be achieved as quickly as possible to maintain quality ;
- it is desirable for the exit conveyor, leading from the defrost tanks, to be equipped with a series of low velocity sprays to wash the shrimps with chilled clean water ;
- immediately after thawing, the shrimps should be re-iced or held in chill to avoid temperature abuse before further processing.

### 14.2.4 Chilled Storage

Refer to Section 8.1.2 "Chilled Storage" for general information concerning fish and fishery products.

*Potential Hazards :* *microbiological contamination*

*Potential Defects :* *decomposition*

*Technical Guidance :*

- chilled storage, preferably under ice in chill rooms at less than 4oC after reception ;
- the chilled storage facility should have a temperature monitoring device (preferably a continuous recording unit) to properly monitor and record ambient temperatures ;
- Unnecessary delays should be avoided during chilled storage in order to prevent quality deterioration.

### 14.2.5 Selection

*Potential Hazards :* *unlikely*

*Potential Defects :* *decomposition*

*Technical Guidance :*

- shrimps may be selected for different quality grades according to specification requirements. This should be undertaken with minimum of delay followed by re-icing of the shrimps

### 14.2.6 Size Grading

*Potential Hazards :* *microbiological contamination*

*Potential Defects :* *decomposition*

*Technical Guidance :*

- Size grading of shrimps is undertaken through mechanical graders of various degrees of sophistication and manually. There is a possibility of shrimps becoming trapped in the bars of the graders so that regular inspection is required to prevent 'carry over' of old prawns and bacteriological contamination.
- Shrimp should be re-iced and stored in chill prior to further processing.
- The grading process should be carried out promptly to prevent unnecessary microbiological growth and product decomposition.

14.2.7 Addition of Ingredients and Use of Additives

*Potential Hazards :* *chemical and microbiological contamination*

*sulphites*

*Potential Defects :* *decomposition*

*improper use of additives*

*Technical Guidance :*

**• according to specification and legislation, certain treatments may be applied to shrimps to improve organoleptic quality, preserve yield or preserve them for further processing ;**

- examples would including sodium metabisulphite to reduce shell blackening, sodium benzoate to extend shelf-life between processes and sodium polyphosphates to maintain succulence through processing and prevent black spot after peeling, whilst common salt would be added as brine for flavour ;
- these ingredients and additives can be added at various stages, for instance common salt and sodium polyphosphates at defrost stages or chilled brine as a flume conveyor between cooking and freezing, or as glaze ;
- at whatever stage ingredients and additives are added, it is essential to monitor the process and product to ensure that any legislative standards are not exceeded, quality parameters are met and that where dip baths are used, the contents are changed on a regular basis according to drawn up plans ;
- chill conditions to be maintained throughout ;
- sulphites used to prevent blackspot formation autolysis should be used in accordance with manufacturer's instructions and Good Manufacturing Practice.

14.2.8 Full and Partial Peeling

*Potential Hazards :* *microbiological cross contamination*

*Potential Defects :* *decomposition*

*shell fragments*

*foreign matter*

*Technical Guidance :*

- this process applies mainly to warm water prawns and could be as simple as inspecting and preparing whole large prawns for freezing and down-grading blemished prawns for full peeling ;
- other peeling stages could including full peeling or partial peeling leaving tail swimmers intact ;
- whatever the process, it is necessary to ensure that the peeling tables are kept clear of contaminated shrimps and shell fragments with water jets and the shrimps are rinsed to ensure no carry over of shell fragments.

14.2.9 Deveining

*Potential Hazards :* *microbiological cross contamination*

*metal contamination*

*Potential Defects :* *objectionable matter*

*decomposition*

*foreign matter*

*Technical Guidance :*

- the vein is the gut which may appear as a dark line in the upper dorsal region of prawn flesh. In large warm water prawns, this may be unsightly, gritty and a source of bacterial contamination.
- removal of the vein is by razor longitudinally cutting along the dorsal region of the shrimp with a razor slide and removal of the vein by pulling. This may be partially achieved with head-off shell-on shrimps as well.
- this operation is considered to be a mechanical though labour intensive process so that :
- cleaning and maintenance schedules should be in place and cover the need for cleaning before, after and during processing by trained operatives ;
- further, it is essential to ensure that damaged and contaminated shrimps are removed from the line and that no debris build up is allowed.

14.2.10 Washing

*Potential Hazards :* *microbiological contamination*

*Potential Defects :* *decomposition*

*foreign matter*

*Technical Guidance :*

- washing of peeled and deveined shrimps is essential to ensure that shell and vein fragments are removed ;
- shrimps should be drained and chilled without delay prior to further processing.

14.2.11 Cooking Processes

*Potential Hazards :* *survival of pathogenic micro-organisms due to insufficient cooking*

*microbiological cross contamination*

*Potential Defects :* *over cooking*

*Technical Guidance :*

- the cooking procedure, in particular time and temperature, should be fully defined according to the specification requirements of the final product, for example whether it is to be consumed without further processing and the nature and origin of the raw shrimp and uniformity of size grading ;
- the cooking schedule should be reviewed before each batch and where continuous cookers are in use, constant logging of process parameters should be available ;
- only potable water should be used for cooking, whether in water or via steam injection ;
- the monitoring methods and frequency should be appropriate for the critical limits identified in the scheduled process ;
- maintenance and cleaning schedules should be available for cookers and all operations should only be undertaken by fully trained staff ;

- adequate separation of cooked shrimps exiting the cooking cycle utilising different equipment is essential to ensure no cross contamination.

14.2.12 Peeling of Cooked Shrimps

*Potential Hazards :* *microbiological cross contamination*

*Potential Defects :* *presence of shell*

*Technical Guidance :*

- cooked shrimps have to be properly peeled through mechanical or manual peeling in line with cooling and freezing processes ;
- cleaning and maintenance schedules should be available, implemented by fully trained staff to ensure efficient and safe processing are essential.

14.2.13 Cooling

*Potential Hazards :* *microbiological cross contamination and toxin formation*

*Potential Defects :* *unlikely*

*Technical Guidance :*

- cooked shrimps, should be cooled as quickly as possible to bring the temperature of the product to a temperature range limiting bacteria proliferation or toxin production ;
- cooling schedules should enable the time-temperature requirements to be met and maintenance and cleaning schedules should be in place and complied with by fully trained operatives ;
- only cold/iced potable water or clean water should be used for cooling and should not be used for further batches, although for continuous operations a top-up procedure and maximum run-length will be defined ;
- raw/cooked separation is essential ;
- after cooling and draining, the shrimps should be frozen as soon as possible, avoiding any environmental contamination.

14.2.14 Freezing Processes

*Potential Hazards :* *microbiological contamination*

*Potential Defects :* *slow freezing - textural quality and clumping of shrimps*

*Technical Guidance :*

- the freezing operation will vary tremendously according to the type of product. At its simplest, raw whole or head-off shrimps may be block or plate frozen in purpose-designed cartons into which potable water is poured to form a solid block with protective ice.
- cooked and peeled *Pandalus* cold water prawns, at the other extreme, tend to be frozen through fluidised bed systems, whilst many of the warm water shrimp products are IQF frozen either on trays in blast freezers or in continuous belt freezers.
- whichever the freezing process, it is necessary to ensure that the freezing conditions specified are met and that for IQF products, there is no clumping, i.e. pieces frozen together. Putting product into a blast freezer before it is at operating temperature may result in glazed, slow frozen product and contamination.
- freezers are complex machines requiring cleaning and maintenance schedules operated by fully trained staff.

14.2.15 Glazing

*Potential Hazards :* *microbiological cross-contamination*

*Potential Defects :* *inadequate glaze, too much glaze, spot welding, incorrect labelling.*

*Technical Guidance :*

- glazing is applied to frozen shrimps to protect against dehydration and maintain quality during storage and distribution.
- ice block frozen shrimps is the simplest form of glazing, followed by dipping and draining frozen shrimps in chilled potable water. A more sophisticated process is to pass frozen size graded shrimps under cold-water sprays on vibratory belts such that the shrimps pass at a steady rate to receive an even and calculable glaze cover.
- ideally, glazed shrimps should receive a secondary re-freezing prior to packing, but if not, they should be packaged as quickly as possible and moved to cold storage. If this is not achieved, the shrimps may freeze together and 'spot weld' or clump as the glaze hardens.
- there are Codex methods for the determination of glaze.

### 14.2.16 Weighing, Packing and Labelling of All Products

Refer to Section 8.4.4 "Wrapping and Packing" and Section 8.5. "Packaging, Labels & Ingredients".

*Potential Hazards :* *sulphites*

*Potential Defects :* *incorrect labelling, decomposition*

*Technical Guidance :*

- all wrappings for products and packaging including glues and inks should have been specified to be food grade, odourless with no risk of substances likely to be harmful to health being transferred to the packed food.
- all food products should be weighed in packaging with scales appropriately tared and calibrated to ensure correct weight.
- where products are glazed, checks should be carried out to ensure the correct compositional standards to comply with legislation and packaging declarations.
- ingredients lists on packaging and labelling should declare presence of ingredients in the food product in descending order by weight, including any additives used and still present in the food.
- all wrapping and packaging should be carried out in a manner to ensure that the frozen products remain frozen and that temperature rises are minimal before transfer back to frozen storage.
- sulphites should be used in accordance with manufacturer's instructions and Good manufacturing Practice.
- where sulphites were used in the process, care should be taken that they are properly labelled.

### 14.2.17 Metal Detection

*Potential Hazard :* *presence of metal*

*Potential Defect :* *unlikely*

*Technical Guidance :*

- products should be metal detected in final pack through machines set to the highest sensitivity possible.
- larger packs will be detected at a lower sensitivity than smaller packs so that consideration should be given to testing product prior to packing. However, unless potential re-contamination prior to packing can be eliminated, it is probably still better to check in-pack.

### 14.2.18 Frozen Storage of End Product

Refer to Section 8.1.3. "Frozen storage" for general information concerning fish and fishery products.

*Potential Hazard :* *unlikely*

*Potential Defects :* *texture and flavour deviations due to fluctuations in temperature, deep freezer burn, cold store flavour, cardboard flavour*

*Technical Guidance :*

- frozen products should be stored at frozen temperature in a clean, sound and hygienic environment ;
- the facility should be capable of maintaining the temperature of the shrimp at or below minus 18℃ with minimal temperature fluctuations (+ or - 3℃) ;
- the storage area should be equipped with a calibrated indicating thermometer. Fitting of a recording thermometer is strongly recommended.
- a systematic stock rotation plan should be developed and maintained ;
- products should be properly protected from dehydration, dirt and other forms of contamination ;
- all end products should be stored in the freezer to allow proper air circulation.

## SECTION 15 - PROCESSING OF CEPHALOPODS

In the context of recognising controls at individual processing steps, this section provides examples of potential hazards and defects and describes technological guidelines, which can be used to develop control measures and corrective action. At a particular step only the hazards and defects, which are likely to be introduced or controlled at that step, are listed. It should be recognised that in preparing a HACCP and/or DAP plan it is essential to consult Section 5 which provides guidance for the application of the principles of HACCP and DAP analysis. However, within the scope of this Code of Practice it is not possible to give details of critical limits, monitoring, record keeping and verification for each of the steps since these are specific to particular hazards and defects.

This section applies to fresh and processed cephalopods including cuttlefish (Sepia and Sepiella), squid (Alloteuthis, Berryteuthis, Dosidicus, Ilex, Lolliguncula, Loligo, Loliolus, Nototodarus, Ommastrephes, Onychoteuthis, Rossia, Sepiola, Sepioteuthis, Symplectoteuthis and Todarodes) and octopuses (Octopus and Eledone) intended for human consumption.

Fresh Cephalopods are extremely perishable and should be handled at all times with great care and in such a way as to prevent contamination and inhibit the growth of micro-organisms. Cephalopods should not be exposed to direct sunlight or to the drying effects of winds, or any other harmful effects of the elements, but should be carefully cleaned and cooled down to the temperature of melting ice, 0℃ (32°F), as quickly as possible.

This section shows an example of a cephalopod process. Figure 15.1 lists the steps associated with receiving and processing fresh squid. It should be noted that there are a variety of processing operations for cephalopods and this process is being used for illustrative purposes only.

*This flow chart is for illustrative purposes only. For in-factory HACCP implementation a complete and comprehensive flow chart has to be drawn up for each process.*

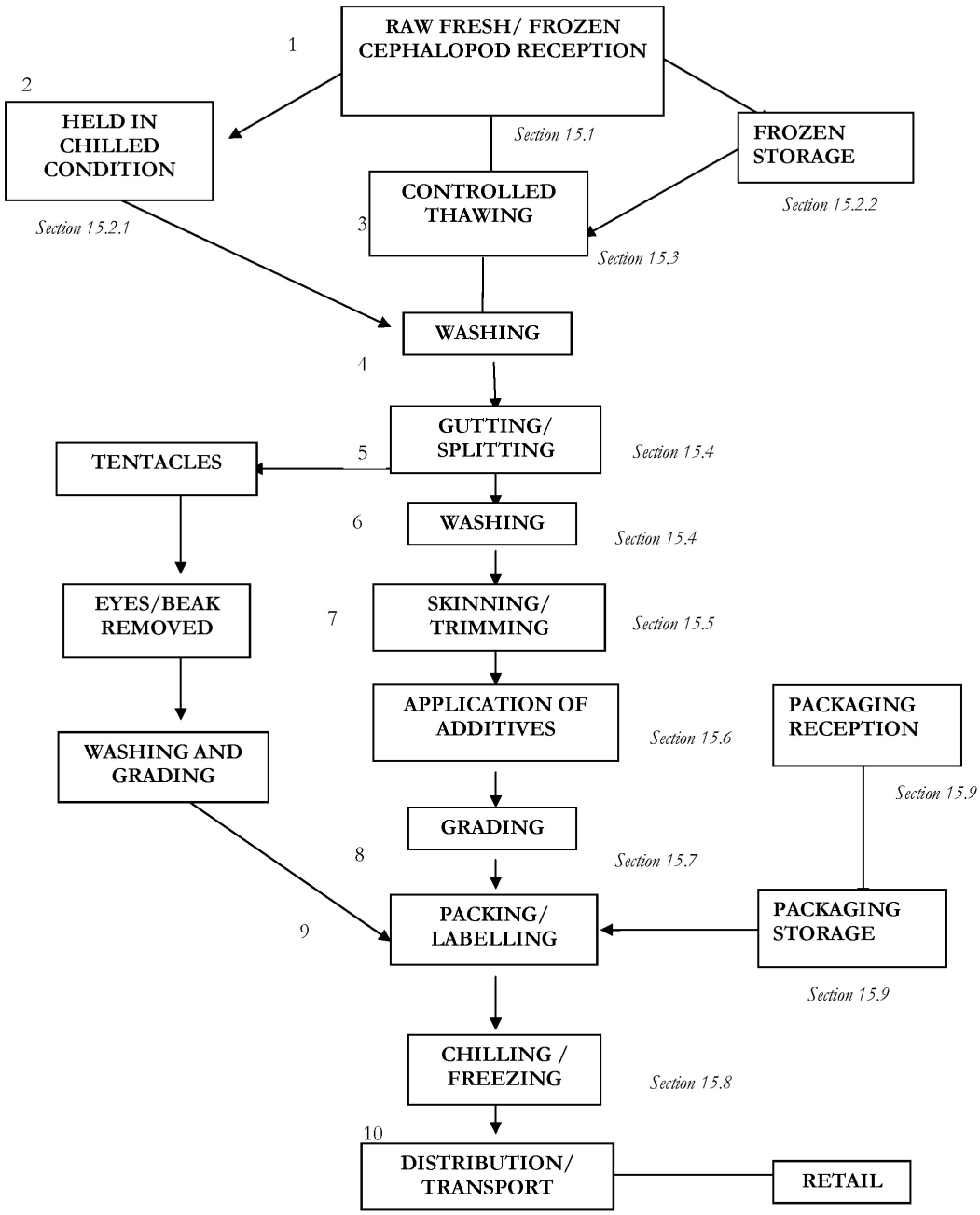


**Figure 15.1 Example of a possible squid processing line**

15.1 Reception of Cephalopods (Processing Step 1)

*Potential Hazards :* *Microbiological contamination, chemical contamination, parasites*

*Potential Defects :* *Damaged products, foreign matter*

*Technical Guidance :*

- The processing facility should have in place a programme for inspecting cephalopods on catching or arrival at the factory. Only sound product should be accepted for processing.
- Product specifications could include :

– organoleptic characteristics such as appearance, odour, texture etc. which can also used as indicators of fitness of consumption ;
– chemical indicators of decomposition and /or contamination e.g. TVBN, heavy metals (cadmium) ;
– microbiological criteria ;
– parasites e.g. *Anisakis* foreign matter ;
– the presence of lacerations, breakages and discolouration of the skin, or a yellowish tinge spreading from the liver and digestive organs inside the mantle, which are indicative of product deterioration.

- Personnel inspecting product should be trained and experienced with the relevant species in order to recognise any defects and potential hazards.

Further information can be found on Section 8 "Processing of Fresh, Frozen and Minced Fish" and Codex Guidelines for Sensory Evaluation of Fish and Shellfish in Laboratories.

15.2 Storage of Cephalopods

15.2.1 Chilled storage (Processing steps 2 and 10)

*Potential Hazards :* *Microbiological contamination*

*Potential Defects :* *Decomposition, physical damage*

*Technical Guidance :*

Refer to Section 8.1.2 "Chilled Storage"

15.2.2 Frozen Storage (Processing steps 2 & 10)

*Potential Hazards :* *Heavy metals e.g. cadmium migration from the gut.*

*Potential Defects :* *Freezer-burn*

*Technical Guidance :*

Refer to Section 8.1.3 "Frozen Storage".

- Consideration needs to be given to the fact that when there are high cadmium levels in the gut contents there may be migration of this heavy metal into the flesh.
- Products should be properly protected from dehydration by sufficient packaging or glaze.

15.3 Controlled Thawing (Processing step 3)

*Potential Hazards :* *Microbiological contamination*

*Potential Defects :* *Decomposition, discoloration*

*Technical Guidance :*

- The thawing parameters should be clearly defined and include time and temperature. This is important to prevent the development of pale pink discoloration.
- Critical limits for the thawing time and temperature of the product should be developed. Particular attention should be paid to the volume of product being thawed in order to control discoloration.

- If water is used as the thawing medium then it should be of potable quality
- If re-circulated water is used then care must be taken to avoid the build up of micro organisms.

For further guidance refer to Section 8.1.4 "Control Thawing".

15.4 Splitting, Gutting and Washing (Processing Steps 4, 5, 6, 11, 12 &13)

*Potential Hazards :* *Microbiological contamination*

*Potential Defects :* *Presence of gut contents, parasites, shells, ink discolouration, beaks, decomposition.*

*Technical Guidance :*

- Gutting should remove all intestinal material and the cephalopod shell and beaks if present.
- Any by-product of this process which is intended for human consumption e.g. tentacles, mantle should be handled in a timely and hygienic manner.
- Cephalopods should be washed in clean seawater or potable water immediately after gutting to remove any remaining material from the tube cavity and to reduce the level of micro-organisms present on the product.
- An adequate supply of clean seawater or potable water should be available for the washing of whole cephalopods and cephalopod products.

15.5 Skinning, Trimming (Processing Step 7)

*Potential Hazards :* *Microbiological contamination*

*Potential Defects :* *presence of objectionable matter, bite damage, skin damage, decomposition*

*Technical Guidance :*

- The method of skinning should not contaminate the product nor should it allow the growth of micro-organisms e.g. enzymatic skinning or hot water techniques should have defined time/temperature parameters to prevent the growth of micro-organisms.
- Care should be taken to prevent waste material from cross contaminating the product.
- An adequate supply of clean seawater or potable water should be available for the washing or product during and after skinning.

15.6 Application of Additives

*Potential Hazards :* *Physical contamination, non approved additives, non fish allergens*

*Potential Defects :* *Physical contamination, additives exceeding their regulatory limits*

*Technical Guidance :*

- Mixing and application of appropriate additives should be carried out by trained operators
- It is essential to monitor the process and product to ensure that regulatory standards are not exceeded and quality parameters are met
- Additives should comply with requirements of the Codex General Standard for Food Additives.

15.7 Grading/Packing/Labelling (Processing Steps 8 & 9)

Refer to Section 8.2.3 "Labelling".

*Potential Hazards :* *chemical or physical contamination from packaging*

*Potential Defects :* *incorrect labelling, incorrect weight, dehydration*

*Technical Guidance :*

- Packaging material should be clean, be suitable for it's intended purpose and manufactured from

food grade materials ;

- Grading and packing operations should be carried out with minimal delay to prevent deterioration of the cephalopod ;
- Where sulphites were used in the process, care should be taken that they are properly labelled.

15.8 Freezing (Processing Step 10)

*Potential Hazards :* *parasites*

*Potential Defects :* *freezer burn, decomposition, loss of quality due to slow freezing.*

*Technical Guidance :*

Cephalopods should be frozen as rapidly as possible to prevent deterioration of the product and a resulting reduction in shelf life due to microbial growth and chemical reactions.

- The time/temperature parameters developed should ensure rapid freezing of product and should take into consideration the type of freezing equipment, capacity, the size and shape of the product, and production volume. Production should be geared to the freezing capacity of the processing facility.
- If freezing is used as a control point for parasites, then the time/temperature parameters need to ensure that the parasites are no longer viable need to be established.
- The product temperature should be monitored regularly to ensure the completeness of the freezing operation as it relates to the core temperature.
- Adequate records should be kept for all freezing and frozen storage operations.

For further guidance refer to Section 8.3.1 "Freezing Process" and to Annex 1 on Parasites.

15.9 Packaging, Labels and Ingredients – Reception and Storage

Consideration should be given to the potential hazards and defects associated with packaging, labelling and ingredients. It is recommended that users of this code consult Section 8.5 "Packaging, Labels and Ingredients".

## SECTION 16 - PROCESSING OF CANNED FISH, SHELLFISH AND OTHER AQUATIC INVERTEBRATES

This section applies to fish, shellfish, cephalopods and other aquatic invertebrates.

In the context of recognising controls at individual processing steps, this section provides examples of potential hazards and defects and describes technological guidelines, which can be used to develop *control measures* and corrective action. At a particular step only the hazards and defects, which are likely to be introduced or controlled at that step, are listed. It should be recognised that in preparing a HACCP and/or DAP plan it is essential to consult Section 5 (Hazard Analysis Critical Control Point (HACCP) and Defect Action Point (DAP) Analysis) which provides guidance for the application of the principles of HACCP and DAP analysis. However, within the scope of this Code of Practice it is not possible to give details of critical limits, monitoring, record keeping and verification for each of the steps since these are specific to particular hazards and defects.

This section concerns the processing of heat processed sterilised canned fish and shellfish products which have been packed in hermetically sealed containers[10] and intended for human consumption.

As stressed by this Code, the application of appropriate elements of the pre-requisite programme (Section 3) and HACCP principles (Section 5) at these steps will provide the processor with reasonable assurance that the essential quality, composition and labelling provisions of the appropriate Codex standard will be maintained and food safety issues controlled. The example of

10 Aseptic filling is not covered by this Code. Reference of the relevant code is made in Appendix Xii.

the flow diagram (Figure 16.1) will provide guidance to some of the common steps involved in a canned fish or shellfish preparation line.

*This flow chart is for illustrative purpose only. For in-factory implementation of HACCP principles, a complete and comprehensive flow chart has to be drawn up for each product.*

*References correspond to relevant Sections of the Code.*

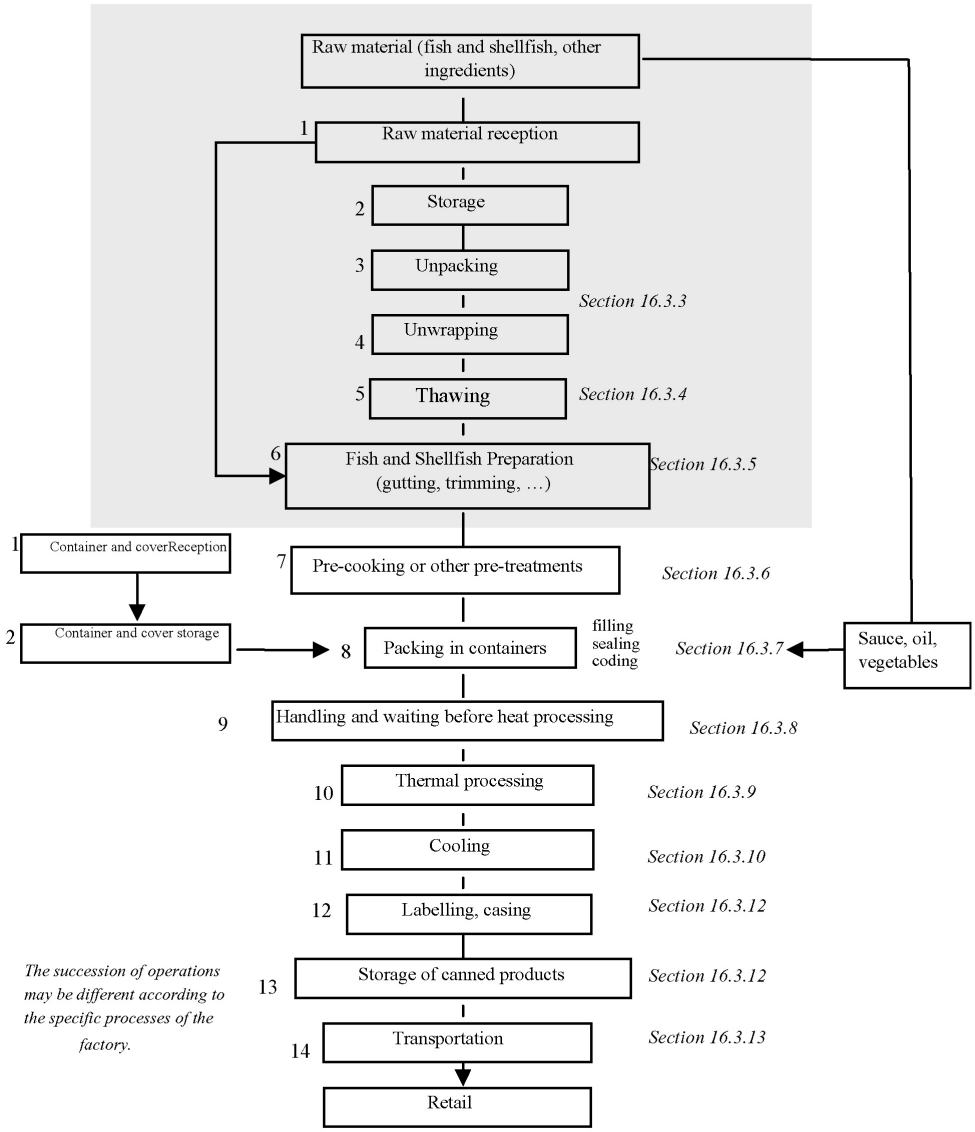


**Figure 16.1 Example of a flow chart for the processing of canned fish and shellfish**

## 16.1 GENERAL - ADDITION TO PRE-REQUISITE PROGRAMME

Section 3 (Pre-requisite programme) gives the minimum requirements for good hygienic practices for a processing facility prior to the application of hazard and defect analyses.

For fish and shellfish canneries, additional requirements to the guidelines described in Section 3 are necessary due to the specific technology involved. Some of them are listed below, but reference should also be made to the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Food (CAC/RCP 23-1979) for further information.

- design, working and maintenance of baskets and handling and loading devices aimed at retorting should be appropriate for the kind of containers and materials used. These devices should prevent any excessive abuse to the containers.
- an adequate number of efficient sealing machines should be available to avoid undue delay in processing ;
- retorts should have a suitable supply of energy, vapour, water and/or air so as to maintain in it sufficient pressure during the heat treatment of sterilisation; their dimensions should be adapted to the production to avoid undue delays ;
- every retort should be equipped with an indicating thermometer, a pressure gauge and a time and temperature recorder ;
- an accurate clearly visible clock should be installed in the retorting room ;
- canneries using steam retorts should consider installing automatic steam controller valves ;
- Instruments used to control and to monitor in particular the thermal process should be kept in good condition and should be regularly verified or calibrated. Calibration of instruments used to measure temperature should be made in comparison with a reference thermometer. This thermometer should be regularly calibrated. Records concerning the calibration of instruments should be established and kept.

## 16.2 IDENTIFICATION OF HAZARDS AND DEFECTS

Refer also to Section 4.1 (Potential Hazards Associated with Fresh Fish and Shellfish).

This section describes the main potential hazards and defects specific to canned fish and shellfish.

### 16.2.1 Hazards

#### A Biological Hazards

#### A1 Naturally occurring marine toxins

Biotoxins such as tetrodotoxins or ciguatoxins are known to be generally heat-stable, so the knowledge of the identity of the species and/or the origin of fish intended for processing is important.

Phycotoxins such as DSP, PSP or ASP are also heat stable, so it important to know the origin and the status of the area of origin of molluscan shellfish or other affected species intended for processing.

#### A2 Scombrotoxins

Histamine

Histamine is heat-stable, and so its toxicity remains practically intact in containers. Good practices for the conservation and handling from capture to heat processing are essential to prevent the histamine production. The Codex Commission adopted in its standards for some fish species maximum levels tolerated for histamine.

#### A3 Microbiological toxins

Clostridium botulinum

The botulism risk usually appears after an inadequate heat processing and inadequate container

integrity. The toxin is heat-sensitive, on the other hand, the destruction of *Clostridium botulinum* spores, in particular from proteolytic strains, requires high sterilisation values. The heat processing effectiveness depends on the contamination level at the time of the treatment. Therefore, it is advisable to limit proliferation and the contamination risks during processing. A higher risk of botulinum could result from any of the following : inadequate heat processing, inadequate container integrity, unsanitary post process cooling water and unsanitary wet conveying equipment.

Staphylococcus aureus

Toxins from *Staphylococcus aureus* can be present in a highly contaminated raw material or can be produced by bacterial proliferation during processing. After canning, there is also the potential risk of post process contamination with *Staphylococcus aureus* if the warm wet containers are handled in an unsanitary manner. These toxins are heat-resistant, so they have to be taken into account in the hazard analysis.

B Chemical Hazards

Care should be taken to avoid contamination of the product from components of the containers (e.g. lead) and chemical products (lubricants, sanitizers, detergents).

C Physical Hazards

Containers prior to filling may contain materials such as metal or glass fragments.

16.2.2 Defects

Potential defects are outlined in the essential quality, labelling and composition requirements described in the relevant Codex Standards listed in Appendix X ii . Where no Codex Standard exists regard should be made to national regulations and/or commercial specifications.

End product specifications outlined in Appendix IX describe optional requirements specific to canned products.

16.3 PROCESSING OPERATIONS

Processors can also refer to the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (CAC/RCP 23-1979) in order to obtain detailed advice on canning operations.

16.3.1 Reception of raw material, containers, covers and packaging material and other ingredients

16.3.1.1 Fish and shellfish (Processing step 1)

*Potential Hazards :* *Chemical and biochemical contamination (DSP, PSP, scombrotoxin, heavy metals...)*

*Potential Defects :* *Species substitution, decomposition, parasites*

*Technical Guidance :*

Refer to section 8.1.1 (Raw Fresh or Frozen Fish Reception) and to other relevant sections ; and also :

- When live shellfish (crustaceans) are received for canning processing, inspection should be carried out in order to discard dead or badly damaged animals.

16.3.1.2 Container, cover and packaging materials (Processing step 1)

*Potential Hazards :* *Subsequent microbiological contamination*

*Potential Defects :* *Tainting of the product*

*Technical*

*Guidance :*

Refer to section 8.5.1 (Raw Material Reception –- Packaging, Labels & Ingredients) ; and also :

- Containers, cover and packaging materials should be suitable for the type of product, the conditions

provided for storage, the filling, sealing and packaging equipment and the transportation conditions ;

- the containers in which fish and shellfish products are canned should be made from suitable material and constructed so that they can be easily closed and sealed to prevent the entry of any contaminating substance ;
- containers and cover for canned fish and shellfish should meet the following requirements :

– they should protect the contents from contamination by micro-organisms or any other substance ;
– their inner surfaces should not react with the contents in any way that would adversely affect the product or the containers ;
– their outer surfaces should be resistant to corrosion under any likely conditions of storage ;
– they should be sufficiently durable to withstand the mechanical and thermal stresses encountered during the canning process and to resist physical damage during distribution ;

16.3.1.3 Other ingredients (Processing step 1)

Refer to section 8.5.1 (Raw Material Reception – Packaging, Labels & Ingredients).

### 16.3.2 Storage of raw material, containers, covers and packaging materials

16.3.2.1 Fish and shellfish (Processing step 2)

Refer to sections 8.1.2 (Chilled storage), 8.1.3 (Frozen storage and 7.6.2 Conditioning and storage of molluscan shellfish in sea water tanks, basins, etc.)

16.3.2.2 Containers and packaging (Processing step 2)

*Potential Hazards :* *Unlikely*

*Potential Defects :* *Foreign matters*

*Technical Guidance :*

Refer to section 8.5.2 (Raw Material Storage - Packaging, Labels & Ingredients) ; and also :

- all materials for containers or packages should be stored in satisfactory clean and hygienic conditions ;
- during storage, empty containers and covers should be protected from dirt, moisture and temperature fluctuations, in order to avoid condensations on containers and in the case of tin cans, the development of corrosion ;
- during loading, stowing, transportation and unloading of empty containers, any shock should be avoided. Containers shouldn't be stepped on. These precautions become more imperative when containers are put in bags or on pallets. Shocks can deform the containers (can body or flange), that can compromise tightness (shocks on the seam, deformed flange) or be prejudicial to appearance.

16.3.2.3 Other ingredients (Processing step 2)

Refer to section 8.5.2 (Raw Material Storage - Packaging, Labels & Ingredients).

### 16.3.3 Unwrapping, unpacking (Processing steps 3 and 4)

*Potential Hazards :* *Unlikely*

*Potential Defects :* *Foreign matter*

*Technical Guidance :*

- During unwrapping and unpacking operations, precautions should be taken in order to limit product contamination and foreign matters introduction into the product. To avoid microbial proliferation, waiting periods before further processing should be minimised.

### 16.3.4 Thawing (Processing step 5)

Refer to section 8.1.4 (Control Thawing)

16.3.5 Fish and shellfish preparatory processes (Processing step 6)

16.3.5.1 Fish preparation (gutting, trimming...)

*Potential Hazards :* *Microbiological contamination biochemical development (histamine)*

*Potential Defects :* *Objectionable matters (viscera, skin, scales, ... in certain products), off flavours, presence of bones, parasites...*

*Technical Guidance :*

Refer to sections 8.1.5 (Washing and Gutting) and 8.1.6 (Filleting, Skinning, Trimming and Candling) ; and also :

- when skinning of fish is operated by soaking in soda solution, a particular care should be taken to carry out an appropriate neutralisation.

16.3.5.2 Preparation of molluscs and crustaceans

*Potential Hazards :* *Microbiological contamination, hard shell fragments*

*Potential Defects :* *Objectionable matters*

*Technical Guidance :*

Refer to sections 7.7 (Heat Treatment/Heat Shocking of Molluscan Shellfish in Establishment ; and also :

- when live shellfish are used, inspection should be carried out in order to discard dead or badly damaged animals ;
- particular care should be taken to ensure that shell fragments are removed from shellfish meat.

16.4 PRE-COOKING AND OTHER TREATMENTS

16.4.1 Pre-Cooking

*Potential hazards :* *chemical contamination (polar components of oxidised oils), microbiological or biochemical (scombrotoxin) growth.*

*Potential defects :* *water release in the final product (for products canned in oil), abnormal flavours.*

*Technical guidance :*

16.4.1.1 General Considerations

- methods used to pre-cook fish or shellfish for canning should be designed to bring about the desired effect with a minimum delay and a minimum amount of handling ; the choice of method is usually strongly influenced by the nature of the treated material. For products canned in oil such as sardines or tunas, pre-cooking should be sufficient in order to avoid excessive release of water during heat processing ;
- means should be found to reduce the amount of handling subsequent to pre-cooking, wherever practical ;
- if eviscerated fish is used, then the fish should be arranged in the belly down position for precooking to allow for the drainage of fish oils and juices which may accumulate and affect product quality during the heating process ;
- where appropriate, molluscan shellfish, lobsters and crabs, shrimps and prawns and cephalopods should be pre-cooked according to technical guidance laid down in sections 7 (Processing of Live and Raw Bivalve Molluscs), 13 (Processing of Lobsters and Crabs), 14 (Processing of Shrimps and Prawns) and 15 (Processing of Cephalopods) ;
- care should be taken to prevent temperature abuse of scombrotoxic species before pre-cooking.

16.4.1.1.2 Pre-cooking Schedule

- the pre-cooking method, in particular, in terms of time and temperature, should be clearly defined. The pre-cooking schedule should be checked ;
- fish pre-cooked together in batches should be very similar in size. It also follows that they should all be at the same temperature when they enter the cooker.

16.4.1.1.3 Control of Quality of Pre-cooking Oils and Other Fluids

- only good quality vegetable oils should be used in pre-cooking fish or shellfish for canning (see Codex Standard for Named Vegetable Oils (CODEX STAN 210-1999), Codex Standard for Olive Oils and Olive Pomace Oils (CODEX STAN 33-1981) and Codex Standard for Fats and Oils not Covered by Individual Standards CODEX STAN 19-1981) ;
- cooking oils should be changed frequently in order to avoid the formation of polar compounds. Water used for pre-cooking should also be changed frequently in order to avoid contaminants ;
- care must be taken that the oil or the other fluids used such as vapour or water do not impart an undesirable flavour to the product.

16.4.1.1.4 Cooling

- except for products, which are packed when still hot, cooling of pre-cooked fish or shellfish should be done as quickly as possible to bring the product temperatures in a range limiting proliferation or toxin production, and under conditions where contamination of the product can be avoided ;
- where water is used to cool crustacea for immediate shucking, it should be potable water or clean seawater. The same water should not be used for cooling more than one batch.

16.4.1.2 Smoking

- refer to section 12 (Processing of smoked fish)

16.4.1.3 Use of Brine and Other Dips

*Potential hazards :* *microbiological and chemical contamination by the dip solution*

*Potential defects :* *adulteration (additives), abnormal flavours.*

*Technical guidance :*

- Where fish or shellfish are dipped or soaked in brine or in solutions of other conditioning or flavouring agents or additives in preparation for canning, solution strength and time of immersion should both be carefully controlled to bring about the optimum effect ;
- dip solutions should be replaced and dip tanks and other dipping apparatus should be thoroughly cleaned at frequent intervals ;
- care should be taken to ascertain whether or not the ingredients or additives used in dips would be permitted in canned fish and shellfish by the related Codex Standards and in the countries where the product will be marketed.

16.4.2 Packing in Containers (Filling, Sealing and Coding) (Processing Step 8)

16.4.2.1 Filling

*Potential hazards :* *microbiological growth (waiting period), microbiological survival growth and recontamination after heat processing due to incorrect filling or faulty containers, foreign material.*

*Potential defects :* *incorrect weight, foreign matter.*

*Technical guidance*

- a representative number of containers and covers should be inspected immediately before delivery

to the filling machines or packing tables to ensure that they are clean, undamaged and without visible flaws ;

- if necessary, empty containers should be cleaned. It is also a wise precaution to have all containers turned upside down to make certain that they do not contain any foreign material before they are used ;
- care should also be taken to remove faulty containers, because they can jam a filling or sealing machine, or cause trouble during heat processing (bad sterilisation, leaks) ;
- empty containers should not be left on the packing tables or in conveyor systems during clean up of premises to avoid contamination or splashes ;
- where appropriate, to prevent microbial proliferation, containers should be filled with hot fish and shellfish (〉63℃, for example for fish soups) or should be filled quickly (the shortest possible waiting period) after the end of the pre-treatments ;
- if the fish and shellfish must be held for a long time before packing into containers, they should be chilled ;
- containers of canned fish and shellfish should be filled as directed in the scheduled process ;
- mechanical or manual filling of containers should be checked in order to comply with the filling rate and the headspace specified in the adopted sterilisation schedule. A regular filling is important not only for economical reasons, but also because the heat penetration and the container integrity can be affected by excessive filling changes ;
- the necessary amount of headspace will depend partly on the nature of the contents. The filling should also take into account the heat processing method. Headspace should be allowed as specified by the container manufacturer ;
- furthermore, containers should be filled such as the end product meets the regulatory provisions or the accepted standards concerning weight of contents ;
- where canned fish and shellfish is packed by hand, there should be a steady supply of fish, shellfish and eventually other ingredients. Build-up of fish and shellfish, as well as filled containers at the packing table should be avoided ;
- the operation, maintenance, regular inspection, calibration and adjustment of filling machines should received particular care. The machine manufacturers' instructions should be carefully followed ;
- the quality and the amount of other ingredients such as oil, sauce, vinegar…should be carefully controlled to bring about the optimum desired effect ;
- if fish has been brine-frozen or stored in refrigerated brine, the amount of salt absorbed should be taken into consideration when salt is added to the product for flavouring ;
- filled containers should be inspected :

– to ensure that they have been properly filled and will meet accepted standards for weight of contents

– and to verify product quality and workmanship just before they are closed ;

- manual filled products such as small pelagic fish should be carefully checked by the operators to verify that container flanges or closure surface have not any product residues, which could impede the formation of a hermetic seal. For automatic filled products, a sampling plan should be implemented.

16.4.2.2 Sealing

Sealing the container and covers are one of the most essential processes in canning.

*Potential hazards :* *subsequent contamination due to a bad seam*

*Potential defects :* *unlikely*

*Technical guidance*

- the operation, maintenance, regular inspection and adjustment of sealing machines should received particular care. The sealing machines should be adapted and adjusted for each type of container and each closing method which are used. Whatever the type of sealing equipment, the manufacturers or equipment supplier's instructions should be followed meticulously ;
- seams and other closures should be well formed with dimensions within the accepted tolerances for the particular container ;
- qualified personnel should conduct this operation ;
- if vacuum is used during packing, it should be sufficient to prevent the containers from bulging under any condition (high temperature or low atmospheric pressure) likely to be encountered during the distribution of the product. This is useful for deep containers or glass containers. It is difficult and hardly necessary to create a vacuum in shallow containers that have relatively large flexible covers ;
- excessive vacuum may cause the container to panel, particularly if the headspace is large, and may also cause contaminants to be sucked into the container if there is a slight imperfection in the seam ;
- to find the best methods to create vacuum, competent technologists should be consulted ;
- regular inspections should be made during production to detect potential external defects on containers. At intervals sufficiently close to each other in order to guarantee a closure in accordance with specifications, the operator, the supervisor of the closure or any other competent person should examine the seams or the closure system for the other types of containers, which are used. Inspections should consider for example vacuum measurements and seam teardown. A sampling plan should be used for the checks ;
- in particular, at each start of the production line and at each change in container dimensions, after a jamming, a new adjustment or a restarting after a prolonged stop of the sealing machine, a check should be carried out ;
- all appropriate observations should be recorded.

16.4.2.3 Coding

*Potential hazards :* *subsequent contamination due to damaged containers*

*Potential defects :* *loss of traceability due to an incorrect coding.*

*Technical guidance*

- each container of canned fish and shellfish should bear indelible code markings from which allimportant details concerning its manufacture (type of product, cannery where the canned fish or shellfish was produced, production date, etc.) can be determined
- coding equipment must be carefully adjusted so that the containers are not damaged and the code remains legible ;
- coding may sometimes be carried out after the cooling step.

16.4.3 Handling of Containers After Closure - Staging Before Heat Processing (Processing Step 9)

*Potential hazards :* *microbiological growth (waiting period), subsequent contamination due to damaged containers.*

*Potential defects :* *Unlikely*

*Technical guidance*

- containers after closure should always be handled carefully in such a way as to prevent every damage capable to cause defects and microbiological recontamination ;

- if necessary, filled and sealed metal containers should be thoroughly washed before heat processing to remove grease, dirt and fish or shellfish stains on their outside walls ;
- to avoid microbial proliferation, the waiting period should be as short as possible ;
- if the filled and sealed containers must be held for a long time before heat processing, the product should be held at temperature conditions which minimise microbial growth ;
- every cannery should develop a system, which will prevent non heat-processed canned fish and shellfish from being accidentally taken past the retorts into the storage area.

16.4.4 Thermal Processing (Processing Step 10)

Heat processing is one of the most essential operations in canning.

Canners can refer to the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (CAC/RCP 23-1979) in order to obtain detailed advice on heat processing. In this Section, only some essential elements are pointed out.

*Potential hazards :* *survival of spores of Clostridium botulinum.*

*Potential defects :* *survival of micro-organisms responsible of decomposition*

*Technical guidance*

16.4.4.1 Sterilisation Schedule

- to determine the sterilisation schedule, at first, the heat process required to obtain the commercial sterility should be established taking into account some factors (microbial flora, dimensions and nature of the container, product formulation, etc.). A sterilisation schedule is established for a certain product in a container of a given size.
- Proper heat generation and temperature distribution should be carried out. Standard heat processing procedures and experimentally established sterilisation schedules should be checked and validated by an expert to confirm that the values are appropriate for each product and retort.
- before any changes in operations (initial temperature of filling, product composition, size of containers, fullness of the retort, etc.) are made, competent technologists should be consulted as to the need for re-evaluation of the process.

16.4.4.2 Heat Processing Operation

- only qualified and properly trained personnel should operate retorts. Therefore it is necessary that retort operators control the processing operations and ensure the sterilisation schedule is closely followed, including meticulous care in timing, monitoring temperatures and pressures, and in maintaining records ;
- it is essential to comply with the initial temperature described in the schedule process to avoid under-processing. If the filled containers were held at refrigerated temperatures because of a too long waiting period before heat processing, the sterilisation schedule should take into account these temperatures ;
- in order that the heat processing is effective and process temperature is controlled, air must be evacuated from the retort through a venting procedure that is deemed efficient by a competent technologist. Container size and type, retort installation and loading equipment and procedures should be considered ;
- the timing of the heat processing should not commence until the specified heat processing temperature has been reached, and the conditions to maintain uniform temperature throughout the retort achieved, in particular, until the minimum safe venting time has elapsed ;
- for other types of retorts (water, steam/air, flame, etc.) refer to the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (CAC/RCP 23-1979) ;
- if canned fish and shellfish in different size containers are processed together in the same retort

load care must be taken to ensure the process schedule used is sufficient to provide commercial sterility for all container sizes processed;

- when processing fish and shellfish in glass containers, care must be taken to ensure that the initial temperature of the water in the retort is slightly lower than that of the product being loaded. The air pressure should be applied before the water temperature is raised.

16.4.4.3 Monitoring of Heat Processing Operation

- during the application of heat processing, it is important to ensure that the sterilisation process and factors such as container filling, minimal internal depression at closing, retort loading, initial product temperature, etc. are in accordance with the sterilisation schedule;
- retort temperatures should always be determined from the indicating thermometer, never from the temperature recorder;
- permanent records of the time, temperature and other pertinent details should be kept concerning each retort load;
- the thermometers should be tested regularly to ensure that they are accurate. Calibration records should be maintained; the recording thermometer readings should never exceed the indicating thermometer reading;
- inspections should be made periodically to ensure that retorts are equipped and operated in a manner that will provide thorough and efficient heat processing, that each retort is properly equipped, filled and used, so that the whole load is brought up to processing temperature quickly and can be maintained at that temperature throughout the whole of the processing period;
- the inspections should be made under the guidance of a competent technologist.

16.4.5 Cooling (Processing Step 11)

*Potential hazards:* *recontamination due to a bad seam and contaminated water*

*Potential defects:* *formation of struvite crystals, buckled containers, scorch.*

*Technical guidance:*

- after heat processing, canned fish and shellfish should, wherever practical, be water cooled under pressure to prevent deformations, which could result in a loss of tightness. In case of recycling, potable water should always be chlorinated (or other appropriate treatments used) for this purpose. The residual chlorine level in cooling water and the contact time during cooling should be checked in order to minimise the risk of post-processing contamination. The efficiency of the treatment other than chlorination should be monitored and verified;
- in order to avoid organoleptic defects of the canned fish and shellfish, such as scorch or overcooking, the internal temperature of containers should be lowered as quickly as possible;
- for glass containers, the temperature of the coolant in the retort should be, at the beginning, lowered slowly in order to reduce the risks of breaking due to thermal shock;
- where canned fish and shellfish products are not cooled in water after heat processing, they should be stacked in such a way that they will cool rapidly in air;
- heat processed canned fish and shellfish should not be touched by hand or articles of clothing unnecessarily before they are cooled and thoroughly dry. They should never be handled roughly or in such a way that their surfaces, and in particular their seams, are exposed to contamination;
- rapid cooling of canned fish and shellfish avoids the formation of struvite crystals;
- every cannery should develop a system to prevent unprocessed containers being mixed with processed containers.

16.4.5.1 Monitoring After Heat Processing and Cooling

- canned fish and shellfish should be inspected for faults and for quality assessment soon

after it is produced and before labelling ;

- representative samples from each code lot should be examined to ensure that the containers do not exhibit external defects and the product meets the standards for weight of contents, vacuum, workmanship and wholesomeness. Texture, colour, odour, flavour and condition of the packing medium should be assessed.
- if desired, stability tests could be made in order to verify in particular the heat processing ;
- this examination should be made as soon as practical after the canned fish and shellfish have been produced, so that if there are any faults due to failings on the part of cannery workers or canning equipment, these failings can be corrected without delay. Segregating and properly disposing of all defective units or lots that are unfit for human consumption should be ensured.

16.4.6 Labelling, Casing and Storage of Finished Products (Processing steps 12 and 13)

Refer to Section 8.2.3 "Labelling"

*Potential hazards :* *subsequent recontamination due to the damage of containers or to an exposition to extreme conditions*

*Potential defects :* *incorrect labelling*

*Technical guidance*

- the materials used for labelling and casing canned fish and shellfish should not be conducive to corrosion of the container. Cases should have an adequate size in order that the containers fit them and are not damaged by any move inside. Cases and boxes should be the correct size and strong enough to protect the canned fish and shellfish during distribution.
- code marks appearing on containers of canned fish and shellfish should also be shown on the cases in which they are packed ;
- storage of canned fish and shellfish should be made in order not to damage the containers. In particular, pallets of finished products should not be stacked excessively high and the forklift trucks used for the storage should be used in a proper manner ;
- canned fish and shellfish should be so stored that they will be kept dry and not exposed to extremes of temperature.

16.4.7 Transportation of Finished Products (Processing step 14)

*Potential hazards :* *subsequent recontamination due to the damage of containers or to an exposition to extreme conditions*

*Potential defects :* *Unlikely*

*Technical guidance*

Refer to section 17 (Transportation) ; and also :

- transportation of canned fish and shellfish should be made in order not to damage the containers. In particular, the forklift trucks used during the loading and unloading should be used in a proper manner.
- cases and boxes should be completely dry. In fact, moisture has effects on the mechanical characteristics of boxes and the protection of containers against damages during transportation couldn't be sufficient.
- metal containers should be kept dry during transportation in order to avoid corroding and/or rust.

## SECTION 17 - TRANSPORT

Refer to the Recommended International Code of Practice-General Principles of Food Hygiene, Section Viii - Transportation, CAC/RCP 1-1969 and the Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packaged Food (CAC/RCP 47-2001).

Transportation applies to all sections and is a step of the flow diagram which needs specific skills. It should be considered with the same care as the other processing steps. This section provides examples of potential hazards and defects and describes technological guidelines, which can be used to develop control measures and corrective action. At a particular step only the hazards and defects, which are likely to be introduced or controlled at that step, are listed. It should be recognised that in preparing a HACCP and/or DAP plan it is essential to consult Section 5 which provides guidance for the application of the principles of HACCP and DAP analysis. However, within the scope of this Code of Practice it is not possible to give details of critical limits, monitoring, record keeping and verification for each of the steps since these are specific to particular hazards and defects.

It is particularly important throughout the transportation of fresh, frozen or refrigerated fish, shellfish and their products that care is taken to minimise any rise in temperature of the product and that the chill or frozen temperature, as appropriate, is maintained under controlled conditions. Moreover, appropriate measures should be applied to minimize damage to products and also their packaging.

### 17.1 For fresh, refrigerated and frozen products

Refer to 3.6 Transportation.

*Potential Hazards :* *Biochemical development (histamine). Microbial growth and contamination*

*Potential Defects :* *Decomposition, physical damage. Chemical contamination (fuel).*

*Technical Guidance :*

- check temperature of product before loading ;
- avoid unnecessary exposure to elevated temperatures during loading and unloading of fish, shellfish and their products ;
- load in order to ensure a good air flow between product and wall, floor and roof panels ; load stabilizer devices are recommended ;
- monitor air temperatures inside the cargo hold during transportation ; the use of a recording thermometer is recommended ;
- during transportation

  - frozen products should be maintained at -18℃ or below (maximum fluctuation +3℃) ;
  - fresh fish, shellfish and their products should be kept at a temperature as close as possible to 0℃. Fresh whole fish should be kept in shallow layers and surrounded by finely divided melting ice ; adequate drainage should be provided in order to ensure that water from melted ice does not stay in contact with the products or melted water from one container does not cross contaminate products in other containers ;
  - transportation of fresh fish in containers with dry freezer bags and not ice should be considered where appropriate ;
  - transportation of fish in an ice slurry, chilled sea water or refrigerated sea water (e.g. pelagic fish) should be considered where appropriate. Chilled sea water or refrigerated sea water should be used under approved conditions ;
  - refrigerated processed products should be maintained at the temperature specified by the processor but generally should not exceed 4℃ ;
  - provide fish, shellfish and their products with adequate protection against contamination from dust, exposure to higher temperatures and the drying effects of the sun or wind.

17.2 For live fish and shellfish

- refer to the specific provisions laid down in the relevant sections of the Code.

17.3 For canned fish and shellfish

- refer to the specific provisions laid down in section 16.

17.4 For all products

- before loading, the cleanliness, suitability and sanitation of the cargo hold of the vehicles should be verified ;
- loading and transportation should be made in order to avoid damage and contamination of the products and to ensure the packaging integrity ;
- after unloading, the accumulation of waste should be avoided and should be disposed of in a proper manner.

**SECTION 18 - RETAIL**

In the context of recognising controls at individual processing steps, this section provides examples of potential hazards and defects and describes technological guidelines, which can be used to develop control measures and corrective action. At a particular step only the hazards and defects, which are likely to be introduced or controlled at that step, are listed. It should be recognised that in preparing a HACCP and/or DAP plan it is essential to consult Section 5 which provides guidance for the application of the principles of HACCP and DAP analysis. However, within the scope of this Code of Practice it is not possible to give details of critical limits, monitoring, record keeping and verification for each of the steps since these are specific to particular hazards and defects.

Fish, shellfish and their products at retail should be received, handled, stored and displayed to consumers in a manner that minimizes potential food safety hazards and defects and maintains essential quality. Consistent with the HACCP and DAP approaches to food safety and quality, products should be purchased from known or approved sources under the control of competent health authorities that can verify HACCP controls. Retail operators should develop and use written purchase specifications designed to ensure food safety and desired quality levels. Retail operators should be responsible to maintain quality and safety of products.

Proper storage temperature after receipt is critical to maintain product safety and essential quality. Chilled products should be stored in a hygienic manner at temperatures less than or equal to 4℃ (40°F), MAP products at 3℃ (38°F) or lower, while frozen products should be stored at temperatures less than or equal to -18℃ (0°F).

Preparation and packaging should be carried out in a manner consistent with the principles and recommendations found in Section 3, Prerequisite Programmes and Codex Labelling Standards. Product in an open full display should be protected from the environment such as use of display covers (sneeze guards).

At all times, displayed seafood items should be held at temperatures and conditions that minimize the development of potential bacterial growth, toxins and other hazards in addition to loss of essential quality.

Consumer information at the point of purchase, for example placards or brochures, that inform consumers about storage, preparation procedures and potential risks of seafood products if mishandled or improperly prepared, is important to ensure that product safety and quality is maintained.

A system of tracking the origin and codes of fish, shellfish and their products should be established to facilitate product recall or public health investigations in the event of the failure of preventive health protection processes and measures. These systems exist for molluscan shellfish in some

countries in the form of molluscan shellfish tagging requirements.

## 18.1 Reception of Fish, Shellfish and their Products at Retail – General Considerations

*Potential Hazards :* *see Reception 7.1, 8.1*

*Potential Defects :* *see Reception 7.1, 8.1*

*Technical Guidance :*

- The transport vehicle should be examined for overall hygienic condition. Products subject to filth, taint or contamination should be rejected.
- The transport vehicle should be examined for possible cross contamination of ready to eat fish and fishery products by raw fish and fishery products. Determine that cooked-ready-to-eat product has not been exposed to raw product or juices or live molluscan shellfish and that raw molluscan shellfish have not been exposed to other raw fish or shellfish.
- Seafood should be regularly examined for adherence to purchasing specifications.
- All products should be examined for decomposition and spoilage at receipt. Products exhibiting signs of decomposition should be refused
- When a log of the cargo hold temperature for the transport vehicle is kept, records should be examined to verify adherence to temperature requirements.

### 18.1.1 Reception of Chilled Products at Retail

*Potential Hazards :* *Pathogen growth, microbiological contamination, chemical and physical contamination, Scombrotoxin formation, C. botulinum toxin formation*

*Potential Defects :* *Spoilage (decomposition), Contaminants, Filth*

*Technical Guidance :*

- Product temperature should be taken from several locations in the shipment and recorded. Chilled fish, shellfish and their products should be maintained at or below 4℃ (40°F). MAP product, if not frozen, should be maintained at or below 3℃ (38°F).

### 18.1.2 Reception of Frozen Products at Retail

*Potential Hazards :* *Unlikely*

*Potential Defects :* *Thawing, Contaminants, Filth*

*Technical Guidance :*

- Incoming frozen seafood should be examined for signs of thawing and evidence of filth or contamination. Suspect shipments should be refused.
- Incoming frozen seafood should be checked for internal temperatures, taken and recorded from several locations in the shipment. Frozen fish, shellfish and their products should be maintained at or below -18℃ (0°F).

### 18.1.3 Chilled Storage of Products at Retail

*Potential Hazards :* *Scombrotoxin formation, microbiological contamination, pathogen growth, chemical contamination, C. botulinum toxin formation*

*Potential Defects :* *Decomposition, Contaminants, Filth*

*Technical Guidance :*

- Products in chilled storage should be held at 4℃ (40°F). MAP product should be held at 3℃ (3 8°F) or below.
- Seafood should be properly protected from filth and other contaminants through proper packaging and stored off the floor.

- A continuous temperature recording chart for seafood storage coolers is recommended.
- The cooler room should have proper drainage to prevent product contamination.
- Ready-to-eat items and molluscan shellfish should be kept separate from each other and other raw food products in chilled storage. Raw product should be stored on shelves below cooked product to avoid cross contamination from drip.
- A proper product rotation system should be established. This system could be based on first in, first out usage, production date or best before date on labels, sensory quality of the lot, etc, as appropriate.

### 18.1.4 Frozen Storage of Products at Retail

*Potential Hazards :* *Unlikely*

*Potential Defects :* *Chemical decomposition (rancidity), Dehydration*

*Technical Guidance :*

- Product should be maintained at -18℃ (0°F) or less. Regular temperature monitoring should be carried out. A recording thermometer is recommended.
- Seafood products should not be stored directly on the floor. Product should be stacked to allow proper air circulation.

### 18.1.5 Preparation and Packaging Chilled Product at Retail

Refer to Section 8.2.3, "abelling"

*Potential Hazards :* *Microbiological contamination, Scombrotoxin formation, pathogen growth, physical and chemical contamination, allergens*

*Potential Defects :* *Decomposition, Incorrect Labelling*

*Technical Guidance :*

- Care should be taken to ensure that handling and packaging product is conducted in accordance to guidelines in Section 3, Pre-requisite Programmes.
- Care should be taken to ensure that labelling is in accordance to guidelines in Section 3, Prerequisite Programmes and Codex Labelling Standards especially for known allergens.
- Care should be taken to ensure that product is not subjected to temperature abuse during packaging and handling.
- Care should be taken to avoid cross contamination of ready-to-eat and raw shellfish, shellfish and their products at the work areas or by utensils or personnel.

### 18.1.6 Preparation and Packaging of Frozen Seafood at Retail

Refer to Section 8.2.3, "abelling"

*Potential Hazards :* *Microbiological contamination, chemical or physical contamination, allergens*

*Potential Defects :* *Thawing, Incorrect Labelling*

*Technical Guidance :*

- are should be taken to ensure that allergens are identified, in accordance to Section 3, Prerequisite Programmes and Codex Labelling Standards.
- are should be taken to avoid cross contamination of ready-to-eat and raw product.
- rozen seafood products should not be subjected to ambient room temperatures for a prolonged period of time.

### 18.1.7 Retail Display of Chilled Seafood

*Potential Hazards :* *Scombrotoxin formation, microbiological growth, microbiological contamination, C. botulinum toxin formation.*

*Potential Defects :* *Decomposition, Dehydration*

*Technical Guidance :*

- Products in chilled display should be kept at 4℃ (40°F) or below. Temperatures of product should be taken at regular intervals.
- Ready-to-eat items and molluscan shellfish should be separated from each other and from raw food products in a chilled full service display. A diagram of display is recommended to ensure that cross contamination does not occur.
- If ice is used, proper drainage of melt water should be in place. Retail displays should be selfdraining. Replace ice daily and ensure ready-to-eat products are not placed on ice upon which raw product was previously displayed.
- Each commodity in a full service display should have its own container and serving utensils to avoid cross contamination.
- Care should be taken to avoid arranging product in such a large mass/depth that proper chilling cannot be maintained and product quality is compromised.
- Care should be taken to avoid drying of unprotected products in full service displays. Use of an aerosol spray, under hygienic conditions is recommended
- Product should not be added above the "oad line" where a chilled state cannot be maintained in self-service display cases of packaged product.
- Product should not be exposed to ambient room temperature for a prolonged period of time when filling/stocking display cases.
- Seafood in full service display cases should be properly labelled by signs or placards to indicate the commonly accepted name of the fish so the consumer is informed about the product.

### 18.1.8 Retail Display of Frozen Seafood

*Potential Hazards :* *Unlikely*

*Potential Defects :* *Thawing, Dehydration (Freezer Burn)*

*Technical Guidance :*

- Product should be maintained at -18℃ (0°F) or less. Regular temperature monitoring should be carried out. A recording thermometer is recommended.
- Product should not be added above the "oad line"of cabinet self-service display cases. Upright freezer self-service display cases should have self-closing doors or air curtains to maintain a frozen state.
- Product should not be exposed to ambient room temperature for a prolonged period of time when filling/stocking display cases.
- A product rotation system to ensure first in, first out usage of frozen seafood should be established.
- Frozen seafood in retail displays should be examined periodically to assess packaging integrity and the level of dehydration or freezer burn.

ANNEX I

# POTENTIAL HAZARDS ASSOCIATED WITH FRESH FISH, SHELLFISH AND OTHER AQUATIC INVERTEBRATES

## 1 Examples of Possible Biological Hazards

### 1.1.1 Parasites

The parasites known to cause disease in humans and transmitted by fish or crustaceans are broadly classified as helminths or parasitic worms. These are commonly referred to as Nematodes, Cestodes and Trematodes. Fish can be parasitised by protozoans, but there are no records of fish protozoan disease being transmitted to man. Parasites have complex life cycles, involving one or more intermediate hosts and are generally passed to man through the consumption of raw, minimally processed or inadequately cooked products that contain the parasite infectious stage, causing foodborne disease. Freezing at -20℃ or below for 7 days or -35℃ for about 20 hours for fish intended for raw consumption will kill parasites. Processes such as brining or pickling may reduce the parasite hazard if the products are kept in the brine for a sufficient time but may not eliminate it. Candling, trimming belly flaps and physically removing the parasite cysts will also reduce the hazards but may not eliminate it.

#### *Nematodes*

Many species of nematodes are known to occur worldwide and some species of marine fish act as secondary hosts. Among the nematodes of most concern are *Anisakis* spp., *Capillaria* spp., *Gnathostoma* spp., and *Pseudoteranova* spp., which can be found in the liver, belly cavity and flesh of marine fish. An example of a nematode causing disease in man is *Anisakis simplex;* as the infective stage of the parasite is killed by heating (60℃ for 1 minute) and by freezing (-20℃ for 24 hours) in the fish core.

#### *Cestodes*

Cestodes are tapeworms and the species of most concern associated with the consumption of fish is *Dibothriocephalus latus.* This parasite occurs worldwide and both fresh and marine fish are intermediate hosts. Similar to other parasitic infections, the foodborne disease occurs through the consumption of raw or under-processed fish. Similar freezing and cooking temperatures as applied to nematodes will inactivate the infective stages of this parasite.

#### *Trematodes*

Fish-borne trematode (flatworm) infections are major public health problems that occur endemically in about 20 countries around the world. The most important species with respect to the numbers of people infected belong to the genera *Clonorchis* and *Ophisthorchis* (liver flukes), *Paragonimus* (lung flukes), and to a lesser extent *Heterophyes* and *Echinochasmus* (intestinal flukes). The most important definitive host of these trematodes is man or other mammals. Freshwater fish are the second intermediate host in the life cycles of *Clonorchis* and *Ophistorchis,* and freshwater crustaceans in the case of *Paragonimius.* Foodborne infections take place through the consumption of raw, undercooked or otherwise under-processed products containing the infective stages of these parasites. Freezing fish at -20℃ for 7 days or at -35℃ for 24 hours will kill the infective stages of these parasites.

### 1.1.2 Bacteria

The level of contamination of fish at the time of capture will depend on the environment and the bacteriological quality of the water in which fish are harvested. Many factors will influence the microflora of finfish, the more important being water temperature, salt content, proximity of

harvesting areas to human habitations, quantity and origin of food consumed by fish, and method of harvesting. The edible muscle tissue of finfish is normally sterile at the time of capture and bacteria are usually present on the skin, gills and in the intestinal tract.

There are two broad groups of bacteria of public health importance that may contaminate products at the time of capture - those that are normally or incidentally present in the aquatic environment, referred to as the indigenous microflora, and those introduced through environmental contamination by domestic and / or industrial wastes. Examples of indigenous bacteria, which may pose a health hazard, are Aeromonas *hydrophyla, Clostridium botulinum, Vibrio parahaemolyticus, Vibrio cholerae, Vibrio vulnificus,* and *Listeria monocytogenes.* Non-indigenous bacteria of public health significance include members of the Enterobacteriaceae, such as *Salmonella* spp., *Shigella* spp., and *Escherichia coli.* Other species that cause foodborne illness and which have been isolated occasionally from fish are *Edwardsiella tarda, Pleisomonas shigeloides* and *Yersinia enterocolitica. Staphyloccocus aureus* may also appear and may produce heat resistant toxins.

Indigenous pathogenic bacteria, when present on fresh fish, are usually found in fairly low numbers, and where products are adequately cooked prior to consumption, food safety hazards are insignificant. During storage, indigenous spoilage bacteria will outgrow indigenous pathogenic bacteria, thus fish will spoil before becoming toxic and will be rejected by consumers. Hazards from these pathogens can be controlled by heating seafood sufficiently to kill the bacteria, holding fish at chilled temperatures and avoiding postprocess cross-contamination.

*Vibrio* species are common in coastal and estuarine environments and populations can depend on water depth and tidal levels. They are particularly prevalent in warm tropical waters and can be found in temperate zones during summer months. *Vibrio* species are also natural contaminants of brackish water tropical environments and will be present on farmed fish from these zones. Hazards from *Vibrio* spp. associated with finfish can be controlled by thorough cooking and preventing cross-contamination of cooked products. Health risks can also be reduced by rapidly chilling products after harvest, thus reducing the possibility of proliferation of these organisms. Certain strains of *Vibrio parahaemolyticus* can be pathogenic.

### 1.1.3 Viral Contamination

Molluscan shellfish harvested from inshore waters that are contaminated by human or animal faeces may harbour viruses that are pathogenic to man. Enteric viruses that have been implicated in seafood-associated illness are the hepatitis A virus, caliciviruses, astroviruses and the Norwalk virus. The latter three are often referred to as small round structured viruses. All of the seafood-borne viruses causing illness are transmitted by the faecal-oral cycle and most viral gastro-enteritis outbreaks have been associated with eating contaminated shellfish, particularly raw oysters.

Generally viruses are species specific and will not grow or multiply in foods or anywhere outside the host cell. There is no reliable marker for indicating presence of the virus in shellfish harvesting waters. Seafoodborne viruses are difficult to detect, requiring relatively sophisticated molecular methods to identify the virus.

Occurrence of viral gastro-enteritis can be minimized by controlling sewage contamination of shellfish farming areas and pre-harvest monitoring of shellfish and growing waters as well as controlling other sources of contamination during processing. Depuration or relaying are alternative strategies but longer periods are required for shellfish to purge themselves clean of viral contamination than for bacteria. Thermal processing (85-90℃ for 1.5 min.) will destroy viruses in shellfish.

### 1.1.4 Biotoxins

There are a number of important biotoxins to consider. Around 400 poisonous fish species exist and, by definition, the substances responsible for the toxicity of these species are biotoxins. The poison is usually limited to some organs, or is restricted to some periods during the year.

For some fish, the toxins are present in the blood; these are ichtyohaemotoxin. The involved species are eels from the Adriatic, the moray eels, and the lampreys. In other species, the toxins

are spread all over the tissues (flesh, viscera, skin); these are ichtyosarcotoxins. The tetrodotoxic species responsible for several poisonings, often lethal, are in this category.

In general these toxins are known to be heat-stable and the only possible control measure is to check the identity of the used species.

Phycotoxins

Ciguatoxin

And the other important toxin to consider is ciguatoxin, which can be found in a wide variety of mainly carnivorous fish inhabiting shallow waters in or near tropical and subtropical coral reefs. The source of this toxin is dinoflagellates and over 400 species of tropical fish have been implicated in intoxication. The toxin is known to be heat stable. There is still much to be learnt about this toxin and the only control measure that can reasonably be taken is to avoid marketing fish that have a known consistent record of toxicity.

PSP/DSP/NSP/ASP

Paralytic Shellfish Poison (PSP), Diarrhetic Shellfish Poison (DSP), Neurotoxic Shellfish Poison (NSP), and Amnesic Shellfish Poison complex (ASP) are produced by phytoplankton. They concentrate in bivalve molluscan shellfish which filter the phytoplankton from the water, and also may concentrate in some fish and crustacea.

Generally, the toxins remain toxic through thermal processing so the knowledge of the species identity and/or origin of fish or shellfish intended for processing is important.

Tetrodotoxin

Fish mainly belonging to the family Tetradontidea ( "puffer fishes" ) may accumulate this toxin which is responsible for several poisonings, often lethal. The toxin is generally found in the fish l iver, roe and guts, and less frequent in the flesh. Differently from most other fish biotoxins that accumulate in the live fish or shellfish, algae do not produce this toxin. The mechanism of toxin production is still not clear, however, apparently there are often indications of the involvement of symbiotic bacteria.

### 1.1.5 Scombrotoxin

Scombroid intoxication, sometimes referred to as histamine poisoning, results from eating fish that have been incorrectly chilled after harvesting. Scombrotoxin is attributed mainly to *Enterobacteriaceae* which can produce high levels of histamine and other biogenic amines in the fish muscle when products are not immediately chilled after catching. The main susceptible fish are the scombroids such as tuna, mackerel, and bonito, although it can be found in other fish families such as *Clupeidae*. The intoxication is rarely fatal and symptoms are usually mild. Rapid refrigeration after catching and a high standard of handling during processing should prevent the development of the toxin. The toxin is not inactivated by normal heat processing. In addition, fish may contain toxic levels of histamine without exhibiting any of the usual sensory parameters characteristic of spoilage.

## 1.2 Chemical hazards

Fish may be harvested from coastal zones and inland habitats that are exposed to varying amounts of environmental contaminants. Of greatest concern are fish harvested from coastal and estuarine areas rather than fish harvested from the open seas. Chemicals, organochloric compounds and heavy metals may accumulate in products that can cause public health problems. Veterinary drug residues can occur in aquaculture products when correct withdrawal times are not followed or when the sale and use of these compounds are not controlled. Fish can also be contaminated with chemicals such as diesel oil, when incorrectly handled and detergents or disinfectants when not properly rinsed out.

## 1.3 Physical Hazards

These can include material such as metal or glass fragments, shell, bones, etc.

**APPENDIX VI**

## OPTIONAL FINAL PRODUCT REQUIREMENTS - SALTED FISH

These products specifications describe the optional defects for salted fish. The descriptions of optional defects will assist buyers and sellers in describing those defect provisions. These descriptions are optional and are in addition to the essential requirements prescribed in the appropriate Codex product standards.

### *1. PRODUCT DESIGNATION OF SALTED FISH OF FAMILY GADIDAE*

Reference is given to Standard for Salted Fish and Dried Salted Fish of the Gadidae Family of Fishes (CODEX STAN 167-1989).

Products from the following species, all belonging to the Gadidae family that have been bled, gutted, beheaded and split so that approximately two thirds of the backbone is removed, washed and fully saturated with salt. Salted Fish used for production of Dried Salted Fish shall have reached 95 % salt saturation prior to drying.

| English name | Latin name |
|---|---|
| Cod | *Gadus morhua* |
| Pacific cod | *Gadus macrocephalus* |
| Polar cod | *Boreogadus saida* |
| Greenland cod | *Gadus ogac* |
| Saithe | *Pollachius virens* |
| Ling | *Molva molva* |
| Blue ling | *Molva dypterygia* |
| Tusk | *Brosme brosme* |
| Haddock | *Gadus aeglefinus / Melanogrammus aeglefinus* |
| Forkbeard | *Phycis blennoides* |
| Pollack | *Pollachius pollachius* |

# GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS CAC / GL 45 - 2003

## SECTION 1 - SCOPE

1. This Guideline supports the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. It addresses safety and nutritional aspects of foods consisting of, or derived from, plants that have a history of safe use as sources of food, and that have been modified by modern biotechnology to exhibit new or altered expression of traits.

2. This document does not address animal feed or animals fed with the feed. This document also does not address environmental risks.

3. The Codex principles of risk analysis, particularly those for risk assessment, are primarily intended to apply to discrete chemical entities such as food additives and pesticide residues, or a specific chemical or microbial contaminant that have identifiable hazards and risks; they are not intended to apply to whole foods as such. Indeed, few foods have been assessed scientifically in a manner that would fully characterise all risks associated with the food. Further, many foods contain substances that would likely be found harmful if subjected to conventional approaches to safety testing. Thus, a more focused approach is required where the safety of a whole food is being considered.

4. This approach is based on the principle that the safety of foods derived from new plant varieties, including recombinant-DNA plants, is assessed relative to the conventional counterpart having a history of safe use, taking into account both intended and unintended effects. Rather than trying to identify every hazard associated with a particular food, the intention is to identify new or altered hazards relative to the conventional counterpart.

5. This safety assessment approach falls within the risk assessment framework as discussed in Section 3 of the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. If a new or altered hazard, nutritional or other food safety concern is identified by the safety assessment, the risk associated with it would first be assessed to determine its relevance to human health. Following the safety assessment and if necessary further risk assessment, the food would be subjected to risk management considerations in accordance with the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology before it is considered for commercial distribution.

6. Risk management measures such as post-market monitoring of consumer health effects may assist the risk assessment process. These are discussed in paragraph 20 of the Principles for the Risk Analysis of Foods derived from Modern Biotechnology.

7. The Guideline describes the recommended approach to making safety assessments of foods derived from recombinant-DNA plants where a conventional counterpart exists, and identifies the data and information that are generally applicable to making such assessments. While this Guideline is designed for foods derived from recombinant - DNA plants, the approach described could, in general, be applied to foods derived from plants that have been altered by other techniques.

## SECTION 2 - DEFINITIONS

8. The definitions below apply to this Guideline :

*"Recombinant-DNA Plant"* - means a plant in which the genetic material has been changed through in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid

into cells or organelles.

*"Conventional Counterpart"* - means a related plant variety, its components and/or products for which there is experience of establishing safety based on common use as food[1].

## SECTION 3 - INTRODUCTION TO FOOD SAFETY ASSESSMENT

9. Traditionally, new varieties of food plants have not been systematically subjected to extensive chemical, toxicological, or nutritional evaluation prior to marketing, with the exception of foods for specific groups, such as infants, where the food may constitute a substantial portion of the diet. Thus, new varieties of corn, soya, potatoes and other common food plants are evaluated by breeders for agronomic and phenotypic characteristics, but generally, foods derived from such new plant varieties are not subjected to the rigorous and extensive food safety testing procedures, including studies in animals, that are typical of chemicals such as food additives or pesticide residues that may be present in food.

10. The use of animal models for assessing toxicological endpoints is a major element in the risk assessment of many compounds such as pesticides. In most cases, however, the substance to be tested is well characterised, of known purity, of no particular nutritional value, and, human exposure to it is generally low. It is therefore relatively straightforward to feed such compounds to animals at a range of doses some several orders of magnitude greater than the expected human exposure levels, in order to identify any potential adverse health effects of importance to humans. In this way, it is possible, in most cases, to estimate levels of exposure at which adverse effects are not observed and to set safe intake levels by the application of appropriate safety factors.

11. Animal studies cannot readily be applied to testing the risks associated with whole foods, which are complex mixtures of compounds, often characterised by a wide variation in composition and nutritional value. Due to their bulk and effect on satiety, they can usually only be fed to animals at low multiples of the amounts that might be present in the human diet. In addition, a key factor to consider in conducting animal studies on foods is the nutritional value and balance of the diets used, in order to avoid the induction of adverse effects which are not related directly to the material itself. Detecting any potential adverse effects and relating these conclusively to an individual characteristic of the food can therefore be extremely difficult. If the characterization of the food indicates that the available data are insufficient for a thorough safety assessment, properly designed animal studies could be requested on the whole foods. Another consideration in deciding the need for animal studies is whether it is appropriate to subject experimental animals to such a study if it is unlikely to give rise to meaningful information.

12. Due to the difficulties of applying traditional toxicological testing and risk assessment procedures to whole foods, a more focused approach is required for the safety assessment of foods derived from food plants, including recombinant - DNA plants. This has been addressed by the development of a multidisciplinary approach for assessing safety which takes into account both intended and unintended changes that may occur in the plant or in the foods derived from it, using the concept of substantial equivalence.

13. The concept of substantial equivalence is a key step in the safety assessment process. However, it is not a safety assessment in itself; rather it represents the starting point which is used to structure the safety assessment of a new food relative to its conventional counterpart. This concept is used to identify similarities and differences between the new food and its conventional counterpart[2]. It aids in the identification of potential safety and nutritional issues and is considered the most appropriate strategy to date for safety assessment of foods derived from recombinant-DNA plants. The safety assessment carried out in this way does not imply absolute safety of the new product ; rather, it focuses on assessing the safety of any identified differences so that the safety of the new

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1 It is recognized that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts.

2 The concept of *substantial equivalence* as described in the report of the 2000 joint FAO /WHO expert consultations (Document WHO/SDE/PHE/FOS/00.6, WHO, Geneva, 2000).

product can be considered relative to its conventional counterpart.

## UNINTENDED EFFECTS

14. In achieving the objective of conferring a specific target trait (intended effect) to a plant by the insertion of defined DNA sequences, additional traits could, in some cases, be acquired or existing traits could be lost or modified (unintended effects). The potential occurrence of unintended effects is not restricted to the use of *in vitro* nucleic acid techniques. Rather, it is an inherent and general phenomenon that can also occur in conventional breeding. Unintended effects may be deleterious, beneficial, or neutral with respect to the health of the plant or the safety of foods derived from the plant. Unintended effects in recombinant-DNA plants may also arise through the insertion of DNA sequences and/or they may arise through subsequent conventional breeding of the recombinant-DNA plant. Safety assessment should include data and information to reduce the possibility that a food derived from a recombinant-DNA plant would have an unexpected, adverse effect on human health.

15. Unintended effects can result from the random insertion of DNA sequences into the plant genome which may cause disruption or silencing of existing genes, activation of silent genes, or modifications in the expression of existing genes. Unintended effects may also result in the formation of new or changed patterns of metabolites. For example, the expression of enzymes at high levels may give rise to secondary biochemical effects or changes in the regulation of metabolic pathways and/or altered levels of metabolites.

16. Unintended effects due to genetic modification may be subdivided into two groups: those that are "predictable" and those that are "unexpected". Many unintended effects are largely predictable based on knowledge of the inserted trait and its metabolic connections or of the site of insertion. Due to the expanding information on plant genome and the increased specificity in terms of genetic materials introduced through recombinant-DNA techniques compared with other forms of plant breeding, it may become easier to predict unintended effects of a particular modification. Molecular biological and biochemical techniques can also be used to analyse potential changes at the level of gene transcription and message translation that could lead to unintended effects.

17. The safety assessment of foods derived from recombinant-DNA plants involves methods to identify and detect such unintended effects and procedures to evaluate their biological relevance and potential impact on food safety. A variety of data and information are necessary to assess unintended effects because no individual test can detect all possible unintended effects or identify, with certainty, those relevant to human health. These data and information, when considered in total, provide assurance that the food is unlikely to have an adverse effect on human health. The assessment for unintended effects takes into account the agronomic/phenotypic characteristics of the plant that are typically observed by breeders in selecting new varieties for commercialization. These observations by breeders provide a first screen for plants that exhibit unintended traits. New varieties that pass this screen are subjected to safety assessment as described in Sections 4 and 5.

## FRAMEWORK OF FOOD SAFETY ASSESSMENT

18. The safety assessment of a food derived from a recombinant - DNA plant follows a stepwise process of addressing relevant factors that include :

A) Description of the recombinant - DNA plant ;

B) Description of the host plant and its use as food ;

C) Description of the donor organism(s) ;

D) Description of the genetic modification(s) ;

E) Characterization of the genetic modification(s) ;

F) Safety assessment :

a) expressed substances (non-nucleic acid substances) ;

b) compositional analyses of key components ;

c) evaluation of metabolites ;

d) food processing ;

e) nutritional modification ; and

G) Other considerations.

19. In certain cases, the characteristics of the product may necessitate development of additional data and information to address issues that are unique to the product under review.

20. Experiments intended to develop data for safety assessments should be designed and conducted in accordance with sound scientific concepts and principles, as well as, where appropriate, Good Laboratory Practice. Primary data should be made available to regulatory authorities at request. Data should be obtained using sound scientific methods and analysed using appropriate statistical techniques. The sensitivity of all analytical methods should be documented.

21. The goal of each safety assessment is to provide assurance, in the light of the best available scientific knowledge, that the food does not cause harm when prepared, used and/or eaten according to its intended use. The expected endpoint of such an assessment will be a conclusion regarding whether the new food is as safe as the conventional counterpart taking into account dietary impact of any changes in nutritional content or value. In essence, therefore, the outcome of the safety assessment process is to define the product under consideration in such a way as to enable risk managers to determine whether any measures are needed and if so to make well-informed and appropriate decisions.

## SECTION 4 - GENERAL CONSIDERATIONS

### DESCRIPTION OF THE RECOMBINANT - DNA PLANT

22. A description of the recombinant-DNA plant being presented for safety assessment should be provided. This description should identify the crop, the transformation event(s) to be reviewed and the type and purpose of the modification. This description should be sufficient to aid in understanding the nature of the food being submitted for safety assessment.

### DESCRIPTION OF THE HOST PLANT AND ITS USE AS FOOD

23. A comprehensive description of the host plant should be provided. The necessary data and information should include, but need not be restricted to :

A) common or usual name; scientific name; and, taxonomic classification ;

B) history of cultivation and development through breeding, in particular identifying traits that may adversely impact on human health ;

C) information on the host plant's genotype and phenotype relevant to its safety, including any known toxicity or allergenicity ; and

D) history of safe use for consumption as food.

24. Relevant phenotypic information should be provided not only for the host plant, but also for related species and for plants that have made or may make a significant contribution to the genetic background of the host plant.

25. The history of use may include information on how the plant is typically cultivated, transported and stored, whether special processing is required to make the plant safe to eat, and the plant's normal role in the diet (e.g. which part of the plant is used as a food source, whether its consumption is

important in particular subgroups of the population, what important macro - or micro-nutrients it contributes to the diet).

## DESCRIPTION OF THE DONOR ORGANISM(S)

26. Information should be provided on the donor organism(s) and, when appropriate, on other related species. It is particularly important to determine if the donor organism(s) or other closely related members of the family naturally exhibit characteristics of pathogenicity or toxin production, or have other traits that affect human health (e.g. presence of anti-nutrients). The description of the donor organism(s) should include :

A) its usual or common name ;

B) scientific name ;

C) taxonomic classification ;

D) information about the natural history as concerns food safety ;

E) information on naturally occurring toxins, anti-nutrients and allergens ; for microorganisms, additional information on pathogenicity and the relationship to known pathogens ; and

F) information on the past and present use, if any, in the food supply and exposure route(s) other than intended food use (e.g. possible presence as contaminants).

## DESCRIPTION OF THE GENETIC MODIFICATION(S)

27. Sufficient information should be provided on the genetic modification to allow for the identification of all genetic material potentially delivered to the host plant and to provide the necessary information for the analysis of the data supporting the characterization of the DNA inserted in the plant.

28. The description of the transformation process should include :

A) information on the specific method used for the transformation (e.g. Agrobacterium-mediated transformation) ;

B) information, if applicable, on the DNA used to modify the plant (e.g. helper plasmids), including the source (e.g. plant, microbial, viral, synthetic), identity and expected function in the plant ; and

C) intermediate host organisms including the organisms (e.g. bacteria) used to produce or process DNA for transformation of the host organism.

29. Information should be provided on the DNA to be introduced, including:

A) the characterization of all the genetic components including marker genes, regulatory and other elements affecting the function of the DNA ;

B) the size and identity ;

C) the location and orientation of the sequence in the final vector/construct ; and

D) the function.

## CHARACTERIZATION OF THE GENETIC MODIFICATION(S)

30. In order to provide clear understanding of the impact on the composition and safety of foods derived from recombinant-DNA plants, a comprehensive molecular and biochemical characterization of the genetic modification should be carried out.

31. Information should be provided on the DNA insertions into the plant genome ; this should include :

A) the characterization and description of the inserted genetic materials ;

B) the number of insertion sites ;

C) the organisation of the inserted genetic material at each insertion site including copy number and sequence data of the inserted material and of the surrounding region, sufficient to identify any substances expressed as a consequence of the inserted material, or, where more appropriate, other information such as analysis of transcripts or expression products to identify any new substances that may be present in the food ; and

D) identification of any open reading frames within the inserted DNA or created by the insertions with contiguous plant genomic DNA including those that could result in fusion proteins.

32. Information should be provided on any expressed substances in the recombinant-DNA plant; this should include :

A) the gene product(s) (e.g. a protein or an untranslated RNA) ;

B) the gene product(s)' function ;

C) the phenotypic description of the new trait(s) ;

D) the level and site of expression in the plant of the expressed gene product(s), and the levels of its metabolites in the plant, particularly in the edible portions ; and

E) where possible, the amount of the target gene product(s) if the function of the expressed sequence(s)/gene(s) is to alter the accumulation of a specific endogenous mRNA or protein.

33. In addition, information should be provided :

A) to demonstrate whether the arrangement of the genetic material used for insertion has been conserved or whether significant rearrangements have occurred upon integration ;

B) to demonstrate whether deliberate modifications made to the amino acid sequence of the expressed protein result in changes in its post-translational modification or affect sites critical for its structure or function ;

C) to demonstrate whether the intended effect of the modification has been achieved and that all expressed traits are expressed and inherited in a manner that is stable through several generations consistent with laws of inheritance. It may be necessary to examine the inheritance of the DNA insert itself or the expression of the corresponding RNA if the phenotypic characteristics cannot be measured directly ;

D) to demonstrate whether the newly expressed trait(s) are expressed as expected in the appropriate tissues in a manner and at levels that are consistent with the associated regulatory sequences driving the expression of the corresponding gene ;

E) to indicate whether there is any evidence to suggest that one or several genes in the host plant has been affected by the transformation process ; and

F) to confirm the identity and expression pattern of any new fusion proteins.

**SAFETY ASSESSMENT**

**Expressed Substances (non-nucleic acid substances)**

**Assessment of possible toxicity**

34. In vitro nucleic acid techniques enable the introduction of DNA that can result in the synthesis of new substances in plants. The new substances can be conventional components of plant foods such as proteins, fats, carbohydrates, vitamins which are novel in the context of that recombinant-DNA plant. New substances might also include new metabolites resulting from the activity of enzymes generated by the expression of the introduced DNA.

35. The safety assessment should take into account the chemical nature and function of the newly

expressed substance and identify the concentration of the substance in the edible parts of the recombinant-DNA plant, including variations and mean values. Current dietary exposure and possible effects on population sub-groups should also be considered.

36. Information should be provided to ensure that genes coding for known toxins or anti-nutrients present in the donor organisms are not transferred to recombinant-DNA plants that do not normally express those toxic or anti-nutritious characteristics. This assurance is particularly important in cases where a recombinant - DNA plant is processed differently from a donor plant, since conventional food processing techniques associated with the donor organisms may deactivate, degrade or eliminate anti-nutrients or toxicants.

37. For the reasons described in Section 3, conventional toxicology studies may not be considered necessary where the substance or a closely related substance has, taking into account its function and exposure, been consumed safely in food. In other cases, the use of appropriate conventional toxicology or other studies on the new substance may be necessary.

38. In the case of proteins, the assessment of potential toxicity should focus on amino acid sequence similarity between the protein and known protein toxins and anti-nutrients (e.g. protease inhibitors, lectins) as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems. Appropriate oral toxicity studies[3] may need to be carried out in cases where the protein present in the food is not similar to proteins that have previously been consumed safely in food, and taking into account its biological function in the plant where known.

39. Potential toxicity of non-protein substances that have not been safely consumed in food should be assessed on a case-by-case basis depending on the identity and biological function in the plant of the substance and dietary exposure. The type of studies to be performed may include studies on metabolism, toxicokinetics, sub-chronic toxicity, chronic toxicity/carcinogenicity, reproduction and development toxicity according to the traditional toxicological approach.

40. This may require the isolation of the new substance from the recombinant - DNA plant, or the synthesis or production of the substance from an alternative source, in which case, the material should be shown to be biochemically, structurally, and functionally equivalent to that produced in the recombinant-DNA plant.

**Assessment of possible allergenicity (proteins)**

41. When the protein(s) resulting from the inserted gene is present in the food, it should be assessed for potential allergenicity in all cases. An integrated, stepwise, case-by-case approach used in the assessment of the potential allergenicity of the newly-expressed protein(s) should rely upon various criteria used in combination (since no single criterion is sufficiently predictive on either allergenicity or non-allergenicity). As noted in paragraph 20, the data should be obtained using sound scientific methods. A detailed presentation of issues to be considered can be found in Annex 1 to this document[4].

42. The newly expressed proteins in foods derived from recombinant-DNA plants should be evaluated for any possible role in the elicitation of gluten-sensitive enteropathy, if the introduced genetic material is obtained from wheat, rye, barley, oats, or related cereal grains.

43. The transfer of genes from commonly allergenic foods and from foods known to elicit gluten-sensit ive enteropathy in sensitive individuals should be avoided unless it is documented that the transferred gene does not code for an allergen or for a protein involved in gluten-sensitive enteropathy.

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3 Guidelines for oral toxicity studies have been developed in international fora, for example, the OECD Guidelines for the Testing of Chemicals.

4 The FAO/WHO expert consultation 2001 report, which includes reference to several decision trees, was used in developing Annex 1 to these guidelines.

### Compositional Analyses of Key Components

44. Analyses of concentrations of key components[5] of the recombinant-DNA plant and, especially those typical of the food, should be compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions. In some cases, a further comparison with the recombinant-DNA plant grown under its expected agronomic conditions may need to be considered (e.g. application of an herbicide). The statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its biological significance. The comparator(s) used in this assessment should ideally be the near isogenic parental line. In practice, this may not be feasible at all times, in which case a line as close as possible should be chosen. The purpose of this comparison, in conjunction with an exposure assessment as necessary, is to establish that substances that are nutritionally important or that can affect the safety of the food have not been altered in a manner that would have an adverse impact on human health.

45. The location of trial sites should be representative of the range of environmental conditions under which the plant varieties would be expected to be grown. The number of trial sites should be sufficient to allow accurate assessment of compositional characteristics over this range. Similarly, trials should be conducted over a sufficient number of generations to allow adequate exposure to the variety of conditions met in nature. To minimise environmental effects, and to reduce any effect from naturally occurring genotypic variation within a crop variety, each trial site should be replicated. An adequate number of plants should be sampled and the methods of analysis should be sufficiently sensitive and specific to detect variations in key components.

### Evaluation of Metabolites

46. Some recombinant - DNA plants may have been modified in a manner that could result in new or altered levels of various metabolites in the food. Consideration should be given to the potential for the accumulation of metabolites in the food that would adversely affect human health. Safety assessment of such plants requires investigation of residue and metabolite levels in the food and assessment of any alterations in nutrient profile. Where altered residue or metabolite levels are identified in foods, consideration should be given to the potential impacts on human health using conventional procedures for establishing the safety of such metabolites (e.g. procedures for assessing the human safety of chemicals in foods).

### Food Processing

47. The potential effects of food processing, including home preparation, on foods derived from recombinant - DNA plants should also be considered. For example, alterations could occur in the heat stability of an endogenous toxicant or the bioavailability of an important nutrient after processing. Information should therefore be provided describing the processing conditions used in the production of a food ingredient from the plant. For example, in the case of vegetable oil, information should be provided on the extraction process and any subsequent refining steps.

### Nutritional Modification

48. The assessment of possible compositional changes to key nutrients, which should be conducted for all recombinant - DNA plants, has already been addressed under 'Compositional analyses of key components'. However, foods derived from recombinant-DNA plants that have undergone modification to intentionally alter nutritional quality or functionality should be subjected to additional

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5 Key nutrients or key anti-nutrients are those components in a particular food that may have a substantial impact in the overall diet. They may be major constituents (fats, proteins, carbohydrates as nutrients or enzyme inhibitors as anti-nutrients) or minor compounds (minerals, vitamins). Key toxicants are those toxicologically significant compounds known to be inherently present in the plant, such as those compounds whose toxic potency and level may be significant to health (e.g. solanine in potatoes if the level is increased, selenium in wheat) and allergens.

nutritional assessment to assess the consequences of the changes and whether the nutrient intakes are likely to be altered by the introduction of such foods into the food supply. A detailed presentation of issues to be considered can be found in Annex 2 to this document.

49. Information about the known patterns of use and consumption of a food, and its derivatives should be used to estimate the likely intake of the food derived from the recombinant-DNA plant. The expected intake of the food should be used to assess the nutritional implications of the altered nutrient profile both at customary and maximal levels of consumption. Basing the estimate on the highest likely consumption provides assurance that the potential for any undesirable nutritional effects will be detected. Attention should be paid to the particular physiological characteristics and metabolic requirements of specific population groups such as infants, children, pregnant and lactating women, the elderly and those with chronic diseases or compromised immune systems. Based on the analysis of nutritional impacts and the dietary needs of specific population subgroups, additional nutritional assessments may be necessary. It is also important to ascertain to what extent the modified nutrient is bioavailable and remains stable with time, processing and storage.

50. The use of plant breeding, including in vitro nucleic acid techniques, to change nutrient levels in crops can result in broad changes to the nutrient profile in two ways. The intended modification in plant constituents could change the overall nutrient profile of the plant product and this change could affect the nutritional status of individuals consuming the food. Unexpected alterations in nutrients could have the same effect. Although the recombinant - DNA plant components may be individually assessed as safe, the impact of the change on the overall nutrient profile should be determined.

51. When the modification results in a food product, such as vegetable oil, with a composition that is significantly different from its conventional counterpart, it may be appropriate to use additional conventional foods or food components (i.e. foods or food components whose nutritional composition is closer to that of the food derived from recombinant-DNA plant) as appropriate comparators to assess the nutritional impact of the food.

52. Because of geographical and cultural variation in food consumption patterns, nutritional changes to a specific food may have a greater impact in some geographical areas or in some cultural population than in others. Some food plants serve as the major source of a particular nutrient in some populations. The nutrient and the populations affected should be identified.

53. Some foods may require additional testing. For example, animal feeding studies may be warranted for foods derived from recombinant - DNA plants if changes in the bioavailability of nutrients are expected or if the composition is not comparable to conventional foods. Also, foods designed for health benefits may require specific nutritional, toxicological or other appropriate studies. If the characterization of the food indicates that the available data are insufficient for a thorough safety assessment, properly designed animal studies could be requested on the whole foods.

## SECTION 5 – OTHER CONSIDERATIONS

### POTENTIAL ACCUMULATION OF SUBSTANCES SIGNIFICANT TO HUMAN HEALTH

54. Some recombinant-DNA plants may exhibit traits (e.g., herbicide tolerance) which may indirectly result in the potential for accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances which may be relevant to human health. The safety assessment should take this potential for accumulation into account. Conventional procedures for establishing the safety of such compounds (e.g., procedures for assessing the human safety of chemicals) should be applied.

### USE OF ANTIBIOTIC RESISTANCE MARKER GENES

55. Alternative transformation technologies that do not result in antibiotic resistance marker genes in foods should be used in the future development of recombinant - DNA plants, where such

technologies are available and demonstrated to be safe.

56. Gene transfer from plants and their food products to gut microorganisms or human cells is considered a rare possibility because of the many complex and unlikely events that would need to occur consecutively. Nevertheless, the possibility of such events cannot be completely discounted[6].

57. In assessing safety of foods containing antibiotic resistance marker genes, the following factors should be considered :

A) the clinical and veterinary use and importance of the antibiotic in question ;
(Certain antibiotics are the only drug available to treat some clinical conditions (e.g. vancomycin for use in treating certain staphylococcal infections). Marker genes encoding resistance to such antibiotics should not be used in recombinant - DNA plants.)

B) whether the presence in food of the enzyme or protein encoded by the antibiotic resistance marker gene would compromise the therapeutic efficacy of the orally administered antibiotic ; and (This assessment should provide an estimate of the amount of orally ingested antibiotic that could be degraded by the presence of the enzyme in food, taking into account factors such as dosage of the antibiotic, amount of enzyme likely to remain in food following exposure to digestive conditions, including neutral or alkaline stomach conditions and the need for enzyme cofactors (e.g. ATP) for enzymatic activity and estimated concentration of such factors in food.)

C) safety of the gene product, as would be the case for any other expressed gene product.

58. If evaluation of the data and information suggests that the presence of the antibiotic resistance marker gene or gene product presents risks to human health, the marker gene or gene product should not be present in the food. Antibiotic resistance genes used in food production that encode resistance to clinically used antibiotics should not be present in foods.

**REVIEW OF SAFETY ASSESSMENTS**

59. The goal of the safety assessment is a conclusion as to whether the new food is as safe as the conventional counterpart taking into account dietary impact of any changes in nutritional content or value. Nevertheless, the safety assessment should be reviewed in the light of new scientific information that calls into question the conclusions of the original safety assessment.

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6 In cases where there are high levels of naturally occurring bacteria which are resistant to the antibiotic, the likelihood of such bacteria transferring this resistance to other bacteria will be orders of magnitude higher than the likelihood of transfer between ingested foods and bacteria.

## ANNEX 1 : ASSESSMENT OF POSSIBLE ALLERGENICITY

### SECTION 1 - INTRODUCTION

1. All newly expressed proteins[7] in recombinant-DNA plants that could be present in the final food should be assessed for their potential to cause allergic reactions. This should include consideration of whether a newly expressed protein is one to which certain individuals may already be sensitive as well as whether a protein new to the food supply is likely to induce allergic reactions in some individuals.

2. At present, there is no definitive test that can be relied upon to predict allergic response in humans to a newly expressed protein, therefore, it is recommended that an integrated, stepwise, case by case approach, as described below, be used in the assessment of possible allergenicity of newly expressed proteins. This approach takes into account the evidence derived from several types of information and data since no single criterion is sufficiently predictive.

3. The endpoint of the assessment is a conclusion as to the likelihood of the protein being a food allergen.

### SECTION 2 - ASSESSMENT STRATEGY

4. The initial steps in assessing possible allergenicity of any newly expressed proteins are the determination of : the source of the introduced protein; any significant similarity between the amino acid sequence of the protein and that of known allergens; and its structural properties, including but not limited to, its susceptibility to enzymatic degradation, heat stability and/or, acid and enzymatic treatment.

5. As there is no single test that can predict the likely human IgE response to oral exposure, the first step to characterize newly expressed proteins should be the comparison of the amino acid sequence and certain physicochemical characteristics of the newly expressed protein with those of established allergens in a weight of evidence approach. This will require the isolation of any newly expressed proteins from the recombinant-DNA plant, or the synthesis or production of the substance from an alternative source, in which case the material should be shown to be structurally, functionally and biochemically equivalent to that produced in the recombinant - DNA plant. Particular attention should be given to the choice of the expression host, since post-translational modifications allowed by different hosts (i.e. : eukaryotic vs. prokaryotic systems) may have an impact on the allergenic potential of the protein.

6. It is important to establish whether the source is known to cause allergic reactions. Genes derived from known allergenic sources should be assumed to encode an allergen unless scientific evidence demonstrates otherwise.

### SECTION 3 - INITIAL ASSESSMENT

#### SECTION 3.1 - SOURCE OF THE PROTEIN

7. As part of the data supporting the safety of foods derived from recombinant - DNA plants, information should describe any reports of allergenicity associated with the donor organism. Allergenic sources of genes would be defined as those organisms for which reasonable evidence of IgE mediated oral, respiratory or contact allergy is available. Knowledge of the source of the introduced protein allows the identification of tools and relevant data to be considered in the allergenicity assessment. These include: the availability of sera for screening purposes; documented

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7 This assessment strategy is not applicable for assessing whether newly expressed proteins are capable of inducing glutensensitive or other enteropathies. The issue of enteropathies is already addressed in Assessment of possible allergenicity (proteins), paragraph 42 of the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant - DNA Plants. In addition, the strategy is not applicable to the evaluation of foods where gene products are down regulated for hypoallergenic purposes.

type, severity and frequency of allergic reactions ; structural characteristics and amino acid sequence; physicochemical and immunological properties (when available) of known allergenic proteins from that source.

SECTION 3.2 - AMINO ACID SEQUENCE HOMOLOGY

8. The purpose of a sequence homology comparison is to assess the extent to which a newly expressed protein is similar in structure to a known allergen. This information may suggest whether that protein has an allergenic potential. Sequence homology searches comparing the structure of all newly expressed proteins with all known allergens should be done. Searches should be conducted using various algorithms such as FASTA or BLASTP to predict overall structural similarities. Strategies such as stepwise contiguous identical amino acid segment searches may also be performed for identifying sequences that may represent linear epitopes. The size of the contiguous amino acid search should be based on a scientifically justified rationale in order to minimize the potential for false negative or false positive results.[8] Validated search and evaluation procedures should be used in order to produce biologically meaningful results.

9. IgE cross - reactivity between the newly expressed protein and a known allergen should be considered a possibility when there is more than 35% identity in a segment of 80 or more amino acids (FAO/WHO 2001) or other scientifically justified criteria. All the information resulting from the sequence homology comparison between the newly expressed protein and known allergens should be reported to allow a case-by-case scientifically based evaluation.

10. Sequence homology searches have certain limitations. In particular, comparisons are limited to the sequences of known allergens in publicly available databases and the scientific literature. There are also limitations in the ability of such comparisons to detect non-contiguous epitopes capable of binding themselves specifically with IgE antibodies.

11. A negative sequence homology result indicates that a newly expressed protein is not a known allergen and is unlikely to be cross-reactive to known allergens. A result indicating absence of significant sequence homology should be considered along with the other data outlined under this strategy in assessing the allergenic potential of newly expressed proteins. Further studies should be conducted as appropriate (see also sections 4 and 5). A positive sequence homology result indicates that the newly expressed protein is likely to be allergenic. If the product is to be considered further, it should be assessed using serum from individuals sensitized to the identified allergenic source.

SECTION 3.3 - PEPSIN RESISTANCE

12. Resistance to pepsin digestion has been observed in several food allergens ; thus a correlation exists between resistance to digestion by pepsin and allergenic potential.[9] Therefore, the resistance of a protein to degradation in the presence of pepsin under appropriate conditions indicates that further analysis should be conducted to determine the likelihood of the newly expressed protein being allergenic. The establishment of a consistent and well-validated pepsin degradation protocol may enhance the utility of this method. However, it should be taken into account that a lack of resistance to pepsin does not exclude that the newly expressed protein can be a relevant allergen.

13. Although the pepsin resistance protocol is strongly recommended, it is recognized that other enzyme susceptibility protocols exist. Alternative protocols may be used where adequate justification is provided[10].

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8 It is recognized that the 2001 FAO/WHO consultation suggested moving from 8 to 6 identical amino acid segments in searches. The smaller the peptide sequence used in the stepwise comparison, the greater the likelihood of identifying false positives, inversely, the larger the peptide sequence used, the greater the likelihood of false negatives, thereby reducing the utility of the comparison.

9 The method outlined in the U.S. Pharmacopoeia (1995) was used in the establishment of the correlation (Astwood *et al.* 1996).

10 Report of Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology (2001) : Section "6.4 Pepsin Resistance".

## SECTION 4 - SPECIFIC SERUM SCREENING

14. For those proteins that originate from a source known to be allergenic, or have sequence homology with a known allergen, testing in immunological assays should be performed where sera are available. Sera from individuals with a clinically validated allergy to the source of the protein can be used to test the specific binding to IgE class antibodies of the protein in *in vitro* assays. A critical issue for testing will be the availability of human sera from sufficient numbers of individuals[11] In addition, the quality of the sera and the assay procedure need to be standardized to produce a valid test result. For proteins from sources not known to be allergenic, and which do not exhibit sequence homology to a known allergen, targeted serum screening may be considered where such tests are available as described in paragraph 17.

15. In the case of a newly expressed protein derived from a known allergenic source, a negative result in *in vitro* immunoassays may not be considered sufficient, but should prompt additional testing, such as the possible use of skin test and *ex vivo* protocols.[12] A positive result in such tests would indicate a potential allergen.

## SECTION 5 – OTHER CONSIDERATIONS

16. The absolute exposure to the newly expressed protein and the effects of relevant food processing will contribute toward an overall conclusion about the potential for human health risk. In this regard, the nature of the food product intended for consumption should be taken into consideration in determining the types of processing which would be applied and its effects on the presence of the protein in the final food product.

17. As scientific knowledge and technology evolves, other methods and tools may be considered in assessing the allergenicity potential of newly expressed proteins as part of the assessment strategy. These methods should be scientifically sound and may include targeted serum screening (i.e. the assessment of binding to IgE in sera of individuals with clinically validated allergic responses to broadly-related categories of foods) ; the development of international serum banks; use of animal models; and examination of newly expressed proteins for T-cell epitopes and structural motifs associated with allergens.

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11 According to the Joint Report of the FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology (22-25 January 2001, Rome, Italy) a minimum of 8 relevant sera is required to achieve a 99% certainty that the new protein is not an allergen in the case of a major allergen. Similarly, a minimum of 24 relevant sera is required to achieve the same level of certainty in the case of a minor allergen. It is recognized that these quantities of sera may not be available for testing purposes.

12 *Ex vivo* procedure is described as the testing for allergenicity using cells or tissue culture from allergic human subjects (Report of Joint FAO/WHO Expert Consultation on Allergenicity of Foods derived from Biotechnology).

## ANNEX 2 : FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT - DNA PLANTS MODIFIED FOR NUTRITIONAL OR HEALTH BENEFITS

### SECTION 1 - INTRODUCTION

1. General guidance for the safety assessment of foods derived from recombinant - DNA plants is provided in the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant - DNA Plants (CAC/GL 45-2003) (Codex Plant Guideline). This Annex provides additional considerations that are specific to foods modified for nutritional or health benefits. The document does not extend beyond a safety assessment and therefore, it does not cover assessment of the benefits themselves or any corresponding health claims, or risk-management measures[13].

2. The following factors determine whether a recombinant-DNA plant is a recombinant-DNA Plant Modified for Nutritional or Health Benefits, and as such within the scope of this Annex:

   (a) the recombinant-DNA plant exhibits a particular trait in portion(s) of the plant intended for food use, and ;

   (b) The trait is a result of i ) introduction of a new nutrient(s) or related substance(s), or ii ) alteration of either the quantity or bioavailability of a nutrient(s) or related substance(s), iii) removal or reduction of undesirable substance(s) (e.g. allergens or toxicants), or iv) alteration of the interaction(s) of nutritional or health relevance of these substances.

### SECTION 2 - DEFINITION

3. The definition below applies to this Annex :

   *Nutrient*[14] - means any substance normally consumed as a constituent of food :

   (a) which provides energy ; or

   (b) which is needed for growth and development and maintenance of healthy life; or

   (c) a deficit of which will cause characteristic biochemical or physiological changes to occur.

4. This Annex draws, where appropriate, on the definitions of key nutritional concepts to be found or to be developed in relevant Codex texts, especially those elaborated by the Codex Committee on Nutrition and Foods for Special Dietary Uses.

### SECTION 3 - FOOD SAFETY ASSESSMENT

5. The Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987) are generally applicable to the assessment of food derived from a plant which is modified by increasing the amount of a nutrient(s) or related substance(s) available for absorption and metabolism. The Food Safety Framework outlined within the Codex Plant Guideline[15] applies to the overall safety assessment of a food derived from a recombinant-DNA plant modified for nutritional or health benefits. This Annex presents additional considerations regarding the food safety assessment of those foods.

6. Foods derived from recombinant-DNA plants modified for nutritional or health benefits may benefit certain populations/sub populations, while other populations/sub populations may be at risk from the same food[16].

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13 Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003, paragraph 19)

14 General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987)

15 Paragraphs 18-21(Safety Framework) and 48-53 (Nutrition Modification)

16 Further guidance for susceptible and high-risk population groups is provided in paragraph 49 of the Codex Plant Guideline.

7. Rather than trying to identify every hazard associated with a particular food, the intention of a safety assessment of food derived from recombinant-DNA plants is the identification of new or altered hazards relative to the conventional counterpart[17]. Since recombinant-DNA plants modified for nutritional or health benefits result in food products with a composition that may be significantly different from their conventional counterparts, the choice of an appropriate comparator[18] is of great importance for the safety assessment addressed in this Annex. Those alterations identified in a plant modified to obtain nutritional or health benefits are the subject of this safety assessment.

8. Upper levels of intake for many nutrients that have been set out by some national, regional and international bodies[19] may be considered, as appropriate. The basis for their derivation should also be considered in order to assess the public health implications of exceeding these levels.

9. The safety assessment of related substances should follow a case-by-case approach taking into account upper levels as well as other values, where appropriate.

10. Although it is preferable to use a scientifically-determined upper level of intake of a specific nutrient or related substance, when no such value has been determined, consideration may be given to an established history of safe use for nutrients or related substances that are consumed in the diet if the expected or foreseeable exposure would be consistent with those historical safe levels.

11. With conventional fortification of food, typically a nutrient or a related substance is added at controlled concentrations and its chemical form is characterized. Levels of plant nutrients or related substances may vary in both conventionally bred and recombinant-DNA plants due to growing conditions. In addition, more than one chemical form of the nutrient might be expressed in the food as a result of the modification and these may not be characterized from a nutrition perspective. Where appropriate, information may be needed on the different chemical forms of the nutrient(s) or related substance(s) expressed in the portion of the plant intended for food use and their respective levels.

12. Bioavailability of the nutrient(s), related substance(s), or undesirable substance(s) in the food that were the subject of the modification in the recombinant-DNA plant should be established, where appropriate. If more than one chemical form of the nutrient(s) or related substance(s) is present, their combined bioavailability should be established, where appropriate.

13. Bioavailability will vary for different nutrients, and methods of testing for bioavailability should be relevant to the nutrient, and the food containing the nutrient, as well as the health, nutritional status and dietary practices of the specific populations consuming the food. *In vitro* and in vivo methods to determine bioavailability exist, the latter conducted in animals and in humans. *In vitro* methods can provide information to assess extent of release of a substance from plant tissues during the digestive process. *In vivo* studies in animals are of limited value in assessing nutritional value or nutrient bioavailability for humans and would require careful design in order to be relevant. *In vivo* studies, in particular, human studies may provide more relevant information about whether and to what extent the nutrient or related substance is bioavailable.

14. Guidance on dietary exposure assessment of foods derived from recombinant-DNA plants with nutritional modifications is provided in paragraph 49 of the Codex Plant Guideline. In the context of this Annex, dietary exposure assessment is the estimation of the concentration of the nutrient(s) or related substance(s) in a food, the expected or foreseeable consumption of that food, and any known factors that influence bioavailability. Exposure to a nutrient(s) or related substance(s) should be evaluated in the context of the total diet and the assessment should be carried out based on the customary dietary consumption, by the relevant population(s), of the corresponding food that is likely to be displaced. When evaluating the exposure, it is appropriate to consider information on

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17 Codex Plant Guideline, paragraph 4

18 Codex Plant Guideline, paragraph 51

19 Where such guidance is not provided by Codex, information provided by the FAO/WHO may be preferably considered.

whether the consumption of the modified food could lead to adverse nutritional effects as compared to consumption of the food that it is intended to replace. Most, if not all, aspects of exposure assessment are not unique to recombinant-DNA plants modified for nutritional or health benefits[20].

15. The first step of an exposure assessment is determining the level(s) of the substance(s) in question in the portion of the plant intended for food use. Guidance on determining changes in levels of these substances is provided in the Codex Plant Guideline.[21]

16. Consumption patterns will vary from country to country depending on the importance of the food in the diet(s) of a given population(s). Therefore, it is recommended that consumption estimates are based on national or regional food consumption data when available, using existing guidance on estimation of exposure in a given population(s)[22]. When national or regional food consumption data is unavailable, food availability data may provide a useful resource[23].

17. To assess the safety of a food derived from a recombinant-DNA plant modified for a nutritional or health benefit, the estimated intake of the nutrient or related substance in the population(s) is compared with the nutritional or toxicological reference values, such as upper levels of intake, ADIs for that nutrient or related substance, where these values exist. This may involve assessments of different consumption scenarios against the relevant nutritional reference value, taking into account possible changes in bioavailability, or extend to probabilistic methods that characterise the distribution of exposures within the relevant population(s).

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20 Additional applicable guidance on dietary exposure assessment of nutrients and related substances is provided in the Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment. WHO Headquarters, Geneva, Switzerland, 2-6 May 2005.

21 Paragraphs 44 and 45

22 A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances. Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment. WHO Headquarters, Geneva, Switzerland, 2-6 May 2005

23 Data on staple food products may also be supplemented by information from FAO Food Balance Sheets.

## ANNEX 3 : FOOD SAFETY ASSESSMENT IN SITUATIONS OF LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD

### SECTION 1 - PREAMBLE

1. An increasing number of recombinant - DNA plants are being authorized for commercialization. However, they are authorized at different rates in different countries. As a consequence of these asymmetric authorizations, low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant - DNA Plants (CAC/GL 45-2003) (Codex Plant Guideline) in one or more countries may on occasion be present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined.

2. This Annex describes the recommended approach to the food safety assessment in such situations of low-level presence of recombinant-DNA plant material or in advance preparation for such potential circumstances[24].

3. This Annex also describes data and information sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply.

4. This Annex can be applied in two different dietary exposure situations :

   a. That involving commodities, such as grains, beans or oil seeds, in which exposure to food from a variety not authorized in the importing country would likely be to dilute low level amounts at any one time. This would likely be the more common situation of low-level presence of recombinant-DNA plant material. Because any food serving of grains, beans or oil seeds would almost necessarily come from multiple plants, and because of how these types of commodities generally are sourced from multiple farms, are commingled in grain elevators, are further commingled in export shipments, at import and when used in processed foods, any inadvertently commingled material derived from recombinant-DNA plant varieties would be present only at a low level in any individual serving of food.

   b. That involving foods that are commonly consumed whole and undiluted, such as some fruits and vegetables like potatoes, tomatoes, and papaya, in which exposure would be rare but could be to an undiluted form of the unauthorized recombinant-DNA plant material. While the likelihood of consuming material from such an unauthorized variety would be low and the likelihood of repeated consumption would be much lower, any such consumption might be of an entire unauthorized fruit or vegetable.

5. In both cases, the dietary exposure will be significantly lower than would be considered in a food safety assessment of the recombinant-DNA plant according to the Codex Plant Guideline. As a result, only certain elements of the Codex Plant Guideline will be relevant and therefore are included in this Annex.

6. This Annex does not :

   - address risk management measures ; national authorities will determine when a recombinant-DNA plant material is present at a level low enough for this Annex to be appropriate ;
   - preclude national authorities from conducting a safety assessment according to the Codex Plant Guideline ; countries can decide when and how to use the Annex within the context of their regulatory systems ; or
   - eliminate the responsibility of industries, exporters and, when applicable, national competent authorities to continue to meet countries' relevant import requirements, including in relation to unauthorized recombinant-DNA plant material.

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24 This guidance is not intended for a recombinant-DNA plant that was not authorized in an importing country as a result of that country's food safety assessment.

## SECTION 2 - GENERAL AND OTHER CONSIDERATIONS

7. For the food safety assessment in situations of low-level presence of recombinant DNA plant materials in food, sections 4 and 5 of the Codex Plant Guideline apply as amended as follows. The applicable paragraphs are specifically indicated. Those paragraphs of the Codex Plant Guidelines that are not listed can be omitted from consideration.

## DESCRIPTION OF THE RECOMBINANT-DNA PLANT

8. Paragraph 22 of the Codex Plant Guideline applies.

## DESCRIPTION OF THE HOST PLANT AND ITS USE AS A FOOD

9. Paragraphs 23, 24 and 25 of the Codex Plant Guideline apply.

## DESCRIPTION OF THE DONOR ORGANISM(S)

10. Information should be provided on the donor organism(s) and, when appropriate, on other related species. It is particularly important to determine if the donor organism(s) or other closely related members of the family naturally exhibit characteristics of pathogenicity or toxin production, or have other traits that affect human health. The description of the donor organism(s) should include :

    A. its usual or common name ;

    B. scientific name ;

    C. taxonomic classification ;

    D. information about the natural history as concerns food safety ;

    E. information on naturally occurring toxins and allergens; for microorganisms, additional information on pathogenicity and the relationship to known pathogens ; and,

    F. information on past and present use, if any, in the food supply and exposure route(s) other than intended food use (e.g., possible presence as contaminants)[25].

## DESCRIPTION OF THE GENETIC MODIFICATION(S)

11. Paragraphs 27, 28 and 29 of the Codex Plant Guideline apply.

## CHARACTERIZATION OF THE GENETIC MODIFICATION(S)

12. Paragraphs 30 and 31 of the Codex Plant Guideline apply.

13. Information should be provided on any expressed substances in the recombinant-DNA plant; this should include :

    A) the gene product(s) (e.g. a protein or an untranslated RNA) ;

    B) the gene product(s)' function ;

    C) the phenotypic description of the new trait(s) ;

    D) the level and site of expression in the plant of the expressed gene product(s), and the levels of its metabolites in the edible portions of the plant ; and

    E) where possible, the amount of the target gene product(s) if the function of the expressed sequence(s)/gene(s) is to alter the accumulation of a specific endogenous mRNA or protein.[26]

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25 The text of this paragraph was adapted from paragraph 26 of the Codex Plant Guideline.

26 The text of this paragraph was adapted from paragraph 32 of the Codex Plant Guideline.

14. Paragraph 33 of the Codex Plant Guideline applies.

## SAFETY ASSESSMENT

### Expressed Substances (non-nucleic acid substances)

### Assessment of possible toxicity

15. The safety assessment should take into account the chemical nature and function of the newly expressed substance and identify the concentration of the substance in the edible parts of the recombinant-DNA plant, including variations and mean values.[27]

16. Information should be provided to ensure that genes coding for known toxins present in the donor organisms are not transferred to recombinant-DNA plants that do not normally express those toxic characteristics. This assurance is particularly important in cases where a recombinant-DNA plant is processed differently from a donor plant, since conventional food processing techniques associated with the donor organisms may deactivate, degrade or eliminate toxicants.[28]

17. Paragraph 37 of the Codex Plant Guideline applies.

18. In the case of proteins, the assessment of potential toxicity should focus on amino acid sequence similarity between the protein and known protein toxins as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems. appropriate oral toxicity studies[29] may need to be carried out in cases where the protein present in the food is not similar to proteins that have previously been consumed safely in food, and taking into account its biological function in the plant where known.[30]

19. Paragraphs 39 and 40 of the Codex Plant Guideline apply.

### Assessment of possible allergenicity (proteins)

20. Paragraphs 41, 42 and 43 of the Codex Plant Guideline apply.

### Analyses of Key Toxicants and Allergens

21. Analyses of key toxicants[31] and allergens are important in certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted, such as potatoes, tomatoes, and papaya). Analyses of concentrations of key toxicants and allergens of the recombinant-DNA plant typical of the food should be compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions. The statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its biological significance. The comparator(s) used in this assessment should ideally be the near isogenic parental line. In practice, this may not be feasible at all times, in which case a line as close as possible should be chosen. The purpose of this comparison is to establish that substances that can affect the safety of the food have not been altered in a manner that would have an adverse impact on human health.[32]

22. The location of trial sites should be representative of the range of environmental conditions under which the plant varieties would be expected to be grown. The number of trial sites should be sufficient to allow accurate assessment of key toxicants and allergens over this range. Similarly,

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27 The text of this paragraph was adapted from paragraph 35 of the Codex Plant Guideline.

28 The text of this paragraph was adapted from paragraph 36 of the Codex Plant Guideline.

29 Guidelines for oral toxicity studies have been developed in international fora, for example, the OECD Guidelines for the Testing of Chemicals.

30 The text of this paragraph was adapted from paragraph 38 of the Codex Plant Guideline.

31 Key toxicants are those toxicologically significant compounds known to be inherently present in the plant, such as those compounds whose toxic potency and level may be significant to health (e.g. solanine in potatoes if the level is increased).

32 The text of this paragraph was adapted from paragraph 44 of the Codex Plant Guideline.

trials should be conducted over a sufficient number of generations to allow adequate exposure to the variety of conditions met in nature. To minimize environmental effects, and to reduce any effect from naturally occurring genotypic variation within a crop variety, each trial site should be replicated. An adequate number of plants should be sampled and the methods of analysis should be sufficiently sensitive and specific to detect variations in key toxicants and allergens.[33]

### Evaluation of Metabolites

23. Some recombinant-DNA plants may have been modified in a manner that could result in new or altered levels of various metabolites in the food. In certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted), consideration should be given to the potential for the accumulation of metabolites in the food that would adversely affect human health. Food safety assessment in situations of low level presence of recombinant-DNA material in foods from such plants requires investigation of residue and metabolite levels in the food. Where altered residue or metabolite levels are identified in foods, consideration should be given to the potential impacts on human health using conventional procedures for establishing the safety of such metabolites (e.g. procedures for assessing the human safety of chemicals in foods).[34]

### Food Processing

24. The potential effects of food processing, including home preparation, on foods derived from recombinant-DNA plants should also be considered. For example, alterations could occur in the heat stability of an endogenous toxicant. Information should therefore be provided describing the processing conditions used in the production of a food ingredient from the plant. For example, in the case of vegetable oil, information should be provided on the extraction process and any subsequent refining steps.[35]

## POTENTIAL ACCUMULATION OF SUBSTANCES SIGNIFICANT TO HUMAN HEALTH

25. Some recombinant-DNA plants may exhibit traits (e.g. herbicide tolerance) which may indirectly result in the potential for accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances which may be relevant to human health. In certain cases of foods from recombinant-DNA plants (e.g. those that are commonly consumed whole and undiluted), the risk assessment should take this potential for accumulation into account. Conventional procedures for establishing the safety of such compounds (e.g. procedures for assessing the human safety of chemicals) should be applied.[36]

## USE OF ANTIBIOTIC RESISTANCE MARKER GENES

26. Paragraphs 55, 56, 57 and 58 of the Codex Plant Guideline apply.

## SECTION 3 - GUIDANCE ON DATA AND INFORMATION SHARING

27. In order for Codex Members to use this Annex, it is essential that they have access to requisite data and information.

28. Codex Members should make available to a publicly accessible central database to be maintained by FAO information on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline. This information should be presented in accordance with the following format :

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33 The text of this paragraph was adapted from paragraph 45 of the Codex Plant Guideline.

34 The text of this paragraph was adapted from paragraph 46 of the Codex Plant Guideline.

35 The text of this paragraph was adapted from paragraph 47 of the Codex Plant Guideline.

36 The text of this paragraph was adapted from paragraph 54 of the Codex Plant Guideline.

a. name of product applicant ;

b. summary of application ;

c. country of authorization ;

d. date of authorization ;

e. scope of authorization ;

f. unique identifier ;

g. links to the information on the same product in other databases maintained by relevant international organizations, as appropriate ;

h. summary of the safety assessment, which should be consistent with the framework of food safety assessment of the Codex Plant Guideline ;

I. where detection method protocols and appropriate reference material (non-viable, or in certain circumstances, viable) suitable for low-level situation may be obtained[37]; and

j. contact details of the competent authority(s) responsible for the safety assessment and the product applicant.

29. This process should facilitate rapid access by importing Codex Members to additional information relevant to the assessment of food safety assessment in situations of low-level presence of recombinant-DNA plant material in foods in accordance with this Annex.

30. The authorizing Codex Members should make available complementary information to other Codex Members on its safety assessment in accordance with the Codex Plant Guideline, in conformity with its regulatory/legal framework.

31. The product applicant should provide further information and clarification as necessary to allow the assessment according to this Annex to proceed, as well as a validated protocol for an event-specific or trait-specific detection method suitable for low level situations and appropriate reference materials (non-viable, or in certain circumstances, viable). This is without prejudice to legitimate concerns to safeguard the confidentiality of commercial and industrial information.

32. As appropriate, new scientific information relevant to the conclusions of the food safety assessment conducted in accordance with the Codex Plant Guideline by the authorizing Codex member should be made available.

37 This information may be provided by the product applicant or in some cases by Codex members.

# PRINCIPLES FOR THE RISK ANALYSIS OF FOODS DERIVED FROM MODERN BIOTECHNOLOGY
# CAC / GL 44 - 2003

## SECTION 1 - INTRODUCTION

1. For many foods, the level of food safety generally accepted by the society reflects the history of their safe consumption by humans. It is recognised that in many cases the knowledge required to manage the risks associated with foods has been acquired in the course of their long history of use. Foods are generally considered safe, provided that care is taken during development, primary production, processing, storage, handling and preparation.

2. The hazards associated with foods are subjected to the risk analysis process of the Codex Alimentarius Commission to assess potential risks and, if necessary, to develop approaches to manage these risks. The conduct of risk analysis is guided by general decisions of the Codex Alimentarius Commission[1] as well as the Codex Working Principles for Risk Analysis[2].

3. While risk analysis has been used over a long period of time to address chemical hazards (e.g. residues of pesticides, contaminants, food additives and processing aids), and it is being increasingly used to address microbiological hazards and nutritional factors, the principles were not elaborated specifically for whole foods.

4. The risk analysis approach can, in general terms, be applied to foods including foods derived from modern biotechnology. However, it is recognised that this approach must be modified when applied to a whole food rather than to a discrete hazard that may be present in food.

5. The principles presented in this document should be read in conjunction with the Codex Working Principles for Risk Analysis to which these principles are supplemental.

6. Where appropriate, the results of a risk assessment undertaken by other regulatory authorities may be used to assist in the risk analysis and avoid duplication of work.

## SECTION 2 - SCOPE AND DEFINITIONS

7. The purpose of these Principles is to provide a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology. This document does not address environmental, ethical, moral and socio-economic aspects of the research, development, production and marketing of these foods[3].

8. The definitions below apply to these Principles :

   *"Modern Biotechnology"* means the application of :

   i ) *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

   ii ) Fusion of cells beyond the taxonomic family,

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1 These decisions include the *Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account and the Statements of principle relating to the role of food safety risk assessment* (Codex Alimentarius Commission Procedural Manual; Thirteenth edition).

2 "Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius"(adopted by the 26th Session of the Codex Alimentarius Commission, 2003; Codex Alimentarius Commission Procedural Manual; Thirteenth edition)

3 This document does not address animal feed and animals fed such feed except insofar as these animals have been developed by using modern biotechnology.

that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection[4].

*"Conventional Counterpart"* means a related organism/variety, its components and/or products for which there is experience of establishing safety based on common use as food[5].

## SECTION 3 - PRINCIPLES

9. The risk analysis process for foods derived from modern biotechnology should be consistent with the Codex Working Principles for Risk Analysis.

## RISK ASSESSMENT

10. Risk assessment includes a safety assessment, which is designed to identify whether a hazard, nutritional or other safety concern is present, and if present, to gather information on its nature and severity. The safety assessment should include a comparison between the food derived from modern biotechnology and its conventional counterpart focusing on determination of similarities and differences. If a new or altered hazard, nutritional or other safety concern is identified by the safety assessment, the risk associated with it should be characterized to determine its relevance to human health.

11. A safety assessment is characterized by an assessment of a whole food or a component thereof relative to the appropriate conventional counterpart :

    A) taking into account both intended and unintended effects ;

    B) identifying new or altered hazards ;

    C) identifying changes, relevant to human health, in key nutrients.

12. A pre-market safety assessment should be undertaken following a structured and integrated approach and be performed on a case-by-case basis. The data and information, based on sound science, obtained using appropriate methods and analysed using appropriate statistical techniques, should be of a quality and, as appropriate, of quantity that would withstand scientific peer review.

13. Risk assessment should apply to all relevant aspects of foods derived from modern biotechnology. The risk assessment approach for these foods is based on a consideration of science-based multidisciplinary data and information taking into account the factors mentioned in the accompanying Guidelines[6].

14. Scientific data for risk assessment are generally obtained from a variety of sources, such as the developer of the product, scientific literature, general technical information, independent scientists, regulatory agencies, international bodies and other interested parties. Data should be assessed using appropriate science-based risk assessment methods.

15. Risk assessment should take into account all available scientific data and information derived from different testing procedures, provided that the procedures are scientifically sound and the parameters being measured are comparable.

## RISK MANAGEMENT

16. Risk management measures for foods derived from modern biotechnology should be proportional to

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4 This definition is taken from the Cartagena Biosafety Protocol under the Convention on Biological Diversity.

5 It is recognized that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts.

6 Reference is made to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003), the Guideline for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Microorganisms (CAC/GL 46-2003) and the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (CAC/GL 68-2008).

the risk, based on the outcome of the risk assessment and, where relevant, taking into account other legitimate factors in accordance with the general decisions of the Codex Alimentarius Commission[7] as well as the Codex Working Principles for Risk Analysis.

17. It should be recognised that different risk management measures may be capable of achieving the same level of protection with regard to the management of risks associated with safety and nutritional impacts on human health, and therefore would be equivalent.

18. Risk managers should take into account the uncertainties identified in the risk assessment and implement appropriate measures to manage these uncertainties.

19. Risk management measures may include, as appropriate, food labelling[8] conditions for marketing approvals and post-market monitoring.

20. Post-market monitoring may be an appropriate risk management measure in specific circumstances. Its need and utility should be considered, on a case-by-case basis, during risk assessment and its practicability should be considered during risk management. Post-market monitoring may be undertaken for the purpose of :

A) verifying conclusions about the absence or the possible occurrence, impact and significance of potential consumer health effects ; and

B) monitoring changes in nutrient intake levels, associated with the introduction of foods likely to significantly alter nutritional status, to determine their human health impact.

21. Specific tools may be needed to facilitate the implementation and enforcement of risk management measures. These may include appropriate analytical methods; reference materials; and, the tracing of products[9] for the purpose of facilitating withdrawal from the market when a risk to human health has been identified or to support post-market monitoring in circumstances as indicated in paragraph 20.

## RISK COMMUNICATION

22. Effective risk communication is essential at all phases of risk assessment and risk management. It is an interactive process involving all interested parties, including government, industry, academia, media and consumers.

23. Risk communication should include transparent safety assessment and risk management decision-making processes. These processes should be fully documented at all stages and open to public scrutiny, whilst respecting legitimate concerns to safeguard the confidentiality of commercial and industrial information. In particular, reports prepared on the safety assessments and other aspects of the decision-making process should be made available to all interested parties.

24. Effective risk communication should include responsive consultation processes. Consultation processes should be interactive. The views of all interested parties should be sought and relevant food safety and nutritional issues that are raised during consultation should be addressed during the risk analysis process.

## CONSISTENCY

25. A consistent approach should be adopted to characterise and manage safety and nutritional risks associated with foods derived from modern biotechnology. Unjustified differences in the level of

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7 See footnote 1.

8 Reference is made to the CCFL in relation to the Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients obtained through certain techniques of genetic modification/genetic engineering at Step 3 of the Codex Elaboration Procedure.

9 It is recognised that there are other applications of product tracing. These applications should be consistent with the provisions of the SPS and TBT Agreements. The application of product tracing to the areas covered by both Agreements was considered by the Codex Committee on Food Import and Export Inspection and Certification Systems, see CAC/GL 60-2006 : *Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System.*

risks presented to consumers between these foods and similar conventional foods should be avoided.

26. A transparent and well-defined regulatory framework should be provided in characterising and managing the risks associated with foods derived from modern biotechnology. This should include consistency of data requirements, assessment frameworks, the acceptable level of risk, communication and consultation mechanisms and timely decision processes.

## CAPACITY BUILDING AND INFORMATION EXCHANGE

27. Efforts should be made to improve the capability of regulatory authorities, particularly those of developing countries, to assess, manage and communicate risks, including enforcement, associated with foods derived from modern biotechnology or to interpret assessments undertaken by other authorities or recognised expert bodies, including access to analytical technology. In addition capacity building for developing countries either through bilateral arrangements or with assistance of international organizations should be directed toward effective application of these principles[10].

28. Regulatory authorities, international organisations and expert bodies and industry should facilitate through appropriate contact points including but not limited to Codex Contact Points and other appropriate means, the exchange of information including the information on analytical methods.

## REVIEW PROCESSES

29. Risk analysis methodology and its application should be consistent with new scientific knowledge and other information relevant to risk analysis.

30. Recognizing the rapid pace of development in the field of biotechnology, the approach to safety assessments of foods derived from modern biotechnology should be reviewed when necessary to ensure that emerging scientific information is incorporated into the risk analysis. When new scientific information relevant to a risk assessment becomes available the assessment should be reviewed to incorporate that information and, if necessary, risk management measures adapted accordingly.

10 Reference is made to technical assistance of provisions in Article 9 of the SPS Agreement and Article 11 of the TBT Agreement.

# CODEX CLASS NAMES AND THE INTERNATIONAL NUMBERING SYSTEM FOR FOOD ADDITIVES CAC / GL 36 - 1989

## SECTION 1 - INTRODUCTION

### Background

The International Numbering System for Food Additives (INS) is intended as a harmonised naming system for food additives as an alternative to the use of the specific name, which may be lengthy. Inclusion in the INS does not imply approval by Codex for use as food additives. The list may include those additives that have not been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

The INS does not include flavourings, which have a JECFA number as identifier, chewing gum bases, and dietetic and nutritive additives. Enzymes which function as food additives have been included in an 1100 series.

### Explanatory notes on the lay-out of the INS

The INS in numerical order (Section 3) is set out in three columns giving the identification number, the name of the food additive and the technological purposes. The identification number usually consists of three or four digits such as 100 for curcumins and 1001 for choline salts and esters. However in some instances the number is followed by an alphabetical suffix, for example, 150a identifies caramel I-plain, 150b identifies caramel ii caustic sulfite process, and so on. The alphabetical designations are included in order to further characterize the different classes of additives (e.g. caramel produced by different processes).

Under the column listing the name of the food additive, some additives are further subdivided by numerical subscripts. For example, curcumins are subdivided into (i) curcumin and (ii) turmeric. These identifications identify sub-classes (in this case of curcumins) which are covered by separate Codex specifications.

The various technological purposes of the food additives are included in the INS in a third column. The purposes listed are indicative rather than exhaustive. The technological purposes are grouped under more descriptive functional class titles which are intended to be meaningful to consumers. These are listed in Section 2 along with simple definitions of the function performed.

A single food additive can often be used for a range of technological purposes in a food and it remains the responsibility of the manufacturer to declare the most descriptive functional class in the list of ingredients.

In preparing the INS in numerical order, an effort has been made to group food additives with similar purposes together. However, because of the extension of the list and its open nature, most of the three digit numbers have already been allocated. Consequently, the positioning of a food additive in the list can no longer be taken as an indication of the purpose, although this will often be the case.

The food additives that have been allocated an ADI by JECFA, may be found at : http://www.fao.org/ag/agn/agns/jecfa_index_en.asp and http://www.who.int/ipcs/food/jecfa/en/

JECFA specifications adopted by the Codex Alimentarius Commission are listed in CAC/MISC 6 "Codex Specifications for Food Additives" that can be found on Codex website : http://www.codexalimentarius.net/download/standards/9/CXA_006e.pdf

**The open nature of the list**

Because of its primary purpose of identification, the INS is an open list subject to the inclusion of additional additives or removal of existing ones on an ongoing basis.

## SECTION 2 - TABLE OF FUNCTIONAL CLASSES, DEFINITIONS AND TECHNOLOGICAL PURPOSES

| FUNCTIONAL CLASSES | DEFINITION | TECHNOLOGICAL PURPOSE |
|---|---|---|
| 1. Acidity regulator | A food additive, which controls the acidity or alkalinity of a food. | acidity regulator, acid, acidifier, alkali, base, buffer, buffering agent, pH adjusting agent |
| 2. Anticaking agent | A food additive, which reduces the tendency of components of food to adhere to one another. | anticaking agent, anti-stick agent, drying agent, dusting agent |
| 3. Antifoaming agent | A food additive, which prevents or reduces foaming. | antifoaming agent, defoaming agent |
| 4. Antioxidant | A food additive, which prolongs the shelflife of foods by protecting against deterioration caused by oxidation. | antioxidant, antioxidant synergist, antibrowning agent |
| 5. Bleaching agent | A food additive (non-flour use) used to decolourize food. Bleaching agents do not include pigments. | bleaching agent |
| 6. Bulking agent | A food additive, which contributes to the bulk of a food without contributing significantly to its available energy value. | bulking agent, filler |
| 7. Carbonating agent | A food additive used to provide carbonation in a food. | carbonating agent |
| 8. Carrier | A food additive used to dissolve, dilute, disperse or otherwise physically modify a food additive or nutrient without altering its function (and without exerting any technological effect itself) in order to facilitate its handling, application or use of the food additive or nutrient. | carrier, carrier solvent, nutrient carrier, diluent for other food additives, encapsulating agent |
| 9. Colour | A food additive, which adds or restores colour in a food. | colour, decorative pigment, surface colourant |
| 10. Colour retention agent | A food additive, which stabilizes, retains or intensifies the colour of a food. | colour retention agent, colour fixative, colour stabilizer, colour adjunct |
| 11. Emulsifier | A food additive, which forms or maintains a uniform emulsion of two or more phases in a food. | emulsifier, plasticizer, dispersing agent, surface active agent, crystallization inhibitor, density adjustment (flavouring oils in beverages), suspension agent, clouding agent |
| 12. Emulsifying salt | A food additive, which, in the manufacture of processed food, rearranges proteins in order to prevent fat separation. | emulsifying salt, melding salt |

| FUNCTIONAL CLASSES | DEFINITION | TECHNOLOGICAL PURPOSE |
|---|---|---|
| 13. Firming agent | A food additive, which makes or keeps tissues of fruit or vegetables firm and crisp, or interacts with gelling agents to produce or strengthen a gel. | firming agent |
| 14. Flavour enhancer | A food additive, which enhances the existing taste and/or odour of a food. | flavour enhancer, flavour synergist |
| 15. Flour treatment agent | A food additive, which is added to flour or dough to improve its baking quality or colour. | flour treatment agent, flour bleaching agent, flour improver, dough conditioner, dough strengthening agent |
| 16. Foaming agent | A food additive, which makes it possible to form or maintain a uniform dispersion of a gaseous phase in a liquid or solid food. | foaming agent, whipping agent, aerating agent |
| 17. Gelling agent | A food additive, which gives a food texture through formation of a gel. | gelling agent |
| 18. Glazing agent | A food additive, which when applied to the external surface of a food, imparts a shiny appearance or provides a protective coating. | glazing agent, sealing agent, coating agent, surface-finishing agent, polishing agent, filmforming agent |
| 19. Humectant | A food additive, which prevents food from drying out by counteracting the effect of a dry atmosphere. | humectant, moisture-retention agent, wetting agent |
| 20. Packaging gas | A food additive gas, which is introduced into a container before, during or after filling with food with the intention to protect the food, for example, from oxidation or spoilage. | packaging gas |
| 21. Preservative | A food additive, which prolongs the shelflife of a food by protecting against deterioration caused by microorganisms. | preservative, antimicrobial preservative, antimycotic agent, bacteriophage control agent, fungistatic agent, antimould and antirope agent, antimicrobial synergist |
| 22. Propellant | A food additive gas, which expels a food from a container. | propellant |
| 23. Raising agent | A food additive or a combination of food additives, which liberate(s) gas and thereby increase(s) the volume of a dough or batter. | raising agent |
| 24. Sequestrant | A food additive, which controls the availability of a cation. | sequestrant |
| 25. Stabilizer | A food additive, which makes it possible to maintain a uniform dispersion of two or more components. | stabilizer, foam stabilizer, colloidal stabilizer, emulsion stabilizer |
| 26. Sweetener | A food additive (other than a mono-or disaccharide sugar), which imparts a sweet taste to a food. | sweetener, intense sweetener, bulk sweetener |
| 27. Thickener | A food additive, which increases the viscosity of a food. | thickener, bodying agent, binder, texturizing agent |

## SECTION 3

## INTERNATIONAL NUMBERING SYSTEM FOR FOOD ADDITIVES

*List in numerical order*

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 100 | Curcumins | colour |
| 100( i ) | Curcumin | colour |
| 100( ii ) | Turmeric | colour |
| 101 | Riboflavins | colour |
| 101( i ) | Riboflavin, synthetic | colour |
| 101( ii ) | Riboflavin 5'-phosphate sodium | colour |
| 101(iii) | Riboflavin (*Bacillus subtilis*) | colour |
| 102 | Tartarzine | colour |
| 103 | Alkanet | colour |
| 104 | Quinoline yellow | colour |
| 107 | Yellow 2G | colour |
| 110 | Sunset yellow FCF | colour |
| 120 | Carmines | colour |
| 121 | Citrus red No. 2 | colour |
| 122 | Azorubine (carmoisine) | colour |
| 123 | Amaranth | colour |
| 124 | Ponceau 4R (Cochineal red A) | colour |
| 125 | Ponceau SX | colour |
| 127 | Erythrosine | colour |
| 128 | Red 2G | colour |
| 129 | Allura red AC | colour |
| 130 | Manascorubin | colour |
| 131 | Patent blue V | colour |
| 132 | Indigotine (Indigo carmine) | colour |
| 133 | Brilliant blue FCF | colour |
| 140 | Chlorophyll | colour |
| 141 | Chlorophylls and chlorophyllins, copper complexes | colour |
| 141( i ) | Chlorophylls, copper complexes | colour |
| 141( ii ) | Chlorophyllins, copper complexes, potassium and sodium salts | colour |
| 142 | Fast Green FCF | colour |
| 143 | Caramel I - plain | colour |
| 150a | Caramel II - caustic sulfite process | colour |
| 150b | Caramel III - ammonia process | colour |
| 150c | Caramel IV - sulfite ammonia process | colour |
| 150d | 151 Brilliant black (Black PN) | colour |
| 152 | Carbon black (Hydrocarbon) | colour |
| 153 | Vegetable carbon | colour |
| 154 | Brown FK | colour |
| 155 | Brown HT | colour |
| 160a | Carotenes | colour |
| 160a( i ) | Carotenes, *beta*-, (synthetic) | colour |
| 160a( ii ) | Carotenes, *beta*- (vegetable) | colour |
| 160a(iii) | Carotenes, *beta*- (Blakeslea trispora) | colour |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 160a(iv) | Carotenes, *beta-* (algae) | colour |
| 160b | Annatto extracts | colour |
| 160b( i ) | Annatto extracts, bixin-based | colour |
| 160b( ii ) | Annatto extracts, norbixin-based | colour |
| 160c | Paprika oleoresin | colour |
| 160d | Lycopenes | colour |
| 160d( i ) | Lycopene (synthetic) | colour |
| 160d( ii ) | Lycopene (tomato) | colour |
| 160d(iii) | Lycopene (*Blakeslea trispora*) | colour |
| 160e | Carotenal, *beta*-apo-8'- | colour |
| 160f | Carotenoic acid, methyl or ethyl ester, *beta*-apo-8'- | colour |
| 161a | Flavoxanthin | colour |
| 161b | Luteins | colour |
| 161b( i ) | Lutein from *Tagetes erecta* | colour |
| 161b( ii ) | Tagetes extract | colour |
| 161c | Kryptoxanthin | colour |
| 161d | Rubixanthin | colour |
| 161e | Violoxanthin | colour |
| 161f | Rhodoxanthin | colour |
| 161g | Canthaxanthin | colour |
| 161h | Zeaxanthins | colour |
| 161h( i ) | Zeaxanthin (synthetic) | colour |
| 161h( ii ) | Zeaxanthin-rich extract from *Tagetes erecta* | colour |
| 162 | Beet red | colour |
| 163 | Anthocyanins | colour |
| 163( ii ) | Grape skin extract | colour |
| 163(iii) | Blackcurrant extract | colour |
| 163(iv) | Purple corn colour | colour |
| 163( v ) | Red cabbage colour | colour |
| 164 | Gardenia yellow | colour |
| 165 | Gardenia blue | colour |
| 166 | Sandalwood | colour |
| 170 | Calcium carbonates | surface colourant,<br>anticaking agent,<br>stabilizer |
| 170( i ) | Calcium carbonate | surface colourant<br>anticaking agent<br>stabilizer<br>acidity regulator |
| 170( ii ) | Calcium hydrogen carbonate | surface colourant<br>anticaking agent<br>stabilizer<br>acidity regulator |
| 171 | Titanium dioxide | colour |
| 172 | Iron oxides | colour |
| 172( i ) | Iron oxide, black | colour |
| 172( ii ) | Iron oxide, red | colour |
| 172(iii) | Iron oxide, yellow | colour |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 173 | Aluminium | colour |
| 174 | Silver | colour |
| 175 | Gold (metallic) | colour |
| 180 | Lithol rupine BK | colour |
| 181 | Tannins, food grade | colour<br>emulsifier<br>stabilizer<br>thickener |
| 182 | Orchil | colour |
| 200 | Sorbic acid | preservative |
| 201 | Sodium sorbate | preservative |
| 202 | Potassium sorbate | preservative |
| 203 | Calcium sorbate | preservative |
| 209 | Heptyl para-hydroxybenzoate | preservative |
| 210 | Benzoic acid | preservative |
| 211 | Sodium benzoate | preservative |
| 212 | Potassium benzoate | preservative |
| 213 | Calcium benzoate | preservative |
| 214 | Ethyl para-hydroxybenzoate | preservative |
| 215 | Sodium ethyl para-hydroxybenzoate | preservative |
| 216 | Propyl para-hydroxybenzoate | preservative |
| 217 | Sodium propyl para-hydroxybenzoate | preservative |
| 218 | Methyl para-hydroxybenzoate | preservative |
| 219 | Sodium methyl para-hydroxybenzoate | preservative |
| 220 | Sulfur dioxide | preservative<br>antioxidant |
| 221 | Sodium sulfite | preservative<br>antioxidant |
| 222 | Sodium hydrogen sulfite | preservative<br>antioxidant |
| 223 | Sodium metabisulfite | preservative<br>bleaching agent<br>antioxidant<br>flour treatment agent |
| 224 | Potassium metabisulfite | preservative<br>antioxidant |
| 225 | Potassium sulfite | preservative<br>antioxidant |
| 226 | Calcium sulfite | preservative<br>antioxidant |
| 227 | Calcium hydrogen sulfite | preservative<br>antioxidant |
| 228 | Potassium bisulfite | preservative<br>antioxidant |
| 230 | Diphenyl | preservative |
| 231 | Ortho-phenylphenol | preservative |
| 232 | Sodium ortho-phenylphenol | preservative |
| 233 | Thiabendazole | preservative |
| 234 | Nisin | preservative |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 235 | Pimaricin (Natamycin) | preservative |
| 236 | Formic acid | preservative |
| 237 | Sodium formate | preservative |
| 238 | Calcium formate | preservative |
| 239 | Hexamethylene tetramine | preservative |
| 240 | Formaldehyde | preservative |
| 241 | Gum guaicum | preservative |
| 242 | Dimethyl dicarbonate | preservative |
| 243 | Ethyl lauroyl arginate | preservative |
| 249 | Potassium nitrite | preservative<br>colour fixative |
| 250 | Sodium nitrite | preservative<br>colour fixative |
| 251 | Sodium nitrate | preservative<br>colour fixative |
| 252 | Potassium nitrate | preservative<br>colour fixative |
| 260 | Acetic acid (glacial) | preservative<br>acidity regulator |
| 261 | Potassium acetates | preservative<br>acidity regulator |
| 261( i ) | Potassium acetate | preservative<br>acidity regulator |
| 261( ii ) | Potassium diacetate | preservative<br>acidity regulator |
| 262 | Sodium acetates | preservative<br>acidity regulator<br>sequestrant |
| 262( i ) | Sodium acetate | preservative<br>acidity regulator<br>sequestrant |
| 262( ii ) | Sodium diacetate | preservative<br>acidity regulator<br>sequestrant |
| 263 | Calcium acetate | preservative<br>stabilizer<br>acidity regulator |
| 264 | Ammonium acetate | acidity regulator |
| 265 | Dehydroacetic acid | preservative |
| 266 | Sodium dehydroacetate | preservative |
| 270 | Lactic acid (L-, D-, and DL-) | acidity regulator |
| 280 | Propionic acid | preservative |
| 281 | Sodium propionate | preservative |
| 282 | Calcium propionate | preservative |
| 283 | Potassium propionate | preservative |
| 290 | Carbon dioxide | carbonating agent<br>packaging gas<br>propellant<br>preservative |
| 296 | Malic acid (DL-) | acidity regulator |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 297 | Fumaric acid | acidity regulator |
| 300 | Ascorbic acid (L-) | antioxidant |
| 301 | Sodium ascorbate | antioxidant |
| 302 | Calcium ascorbate | antioxidant |
| 303 | Potassium ascorbate | antioxidant |
| 304 | Ascorbyl palmitate | antioxidant |
| 305 | Ascorbyl stearate | antioxidant |
| 307 | Tocopherols | antioxidant |
| 307a | Tocopherol, d-*alpha*- | antioxidant |
| 307b | Tocopherol concentrate, mixed | antioxidant |
| 307c | Tocopherol, dl-*alpha*- | antioxidant |
| 308 | Tocopherol, *gamma*- (synthetic) | antioxidant |
| 309 | Tocopherol, *delta*- (synthetic) | antioxidant |
| 310 | Propyl gallate | antioxidant |
| 311 | Octyl gallate | antioxidant |
| 312 | Dodecyl gallate | antioxidant |
| 313 | Ethyl gallate | antioxidant |
| 314 | Guaiac resin | antioxidant |
| 315 | Isoascorbic acidz (Erythorbic acid) | antioxidant |
| 316 | Sodium isoascorbate | antioxidant |
| 317 | Potassium isoascorbate | antioxidant |
| 318 | Calcium isoascorbate | antioxidant |
| 319 | Tertiary butylhydroquinone | antioxidant |
| 320 | Butylated hydroxyanisole | antioxidant |
| 321 | Butylated hydroxytoluene | antioxidant |
| 322 | Lecithins | antioxidant<br>emulsifier |
| 322( i ) | Lecithin | antioxidant<br>emulsifier |
| 322( ii ) | Lecithin, partially hydrolysed | antioxidant<br>emulsifier |
| 323 | Anoxomer | antioxidant |
| 324 | Ethoxyquin | antioxidant |
| 325 | Sodium lactate | antioxidant synergist<br>humectant<br>bulking agent<br>acidity regulator<br>bodying agent |
| 326 | Potassium lactate | antioxidant synergist<br>acidity regulator |
| 327 | Calcium lactate | acidity regulator<br>flour treatment agent |
| 328 | Ammonium lactate | acidity regulator<br>flour treatment agent |
| 329 | Magnesium lactate (DL-) | acidity regulator<br>flour treatment agent |
| 330 | Citric acid | acidity regulator<br>antioxidant<br>sequestrant |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 331 | Sodium citrates | acidity regulator<br>sequestrant<br>emulsifier<br>stabilizer |
| 331( i ) | Sodium dihydrogen citrate | acidity regulator<br>sequestrant<br>emulsifier<br>stabilizer |
| 331( ii ) | Disodium monohydrogen citrate | acidity regulator<br>sequestrant<br>emulsifier<br>stabilizer |
| 331(iii) | Trisodium citrate | acidity regulador<br>sequestrant<br>emulsifier<br>stabilizer |
| 332 | Potassium citrates | acidity regulator<br>sequestrant<br>stabilizer |
| 332( i ) | Potassium dihydrogen citrate | acidity regulator<br>sequestrant<br>stabilizer |
| 332( ii ) | Tripotassium citrate | acidity regulator<br>sequestrant<br>stabilizer |
| 333 | Calcium citrates | acidity regulator<br>firming agent<br>sequestrant<br>stabilizer |
| 333( i ) | Monocalcium citrate | acidity regulator<br>firming agent<br>sequestrant<br>stabilizer |
| 333( ii ) | Dicalcium citrate | acidity regulator<br>firming agent<br>sequestrant<br>stabilizer |
| 333(iii) | Tricalcium citrate | acidity regulator<br>firming agent<br>sequestrant<br>stabilizer |
| 334 | Tartaric acid (L(+)-) | acidity regulator<br>sequestrant<br>antioxidant synergist |
| 335 | Sodium tartrates | stabilizer<br>sequestrant |
| 335( i ) | Monosodium tartrate | stabilizer<br>sequestrant<br>acidity regulator |
| 335( ii ) | Disodium tartrate | stabilizer<br>sequestrant<br>acidity regulator |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 336 | Potassium tartrates | stabilizer<br>sequestrant |
| 336( i ) | Monopotassium tartrate | stabilizer<br>sequestrant<br>acidity regulator |
| 336( ii ) | Dipotassium tartrate | stabilizer<br>sequestrant<br>acidity regulator |
| 337 | Potassium sodium tartrate | stabilizer<br>sequestrant<br>acidity regulator |
| 338 | Orthophosphoric acid | acidity regulator<br>antioxidant synergist<br>sequestrant |
| 339 | Sodium phosphates | acidity regulator<br>sequestrant<br>emulsifier<br>texturizing agent<br>stabilizer<br>moisture-retention agent |
| 339( i ) | Monosodium orthophosphate | acidity regulator<br>sequestrant<br>emulsifier<br>texturizing agent<br>stabilizer<br>moisture-retention agent |
| 339( ii ) | Disodium orthophosphate | acidity regulator<br>sequestrant<br>emulsifier<br>texturizing agent<br>stabilizer<br>moisture-retention agent |
| 339(iii) | Trisodium orthophosphate | acidity regulator<br>sequestrant<br>emulsifier<br>texturizing agent<br>stabilizer<br>moisture-retention agent |
| 340 | Potassium phosphates | acidity regulator<br>sequestrant<br>emulsifier<br>texturizing agent<br>stabilizer<br>moisture-retention agent |
| 340( i ) | Monopotassium orthophosphate | acidity regulator<br>sequestrant<br>emulsifier<br>texturizing agent<br>stabilizer<br>moisture-retention agent |
| 340( ii ) | Dipotassium orthophosphate | acidity regulator<br>sequestrant<br>emulsifier<br>texturizing agent<br>stabilizer<br>moisture-retention agent |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 340(iii) | Tripotassium orthophosphate | acidity regulator<br>sequestrant<br>emulsifier<br>texturizing agent<br>stabilizer<br>moisture-retention agent |
| 341 | Calcium phosphates | acidity regulator<br>flour treatment agent<br>firming agent<br>texturizing agent<br>raising agent<br>anticaking agent<br>moisture-retention agent |
| 341( i ) | Monocalcium orthophosphate | acidity regulator<br>flour treatment agent<br>firming agent<br>texturizing agent<br>raising agent<br>anticaking agent<br>moisture-retention agent<br>stabilizer |
| 341( ii ) | Dicalcium orthophosphate | acidity regulator<br>flour treatment agent<br>firming agent<br>texturizing agent<br>raising agent<br>anticaking agent<br>moisture-retention agent<br>stabilizer |
| 341(iii) | Tricalcium orthophosphate | acidity regulator<br>flour treatment agent<br>firming agent<br>texturizing agent<br>raising agent<br>anticaking agent<br>moisture-retention agent<br>stabilizer<br>buffer |
| 342 | Ammonium phosphates | acidity regulator<br>flour treatment agent |
| 342( i ) | Monoammonium orthophosphate | acidity regulator<br>flour treatment agent |
| 342( ii ) | Diammonium orthophosphate | acidity regulator<br>flour treatment agent |
| 343 | Magnesium phosphates | acidity regulator<br>anticaking agent |
| 343( i ) | Monomagnesium orthophosphate | acidity regulator<br>anticaking agent |
| 343( ii ) | Dimagnesium orthophosphate | acidity regulator<br>anticaking agent |
| 343(iii) | Trimagnesium orthophosphate | acidity regulator<br>anticaking agent |
| 344 | Lecithin citrate | preservative |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 345 | Magnesium citrate | acidity regulator |
| 349 | Ammonium malate | acidity regulator |
| 350 | Sodium malates | acidity regulator<br>humectant |
| 350( i ) | Sodium hydrogen malate | acidity regulator<br>humectant |
| 350( ii ) | Sodium malate | acidity regulator<br>humectant |
| 351 | Potassium malates | acidity regulator |
| 351( i ) | Potassium hydrogen malate | acidity regulator |
| 351( ii ) | Potassium malate | acidity regulator |
| 352 | Calcium malates | acidity regulator |
| 352( i ) | Calcium hydrogen malate | acidity regulator |
| 352( ii ) | Calcium malate (D,L-) | acidity regulator |
| 353 | Metatartaric acid | acidity regulator |
| 354 | Calcium tartrate(DL-) | acidity regulator |
| 355 | Adipic acid | acidity regulator |
| 356 | Sodium adipates | acidity regulator |
| 357 | Potassium adipates | acidity regulator |
| 359 | Ammonium adipates | acidity regulator |
| 363 | Succinic acid | acidity regulator |
| 364 | Sodium succinates | acidity regulator<br>flavour enhancer |
| 364( i ) | Monosodium succinate | acidity regulator<br>flavour enhancer |
| 364( ii ) | Disodium succinate | acidity regulator<br>flavour enhancer |
| 365 | Sodium fumarates | acidity regulator |
| 366 | Potassium fumarates | acidity regulator |
| 367 | Calcium fumarates | acidity regulator |
| 368 | Ammonium fumarate | acidity regulator |
| 370 | Heptonolactone, 1,4- | acidity regulator<br>sequestrant |
| 375 | Nicotinic acid | colour retention agent |
| 380 | Triammonium citrate | acidity regulator |
| 381 | Ferric ammonium citrate | anticaking agent |
| 383 | Calcium glycerophosphate | thickener<br>gelling agent<br>stabilizer |
| 384 | Isopropyl citrates | antioxidant<br>preservative<br>sequestrant |
| 385 | Calcium disodium ethylenediaminetetraacetate | antioxidant<br>preservative<br>sequestrant |
| 386 | Disodium ethylenediaminetetraacetate | antioxidant<br>preservative |
| 387 | Oxystearin | antioxidant<br>sequestrant |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 388 | Thiodipropionic acid | antioxidant |
| 389 | Dilauryl thiodipropionate | antioxidant |
| 390 | Distearyl thiodipropionate | antioxidant |
| 391 | Phytic acid | preservative |
| 399 | Calcium lactobionate | stabilizer |
| 400 | Alginic acid | thickener<br>stabilizer<br>gelling agent<br>emulsifier |
| 401 | Sodium alginate | thickener<br>stabilizer<br>gelling agent<br>emulsifier |
| 402 | Potassium alginate | thickener<br>stabilizer<br>gelling agent<br>emulsifier |
| 403 | Ammonium alginate | thickener<br>stabilizer<br>gelling agent<br>emulsifier |
| 404 | Calcium alginate | thickener<br>stabilizer<br>gelling agent<br>antifoaming agent |
| 405 | Propylene glycol alginate | thickener<br>emulsifier<br>stabilizer |
| 406 | Agar | thickener<br>stabilizer<br>gelling agent<br>emulsifier |
| 407 | Carrageenan and its ammonium, calcium, magnesium, potassium and sodium salts(includes furcellaran) | thickener<br>gelling agent<br>stabilizer<br>emulsifier |
| 407a | Processed euchema seaweed (PES) | thickener<br>stabilizer<br>gelling agent<br>emulsifier |
| 408 | Bakers yeast glycan | thickener<br>gelling agent<br>stabilizer |
| 409 | Arabinogalactan | thickener<br>gelling agent<br>stabilizer |
| 410 | Carob bean gum | thickener<br>stabilizer<br>emulsifier |
| 411 | Oat gum | thickener<br>stabilizer |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 412 | Guar gum | thickener<br>stabilizer<br>emulsifier |
| 413 | Tragacanth gum | thickener<br>stabilizer<br>emulsifier |
| 414 | Gum arabic (Acacia gum) | thickener<br>stabilizer<br>emulsifier |
| 415 | Xanthan gum | thickener<br>stabilizer<br>emulsifier<br>foaming agent |
| 416 | Karaya gum | thickener<br>stabilizer<br>emulsifier |
| 417 | Tara gum | thickener<br>stabilizer |
| 418 | Gellan gum | thickener<br>stabilizer<br>gelling agent |
| 419 | Gum ghatti | thickener<br>stabilizer<br>emulsifier |
| 420 | Sorbitols | sweetener<br>humectant<br>sequestrant<br>stabilizer<br>bulking agent |
| 420( i ) | Sorbitol | sweetener<br>humectant<br>sequestrant<br>stabilizer<br>bulking agent |
| 420( ii ) | Sorbitol syrup | sweetener<br>humectant<br>sequestrant<br>stabilizer<br>bulking agent |
| 421 | Mannitol | sweetener<br>anticaking agent<br>humectant<br>stabilizer<br>bulking agent |
| 422 | Glycerol | humectant<br>bodying agent |
| 424 | Curdlan | thickener<br>stabilizer<br>firming agent<br>gelling agent |
| 425 | Konjac flour | thickener<br>gelling agent<br>emulsifier<br>stabilizer |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 426 | Soybean hemicellulose | emulsifier<br>thickener<br>stabilizer<br>anticaking agent |
| 427 | Cassia gum | emulsifier<br>stabilizer<br>gelling agent<br>thickener |
| 428 | Gelatin | stabilizer<br>gelling agent<br>emulsifier<br>thickener<br>carrier |
| 429 | Peptones | emulsifier |
| 430 | Polyoxyethylene (8) stearate | emulsifier |
| 431 | Polyoxyethylene (40) stearate | emulsifier |
| 432 | Polyoxyethylene (20) sorbitan monolaurate | emulsifier<br>dispersing agent |
| 433 | Polyoxyethylene (20) sorbitan monooleate | emulsifier<br>dispersing agent |
| 434 | Polyoxyethylene (20) sorbitan monopalmitate | emulsifier<br>dispersing agent |
| 435 | Polyoxyethylene (20) sorbitan monostearate | emulsifier<br>dispersing agent |
| 436 | Polyoxyethylene (20) sorbitan tristearate | emulsifier<br>dispersing agent |
| 440 | Pectins | thickener<br>stabilizer<br>gelling agent<br>emulsifier |
| 441 | Superglycerinated hydrogenated rapeseed oil | emulsifier |
| 442 | Ammonium salts of phosphatidic acid | emulsifier |
| 443 | Brominated vegetable oils | emulsifier<br>stabilizer |
| 444 | Sucrose acetate isobutyrate | emulsifier<br>stabilizer |
| 445 | Glycerol esters of wood rosin | emulsifier<br>stabilizer<br>glazing agent |
| 446 | Succistearin | emulsifier |
| 450 | Diphosphates | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 450( i ) | Disodium diphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 450( ii ) | Trisodium diphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 450(iii) | Tetrasodium diphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 450(iv) | Dipotassium diphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 450( v ) | Tetrapotassium diphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 450(vi) | Dicalcium diphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent<br>buffering agent |
| 450(vii) | Calcium dihydrogen diphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 450(viii) | Dimagnesium diphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 451 | Triphosphates | sequestrant<br>acidity regulator<br>texturizing agent |
| 451( i ) | Pentasodium triphosphate | sequestrant<br>acidity regulator<br>texturizing agent |
| 451( ii ) | Pentapotassium triphosphate | sequestrant<br>acidity regulator<br>texturizing agent |
| 452 | Polyphosphates | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 452( i ) | Sodium polyphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 452( ii ) | Potassium polyphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 452(iii) | Sodium calcium polyphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 452(iv) | Calcium polyphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 452( v ) | Ammonium polyphosphate | emulsifier<br>stabilizer<br>sequestrant<br>texturizing agent<br>moisture-retention agent |
| 452(vi) | Sodium potassium tripolyphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 457 | Cyclodextrin, *alpha-* | stabilizer<br>binder |
| 458 | Cyclodextrin, *gamma-* | stabilizer<br>binder |
| 459 | Cyclodextrin, *beta-* | stabilizer<br>binder<br>carrier |
| 460 | Celluloses | emulsifier<br>anticaking agent<br>texturizing agent<br>dispersing agent<br>stabilizer<br>thickener |
| 460( i ) | Microcrystalline cellulose | emulsifier<br>anticaking agent<br>texturizing agent<br>dispersing agent<br>stabilizer<br>thickener |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 460( ii ) | Powdered cellulose | emulsifier<br>anticaking agent<br>texturizing agent<br>dispersing agent<br>stabilizer<br>thickener |
| 461 | Methyl cellulose | thickener<br>emulsifier<br>stabilizer |
| 462 | Ethyl cellulose | binder<br>filler |
| 463 | Hydroxypropyl cellulose | thickener<br>emulsifier<br>stabilizer |
| 464 | Hydroxypropyl methyl cellulose | thickener<br>emulsifier<br>stabilizer |
| 465 | Methyl ethyl cellulose | thickener<br>emulsifier<br>stabilizer<br>foaming agent |
| 466 | Sodium carboxymethyl cellulose (cellulose gum) | thickener<br>stabilizer<br>emulsifier |
| 467 | Ethyl hydroxyethyl cellulose | thickener<br>stabilizer<br>emulsifier |
| 468 | Cross-linked sodium carboxymethyl cellulose (crosslinked cellulose gum) | stabilizer<br>binder |
| 469 | Sodium carboxymethyl cellulose, enzymatically hydrolysed (cellulose gum, enzymatically hydrolyzed) | thickener<br>stabilizer |
| 470 | Salts of fatty acids (with base aluminium, ammonium, calcium, magnesium, potassium, sodium) | emulsifier<br>stabilizer<br>anticaking agent |
| 470( i ) | Salts of myristic, palmitic and stearic acids with ammonia, calcium, potassium and sodium | emulsifier<br>stabilizer<br>anticaking agent |
| 470( ii ) | Salts of oleic acid with calcium, potassium and sodium | emulsifier<br>stabilizer<br>anticaking agent |
| 471 | Mono- and di- glycerides of fatty acids | emulsifier<br>stabilizer |
| 472a | Acetic and fatty acid esters of glycerol | emulsifier<br>stabilizer<br>sequestrant |
| 472b | Lactic and fatty acid esters of glycerol | emulsifier<br>stabilizer<br>sequestrant |
| 472c | Citric and fatty acid esters of glycerol | emulsifier<br>stabilizer<br>sequestrant<br>dough conditioner<br>antioxidant synergist |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 472d | Tartaric acid esters of mono- and di-glycerides of fatty acids | emulsifier<br>stabilizer<br>sequestrant |
| 472e | Diacetyltartaric and and fatty acid esters of glycerol | emulsifier<br>stabilizer<br>sequestrant |
| 472g | Succinylated monoglycerides | emulsifier<br>stabilizer<br>sequestrant |
| 473 | Sucrose esters of fatty acids | emulsifier<br>stabilizer |
| 473a | Sucrose oligoesters, type I and type II | emulsifier<br>stabilizer |
| 474 | Sucroglycerides | emulsifier |
| 475 | Polyglycerol esters of fatty acids | emulsifier |
| 476 | Polyglycerol esters of interesterified ricinoleic acid | emulsifier |
| 477 | Propylene glycol esters of fatty acids | emulsifier |
| 478 | Lactylated fatty acid esters of glycerol and propylene glycol | emulsifier |
| 479 | Thermally oxidized soya bean oil with mono- and diglycerides of fatty acids | emulsifier |
| 480 | Dioctyl sodium sulfosuccinate | emulsifier<br>wetting agent |
| 481 | Sodium lactylates | emulsifier<br>stabilizer |
| 481( i ) | Sodium stearoyl lactylate | emulsifier<br>stabilizer |
| 481( ii ) | Sodium oleyl lactylate | emulsifier<br>stabilizer |
| 482 | Calcium lactylates | emulsifier<br>stabilizer |
| 482( i ) | Calcium stearoyl lactylate | emulsifier |
| 482( ii ) | Calcium oleyl lactylate | emulsifier<br>stabilizer |
| 483 | Stearyl tartrate | flour treatment agent |
| 484 | Stearyl citrate | emulsifier<br>sequestrant |
| 485 | Sodium stearoyl fumarate | emulsifier |
| 486 | Calcium stearoyl fumarate | emulsifier |
| 487 | Sodium laurylsulfate | emulsifier |
| 488 | Ethoxylated mono- and di-glycerides | emulsifier |
| 489 | Methyl glucoside-coconut oil ester | emulsifier |
| 491 | Sorbitan monostearate | emulsifier |
| 492 | Sorbitan tristearate | emulsifier |
| 493 | Sorbitan monolaurate | emulsifier<br>stabilizer |
| 494 | Sorbitan monooleate | emulsifier<br>stabilizer |
| 495 | Sorbitan monopalmitate | emulsifier |
| 496 | Sorbitan trioleate | stabilizer<br>emulsifier |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 472d | Tartaric acid esters of mono- and di-glycerides of fatty acids | emulsifier<br>stabilizer<br>sequestrant |
| 472e | Diacetyltartaric and and fatty acid esters of glycerol | emulsifier<br>stabilizer<br>sequestrant |
| 472g | Succinylated monoglycerides | emulsifier<br>stabilizer<br>sequestrant |
| 473 | Sucrose esters of fatty acids | emulsifier<br>stabilizer |
| 473a | Sucrose oligoesters, type I and type II | emulsifier<br>stabilizer |
| 474 | Sucroglycerides | emulsifier |
| 475 | Polyglycerol esters of fatty acids | emulsifier |
| 476 | Polyglycerol esters of interesterified ricinoleic acid | emulsifier |
| 477 | Propylene glycol esters of fatty acids | emulsifier |
| 478 | Lactylated fatty acid esters of glycerol and propylene glycol | emulsifier |
| 479 | Thermally oxidized soya bean oil with mono- and diglycerides of fatty acids | emulsifier |
| 480 | Dioctyl sodium sulfosuccinate | emulsifier<br>wetting agent |
| 481 | Sodium lactylates | emulsifier<br>stabilizer |
| 481( i ) | Sodium stearoyl lactylate | emulsifier<br>stabilizer |
| 481( ii ) | Sodium oleyl lactylate | emulsifier<br>stabilizer |
| 482 | Calcium lactylates | emulsifier<br>stabilizer |
| 482( i ) | Calcium stearoyl lactylate | emulsifier |
| 482( ii ) | Calcium oleyl lactylate | emulsifier<br>stabilizer |
| 483 | Stearyl tartrate | flour treatment agent |
| 484 | Stearyl citrate | emulsifier<br>sequestrant |
| 485 | Sodium stearoyl fumarate | emulsifier |
| 486 | Calcium stearoyl fumarate | emulsifier |
| 487 | Sodium laurylsulfate | emulsifier |
| 488 | Ethoxylated mono- and di-glycerides | emulsifier |
| 489 | Methyl glucoside-coconut oil ester | emulsifier |
| 491 | Sorbitan monostearate | emulsifier |
| 492 | Sorbitan tristearate | emulsifier |
| 493 | Sorbitan monolaurate | emulsifier<br>stabilizer |
| 494 | Sorbitan monooleate | emulsifier<br>stabilizer |
| 495 | Sorbitan monopalmitate | emulsifier |
| 496 | Sorbitan trioleate | stabilizer<br>emulsifier |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 500 | Sodium carbonates | acidity regulator<br>raising agent<br>anticaking agent |
| 500( i ) | Sodium carbonate | acidity regulator<br>raising agent<br>anticaking agent |
| 500( ii ) | Sodium hydrogen carbonate | acidity regulator<br>raising agent<br>anticaking agent |
| 500(iii) | Sodium sesquicarbonate | acidity regulator<br>raising agent<br>anticaking agent |
| 501 | Potassium carbonates | acidity regulator<br>stabilizer |
| 501( i ) | Potassium carbonate | acidity regulator<br>stabilizer |
| 501( ii ) | Potassium hydrogen carbonate | acidity regulator<br>stabilizer |
| 503 | Ammonium carbonates | acidity regulator<br>raising agent |
| 503( i ) | Ammonium carbonate | acidity regulator<br>raising agent |
| 503( ii ) | Ammonium hydrogen carbonate | acidity regulator<br>raising agent |
| 504 | Magnesium carbonates | acidity regulator<br>anticaking agent<br>colour retention agent |
| 504( i ) | Magnesium carbonate | acidity regulator<br>anticaking agent<br>colour retention agent |
| 504( ii ) | Magnesium hydrogen carbonate | acidity regulator<br>anticaking agent<br>colour retention agent<br>carrier<br>drying agent |
| 505 | Ferrous carbonate | acidity regulator |
| 507 | Hydrochloric acid | acidity regulator |
| 508 | Potassium chloride | gelling agent<br>stabilizer<br>flavour enhancer<br>thickener |
| 509 | Calcium chloride | firming agent<br>stabilizer<br>thickener |
| 510 | Ammonium chloride | flour treatment agent |
| 511 | Magnesium chloride | firming agent<br>colour retention agent<br>stabilizer |
| 512 | Stannous chloride | antioxidant<br>colour retention agent |
| 513 | Sulfuric acid | acidity regulator |
| 514 | Sodium sulfates | acidity regulator |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 515 | Potassium sulfates | acidity regulator |
| 516 | Calcium sulfate | flour treatment agent<br>sequestrant<br>firming agent<br>stabilizer |
| 517 | Ammonium sulfate | flour treatment agent<br>stabilizer |
| 518 | Magnesium sulfate | firming agent |
| 519 | Cupric sulfate | colour fixative<br>preservative |
| 520 | Aluminium sulfate | firming agent |
| 521 | Aluminium sodium sulfate | firming agent |
| 522 | Aluminium potassium sulfate | acidity regulator<br>stabilizer |
| 523 | Aluminium ammonium sulfate | stabilizer<br>firming agent |
| 524 | Sodium hydroxide | acidity regulator |
| 525 | Potassium hydroxide | acidity regulator |
| 526 | Calcium hydroxide | acidity regulator<br>firming agent |
| 527 | Ammonium hydroxide | acidity regulator |
| 528 | Magnesium hydroxide | acidity regulator<br>colour retention agent |
| 529 | Calcium oxide | acidity regulator<br>flour treatment agent<br>dough conditioner |
| 530 | Magnesium oxide | anticaking agent |
| 535 | Sodium ferrocyanide | anticaking agent |
| 536 | Potassium ferrocyanide | anticaking agent |
| 537 | Ferrous hexacyanomanganate | anticaking agent |
| 538 | Calcium ferrocyanide | anticaking agent |
| 539 | Sodium thiosulfate | antioxidant<br>sequestrant<br>antibrowning agent |
| 541 | Sodium aluminium phosphate | acidity regulator<br>emulsifier |
| 541( i ) | Sodium aluminium phosphate (acidic) | acidity regulator<br>emulsifier<br>raising agent |
| 541( ii ) | Sodium aluminium phosphate (basic) | acidity regulator<br>emulsifier |
| 542 | Bone phosphate (essentially calcium phosphate, tribasic) | emulsifier<br>anticaking agent<br>moisture-retention agent |
| 550 | Sodium silicates | anticaking agent |
| 550( i ) | Sodium silicate | anticaking agent |
| 550( ii ) | Sodium metasilicate | anticaking agent |
| 551 | Silicon dioxide, amorphous | anticaking agent |
| 552 | Calcium silicate | anticaking agent |
| 553 | Magnesium silicates | anticaking agent<br>dusting agent |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 553( i ) | Magnesium silicate | anticaking agent<br>dusting agent |
| 553( ii ) | Magnesium trisilicate | anticaking agent<br>dusting agent |
| 553(iii) | Talc | anticaking agent<br>dusting agent<br>coating agent<br>surface-finishing agent<br>texturizing agent |
| 554 | Sodium aluminosilicate | anticaking agent |
| 555 | Potassium aluminium silicate | anticaking agent |
| 556 | Calcium aluminium silicate | anticaking agent |
| 557 | Zinc silicate | anticaking agent |
| 558 | Bentonite | anticaking agent |
| 559 | Aluminium silicate | anticaking agent |
| 560 | Potassium silicate | anticaking agent |
| 570 | Fatty acids | foam stabilizer<br>glazing agent<br>antifoaming agent |
| 574 | Gluconic acid (D-) | acidity regulator<br>raising agent |
| 575 | Glucono delta-lactone | acidity regulator<br>raising agent<br>sequestrant |
| 576 | Sodium gluconate | sequestrant |
| 577 | Potassium gluconate | sequestrant<br>acidity regulator |
| 578 | Calcium gluconate | acidity regulator<br>firming agent<br>sequestrant |
| 579 | Ferrous gluconate | colour retention agent |
| 580 | Magnesium gluconate | acidity regulator<br>firming agent<br>flavour enhancer |
| 585 | Ferrous lactate | colour retention agent |
| 586 | Hexylresorcinol, 4- | colour retention agent<br>antioxidant |
| 620 | Glutamic acid, (L(+)-) | flavour enhancer |
| 621 | Monosodium glutamate | flavour enhancer |
| 622 | Monopotassium glutamate | flavour enhancer |
| 623 | Calcium glutamate (D,L-) | flavour enhancer |
| 624 | Monoammonium glutamate | flavour enhancer |
| 625 | Magnesium glutamate | flavour enhancer |
| 626 | Guanylic acid, 5'- | flavour enhancer |
| 627 | Disodium 5'-guanylate | flavour enhancer |
| 628 | Dipotassium 5'-guanylate | flavour enhancer |
| 629 | Calcium 5'-guanylate | flavour enhancer |
| 630 | Inosinic acid | flavour enhancer |
| 631 | Disodium 5'-inosinate | flavour enhancer |
| 632 | Potassium inosinate | flavour enhancer |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 633 | Calcium 5'-inosinate | flavour enhancer |
| 634 | Calcium 5'-ribonucleotides | flavour enhancer |
| 635 | Disodium 5'-ribonucleotides | flavour enhancer |
| 636 | Maltol | flavour enhancer |
| 637 | Ethyl maltol | flavour enhancer |
| 638 | Sodium L-aspartate | flavour enhancer |
| 639 | Alanine, DL- | flavour enhancer |
| 640 | Glycine | flavour enhancer |
| 641 | Leucine, L- | flavour enhancer |
| 642 | Lysin hydrochloride | flavour enhancer |
| 650 | Zinc acetate | flavour enhancer |
| 900a | Polydimethylsiloxane | antifoaming agent<br>anticaking agent<br>emulsifier |
| 900b | Methylphenylpolysiloxane | antifoaming agent |
| 901 | Beeswax | glazing agent, clouding agent |
| 902 | Candelilla wax | glazing agent<br>clouding agent |
| 903 | Carnauba wax | glazing agent<br>bulking agent<br>acidity regulator<br>carrier |
| 904 | Shellac | glazing agent |
| 905a | Mineral oil, food grade | glazing agent<br>sealing agent |
| 905b | Petrolatum (Petroleum jelly) | glazing agent<br>sealing agent<br>antifoaming agent |
| 905c | Petroleum wax | glazing agent<br>sealing agent |
| 905c( i ) | Microcrystalline wax | glazing agent |
| 905c( ii ) | Paraffin wax | glazing agent |
| 905d | Mineral oil, high viscosity | glazing agent<br>sealing agent |
| 905e | Mineral oil, medium and low viscosity (class i ) | glazing agent<br>sealing agent |
| 905f | Mineral oil, medium and low viscosity (class II) | glazing agent<br>sealing agent |
| 905g | Mineral oil, medium and low viscosity (class III) | glazing agent<br>sealing agent |
| 906 | Benzoin gum | glazing agent |
| 907 | Hydrogenated poly-decenes | glazing agent |
| 908 | Rice bran wax | glazing agent |
| 909 | Spermaceti wax | glazing agent |
| 910 | Wax esters | glazing agent |
| 911 | Methyl esters of fatty acids | glazing agent |
| 913 | Lanolin | glazing agent |
| 915 | Glycerol, methyl, or pentaerithrytol esters of colophane | glazing agent |
| 916 | Calcium iodate | flour treatment agent |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 917 | Potassium iodate | flour treatment agent |
| 918 | Nitrogen oxides | flour treatment agent |
| 919 | Nitrosyl chloride | flour treatment agent |
| 920 | Cysteine, L- and its hydrochlorides – sodium and potassium salts | flour treatment agent |
| 921 | Cystine, L-and its hydrochlorides sodium and potassium salts | flour treatment agent |
| 922 | Potassium persulfate | flour treatment agent |
| 923 | Ammonium persulfate | flour treatment agent |
| 924a | Potassium bromate | flour treatment agent |
| 924b | Calcium bromate | flour treatment agent |
| 925 | Chlorine | flour bleaching agent |
| 926 | Chlorine dioxide | flour treatment agent |
| 927a | Azodicarbonamide | flour treatment agent |
| 927b | Urea (Carbamide) | flour treatment agent |
| 928 | Benzoyl peroxide | flour treatment agent<br>preservative |
| 929 | Acetone peroxide | flour treatment agent |
| 930 | Calcium peroxide | flour treatment agent |
| 940 | Dichlorodifluormethane | propellant |
| 941 | Nitrogen | packaging gas<br>propellant |
| 942 | Nitrous oxide | propellant<br>antioxidant<br>foaming agent<br>packaging gas |
| 943a | Butane | propellant |
| 943b | Isobutane | propellant |
| 944 | Propane | propellant |
| 945 | Chloropentafluorethane | propellant |
| 946 | Octafluorcyclobutane | propellant |
| 949 | Hydrogen | packaging gas |
| 950 | Acesulfame potassium | sweetener<br>flavour enhancer |
| 951 | Aspartame | sweetener<br>flavour enhancer |
| 952 | Cyclamates | sweetener |
| 952( i ) | Cyclamic acid | sweetener |
| 952( ii ) | Calcium cyclamate | sweetener |
| 952(iii) | Potassium cyclamate | sweetener |
| 952(iv) | Sodium cyclamate | sweetener |
| 953 | Isomalt (Isomaltitol) | sweetener<br>anticaking agent<br>bulking agent<br>glazing agent |
| 954 | Saccharins | sweetener |
| 954( i ) | Saccharin | sweetener |
| 954( ii ) | Calcium saccharin | sweetener |
| 954(iii) | Potassium saccharin | sweetener |
| 954(iv) | Sodium saccharin | sweetener |
| 955 | Sucralose (Trichlorogalactosucrose) | sweetener |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 956 | Alitame | sweetener |
| 957 | Thaumatin | sweetener<br>flavour enhancer |
| 958 | Glycyrrhizin | sweetener<br>flavour enhancer |
| 959 | Neohesperidine dihydrochalcone | sweetener |
| 960 | Steviol glycosides | sweetener |
| 961 | Neotame | sweetener<br>flavour enhancer |
| 962 | Aspartame-acesulfame salt | sweetener |
| 963 | Tagatose, D- | sweetener |
| 964 | Polyglycitol syrup | sweetener |
| 965 | Maltitols | sweetener<br>stabilizer<br>emulsifier<br>humectant<br>bulking agent |
| 965( i ) | Maltitol | sweetener<br>stabilizer<br>emulsifier<br>humectant<br>bulking agent |
| 965( ii ) | Maltiol syrup | sweetener<br>stabilizer<br>emulsifier<br>humectant<br>bulking agent |
| 966 | Lactitol | sweetener<br>texturizing agent<br>emulsifier |
| 967 | Xylitol | sweetener<br>humectant<br>stabilizer<br>emulsifier<br>thickener |
| 968 | Erythritol | sweetener<br>flavour enhancer<br>humectant |
| 999 | Quillaia extracts | foaming agent<br>emulsifier |
| 999( i ) | Quillaia extract type 1 | foaming agent<br>emulsifier |
| 999( ii ) | Quillaia extract type 2 | foaming agent<br>emulsifier |
| 1000 | Cholic acid | emulsifier |
| 1001 | Choline salts and esters | emulsifier |
| 1001( i ) | Choline acetate | emulsifier |
| 1001( ii ) | Choline carbonate | emulsifier |
| 1001(iii) | Choline chloride | emulsifier |
| 1001(iv) | Choline citrate | emulsifier |
| 1001( v ) | Choline tartrate | emulsifier |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 1001(vi) | Choline lactate | emulsifier |
| 1100 | Amylases | flour treatment agent |
| 1101 | Proteases | flour treatment agent<br>stabilizer<br>flavour enhancer |
| 1101( i ) | Protease | flour treatment agent<br>stabilizer<br>flavour enhancer |
| 1101( ii ) | Papain | flavour enhancer |
| 1101(iii) | Bromelain | flour treatment agent<br>stabilizer<br>flavour enhancer |
| 1101(iv) | Ficin | flour treatment agent<br>stabilizer<br>flavour enhancer |
| 1102 | Glucose oxidase | antioxidant |
| 1103 | Invertases | stabilizer |
| 1104 | Lipases | flavour enhancer |
| 1105 | Lysozyme | preservative |
| 1200 | Polydextroses A and N | bulking agent<br>stabilizer<br>thickener<br>humectant<br>texturizing agent |
| 1201 | Polyvinylpyrrolidone | bodying agent<br>stabilizer<br>dispersing agent |
| 1202 | Polyvinylpyrrolidone (insoluble) | colour stabilizer<br>colloidal stabilizer<br>stabilizer |
| 1203 | Polyvinyl alcohol | coating agent<br>binder<br>sealing agent<br>surface-finishing agent |
| 1204 | Pullulan | glazing agent<br>film-forming agent |
| 1503 | Castor oil | carrier solvent<br>anticaking agent<br>glazing agent |
| 1505 | Triethyl citrate | foam stabilizer<br>carrier solvent<br>sequestrant |
| 1518 | Triacetin | humectant |
| 1520 | Propylene glycol | humectant<br>wetting agent<br>dispersing agent<br>glazing agent |
| 1521 | Polyethylene glycol | antifoaming agent |

## SUPPLEMENTARY LIST - MODIFIED STARCHES

*List in numerical order*

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 1400 | Dextrins, roasted starch | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1401 | Acid-treated starch | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1402 | Alkaline treated starch | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1403 | Bleached starch | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1404 | Oxidized starch | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1405 | Starches, enzyme treated | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1410 | Monostarch phosphate | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1411 | Distarch glycerol | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1412 | Distarch phosphate | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1413 | Phosphated distarch phosphate | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1414 | Acetylated distarch phosphate | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1420 | Starch acetate | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1422 | Acetylated distarch adipate | stabilizer<br>thickener<br>binder<br>emulsifier |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 1440 | Hydroxypropyl starch | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1442 | Hydroxypropyl distarch phosphate | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1450 | Starch sodium octenyl succinate | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1451 | Acetylated oxidized starch | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1452 | Starch aluminium octenyl succinate | anticaking agent<br>carrier<br>stabilizer |

SECTION 4

## INTERNATIONAL NUMBERING SYSTEM FOR FOOD ADDITIVES

*List in alphabetical order*

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 950 | Acesulfame potassium | sweetener<br>flavour enhancer |
| 260 | Acetic acid (glacial) | preservative<br>acidity regulator |
| 472a | Acetic and fatty acid esters of glycerol | emulsifier<br>stabilizer<br>sequestrant |
| 929 | Acetone peroxide | flour treatment agent |
| 355 | Adipic acid | acidity regulator |
| 406 | Agar | thickener<br>stabilizer<br>gelling agent<br>emulsifier |
| 639 | Alanine, DL- | flavour enhancer |
| 400 | Alginic acid | thickener<br>stabilizer<br>gelling agent<br>emulsifier |
| 956 | Alitame | sweetener |
| 103 | Alkanet | colour |
| 129 | Allura red AC | colour |
| 173 | Aluminium | colour |
| 523 | Aluminium ammonium sulfate | stabilizer<br>firming agent |
| 522 | Aluminium potassium sulfate | acidity regulator<br>stabilizer |
| 559 | Aluminium silicate | anticaking agent |
| 521 | Aluminium sodium sulfate | firming agent |
| 520 | Aluminium sulfate | firming agent |
| 123 | Amaranth | colour |
| 264 | Ammonium acetate | acidity regulator |
| 359 | Ammonium adipates | acidity regulator |
| 403 | Ammonium alginate | thickener<br>stabilizer<br>gelling agent<br>emulsifier |
| 503( i ) | Ammonium carbonate | acidity regulator<br>raising agent |
| 503 | Ammonium carbonates | acidity regulator<br>raising agent |
| 510 | Ammonium chloride | flour treatment agent |
| 368 | Ammonium fumarate | acidity regulator |
| 503( ii ) | Ammonium hydrogen carbonate | acidity regulator<br>raising agent |
| 527 | Ammonium hydroxide | acidity regulator |
| 328 | Ammonium lactate | acidity regulator<br>flour treatment agent |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 349 | Ammonium malate | acidity regulator |
| 923 | Ammonium persulfate | flour treatment agent |
| 342 | Ammonium phosphates | acidity regulator<br>flour treatment agent |
| 452( v ) | Ammonium polyphosphate | emulsifier<br>stabilizer<br>sequestrant<br>texturizing agent<br>moisture-retention agent |
| 442 | Ammonium salts of phosphatidic acid | emulsifier |
| 517 | Ammonium sulfate | flour treatment agent<br>stabilizer |
| 1100 | Amylases | flour treatment agent |
| 160b | Annatto extracts | colour |
| 160b( i ) | Annatto extracts, bixin-based | colour |
| 160b( ii ) | Annatto extracts, norbixin-based | colour |
| 323 | Anoxomer | antioxidant |
| 163 | Anthocyanins | colour |
| 409 | Arabinogalactan | thickener<br>gelling agent<br>stabilizer |
| 300 | Ascorbic acid (L-) | antioxidant |
| 304 | Ascorbyl palmitate | antioxidant |
| 305 | Ascorbyl stearate | antioxidant |
| 951 | Aspartame | sweetener<br>flavour enhancer |
| 962 | Aspartame-acesulfame salt | sweetener |
| 927a | Azodicarbonamide | flour treatment agent |
| 122 | Azorubine (carmoisine) | colour |
| 408 | Bakers yeast glycan | thickener<br>gelling agent<br>stabilizer |
| 901 | Beeswax | glazing agent, clouding agent |
| 162 | Beet red | colour |
| 558 | Bentonite | anticaking agent |
| 210 | Benzoic acid | preservative |
| 906 | Benzoin gum | glazing agent |
| 928 | Benzoyl peroxide | flour treatment agent<br>preservative |
| 163(iii) | Blackcurrant extract | colour |
| 542 | Bone phosphate (essentially calcium phosphate, tribasic) | emulsifier<br>anticaking agent<br>moisture-retention agent |
| 151 | Brilliant black (Black PN) | colour |
| 133 | Brilliant blue FCF | colour |
| 1101(iii) | Bromelain | flour treatment agent<br>stabilizer<br>flavour enhancer |
| 443 | Brominated vegetable oils | emulsifier<br>stabilizer |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 154 | Brown FK | colour |
| 155 | Brown HT | colour |
| 943a | Butane | propellant |
| 320 | Butylated hydroxyanisole | antioxidant |
| 321 | Butylated hydroxytoluene | antioxidant |
| 629 | Calcium 5'-guanylate | flavour enhancer |
| 633 | Calcium 5'-inosinate | flavour enhancer |
| 634 | Calcium 5'-ribonucleotides | flavour enhancer |
| 263 | Calcium acetate | preservative<br>stabilizer<br>acidity regulator |
| 404 | Calcium alginate | thickener<br>stabilizer<br>gelling agent<br>antifoaming agent |
| 556 | Calcium aluminium silicate | anticaking agent |
| 302 | Calcium ascorbate | antioxidant |
| 213 | Calcium benzoate | preservative |
| 924b | Calcium bromate | flour treatment agent |
| 170( i ) | Calcium carbonate | surface colourant<br>anticaking agent<br>stabilizer<br>acidity regulator |
| 170 | Calcium carbonates | surface colourant,<br>anticaking agent,<br>stabilizer |
| 509 | Calcium chloride | firming agent<br>stabilizer<br>thickener |
| 333 | Calcium citrates | acidity regulator<br>firming agent<br>sequestrant<br>stabilizer |
| 952( ii ) | Calcium cyclamate | sweetener |
| 450(vii) | Calcium dihydrogen diphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 385 | Calcium disodium ethylenediaminetetraacetate | antioxidant<br>preservative<br>sequestrant |
| 538 | Calcium ferrocyanide | anticaking agent |
| 238 | Calcium formate | preservative |
| 367 | Calcium fumarates | acidity regulator |
| 578 | Calcium gluconate | acidity regulator<br>firming agent<br>sequestrant |
| 623 | Calcium glutamate (D, L-) | flavour enhancer |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 383 | Calcium glycerophosphate | thickener<br>gelling agent<br>stabilizer |
| 170( ii ) | Calcium hydrogen carbonate | surface colourant<br>anticaking agent<br>stabilizer<br>acidity regulator |
| 352( i ) | Calcium hydrogen malate | acidity regulator |
| 227 | Calcium hydrogen sulfite | preservative<br>antioxidant |
| 526 | Calcium hydroxide | acidity regulator<br>firming agent |
| 916 | Calcium iodate | flour treatment agent |
| 318 | Calcium isoascorbate | antioxidant |
| 327 | Calcium lactate | acidity regulator<br>flour treatment agent |
| 399 | Calcium lactobionate | stabilizer |
| 482 | Calcium lactylates | emulsifier<br>stabilizer |
| 352( ii ) | Calcium malate (D,L-) | acidity regulator |
| 352 | Calcium malates | acidity regulator |
| 482( ii ) | Calcium oleyl lactylate | emulsifier<br>stabilizer |
| 529 | Calcium oxide | acidity regulator<br>flour treatment agent<br>dough conditioner |
| 930 | Calcium peroxide | flour treatment agent |
| 341 | Calcium phosphates | acidity regulator<br>flour treatment agent<br>firming agent<br>texturizing agent<br>raising agent<br>anticaking agent<br>moisture-retention agent |
| 452(iv) | Calcium polyphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 282 | Calcium propionate | preservative |
| 954( ii ) | Calcium saccharin | sweetener |
| 552 | Calcium silicate | anticaking agent |
| 203 | Calcium sorbate | preservative |
| 486 | Calcium stearoyl fumarate | emulsifier |
| 482( i ) | Calcium stearoyl lactylate | emulsifier |
| 516 | Calcium sulfate | flour treatment agent<br>sequestrant<br>firming agent<br>stabilizer |
| 226 | Calcium sulfite | preservative<br>antioxidant |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 354 | Calcium tartrate(DL-) | acidity regulator |
| 902 | Candelilla wax | glazing agent<br>clouding agent |
| 161g | Canthaxanthin | colour |
| 150a | Caramel I - plain | colour |
| 150b | Caramel II - caustic sulfite process | colour |
| 150c | Caramel III - ammonia process | colour |
| 150d | Caramel IV - sulfite ammonia process | colour |
| 152 | Carbon black (Hydrocarbon) | colour |
| 290 | Carbon dioxide | carbonating agent<br>packaging gas<br>propellant<br>preservative |
| 120 | Carmines | colour |
| 903 | Carnauba wax | glazing agent<br>bulking agent<br>acidity regulator<br>carrie |
| 410 | Carob bean gum | thickener<br>stabilizer<br>emulsifier |
| 160e | Carotenal, *beta*-apo-8'- | colour |
| 160a | Carotenes | colour |
| 160a(iv) | Carotenes, *beta*- (algae) | colour |
| 160a(iii) | Carotenes, beta- (*Blakeslea trispora*) | colour |
| 160a(ii) | Carotenes, *beta*- (vegetable) | colour |
| 160a(i) | Carotenes, *beta*-, (synthetic) | colour |
| 160f | Carotenoic acid, methyl or ethyl ester, *beta*-apo-8'- | colour |
| 407 | Carrageenan and its ammonium, calcium, magnesium, potassium and sodium salts(includes furcellaran) | thickener<br>gelling agent<br>stabilizer<br>emulsifier |
| 427 | Cassia gum | emulsifier<br>stabilizer<br>gelling agent<br>thickener |
| 1503 | Castor oil | carrier solvent<br>anticaking agent<br>glazing agent |
| 460 | Celluloses | emulsifier<br>anticaking agent<br>texturizing agent<br>dispersing agent<br>stabilizer<br>thickener |
| 925 | Chlorine | flour bleaching agent |
| 926 | Chlorine dioxide | flour treatment agent |
| 945 | Chloropentafluorethane | propellant |
| 140 | Chlorophyll | colour |
| 141(ii) | Chlorophyllins, copper complexes, potassium and sodium salts | colour |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 141 | Chlorophylls and chlorophyllins, copper complexes | colour |
| 141( i ) | Chlorophylls, copper complexes | colour |
| 1000 | Cholic acid | emulsifier |
| 1001( i ) | Choline acetate | emulsifier |
| 1001( ii ) | Choline carbonate | emulsifier |
| 1001(iii) | Choline chloride | emulsifier |
| 1001(iv) | Choline citrate | emulsifier |
| 1001(vi) | Choline lactate | emulsifier |
| 1001 | Choline salts and esters | emulsifier |
| 1001( v ) | Choline tartrate | emulsifier |
| 330 | Citric acid | acidity regulator<br>antioxidant<br>sequestrant |
| 472c | Citric and fatty acid esters of glycerol | emulsifier<br>stabilizer<br>sequestrant<br>dough conditioner<br>antioxidant synergist |
| 121 | Citrus red No. 2 | colour |
| 468 | Cross-linked sodium carboxymethyl cellulose (crosslinked cellulose gum) | stabilizer<br>binder |
| 519 | Cupric sulfate | colour fixative<br>preservative |
| 100( i ) | Curcumin | colour |
| 100 | Curcumins | colour |
| 424 | Curdlan | thickener<br>stabilizer<br>firming agent<br>gelling agent |
| 952 | Cyclamates | sweetener |
| 952( i ) | Cyclamic acid | sweetener |
| 457 | Cyclodextrin, *alpha-* | stabilizer<br>binder |
| 459 | Cyclodextrin, *beta-* | stabilizer<br>binder<br>carrier |
| 458 | Cyclodextrin, *gamma-* | stabilizer<br>binder |
| 920 | Cysteine, L- and its hydrochlorides – sodium and potassium salts | flour treatment agent |
| 921 | Cystine, L-and its hydrochlorides sodium and potassium salts | flour treatment agent |
| 265 | Dehydroacetic acid | preservative |
| 472e | Diacetyltartaric and and fatty acid esters of glycerol | emulsifier<br>stabilizer<br>sequestrant |
| 342( ii ) | Diammonium orthophosphate | acidity regulator<br>flour treatment agent |
| 333( ii ) | Dicalcium citrate | acidity regulator<br>firming agent<br>sequestrant<br>stabilizer |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 450(vi) | Dicalcium diphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent<br>buffering agent |
| 341(ii) | Dicalcium orthophosphate | acidity regulator<br>flour treatment agent<br>firming agent<br>texturizing agent<br>raising agent<br>anticaking agent<br>moisture-retention agent<br>stabilizer |
| 940 | Dichlorodifluormethane | propellant |
| 389 | Dilauryl thiodipropionate | antioxidant |
| 450(viii) | Dimagnesium diphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 343(ii) | Dimagnesium orthophosphate | acidity regulator<br>anticaking agent |
| 242 | Dimethyl dicarbonate | preservative |
| 480 | Dioctyl sodium sulfosuccinate | emulsifier<br>wetting agent |
| 230 | Diphenyl | preservative |
| 450 | Diphosphates | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 628 | Dipotassium 5'-guanylate | flavour enhancer |
| 450(iv) | Dipotassium diphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 340(ii) | Dipotassium orthophosphate | acidity regulator<br>sequestrant<br>emulsifier<br>texturizing agent<br>stabilizer<br>moisture-retention agent |
| 336(ii) | Dipotassium tartrate | stabilizer<br>sequestrant<br>acidity regulator |
| 627 | Disodium 5'-guanylate | flavour enhancer |
| 631 | Disodium 5'-inosinate | flavour enhancer |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 635 | Disodium 5'-ribonucleotides | flavour enhancer |
| 450( i ) | Disodium diphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 386 | Disodium ethylenediaminetetraacetate | antioxidant<br>preservative |
| 331( ii ) | Disodium monohydrogen citrate | acidity regulator<br>sequestrant<br>emulsifier<br>stabilizer |
| 339( ii ) | Disodium orthophosphate | acidity regulator<br>sequestrant<br>emulsifier<br>texturizing agent<br>stabilizer<br>moisture-retention agent |
| 364( ii ) | Disodium succinate | acidity regulator<br>flavour enhancer |
| 335( ii ) | Disodium tartrate | stabilizer<br>sequestrant<br>acidity regulator |
| 390 | Distearyl thiodipropionate | antioxidant |
| 312 | Dodecyl gallate | antioxidant |
| 968 | Erythritol | sweetener<br>flavour enhancer<br>humectant |
| 127 | Erythrosine | colour |
| 488 | Ethoxylated mono- and di-glycerides | emulsifier |
| 324 | Ethoxyquin | antioxidant |
| 462 | Ethyl cellulose | binder<br>filler |
| 313 | Ethyl gallate | antioxidant |
| 467 | Ethyl hydroxyethyl cellulose | thickener<br>stabilizer<br>emulsifier |
| 243 | Ethyl lauroyl arginate | preservative |
| 637 | Ethyl maltol | flavour enhancer |
| 214 | Ethyl para-hydroxybenzoate | preservative |
| 143 | Fast Green FCF | colour |
| 570 | Fatty acids | foam stabilizer<br>glazing agent<br>antifoaming agent |
| 381 | Ferric ammonium citrate | anticaking agent |
| 505 | Ferrous carbonate | acidity regulator |
| 579 | Ferrous gluconate | colour retention agent |
| 537 | Ferrous hexacyanomanganate | anticaking agent |
| 585 | Ferrous lactate | colour retention agent |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 1101(iv) | Ficin | flour treatment agent<br>stabilizer<br>flavour enhancer |
| 161a | Flavoxanthin | colour |
| 240 | Formaldehyde | preservative |
| 236 | Formic acid | preservative |
| 297 | Fumaric acid | acidity regulator |
| 165 | Gardenia blue | colour |
| 164 | Gardenia yellow | colour |
| 428 | Gelatin | stabilizer<br>gelling agent<br>emulsifier<br>thickener<br>carrier |
| 418 | Gellan gum | thickener<br>stabilizer<br>gelling agent |
| 574 | Gluconic acid (D-) | acidity regulator<br>raising agent |
| 575 | Glucono delta-lactone | acidity regulator<br>raising agent<br>sequestrant |
| 1102 | Glucose oxidase | antioxidant |
| 620 | Glutamic acid, (L(+)-) | flavour enhancer |
| 422 | Glycerol | humectant<br>bodying agent |
| 445 | Glycerol esters of wood rosin | emulsifier<br>stabilizer<br>glazing agent |
| 915 | Glycerol, methyl, or pentaerithrytol esters of colophane | glazing agent |
| 640 | Glycine | flavour enhancer |
| 958 | Glycyrrhizin | sweetener<br>flavour enhancer |
| 175 | Gold (metallic) | colour |
| 163(ii) | Grape skin extract | colour |
| 142 | Green S | colour |
| 314 | Guaiac resin | antioxidant |
| 626 | Guanylic acid, 5'- | flavour enhancer |
| 412 | Guar gum | thickener<br>stabilizer<br>emulsifier |
| 414 | Gum arabic (Acacia gum) | thickener<br>stabilizer<br>emulsifier |
| 419 | Gum ghatti | thickener<br>stabilizer<br>emulsifier |
| 241 | Gum guaicum | preservative |
| 370 | Heptonolactone, 1,4- | acidity regulator<br>sequestrant |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 209 | Heptyl para-hydroxybenzoate | preservative |
| 239 | Hexamethylene tetramine | preservative |
| 586 | Hexylresorcinol, 4- | colour retention agent<br>antioxidant |
| 507 | Hydrochloric acid | acidity regulator |
| 949 | Hydrogen | packaging gas |
| 907 | Hydrogenated poly-decenes | glazing agent |
| 463 | Hydroxypropyl cellulose | thickener<br>emulsifier<br>stabilizer |
| 464 | Hydroxypropyl methyl cellulose | thickener<br>emulsifier<br>stabilizer |
| 132 | Indigotine (Indigo carmine) | colour |
| 630 | Inosinic acid | flavour enhancer |
| 1103 | Invertases | stabilizer |
| 172( i ) | Iron oxide, black | colour |
| 172( ii ) | Iron oxide, red | colour |
| 172(iii) | Iron oxide, yellow | colour |
| 172 | Iron oxides | colour |
| 315 | Isoascorbic acid (Erythorbic acid) | antioxidant |
| 943b | Isobutane | propellant |
| 953 | Isomalt (Isomaltitol) | sweetener<br>anticaking agent<br>bulking agent<br>glazing agent |
| 384 | Isopropyl citrates | antioxidant<br>preservative<br>sequestrant |
| 416 | Karaya gum | thickener<br>stabilizer<br>emulsifier |
| 425 | Konjac flour | thickener<br>gelling agent<br>emulsifier<br>stabilizer |
| 161c | Kryptoxanthin | colour |
| 270 | Lactic acid (L-, D-, and DL-) | acidity regulator |
| 472b | Lactic and fatty acid esters of glycerol | emulsifier<br>stabilizer<br>sequestrant |
| 966 | Lactitol | sweetener<br>texturizing agent<br>emulsifier |
| 478 | Lactylated fatty acid esters of glycerol and propylene glycol | emulsifier |
| 913 | Lanolin | glazing agent |
| 322( i ) | Lecithin | antioxidant<br>emulsifier |
| 344 | Lecithin citrate | preservative |
| 322( ii ) | Lecithin, partially hydrolysed | antioxidant<br>emulsifier |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 322 | Lecithins | antioxidant<br>emulsifier |
| 641 | Leucine, L- | flavour enhancer |
| 1104 | Lipases | flavour enhancer |
| 180 | Lithol rupine BK | colour |
| 161b( i ) | Lutein from *Tagetes erecta* | colour |
| 161b | Luteins | colour |
| 160d(iii) | Lycopene (*Blakeslea trispora*) | colour |
| 160d( i ) | Lycopene (synthetic) | colour |
| 160d( ii ) | Lycopene (tomato) | colour |
| 160d | Lycopenes | colour |
| 642 | Lysin hydrochloride | flavour enhancer |
| 1105 | Lysozyme | preservative |
| 504( i ) | Magnesium carbonate | acidity regulator<br>anticaking agent<br>colour retention agent |
| 504 | Magnesium carbonates | acidity regulator<br>anticaking agent<br>colour retention agent |
| 511 | Magnesium chloride | firming agent<br>colour retention agent<br>stabilizer |
| 345 | Magnesium citrate | acidity regulator |
| 580 | Magnesium gluconate | acidity regulator<br>firming agent<br>flavour enhancer |
| 625 | Magnesium glutamate | flavour enhancer |
| 504( ii ) | Magnesium hydrogen carbonate | acidity regulator<br>anticaking agent<br>colour retention agent<br>carrier<br>drying agent |
| 528 | Magnesium hydroxide | acidity regulator<br>colour retention agent |
| 329 | Magnesium lactate (DL-) | acidity regulator<br>flour treatment agent |
| 530 | Magnesium oxide | anticaking agent |
| 343 | Magnesium phosphates | acidity regulator<br>anticaking agent |
| 553( i ) | Magnesium silicate | anticaking agent<br>dusting agent |
| 553 | Magnesium silicates | anticaking agent<br>dusting agent |
| 518 | Magnesium sulfate | firming agent |
| 553( ii ) | Magnesium trisilicate | anticaking agent<br>dusting agent |
| 296 | Malic acid (DL-) | acidity regulator |
| 965( ii ) | Maltiol syrup | sweetener<br>stabilizer<br>emulsifier<br>humectant<br>bulking agent |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 965( i ) | Maltitol | sweetener<br>stabilizer<br>emulsifier<br>humectant<br>bulking agent |
| 965 | Maltitols | sweetener<br>stabilizer<br>emulsifier<br>humectant<br>bulking agent |
| 636 | Maltol | flavour enhancer |
| 130 | Manascorubin | colour |
| 421 | Mannitol | sweetener<br>anticaking agent<br>humectant<br>stabilizer<br>bulking agent |
| 353 | Metatartaric acid | acidity regulator |
| 461 | Methyl cellulose | thickener<br>emulsifier<br>stabilizer |
| 911 | Methyl esters of fatty acids | glazing agent |
| 465 | Methyl ethyl cellulose | thickener<br>emulsifier<br>stabilizer<br>foaming agent |
| 489 | Methyl glucoside-coconut oil ester | emulsifier |
| 218 | Methyl para-hydroxybenzoate | preservative |
| 900b | Methylphenylpolysiloxane | antifoaming agent |
| 460( i ) | Microcrystalline cellulose | emulsifier<br>anticaking agent<br>texturizing agent<br>dispersing agent<br>stabilizer<br>thickener |
| 905c( i ) | Microcrystalline wax | glazing agent |
| 905a | Mineral oil, food grade | glazing agent<br>sealing agent |
| 905d | Mineral oil, high viscosity | glazing agent<br>sealing agent |
| 905e | Mineral oil, medium and low viscosity (class i ) | glazing agent<br>sealing agent |
| 905f | Mineral oil, medium and low viscosity (class II) | glazing agent<br>sealing agent |
| 905g | Mineral oil, medium and low viscosity (class III) | glazing agent<br>sealing agent |
| 471 | Mono- and di- glycerides of fatty acids | emulsifier<br>stabilizer |
| 624 | Monoammonium glutamate | flavour enhancer |
| 342( i ) | Monoammonium orthophosphate | acidity regulator<br>flour treatment agent |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 333( i ) | Monocalcium citrate | acidity regulator<br>firming agent<br>sequestrant<br>stabilizer |
| 341( i ) | Monocalcium orthophosphate | acidity regulator<br>flour treatment agent<br>firming agent<br>texturizing agent<br>raising agent<br>anticaking agent<br>moisture-retention agent<br>stabilizer |
| 343( i ) | Monomagnesium orthophosphate | acidity regulator<br>anticaking agent |
| 622 | Monopotassium glutamate | flavour enhancer |
| 340( i ) | Monopotassium orthophosphate | acidity regulator<br>sequestrant<br>emulsifier<br>texturizing agent<br>stabilizer<br>moisture-retention agent |
| 336( i ) | Monopotassium tartrate | stabilizer<br>sequestrant<br>acidity regulator |
| 621 | Monosodium glutamate | flavour enhancer |
| 339( i ) | Monosodium orthophosphate | acidity regulator<br>sequestrant<br>emulsifier<br>texturizing agent<br>stabilizer<br>moisture-retention agent |
| 364( i ) | Monosodium succinate | acidity regulator<br>flavour enhancer |
| 335( i ) | Monosodium tartrate | stabilizer<br>sequestrant<br>acidity regulator |
| 959 | Neohesperidine dihydrochalcone | sweetener |
| 961 | Neotame | sweetener<br>flavour enhancer |
| 375 | Nicotinic acid | colour retention agent |
| 234 | Nisin | preservative |
| 941 | Nitrogen | packaging gas<br>propellant |
| 918 | Nitrogen oxides | flour treatment agent |
| 919 | Nitrosyl chloride | flour treatment agent |
| 942 | Nitrous oxide | propellant<br>antioxidant<br>foaming agent<br>packaging gas |
| 411 | Oat gum | thickener<br>stabilizer |
| 946 | Octafluorcyclobutane | propellant |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 311 | Octyl gallate | antioxidant |
| 182 | Orchil | colour |
| 231 | Ortho-phenylphenol | preservative |
| 338 | Orthophosphoric acid | acidity regulator<br>antioxidant synergist<br>sequestrant |
| 387 | Oxystearin | antioxidant<br>sequestrant |
| 1101( ii ) | Papain | flavour enhancer |
| 160c | Paprika oleoresin | colour |
| 905c( ii ) | Paraffin wax | glazing agent |
| 131 | Patent blue V | colour |
| 440 | Pectins | thickener<br>stabilizer<br>gelling agent<br>emulsifier |
| 451( ii ) | Pentapotassium triphosphate | sequestrant<br>acidity regulator<br>texturizing agent |
| 451( i ) | Pentasodium triphosphate | sequestrant<br>acidity regulator<br>texturizing agent |
| 429 | Peptones | emulsifier |
| 905b | Petrolatum (Petroleum jelly) | glazing agent<br>sealing agent<br>antifoaming agent |
| 905c | Petroleum wax | glazing agent<br>sealing agent |
| 391 | Phytic acid | preservative |
| 235 | Pimaricin (Natamycin) | preservative |
| 1200 | Polydextroses A and N | bulking agent<br>stabilizer<br>thickener<br>humectant<br>texturizing agent |
| 900a | Polydimethylsiloxane | antifoaming agent<br>anticaking agent<br>emulsifier |
| 1521 | Polyethylene glycol | antifoaming agent |
| 475 | Polyglycerol esters of fatty acids | emulsifier |
| 476 | Polyglycerol esters of interesterified ricinoleic acid | emulsifier |
| 964 | Polyglycitol syrup | sweetener |
| 432 | Polyoxyethylene (20) sorbitan monolaurate | emulsifier<br>dispersing agent |
| 433 | Polyoxyethylene (20) sorbitan monooleate | emulsifier<br>dispersing agent |
| 434 | Polyoxyethylene (20) sorbitan monopalmitate | emulsifier<br>dispersing agent |
| 435 | Polyoxyethylene (20) sorbitan monostearate | emulsifier<br>dispersing agent |
| 436 | Polyoxyethylene (20) sorbitan tristearate | emulsifier<br>dispersing agent |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 431 | Polyoxyethylene (40) stearate | emulsifier |
| 430 | Polyoxyethylene (8) stearate | emulsifier |
| 452 | Polyphosphates | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 1203 | Polyvinyl alcohol | coating agent<br>binder<br>sealing agent<br>surface-finishing agent |
| 1201 | Polyvinylpyrrolidone | bodying agent<br>stabilizer<br>dispersing agent |
| 1202 | Polyvinylpyrrolidone (insoluble) | colour stabilizer<br>colloidal stabilizer<br>stabilizer |
| 124 | Ponceau 4R (Cochineal red A) | colour |
| 125 | Ponceau SX | colour |
| 261( i ) | Potassium acetate | preservative<br>acidity regulator |
| 261 | Potassium acetates | preservative<br>acidity regulator |
| 357 | Potassium adipates | acidity regulator |
| 402 | Potassium alginate | thickener<br>stabilizer<br>gelling agent<br>emulsifier |
| 555 | Potassium aluminium silicate | anticaking agent |
| 303 | Potassium ascorbate | antioxidant |
| 212 | Potassium benzoate | preservative |
| 228 | Potassium bisulfite | preservative<br>antioxidant |
| 924a | Potassium bromate | flour treatment agent |
| 501( i ) | Potassium carbonate | acidity regulator<br>stabilizer |
| 501 | Potassium carbonates | acidity regulator<br>stabilizer |
| 508 | Potassium chloride | gelling agent<br>stabilizer<br>flavour enhancer<br>thickener |
| 332 | Potassium citrates | acidity regulator<br>sequestrant<br>stabilizer |
| 952(iii) | Potassium cyclamate | sweetener |
| 261( ii ) | Potassium diacetate | preservative<br>acidity regulator |
| 332( i ) | Potassium dihydrogen citrate | acidity regulator<br>sequestrant<br>stabilizer |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 536 | Potassium ferrocyanide | anticaking agent |
| 366 | Potassium fumarates | acidity regulator |
| 577 | Potassium gluconate | sequestrant<br>acidity regulator |
| 501( ii ) | Potassium hydrogen carbonate | acidity regulator<br>stabilizer |
| 351( i ) | Potassium hydrogen malate | acidity regulator |
| 525 | Potassium hydroxide | acidity regulator |
| 632 | Potassium inosinate | flavour enhancer |
| 917 | Potassium iodate | flour treatment agent |
| 317 | Potassium isoascorbate | antioxidant |
| 326 | Potassium lactate | antioxidant synergist<br>acidity regulator |
| 351( ii ) | Potassium malate | acidity regulator |
| 351 | Potassium malates | acidity regulator |
| 224 | Potassium metabisulfite | preservative<br>antioxidant |
| 252 | Potassium nitrate | preservative<br>colour fixative |
| 249 | Potassium nitrite | preservative<br>colour fixative |
| 922 | Potassium persulfate | flour treatment agent |
| 340 | Potassium phosphates | acidity regulator<br>sequestrant<br>emulsifier<br>texturizing agent<br>stabilizer<br>moisture-retention agent |
| 452( ii ) | Potassium polyphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 283 | Potassium propionate | preservative |
| 954(iii) | Potassium saccharin | sweetener |
| 560 | Potassium silicate | anticaking agent |
| 337 | Potassium sodium tartrate | stabilizer<br>sequestrant<br>acidity regulator |
| 202 | Potassium sorbate | preservative |
| 515 | Potassium sulfates | acidity regulator |
| 225 | Potassium sulfite | preservative<br>antioxidant |
| 336 | Potassium tartrates | stabilizer<br>sequestrant |
| 460( ii ) | Powdered cellulose | emulsifier<br>anticaking agent<br>texturizing agent<br>dispersing agent<br>stabilizer<br>thickener |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 407a | Processed euchema seaweed (PES) | thickener<br>stabilizer<br>gelling agent<br>emulsifier |
| 944 | Propane | propellant |
| 280 | Propionic acid | preservative |
| 310 | Propyl gallate | antioxidant |
| 216 | Propyl para-hydroxybenzoate | preservative |
| 1520 | Propylene glycol | humectant<br>wetting agent<br>dispersing agent<br>glazing agent |
| 405 | Propylene glycol alginate | thickener<br>emulsifier<br>stabilizer |
| 477 | Propylene glycol esters of fatty acids | emulsifier |
| 1101( i ) | Protease | flour treatment agent<br>stabilizer<br>flavour enhancer |
| 1101 | Proteases | flour treatment agent<br>stabilizer<br>flavour enhancer |
| 1204 | Pullulan | glazing agent<br>film-forming agent |
| 163(iv) | Purple corn colour | colour |
| 999( i ) | Quillaia extract type 1 | foaming agent<br>emulsifier |
| 999( ii ) | Quillaia extract type 2 | foaming agent<br>emulsifier |
| 999 | Quillaia extracts | foaming agent<br>emulsifier |
| 104 | Quinoline yellow | colour |
| 128 | Red 2G | colour |
| 163( v ) | Red cabbage colour | colour |
| 161f | Rhodoxanthin | colour |
| 101(iii) | Riboflavin (*Bacillus subtilis*) | colour |
| 101( ii ) | Riboflavin 5'-phosphate sodium | colour |
| 101( i ) | Riboflavin, synthetic | colour |
| 101 | Riboflavins | colour |
| 908 | Rice bran wax | glazing agent |
| 161d | Rubixanthin | colour |
| 954( i ) | Saccharin | sweetener |
| 954 | Saccharins | sweetener |
| 470 | Salts of fatty acids (with base aluminium, ammonium, calcium, magnesium, potassium, sodium) | emulsifier<br>stabilizer<br>anticaking agent |
| 470( i ) | Salts of myristic, palmitic and stearic acids with ammonia, calcium, potassium and sodium | emulsifier<br>stabilizer<br>anticaking agent |
| 470( ii ) | Salts of oleic acid with calcium, potassium and sodium | emulsifier<br>stabilizer<br>anticaking agent |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 166 | Sandalwood | colour |
| 904 | Shellac | glazing agent |
| 551 | Silicon dioxide, amorphous | anticaking agent |
| 174 | Silver | colour |
| 262( i ) | Sodium acetate | preservative<br>acidity regulator<br>sequestrant |
| 262 | Sodium acetates | preservative<br>acidity regulator<br>sequestrant |
| 356 | Sodium adipates | acidity regulator |
| 401 | Sodium alginate | thickener<br>stabilizer<br>gelling agent<br>emulsifier |
| 541 | Sodium aluminium phosphate | acidity regulator<br>emulsifier |
| 541( i ) | Sodium aluminium phosphate (acidic) | acidity regulator<br>emulsifier<br>raising agent |
| 541( ii ) | Sodium aluminium phosphate (basic) | acidity regulator<br>emulsifier |
| 554 | Sodium aluminosilicate | anticaking agent |
| 301 | Sodium ascorbate | antioxidant |
| 211 | Sodium benzoate | preservative |
| 452(iii) | Sodium calcium polyphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 500( i ) | Sodium carbonate | acidity regulator<br>raising agent<br>anticaking agent |
| 500 | Sodium carbonates | acidity regulator<br>raising agent<br>anticaking agent |
| 466 | Sodium carboxymethyl cellulose (cellulose gum) | thickener<br>stabilizer<br>emulsifier |
| 469 | Sodium carboxymethyl cellulose, enzymatically hydrolysed (cellulose gum, enzymatically hydrolyzed) | thickener<br>stabilizer |
| 331 | Sodium citrates | acidity regulator<br>sequestrant<br>emulsifier<br>stabilizer |
| 952(iv) | Sodium cyclamate | sweetener |
| 266 | Sodium dehydroacetate | preservative |
| 262( ii ) | Sodium diacetate | preservative<br>acidity regulator<br>sequestrant |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 331( i ) | Sodium dihydrogen citrate | acidity regulator<br>sequestrant<br>emulsifier<br>stabilizer |
| 215 | Sodium ethyl para-hydroxybenzoate | preservative |
| 535 | Sodium ferrocyanide | anticaking agent |
| 237 | Sodium formate | preservative |
| 365 | Sodium fumarates | acidity regulator |
| 576 | Sodium gluconate | sequestrant |
| 500( ii ) | Sodium hydrogen carbonate | acidity regulator<br>raising agent<br>anticaking agent |
| 350( i ) | Sodium hydrogen malate | acidity regulator<br>humectant |
| 222 | Sodium hydrogen sulfite | preservative<br>antioxidant |
| 524 | Sodium hydroxide | acidity regulator |
| 316 | Sodium isoascorbate | antioxidant |
| 325 | Sodium lactate | antioxidant synergist<br>humectant<br>bulking agent<br>acidity regulator<br>bodying agent |
| 481 | Sodium lactylates | emulsifier<br>stabilizer |
| 638 | Sodium L-aspartate | flavour enhancer |
| 487 | Sodium laurylsulfate | emulsifier |
| 350( ii ) | Sodium malate | acidity regulator<br>humectant |
| 350 | Sodium malates | acidity regulator<br>humectant |
| 223 | Sodium metabisulfite | preservative<br>bleaching agent<br>antioxidant<br>flour treatment agent |
| 550( ii ) | Sodium metasilicate | anticaking agent |
| 219 | Sodium methyl para-hydroxybenzoate | preservative |
| 251 | Sodium nitrate | preservative<br>colour fixative |
| 250 | Sodium nitrite | preservative<br>colour fixative |
| 481( ii ) | Sodium oleyl lactylate | emulsifier<br>stabilizer |
| 232 | Sodium ortho-phenylphenol | preservative |
| 339 | Sodium phosphates | acidity regulator<br>sequestrant<br>emulsifier<br>texturizing agent<br>stabilizer<br>moisture-retention agent |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 452( i ) | Sodium polyphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 452(vi) | Sodium potassium tripolyphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 281 | Sodium propionate | preservative |
| 217 | Sodium propyl para-hydroxybenzoate | preservative |
| 954(iv) | Sodium saccharin | sweetener |
| 500(iii) | Sodium sesquicarbonate | acidity regulator<br>raising agent<br>anticaking agent |
| 550( i ) | Sodium silicate | anticaking agent |
| 550 | Sodium silicates | anticaking agent |
| 201 | Sodium sorbate | preservative |
| 485 | Sodium stearoyl fumarate | emulsifier |
| 481( i ) | Sodium stearoyl lactylate | emulsifier<br>stabilizer |
| 364 | Sodium succinates | acidity regulator<br>flavour enhancer |
| 514 | Sodium sulfates | acidity regulator |
| 221 | Sodium sulfite | preservative<br>antioxidant |
| 335 | Sodium tartrates | stabilizer<br>sequestrant |
| 539 | Sodium thiosulfate | antioxidant<br>sequestrant<br>antibrowning agent |
| 200 | Sorbic acid | preservative |
| 493 | Sorbitan monolaurate | emulsifier<br>stabilizer |
| 494 | Sorbitan monooleate | emulsifier<br>stabilizer |
| 495 | Sorbitan monopalmitate | emulsifier |
| 491 | Sorbitan monostearate | emulsifier |
| 496 | Sorbitan trioleate | stabilizer<br>emulsifier |
| 492 | Sorbitan tristearate | emulsifier |
| 420( i ) | Sorbitol | sweetener<br>humectant<br>sequestrant<br>stabilizer<br>bulking agent |
| 420( ii ) | Sorbitol syrup | sweetener<br>humectant<br>sequestrant<br>stabilizer<br>bulking agent |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 420 | Sorbitols | sweetener<br>humectant<br>sequestrant<br>stabilizer<br>bulking agent |
| 426 | Soybean | hemicellulose emulsifier<br>thickener<br>stabilizer<br>anticaking agent |
| 909 | Spermaceti wax | glazing agent |
| 512 | Stannous chloride | antioxidant<br>colour retention agent |
| 484 | Stearyl citrate | emulsifier<br>sequestrant |
| 483 | Stearyl tartrate | flour treatment agent |
| 960 | Steviol glycosides | sweetener |
| 363 | Succinic acid | acidity regulator |
| 472g | Succinylated monoglycerides | emulsifier<br>stabilizer<br>sequestrant |
| 446 | Succistearin | emulsifier |
| 955 | Sucralose (Trichlorogalactosucrose) | sweetener |
| 474 | Sucroglycerides | emulsifier |
| 444 | Sucrose acetate isobutyrate | emulsifier<br>stabilizer |
| 473 | Sucrose esters of fatty acids | emulsifier<br>stabilizer |
| 473a | Sucrose oligoesters, type I and type II | emulsifier<br>stabilizer |
| 220 | Sulfur dioxide | preservative<br>antioxidant |
| 513 | Sulfuric acid | acidity regulator |
| 110 | Sunset yellow FCF | colour |
| 441 | Superglycerinated hydrogenated rapeseed oil | emulsifier |
| 963 | Tagatose, D- | sweetener |
| 161b( ii ) | Tagetes extract | colour |
| 553(iii) | Talc | anticaking agent<br>dusting agent<br>coating agent<br>surface-finishing agent<br>texturizing agent |
| 181 | Tannins, food grade | colour<br>emulsifier<br>stabilizer<br>thickener |
| 417 | Tara gum | thickener<br>stabilizer |
| 334 | Tartaric acid (L(+)-) | · acidity regulator<br>sequestrant<br>antioxidant synergist |
| 472d | Tartaric acid esters of mono- and di-glycerides of fatty acids | emulsifier<br>stabilizer<br>sequestrant |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 102 | Tartarzine | colour |
| 319 | Tertiary butylhydroquinone | antioxidant |
| 450( v ) | Tetrapotassium diphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 450(iii) | Tetrasodium diphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 957 | Thaumatin | sweetener<br>flavour enhancer |
| 479 | Thermally oxidized soya bean oil with mono - and diglycerides of fatty acids | emulsifier |
| 233 | Thiabendazole | preservative |
| 388 | Thiodipropionic acid | antioxidant |
| 171 | Titanium dioxide | colour |
| 307b | Tocopherol concentrate, mixed | antioxidant |
| 307a | Tocopherol, d-*alpha*- | antioxidant |
| 309 | Tocopherol, *delta*- (synthetic) | antioxidant |
| 307c | Tocopherol, dl-*alpha*- | antioxidant |
| 308 | Tocopherol, *gamma*- (synthetic) | antioxidant |
| 307 | Tocopherols | antioxidant |
| 413 | Tragacanth gum | thickener<br>stabilizer<br>emulsifier |
| 1518 | Triacetin | humectant |
| 380 | Triammonium citrate | acidity regulator |
| 333(iii) | Tricalcium citrate | acidity regulator<br>firming agent<br>sequestrant<br>stabilizer |
| 341(iii) | Tricalcium orthophosphate | acidity regulator<br>flour treatment agent<br>firming agent<br>texturizing agent<br>raising agent<br>anticaking agent<br>moisture-retention agent<br>stabilizer<br>buffer |
| 1505 | Triethyl citrate | foam stabilizer<br>carrier solvent<br>sequestrant |
| 343(iii) | Trimagnesium orthophosphate | acidity regulator<br>anticaking agent |
| 451 | Triphosphates | sequestrant<br>acidity regulator<br>texturizing agent |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 332( ii ) | Tripotassium citrate | acidity regulator<br>sequestrant<br>stabilizer |
| 340(iii) | Tripotassium orthophosphate | acidity regulator<br>sequestrant<br>emulsifier<br>texturizing agent<br>stabilizer<br>moisture-retention agent |
| 331(iii) | Trisodium citrate | acidity regulador<br>sequestrant<br>emulsifier<br>stabilizer |
| 450( ii ) | Trisodium diphosphate | emulsifier<br>stabilizer<br>acidity regulator<br>raising agent<br>sequestrant<br>moisture-retention agent |
| 339(iii) | Trisodium orthophosphate | acidity regulator<br>sequestrant<br>emulsifier<br>texturizing agent<br>stabilizer<br>moisture-retention agent |
| 100( ii ) | Turmeric | colour |
| 927b | Urea (Carbamide) | flour treatment agent |
| 153 | Vegetable carbon | colour |
| 161e | Violoxanthin | colour |
| 910 | Wax esters | glazing agent |
| 415 | Xanthan gum | thickener<br>stabilizer<br>emulsifier<br>foaming agent |
| 967 | Xylitol | sweetener<br>humectant<br>stabilizer<br>emulsifier<br>thickener |
| 107 | Yellow 2G | colour |
| 161h( i ) | Zeaxanthin (synthetic) | colour |
| 161h( ii ) | Zeaxanthin-rich extract from *Tagetes erecta* | colour |
| 161h | Zeaxanthins | colour |
| 650 | Zinc acetate | flavour enhancer |
| 557 | Zinc silicate | anticaking agent |

**SUPPLEMENTARY LIST - MODIFIED STARCHES**

*List in alphabetical order*

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 1422 | Acetylated distarch adipate | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1451 | Acetylated oxidized starch | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1401 | Acid-treated starch | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1402 | Alkaline treated starch | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1403 | Bleached starch | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1400 | Dextrins, roasted starch | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1411 | Distarch glycerol | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1412 | Distarch phosphate | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1442 | Hydroxypropyl distarch phosphate | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1414 | Acetylated distarch phospate | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1440 | Hydroxypropyl starch | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1410 | Monostarch phosphate | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1404 | Oxidized starch | stabilizer<br>thickener<br>binder<br>emulsifier |

| INS No. | Name of Food Additive | Technological purpose |
|---|---|---|
| 1413 | Phosphated distarch phosphate | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1420 | Starch acetate | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1452 | Starch aluminium octenyl succinate | anticaking agent<br>carrier<br>stabilizer |
| 1450 | Starch sodium octenyl succinate | stabilizer<br>thickener<br>binder<br>emulsifier |
| 1405 | Starches, enzyme treated | stabilizer<br>thickener<br>binder<br>emulsifier |

# PREFACE

## *The Codex Alimentarius Commission and the FAO/WHO Food Standards Programme*

The **Codex Alimentarius Commission** is an intergovernmental body with over 170 members, within the framework of the Joint Food Standards Programme established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), with the purpose of protecting the health of consumers and ensuring fair practices in the food trade.

The Commission also promotes coordination of all food standards work undertaken by international governmental and non governmental organizations.

The Codex Alimentarius (Latin, meaning Food Law or Code) is the result of the Commission's work : a collection of internationally adopted food standards, guidelines, codes of practice and other recommendations. The texts in this publication are part of the Codex Alimentarius.

## *Guidelines for the Production, Processing, Marketing and Labelling of Organically Produced Foods*

Food labelling is the primary means of communication between the producer and seller of food on one hand, and the purchaser and consumer of the other.

The Codex Alimentarius standards and guidelines on food labelling are published in a specific volume: *Food Labelling - Complete Texts*. In addition to the general recommendations, the Codex Committee on Food Labelling also provides guidance for certain claims commonly found in the market in order to provide clear information to the consumer.

The Codex Committee on Food Labelling developed the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods* in view of the growing production and international trade in organically produced foods with a view to facilitating trade and preventing misleading claims. The *Guidelines* are intended to facilitate the harmonization of requirements for organic products at the international level, and may also provide assistance to governments wishing to establish national regulations in this area.

The *Guidelines* include general sections describing the organic production concept and the scope of the text; description and definitions; labelling and claims (including products in transition/conversion) ; rules of production and preparation, including criteria for the substances allowed in organic production ; inspection and certification systems; and import control.

The Codex Alimentarius Commission adopted the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods* at its 23rd Session in 1999, with the exception of the provisions for livestock and livestock products that were adopted at its 24th Session in 2001.

The Codex Alimentarius Commission adopted the revised Section 5. *Requirements for Inclusion of Substances in Annex 2 and Criteria for the Development of Lists of Substances by Countries* at its 26th Session in 2003 ; the revised Tables 1 and 2 in *Annex 2 : Permitted Substances for the Production of Organic Foods* at its 27th Session in 2004 ; the revised Table 3. *Ingredients of Non Agricultural Origin Referred to in Section 3 of these Guidelines* at its 30th Session in 2007 ; and the amendment to *Annex 1 : Principles of Organic Production, Section C* allowing the use of ethylene at its 31st Session in 2008.

Further information on labelling texts, or any other aspect of the Codex Alimentarius Commission, may be obtained from :

*The Secretary,*

*Codex Alimentarius Commission,*

*Joint FAO / WHO Food Standards Programme,*

*FAO, Viale delle Terme di Caracalla,*

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# GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS (GL 32 - 1999)

## FOREWORD

1. These guidelines have been prepared for the purpose of providing an agreed approach to the requirements which underpin production of, and the labelling and claims for, organically produced foods.

2. The aims of these guidelines are :

   - to protect consumers against deception and fraud in the market place and unsubstantiated product claims ;
   - to protect producers of organic produce against misrepresentation of other agricultural produce as being organic ;
   - to ensure that all stages of production, preparation, storage, transport and marketing are subject to inspection and comply with these guidelines ;
   - to harmonize provisions for the production, certification, identification and labelling have organically grown produce ;
   - to provide international guidelines for organic food control systems in order to facilitate recognition of national systems as equivalent for the purposes of imports ; and
   - to maintain and enhance organic agricultural systems in each country so as to contribute to local and global preservation.

3. These guidelines are at this stage a first step into official international harmonization of the requirements for organic products in terms of production and marketing standards, inspection arrangements and labelling requirements. In this area the experience with the development of such requirements and their implementation is still very limited. Moreover, consumer perception on the organic production method may, in certain detailed but important provisions, differ from region to region in the world. Therefore, the following is recognized at this stage :

   - the guidelines are a useful instrument in assisting countries to develop national regimes regulating production, marketing and labelling of organic foods ;
   - the guidelines need regular improvement and updating in order to take into account technical progress and the experience with their implementation ;
   - the guidelines do not prejudice the implementation of more restrictive arrangements and more detailed rules by member countries in order to maintain consumer credibility and prevent fraudulent practices, and to apply such rules to products from other countries on the basis of equivalency to such more restrictive provisions.

4. These guidelines set out the principles of organic production at farm, preparation, storage, transport, labelling and marketing stages, and provides an indication of accepted permitted inputs for soil fertilizing and conditioning, plant pest and disease control and, food additives and processing aids. For labelling purposes, the use of terms inferring that organic production methods have been used are restricted to products derived from operators under the supervision of an certification body or authority.

5. Organic agriculture is one among the broad spectrum of methodologies which are supportive of the environment. Organic production systems are based on specific and precise standards of production

which aim at achieving optimal agroecosystems which are socially, ecologically and economically sustainable. Terms such as "biological" and "ecological" are also used in an effort to describe the organic system more clearly. Requirements for organically produced foods differ from those for other agricultural products in that production procedures are an intrinsic part of the identification and labelling of, and claim for, such products.

6. "Organic" is a labelling term that denotes products that have been produced in accordance with organic production standards and certified by a duly constituted certification body or authority. Organic agriculture is based on minimizing the use of external inputs, avoiding the use of synthetic fertilizers and pesticides. Organic agriculture practices cannot ensure that products are completely free of residues, due to general environmental pollution. However, methods are used to minimize pollution of air, soil and water. Organic food handlers, processors and retailers adhere to standards to maintain the integrity of organic agriculture products. The primary goal of organic agriculture is to optimize the health and productivity of interdependent communities of soil life, plants, animals and people.

7. Organic agriculture is a holistic production management system which promotes and enhances agroecosystem health, including biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. This is accomplished by using, where possible, cultural, biological and mechanical methods, as opposed to using synthetic materials, to fulfil any specific function within the system. An organic production system is designed to :

   a) enhance biological diversity within the whole system ;

   b) increase soil biological activity ;

   c) maintain long-term soil fertility ;

   d) recycle wastes of plant and animal origin in order to return nutrients to the land, thus minimizing the use of non-renewable resources ;

   e) rely on renewable resources in locally organized agricultural systems ;

   f) promote the healthy use of soil, water and air as well as minimize all forms of pollution thereto that may result from agricultural practices ;

   g) handle agricultural products with emphasis on careful processing methods in order to maintain the organic integrity and vital qualities of the product at all stages ;

   h) become established on any existing farm through a period of conversion, the appropriate length of which is determined by site-specific factors such as the history of the land, and type of crops and livestock to be produced.

8. The concept of close contact between the consumer and the producer is a long established practice. Greater market demand, the increasing economic interests in production, and the increasing distance between producer and consumer has stimulated the introduction of external control and certification procedures.

9. An integral component of certification is the inspection of the organic management system. Procedures for operator certification are based primarily on a yearly description of the agricultural enterprise as prepared by the operator in cooperation with the inspection body. Likewise, at the processing level, standards are also developed against which the processing operations and plant conditions can be inspected and verified. Where the inspection process is undertaken by the certification body or authority, there must be clear separation of the inspection and certification function. In order to maintain their integrity, certification bodies or authorities which certify the procedures of the operator should be independent of economic interests with regard to the certification of operators.

10. Apart from a small portion of agricultural commodities marketed directly from the farm to consumers, most products find their way to consumers via established trade channels. To minimize

deceptive practices in the market place, specific measures are necessary to ensure that trade and processing enterprises can be audited effectively. Therefore, the regulation of a process, rather than a final product, demands responsible action by all involved parties.

11. Import requirements should be based on the principles of equivalency and transparency as set out in the Principles for Food Import and Export Inspection and Certification[1]. In accepting imports of organic products, countries would usually assess the inspection and certification procedures and the standards applied in the exporting country.

12. Recognizing that organic production systems continue to evolve and that organic principles and standards will continue to be developed under these guidelines, the Codex Committee on Food Labelling (CCFL) shall review these guidelines on a regular basis. The CCFL shall initiate this review process by inviting member governments and international organizations to make proposals to the CCFL regarding amendments to these guidelines prior to each CCFL meeting.

## SECTION 1. SCOPE

1.1 These guidelines apply to the following products which carry, or are intended to carry, descriptive labelling referring to organic production methods :

a) unprocessed plants and plant products, livestock and livestock products to the extent that the principles of production and specific inspection rules for them are introduced in Annexes 1 and 3 ; and

b) processed agricultural crop and livestock products[2] intended for human consumption derived from (a) above.

1.2 A product will be regarded as bearing indications referring to organic production methods where, in the labelling or claims, including advertising material or commercial documents, the product, or its ingredients, is described by the terms "organic", "biodynamic", "biological", "ecological", or words of similar intent including diminutives which, in the country where the product is placed on the market, suggests to the purchaser that the product or its ingredients were obtained according to organic production methods.

1.3 Paragraph 1.2 does not apply where these terms clearly have no connection with the method of production.

1.4 These guidelines apply without prejudice to other Codex Alimentarius Commission (CAC) provisions governing the production, preparation, marketing, labelling and inspection of the products specified in paragraph 1.1.

1.5 All materials and/or the products produced from genetically engineered/modified organisms (GEO/GMO) are not compatible with the principles of organic production (either the growing, manufacturing, or processing) and therefore are not accepted under these guidelines.

## SECTION 2. DESCRIPTION AND DEFINITIONS

2.1 DESCRIPTION

Foods should only refer to organic production methods if they come from an organic farm system employing management practices which seek to nurture ecosystems which achieve sustainable productivity, and provide weed, pest and disease control through a diverse mix of mutually dependent life forms, recycling plant and animal residues, crop selection and rotation, water management, tillage and cultivation. Soil fertility is maintained and enhanced by a system which optimises soil biological activity and the physical and mineral nature of the soil as the means to

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1 CAC/GL 20-1995

2 Until lists of ingredients of non agricultural origin and processing aids permitted in the preparation of products of livestock origin are elaborated, competent authorities should develop their own lists.

provide a balanced nutrient supply for plant and animal life as well as to conserve soil resources. Production should be sustainable with the recycling of plant nutrients as an essential part of the fertilizing strategy. Pest and disease management is attained by means of the encouragement of a balanced host/predator relationship, augmentation of beneficial insect populations, biological and cultural control and mechanical removal of pests and affected plant parts. The basis for organic livestock husbandry is the development of a harmonious relationship between land, plants and livestock, and respect for the physiological and behavioural needs of livestock. This is achieved by a combination of providing good quality organically grown feedstuffs, appropriate stocking rates, livestock husbandry systems appropriate to behavioural needs, and animal management practices that minimize stress and seek to promote animal health and welfare, prevent disease and avoid the use of chemical allopathic veterinary drugs (including antibiotics).

## 2.2 DEFINITIONS

For the purpose of these guidelines :

***Agricultural product/product of agricultural origin*** means any product or commodity, raw or processed, that is marketed for human consumption (excluding water, salt and additives) or animal feed.

***Audit*** is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives[3].

***Certification*** is the procedure by which official certification bodies, or officially recognized certification bodies, provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems and examination of finished products.[4]

***Certification body*** means a body which is responsible for verifying that a product sold or labelled as "organic" is produced, processed, prepared handled, and imported according to these guidelines.

***Competent authority*** means the official government agency having jurisdiction.

***Genetically engineered/modified organisms.*** The following provisional definition is provided for genetically/modified organisms[5]. Genetically engineered/modified organisms, and products thereof, are produced through techniques in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

***Techniques of genetic engineering***/modification include, but are not limited to : recombinant DNA, cell fusion, micro and macro injection, encapsulation, gene deletion and doubling. Genetically engineered organisms will not include organisms resulting from techniques such as conjugation, transduction and hybridization.

***Ingredient*** means any substance, including a food additive, used in the manufacture or preparation of a food and present in the final product although possibly in a modified form[6].

***Inspection*** is the examination of food or systems for control of food, raw materials, processing, and distribution including in-process and finished product testing, in order to verify that they conform to requirements[7]. For organic food, inspection includes the examination of the production and processing system.

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3 CAC/GL 20-1995

4 CAC/GL 20-1995

5 In the absence of a definition of genetically engineered/modified organisms agreed by the Codex Alimentarius Commission, this definition has been developed in order to provide initial guidance for governments in the application of these guidelines. This definition is therefore to remain under review in the light of other considerations by the Commission and its Committees. In the interim, member countries may also apply national definitions.

6 General Standard for the Labelling of Prepackaged Foods, Section 4 - Labelling of Prepackaged Foods (CODEX STAN 1-1985)

7 CAC/GL 20-1995

***Labelling*** means any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal[8].

***Livestock*** means any domestic or domesticated animal including bovine (including buffalo and bison), ovine, porcine, caprine, equine, poultry and bees raised for food or in the production of food[9]. The products of hunting or fishing of wild animals shall not be considered part of this definition.

***Marketing*** means holding for sale or displaying for sale, offering for sale, selling, delivering or placing on the market in any other form.

***Official accreditation*** is the procedure by which a government agency having jurisdiction formally recognizes the competence of an inspection and/or certification body to provide inspection and certification services. For organic production the competent authority may delegate the accreditation function to a private body.

***Officially recognized inspection systems/officially recognized certification systems*** are systems which have been formally approved or recognized by a government agency having jurisdiction.[10]

***Operator*** means any person who produces, prepares or imports, with a view to the subsequent marketing thereof, products as referred to in Section 1.1, or who markets such products.

***Plant protection product*** means any substance intended for preventing, destroying, attracting, repelling, or controlling any pest or disease including unwanted species of plants or animals during the production, storage, transport, distribution and processing of food, agricultural commodities, or animal feeds.

***Preparation*** means the operations of slaughtering, processing, preserving and packaging of agricultural products and also alterations made to the labelling concerning the presentation of the organic production method.

***Production*** means the operations undertaken to supply agricultural products in the state in which they occur on the farm, including initial packaging and labelling of the product.

***Veterinary drug*** means any substance applied or administered to any food-producing animal, such as meat or milk-producing animals, poultry, fish or bees, whether used for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behaviour[11].

## SECTION 3. LABELLING AND CLAIMS

GENERAL PROVISIONS

3.1 Organic products should be labelled in accordance with the Codex General Standard for the Labelling of Prepackaged Foods[12].

3.2 The labelling and claims of a product specified in Section 1.1(a) may refer to organic production methods only where :

a) such indications show clearly that they relate to a method of agricultural production ;

b) the product was produced in accordance with the requirements of Section 4 or imported under the requirements laid down in Section 7 ;

c) the product was produced or imported by an operator who is subject to the inspection measures laid down in Section 6, and

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8 CODEX STAN 1-1985

9 Provisions for aquaculture will be elaborated at a future date.

10 CAC/GL 20-1995

11 Codex Alimentarius Commission Procedural Manual, Definitions

12 CODEX STAN 1-1985

d) the labelling refers to the name and/or code number of the officially recognized inspection or certification body to which the operator who has carried out the production or the most recent processing operation is subject.

3.3 The labelling and claims of a product specified in paragraph 1.1(b) may refer to organic production methods only where :

a) such indication show clearly that they relate to a method of agricultural production and are linked with the name of the agricultural product in question, unless such indication is clearly given in the list of ingredients ;

b) all the ingredients of agricultural origin of the product are, or are derived from, products obtained in accordance with the requirements of Section 4, or imported under the arrangements laid down in Section 7 ;

c) the product should not contain any ingredient of non-agricultural origin not listed in Annex 2, Table 3 ;

d) the same ingredients shall not be derived from an organic and nonorganic origin ;

e) the product or its ingredients have not been subjected during preparation to treatments involving the use of ionizing radiation or substances not listed in Annex 2, Table 4 ;

f) the product was prepared or imported by an operator subject to the regular inspection system as set out in Section 6 of these guidelines ; and

g) the labelling refers to the name and/or the code number of the official or officially recognized certification body or authority to which the operator who has carried out the most recent preparation operation is subject.

3.4 By way of derogation from paragraph 3.3(b),

- certain ingredients of agricultural origin not satisfying the requirement in that paragraph may be used, within the limit of maximum level of 5% m/m of the total ingredients excluding salt and water in the final product, in the preparation of products as referred to in paragraph 1.1(b) ;
- where such ingredients of agricultural origin are not available, or in sufficient quantity, in accordance with the requirements of Section 4 of these guidelines ;

3.5 Pending further review of the guidelines in accordance with Section 8, Member Countries can consider the following with regard to products referred to in paragraph 1.1(b) marketed in their territory :

- the development of specific labelling provisions for products containing less than 95% ingredients of agricultural ingredients ;
- the calculation of the percentages in 3.4 (5%) and in 3.5 (95%) on the basis of the ingredients of agricultural origin (instead of all ingredients excluding only salt and water) ;
- the marketing of product with in transition/conversion labelling containing more than one ingredient of agricultural origin.

3.6 In developing labelling provisions from products containing less than 95% of organic ingredients in accordance with the paragraph above, member countries may consider the following elements in particular for products containing 95% and 70% of organic ingredients :

a) the product satisfies the requirements of paragraphs 3.3(c), (d) (e), (f) and (g) ;

b) the indications referring to organic production methods should only appear on the front panel as a reference to the approximate percentage of the total ingredients including additives but excluding salt and water ;

c) the ingredients, appear in descending order (mass/mass) in the list of ingredients ;

d) indications in the list of ingredients appear in the same colour and with an identical style and

size of lettering as other indications in the list of ingredient.

LABELLING OF PRODUCTS IN TRANSITION/CONVERSION TO ORGANIC

3.7 Products of farms in transition to organic production methods may only be labelled as "transition to organic" after 12 months of production using organic methods providing that :

a) the requirements referred to in paragraphs 3.2 and 3.3 are fully satisfied ;

b) the indications referring to transition/conversion do not mislead the purchaser of the product regarding its difference from products obtained from farms and/or farm units which have fully completed the conversion period ;

c) such indication take the form of words, such as "product under conversion to organic farming", or similar words or phrase accepted by the competent authority of the country where the product is marketed, and must appear in a colour, size and style of lettering which is not more prominent than the sales description of the product ;

d) foods composed of a single ingredient may be labelled as "transition to organic" on the principal display panel ;

e) the labelling refers to the name and/or the code number of the official or officially approved certification body or authority to which the operator who has carried out the most recent preparation is subject.

LABELLING OF NON-RETAIL CONTAINERS

3.8 The labelling of non-retail containers of product specified in paragraph1.1 should meet the requirements set out in Annex 3, paragraph 10.

## SECTION 4. RULES OF PRODUCTION AND PREPARATION

4.1 Organic production methods require that for the production of products referred to in paragraph 1.1(a) :

a) at least the production requirements of Annex 1 should be satisfied ;

b) in the case where (a) (above) is not effective, substances listed in Annex 2, Tables 1 and 2 or substances approved by individual countries that meet the criteria established in Section 5.1, may be used as plant protection products, fertilizers, soil conditioners, insofar as the corresponding use is not prohibited in general agriculture in the country concerned in accordance with the relevant national provisions.

4.2 Organic processing methods require that for the preparation of products referred to in paragraph 1.1(b) :

a) at least the processing requirements of Annex 1 should satisfied ;

b) substances listed in Annex 2, Tables 3 and 4 or substances approved by individual countries that meet the criteria established in Section 5.1 may be used as ingredients of non-agricultural origin or processing aids insofar as the corresponding use is not prohibited in the relevant national requirements concerning the preparation of food products and according to good manufacturing practice.

4.3 Organic products should be stored and transported according to the requirements of Annex 1.

4.4 By derogation of the provisions of paragraphs 4.1 (a) and 4.2 (a), the competent authority may, with regard to the provisions on livestock production at Annex 1, provide for more detailed rules as well as for derogations for implementation periods in order to permit gradual development of organic farming practices.

## SECTION 5. REQUIREMENTS FOR INCLUSION OF SUBSTANCES IN ANNEX 2 AND CRITERIA FOR THE DEVELOPMENT OF LISTS OF SUBSTANCES BY COUNTRIES

5.1 At least the following criteria should be used for the purposes of amending the permitted substance lists referred to in Section 4. In using these criteria to evaluate new substances for use in organic production, countries should take into account all applicable statutory and regulatory provisions and make them available to other countries upon request.

Any proposals for the inclusion in Annex 2 of new substances must meet the following general criteria :

i ) they are consistent with principles of organic production as outlined in these Guidelines ;

ii ) use of the substance is necessary/essential for its intended use ;

iii) manufacture, use and disposal of the substance does not result in, or contribute to, harmful effects on the environment ;

iv) they have the lowest negative impact on human or animal health and quality of life ; and

v ) approved alternatives are not available in sufficient quantity and/or quality.

The above criteria are intended to be evaluated as a whole in order to protect the integrity of organic production. In addition, the following criteria should be applied in the evaluation process :

a) if they are used for fertilization, soil conditioning purposes :

- they are essential for obtaining or maintaining the fertility of the soil or to fulfil specific nutrition requirements of crops, or specific soilconditioning and rotation purposes which cannot be satisfied by the practices included in Annex 1, or other products included in Table 2 of Annex 2 ; and
- the ingredients will be of plant, animal, microbial, or mineral origin and may undergo the following processes : physical (e.g., mechanical, thermal), enzymatic, microbial (e.g., composting, fermentation) ; only when the above processes have been exhausted, chemical processes may be considered and only for the extraction of carriers and binders[13] ; and
- their use does not have a harmful impact on the balance of the soil ecosystem or the physical characteristics of the soil, or water and air quality ; and
- their use may be restricted to specific conditions, specific regions or specific commodities ;

b) if they are used for the purpose of plant disease or pest and weed control :

- they should be essential for the control of a harmful organism or a particular disease for which other biological, physical, or plant breeding alternatives and/or effective management practices are not available ; and
- their use should take into account the potential harmful impact on the environment, the ecology (in particular non-target organisms) and the health of consumers, livestock and bees ; and
- substances should be of plant, animal, microbial, or mineral origin and may undergo the following processes : physical (e.g. mechanical, thermal), enzymatic, microbial (e.g. composting, digestion) ;
- however, if they are products used, in exceptional circumstances, in traps and dispensers such as pheromones, which are chemically synthesized they will be considered for addition to lists if the products are not available in sufficient quantities in their natural form, provided that the conditions for their use do not directly or indirectly result in the presence of residues of the product in the edible parts ;
- their use may be restricted to specific conditions, specific regions or specific commodities ;

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13 The use of chemical processes in the context of these Criteria is an interim measure and should be reviewed in line with the provisions as set out in Section 8 of these Guidelines.

c) if they are used as additives or processing aids in the preparation or preservation of the food :

- these substances are used only if it has been shown that, without having recourse to them, it is impossible to :
  - produce or preserve the food, in the case of additives, or
  - produce the food, in the case of processing aids in the absence of other available technology that satisfies these Guidelines ;
- these substances are found in nature and may have undergone mechanical/physical processes (e.g. extraction, precipitation), biological/enzymatic processes and microbial processes (e.g. fermentation),
- or, if these substances mentioned above are not available from such methods and technologies in sufficient quantities, then those substances that have been chemically synthesized may be considered for inclusion in exceptional circumstances ;
- their use maintains the authenticity of the product ;
- the consumer will not be deceived concerning the nature, substance and quality of the food ;
- the additives and processing aids do not detract from the overall quality of the product.

In the evaluation process of substances for inclusion on lists all stakeholders should have the opportunity to be involved.

5.2 Countries should develop or adopt a list of substances that meet the criteria outlined in Section 5.1.

THE OPEN NATURE OF THE LISTS

5.3 Because of the primary purpose of providing a list of substances, the lists in Annex 2 are open and subject to the inclusion of additional substances or the removal of existing ones on an ongoing basis. When a country proposes inclusion or amendment of a substance in Annex 2 it should submit a detailed description of the product and the conditions of its envisaged use to demonstrate that the requirements under Section 5.1 are satisfied. The procedure for requesting amendments to the lists is set out under Section 8 of these Guidelines

## SECTION 6. INSPECTION AND CERTIFICATION SYSTEMS[14]

6.1 Inspection and certification systems are used to verify the labelling of, and claims for, organically produced foods. Development of these systems should take into account the Principles for Food Import and Export Inspection and Certification[15], the Guideline for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems.[16,17]

6.2 Competent authorities should establish an inspection system operated by one or more designated authorities and/or officially recognized inspection/certification[18] bodies to which the operators producing, preparing or importing products as referred to in paragraph 1.1 should be subject.

6.3 The officially recognized inspection and certification systems should comprise at least the application of the measures and other precautions set out in Annex 3.

6.4 For the application of the inspection system operated by the official or officially recognized

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14 The systems conducted by certification bodies may in some countries be equivalent to those systems conducted by inspection bodies. Therefore, the term "inspection and certification" has been used wherever these systems may be synonymous.

15 CAC/GL 20-1995

16 CAC/GL 26-1997

17 See also other agreed international standards, eg ISO65.

18 In organic approval processes reference is frequently made to certification performed by either a 'certification body' or an 'inspection body'. Where these functions are conducted by the same body there must be clear separation of the inspection and certification roles

certification body or authority, countries should identify a ompetent authority responsible for the approval and supervision of such bodies :

- the identified competent authority may delegate, while maintaining the responsibility for the decisions and actions taken, the assessment and supervision of private inspection and certification bodies to a private or public third party hereafter referred to as its "designate". If delegated, the private or public third party should not be engaged in inspection and/or certification ;
- for this purpose an importing country may recognize a third party accrediting body when the exporting country lacks an identified competent authority and a national program.

6.5 In order to attain approval as an officially recognized certification body or authority, the competent authority, or its designate, when making its assessment should take into account the following :

a) the standard inspection/certification procedures to be followed, including detailed description of the inspection measures and precautions which the body undertakes to impose on operators subject to inspection ;

b) the penalties which the body intends to apply where irregularities and/or infringements are found ;

c) the availability of appropriate resources in the form of qualified staff, administrative and technical facilities, inspection experience and reliability ;

d) the objectivity of the body vis-à-vis the operators subject to inspection.

6.6 The competent authority or its designate should :

a) ensure that the inspections carried out on behalf of the inspection or certification body are objective ;

b) verify the effectiveness of inspections ;

c) take cognizance of any irregularities and/or infringements found and penalties applied ;

d) withdraw approval of the certification body or authority where it fails to satisfy the requirements referred to in (a) and (b) or, no longer fulfils the criteria indicated in paragraph 6.5 or, fails to satisfy the requirements laid down in paragraphs 6.7 to 6.9.

6.7 Official and/or officially recognized certification bodies or authority referred to in paragraph 6.2 should :

a) ensure that at least the inspection measures and precautions specified in Annex 3 are applied to undertakings subject to inspection ; and

b) not disclose confidential information and data obtained in their inspection or certification activities to persons other than the person responsible for the undertaking concerned and the competent authorities.

6.8 Official or officially recognized inspection and/or certification bodies or authority should :

a) give the competent authority or its designate, for audit purposes, access to their offices and facilities and, for random audit of its operators, access to the facilities of the operators, together with any information and assistance deemed necessary by the competent authority or its designate for the fulfilment of its obligations pursuant to these guidelines ;

b) send to the competent authority or its designate each year a list of operators subject to inspection for the previous year and present to the said authority a concise annual report.

6.9 The designated authority and the official or officially recognized certification body or authority referred to in paragraph 6.2 should :

a) ensure that, where an irregularity is found in the implementation of Sections 3 and 4, or of the measures referred to in Annex 3, the indications provided for in paragraph 1.2 referring to the organic production method are removed from the entire lot or production run affected by the

irregularity concerned ;

b) where a manifest infringement, or an infringement with prolonged effects is found, prohibit the operator concerned from marketing products with indications referring to the organic production method for a period to be agreed with the competent authority or its designate.

6.10 The requirements of the Guidelines for the Exchange of Information between Countries on Rejections of Imported Food[19] should apply where the competent authority finds irregularities and/or infringements in the application of these guidelines.

## SECTION 7. IMPORTS

7.1 Products as specified in paragraph 1.1 which are imported may be marketed only where the competent authority or designated body in the exporting country has issued a certificate of inspection stating that the lot designated in the certificate was obtained within a system of production, preparation, marketing and inspection applying at least the rules provided for in all sections and annexes of these guidelines and satisfy the decision on equivalency referred to under 7.4.

7.2 The certificate referred to in paragraph 7.1 above should accompany the goods, in the original copy, to the premises of the first consignee ; thereafter the importer should keep the transactional certificate for not less than two years for inspection/audit purposes.

7.3 The authenticity of the product should be maintained after import through to the consumer. If imports of organic products are not in conformity with the requirements of these guidelines due to treatment required by national regulations for quarantine purposes that is not in conformity with these guidelines they loose their organic status.

7.4 An importing country may :

a) require detailed information, including reports established by independent experts mutually agreed between competent authorities of the exporting and importing countries, on the measures applied in the exporting country to enable it to make judgements and decisions on equivalency with its own rules provided that these rules of the importing country meet the requirements of these guidelines, and/or

b) arrange together with the exporting country for site visits to examine the rules of production and preparation, and the inspection/certification measures including production and preparation itself as applied in the exporting country.

c) require, in order to avoid any confusion to the consumer, that the product is labelled in accordance with the labelling requirements applied, in accordance with the provisions of section 3, in the importing country for the products concerned.

## SECTION 8. ONGOING REVIEW OF THE GUIDELINES

8.1 In line with the purpose of the guidelines to provide advice to governments, member governments and international organizations are invited to make proposals to the Codex Committee on Food Labelling on an ongoing basis. Once a final document is agreed, the Codex Committee on Food Labelling shall conduct a review each 4 years of these guidelines and review each two years (or as required) the lists included in Annex 2 in order to take into account the latest developments in this area.

8.2 Proposals should be directed in the first instance to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, 00100, Rome, Italy.

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19 CAC/GL 25-1997

ANNEX 1

# PRINCIPLES OF ORGANIC PRODUCTION

## A. PLANTS AND PLANT PRODUCTS

1. The principles set out in this Annex should have been applied on the parcels, farm or farm units during a conversion period of at least two years before sowing, or in the case of perennial crops other than grassland, at least three (3) years before the first harvest of products as referred to in paragraph 1.1(a) of these guidelines. The competent authority, or where delegated, the official or officially recognized certification body or authority may decide in certain cases (such as idle use for two years or more) to extend or reduce that period in the light of previous parcel use but the period must equal or exceed 12 months.

2. Whatever the length of the conversion period it may only begin once a production unit has been placed under an inspection system as required by 6.2 and once the unit has started the implementation of the production rules referred to in Section 4 of these Guidelines.

3. In cases where a whole farm is not converted at one time, it may be done progressively whereby these guidelines are applied from the start of conversion on the relevant fields. Conversion from conventional to organic production should be effected using permitted techniques as defined in these guidelines. In cases where a whole farm is not converted at the same time, the holding must be split into units as referred to in Annex 3, part A, paragraphs 3 and 11.

4. Areas in conversion as well as areas converted to organic production must not be alternated (switched back and forth) between organic and conventional production methods.

5. The fertility and biological activity of the soil should be maintained or increased, where appropriate, by :

   a) cultivation of legumes, green manures or deep-rooting plants in an appropriate multi-annual rotation programme ;

   b) incorporation in the soil of organic material, composted or not, from holdings producing in accordance with these guidelines. By-products from livestock farming, such as farmyard manure, may be used if they come from livestock holdings producing in accordance with these guidelines ;

   Substances, as specified in Annex 2, Table 1 may be applied only to the extent that adequate nutrition of the crop or soil conditioning are not possible by the methods set out in 5(a) and (b) above or, in the case of manures, they are not available from organic farming.

   c) for compost activation, appropriate micro-organisms or plant-based preparations may be used ;

   d) biodynamic preparations from stone meal, farmyard manure or plants may also be used for the purpose covered by paragraph 5.

6. Pests, diseases and weeds should be controlled by any one, or a combination, of the following measures :

   - choice of appropriate species and varieties ;
   - appropriate rotation programs ;
   - mechanical cultivation ;
   - protection of natural enemies of pests through provision of favourable habitat, such as hedges and nesting sites, ecological buffer zones which maintain the original vegetation to house pest predators ;
   - diversified ecosystems. These will vary between geographical locations. For example, buffer zones to counteract erosion, agroforestry, rotating crops, etc.

- flame weeding ;
- natural enemies including release of predators and parasites ;
- biodynamic preparations from stone meal, farmyard manure or plants ;
- mulching and mowing ;
- grazing of animals ;
- mechanical controls such as traps, barriers, light and sound ;
- steam sterilization when proper rotation of soil renewal cannot take place.

7. Only in cases of imminent or serious threat to the crop and where the measures identified in 6. (above) are, or would not be effective, recourse may be had to products referred to in Annex 2.

8. Seeds and vegetative reproductive material should be from plants grown in accordance with the provisions of Section 4.1 of these guidelines for at least one generation or, in the case of perennial crops, two growing seasons. Where an operator can demonstrate to the official or officially recognized certification body or authority that material satisfying the above requirements is not available, the certification body or authority may support :

a) in the first instance, use of untreated seeds or vegetative reproductive material, or

b) if (a) is not available, use of seeds and vegetative reproductive material treated with substances other than those included in Annex 2.

The competent authority may establish criteria to limit the application of the derogation in 8 above.

9. The collection of edible plants and parts thereof, growing naturally in natural areas, forests and agricultural areas, is considered an organic production method provided that :

- the products are from a clearly defined collection area that is subject to the inspection/ certification measures set out in Section 6 of these guidelines ;
- those areas have received no treatments with products other than those referred to in Annex 2 for a period of three years before the collection ;
- the collection does not disturb the stability of the natural habitat or the maintenance of the species in the collection area ;
- the products are from an operator managing the harvesting or gathering of the products, who is clearly identified and familiar with the collection area.

## B. LIVESTOCK AND LIVESTOCK PRODUCTS GENERAL PRINCIPLES

1. Where livestock for organic production are maintained, they should be an integral part of the organic farm unit and should be raised and held according to these guidelines.

2. Livestock can make an important contribution to an organic farming system by :

a) improving and maintaining the fertility of the soil ;

b) managing the flora through grazing ;

c) enhancing biodiversity and facilitating complementary interactions on the farm ; and

d) increasing the diversity of the farming system.

3. Livestock production is a land related activity. Herbivores must have access to pasture and all other animals must have access to open-air runs ; the competent authority may allow exceptions when the animals' physiological state, inclement weather conditions, and state of the land so permit, or the structure of certain `traditional` farming systems restrict access to pasture, providing the welfare of the animals can be guaranteed.

4. Stocking rates for livestock should be appropriate for the region in question taking into consideration feed production capacity, stock health, nutrient balance, and environmental impact.

5. Organic livestock management should aim to utilize natural breeding methods, minimize stress, prevent disease, progressively eliminate the use of chemical allopathic veterinary drugs (including antibiotics), reduce the feeding of animals with products of animal origin (e.g. meat meal), and maintain animal health and welfare.

**LIVESTOCK SOURCES/ORIGIN**

6. The choice of breeds, strains and breeding methods shall be consistent with the principles of organic farming, taking into account in particular :

   a) their adaptation to the local conditions ;

   b) their vitality and resistance to disease ;

   c) the absence of specific diseases or health problems associated with some breeds and strains (porcine stress syndrome, spontaneous abortion etc).

7. Livestock used for products satisfying Section 1.1 (a) of these guidelines must come, from birth or hatching, from production units complying with these guidelines, or have been the offspring of parents raised under the conditions set down in these guidelines. They must be raised under this system throughout their life.

   - Livestock may not be transferred between organic and non-organic units. The competent authority can establish detailed rules for the purchase of livestock from other units complying with these Guidelines.
   - Livestock existing on the livestock production unit, but not complying with these Guidelines, may be converted.

8. When an operator can demonstrate to the satisfaction of the official or officially recognized inspection /certification body that livestock satisfying the requirements indicated in the previous paragraph are not available, the official or officially recognized inspection/certification body may allow livestock not raised according these guidelines under circumstances such as :

   a) for considerable expansion of the farm, when a breed is changed or when new livestock specialization is developed ;

   b) for the renewal of a herd, e.g., high mortality of animals caused by catastrophic circumstances ;

   c) males for breeding.

   The competent authority may set the specific conditions under which livestock from non-organic sources may be allowed or not allowed, taking into account that animals be brought in as young as possible as soon as they are weaned.

9. These livestock qualified by the derogations indicated in the previous paragraph must comply with the conditions set out in paragraph 12. These conversion periods must be observed if the products are to be sold as organic according to Section 3 of these guidelines.

**CONVERSION**

10. The conversion of the land intended for feeding crops or pasture must comply with the rules set out in Part A paragraphs 1, 2, and 3 of this Annex.

11. The competent authority may reduce the conversion periods or conditions established in paragraph 10 (for the land) and/or paragraph 12 (for livestock and livestock products) in the following cases :

   a) pasture, open-air runs and exercise areas used by non-herbivore species ;

   b) for bovine, equine, ovine and caprine coming from extensive husbandry during an implementation period established by the competent authority or dairy herds converted for the first time ;

   c) if there is simultaneous conversion of livestock and land used only for feeding within the same

unit, the conversion period for both livestock, pasture and/or land used for animal feed, may be reduced to two years only in the case where the existing livestock and their offspring are fed mainly with products from the unit.

12. Once the land has reached organic status and livestock from a nonorganic source is introduced, and if the products are to be sold as organic, such livestock must be reared according to these Guidelines for at least the following compliance periods :

Bovine and equine

*Meat products* : 12 months and at least $\frac{3}{4}$ of their life span in the organic management system ;

*Calves for meat production* : 6 months when brought in as soon as they are weaned and less than 6 months old ;

*Milk products* : 90 days during the implementation period established by the competent authority, after that, six months.

Ovine and caprine

*Meat products* : six months ;

*Milk products* : 90 days during the implementation period established by the competent authority, after that, six months.

Porcine

*Meat products* : Six months.

Poultry/laying hens

*Meat products* : whole of life span as determined by the competent authority ;

*Eggs* : six weeks.

NUTRITION

13. All livestock systems should provide the optimum level of 100% of the diet from feedstuffs (including 'in conversion' feedstuffs) produced to the requirements of these guidelines.

14. For an implementation period to be set by the competent authority, livestock products will maintain their organic status providing feed, consisting of at least 85% for ruminants and 80% for non-ruminants and calculated on a dry matter basis, is from organic sources produced in compliance with these Guidelines.

15. Notwithstanding the above, where an operator can demonstrate to the satisfaction of the official or officially recognized inspection/certification body that feedstuffs satisfying the requirement outlined in paragraph 13 above are not available, as a result of, for example, unforeseen severe natural or manmade events or extreme climatic weather conditions, the inspection/certification body may allow a restricted percentage of feedstuffs not produced according to these guidelines to be fed for a limited time, providing it does not contain genetically engineered/modified organisms or products thereof. The competent authority shall set both the maximum percentage of non-organic feed allowed and any conditions relating to this derogation.

16. Specific livestock rations should take into account :

- the need of young mammals for natural, preferably maternal, milk ;
- that a substantial proportion of dry matter in the daily rations of herbivores needs to consist of roughage, fresh or dried fodder, or silage ;
- that polygastric animals should be not fed silage exclusively ;
- the need for cereals in the fattening phase of poultry ;
- the need for roughage, fresh or dried fodder or silage in the daily ration for pigs and poultry.

17. All livestock must have ample access to fresh water to maintain the full health and vigour of the livestock.

18. If substances are used as feedstuffs, nutritional elements, feed additives or processing aids in the preparation of feedstuffs, the competent authority shall establish a positive list/s of substances in compliance with the following criteria :

**General Criteria**

a) substances are permitted according to national legislation on animal feeding ;

b) substances are necessary/essential to maintain animal health, animal welfare and vitality ; and

c) such substances :

- contribute to an appropriate diet fulfilling the physiological and behavioural needs of the species concerned ; and
- do not contain genetically engineered/modified organisms and products thereof ; and
- are primarily of plant, mineral or animal origin.

**Specific Criteria for Feedstuffs and Nutritional Elements**

a) feedstuffs of plant origin from non-organic sources can only be used, under the conditions of paragraphs 14 and 15, if they are produced or prepared without the use of chemical solvents or chemical treatment ;

b) feedstuffs of mineral origin, trace elements, vitamins, or provitamins can only be used if they are of natural origin. In case of shortage of these substances, or in exceptional circumstances, chemically well-defined analogic substances may be used ;

c) feedstuffs of animal origin, with the exception of milk and milk products, fish, other marine animals and products derived therefrom should generally not be used or, as provided by national legislation. In any case, the feeding of mammalian material to ruminants is not permitted with the exception of milk and milk products ;

d) synthetic nitrogen or non-protein nitrogen compounds shall not be used.

**Specific Criteria for Additives and Processing Aids :**

a) binders, anti-caking agents, emulsifiers, stabilizers, thickeners, surfactants, coagulants: only natural sources are allowed ;

b) antioxidants: only natural sources are allowed ;

c) preservatives: only natural acids are allowed ;

d) colouring agents (including pigments), flavours and appetite stimulants : only natural sources are allowed ;

e) probiotics, enzymes and microorganisms are allowed ;

f) antibiotics, coccidiostatics, medicinal substances, growth promoters or any other substance intended to stimulate growth or production shall not be used in animal feeding.

19. Silage additives and processing aids may not be derived from genetically engineered/modified organisms or products thereof, and may be comprised of only :

- sea salt ;
- coarse rock salt ;
- yeasts ;

- enzymes ;
- whey;
- sugar ; or sugar products such as molasses ;
- honey ;
- lactic, acetic, formic and propionic bacteria, or their natural acid product when the weather conditions do not allow for adequate fermentation, and with approval of the competent authority.

**HEALTH CARE**

20. Disease prevention in organic livestock production shall be based on the following principles :

a) the choice of appropriate breeds or strains of animals as detailed in paragraph 6 above ;

b) the application of animal husbandry practices appropriate to the requirements of each species, encouraging strong resistance to disease and the prevention of infections ;

c) the use of good quality organic feed, together with regular exercise and access to pasture and/or open-air runs, having the effect of encouraging the natural immunological defence of the animal ;

d) ensuring an appropriate density of livestock, thus avoiding overstocking and any resulting animal health problems.

21. If, despite the above preventative measures, an animal becomes sick or injured it must be treated immediately, if necessary in isolation and in suitable housing. Producers should not withhold medication where it will result in unnecessary suffering of the livestock, even if the use of such medication will cause the animal to lose its organic status.

22. The use of veterinary medicinal products in organic farming shall comply with the following principles :

a) where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted ;

b) phytotherapeutic (excluding antibiotics), homeopathic or ayurvedic products and trace elements shall be used in preference to chemical allopathic veterinary drugs or antibiotics, provided that their therapeutic effect is effective for the species of animal and the condition for which the treatment is intended ;

c) if the use of the above products is unlikely to be effective in combating illness or injury, chemical allopathic veterinary drugs or antibiotics may be used under the responsibility of a veterinarian; withholding periods should be the double of that required by legislation with, in any case, a minimum of 48 hours ;

d) the use of chemical allopathic veterinary drugs or antibiotics for preventative treatments is prohibited.

23. Hormonal treatment may only be used for therapeutic reasons and under veterinary supervision.

24. Growth stimulants or substances used for the purpose of stimulating growth or production are not permitted.

**LIVESTOCK HUSBANDRY, TRANSPORT AND SLAUGHTER**

25. Maintenance of livestock should be guided by an attitude of care, responsibility and respect for living creatures.

26. Breeding methods should be in compliance with the principles of organic farming taking into account :

a) the breeds and strains suitable for raising under local conditions and under an organic system ;

b) the preference for reproduction through natural methods, although artificial insemination may be used ;

c) that embryo transfer techniques and the use of hormonal reproductive treatment shall not be used ;

d) that breeding techniques employing genetic engineering must not be used.

27. Operations such as attaching elastic bands to the tails of sheep, taildocking, cutting of teeth, trimming of beaks and dehorning are generally not allowed in the organic management system. Some of these operations may, however, be authorized in exceptional circumstances by the competent authority or its delegate, for reasons of safety (e.g. dehorning in young animals) or if they are intended to improve the health and welfare of the livestock. Such operations must be carried out at the most appropriate age and any suffering to the animals must be reduced to a minimum. Anaesthetic should be used where appropriate. Physical castration is allowed in order to maintain the quality of products and traditional production practices (meat-type pigs, bullocks, capons, etc) but only under these conditions.

28. The living conditions and the management of the environment should take into account the specific behavioural needs of the livestock and provide for :

- sufficient free movement and opportunity to express normal patterns of behaviour;
- company of other animals, particularly of like kind ;
- the prevention of abnormal behaviour, injury and disease ;
- arrangements to cover emergencies such as the outbreaks of fire, the breakdown of essential mechanical services and the disruption of supplies.

29. The transport of living stock should be managed in a calm and gentle way and in a manner which avoids stress, injury and suffering : the competent authority should establish specific conditions in order to meet these objectives and may establish maximum transport periods. In transporting livestock, the use of electric stimulation or allopathic tranquilizers is not permitted.

30. The slaughter of livestock should be undertaken in a manner which minimizes stress and suffering, and in accordance with national rules.

**HOUSING AND FREE-RANGE CONDITIONS**

31. Housing for livestock will not be mandatory in areas with appropriate climatic conditions to enable animals to live outdoors.

32. Housing conditions should meet the biological and behavioural needs of the livestock by providing :

- easy access to feeding and watering ;
- insulation, heating, cooling and ventilation of the building to ensure that air circulation, dust level, temperature, relative air humidity and gas concentration are kept within limits which are not harmful to the livestock ;
- plentiful natural ventilation and light to enter ;

33. Livestock may be temporarily confined during periods of inclement weather, when their health, safety or well being could be jeopardized, or to protect plant, soil and water quality.

34. The stocking density in buildings should :

- provide for the comfort and well being of the livestock having regard for the species, the breed and the age of the livestock ;
- take into account the behavioural needs of the livestock with respect to the size of the group and the sex of the livestock ;

- provide them with sufficient space to stand naturally, lie down easily, turn round, groom themselves, and assume all natural postures and movements such as stretching and wing flapping.

35. Housing, pens, equipment and utensils should be properly cleaned and disinfected to prevent cross infection and the build-up of disease carrying organisms.

36. Free-range, open-air exercise areas, or open-air runs should, if necessary, provide sufficient protection against rain, wind, sun and extreme temperatures, depending on the local weather conditions and the breed concerned.

37. The outdoor stocking density of livestock kept on pasture, grassland, or other natural or semi-natural habitats, must be low enough to prevent degradation of the soil and over-grazing of vegetation.

**Mammals**

38. All mammals must have access to pasture or an open-air exercise area or run which may be partially covered, and they must be able to use those areas whenever the physiological condition of the animal, the weather conditions and the state of the ground permit.

39. The competent authority may grant exceptions for :

- the access of bulls to pasture or, in case of cows to an open-air exercise area or run during the winter period ;
- the final fattening phase.

40. Livestock housing must have smooth, but not slippery floors. The floor must not be entirely of slatted or grid construction.

41. The housing must be provided with a comfortable, clean and dry laying/rest area of sufficient size, consisting of a solid construction. Ample dry bedding strewn with litter material must be provided in the rest area.

42. The housing of calves in individual boxes and the tethering of livestock are not permitted without the approval of the competent authority.

43. Sows must be kept in groups, except in the last stages of pregnancy and during the suckling period. Piglets may not be kept on flat decks or in piglet cages. Exercise areas must permit dunging and rooting by the animals.

44. The keeping of rabbits in cages is not permitted.

**Poultry**

45. Poultry must be reared in open-range conditions and have free access to open-air run whenever the weather conditions permit. The keeping of poultry in cages is not permitted.

46. Water fowl must have access to a stream, pond or lake whenever the weather conditions permit.

47. Housing for all poultry should provide an area of solid construction covered with litter material such as straw, wood shavings, sand or turf. A sufficiently large part of the floor area must be available to laying hens for the collection of droppings, Perches/higher sleeping areas of a size and number commensurate with the species and size of the group and of the birds and exit/entry holes of an adequate size must be provided.

48. In the case of laying hens, when natural day length is prolonged by artificial light, the competent authority shall prescribe maximum hours respective to species, geographical considerations and general health of the animals.

49. For health reasons, between each batch of poultry reared buildings should be emptied, and runs left empty to allow the vegetation to grow back.

## MANURE MANAGEMENT

50. Manure management practices used to maintain any area in which livestock are housed, penned or pastured should be implemented in a manner that :

a) minimizes soil and water degradation ;

b) does not significantly contribute to contamination of water by nitrates and pathogenic bacteria ;

c) optimizes recycling of nutrients ; and

d) does not include burning or any practice inconsistent with organic practices.

51. All manure storage and handling facilities, including composting facilities should be designed, constructed and operated to prevent contamination of ground and/or surface water.

52. Manure application rates should be at levels that do not contribute to ground and/or surface water contamination. The competent authority may establish maximum application rates for manure or stocking densities. The timing of application and application methods should not increase the potential for run-off into ponds, rivers and streams.

## RECORD KEEPING AND IDENTIFICATION

53. The operator should maintain detailed and up-to-date records as set out in Annex 3, paras 7 - 15.

## SPECIES SPECIFIC REQUIREMENTS

### Beekeeping and bee products

#### General Principles

54. Bee keeping is an important activity that contributes to the enhancement of the environment, agriculture and forestry production through the pollination action of bees.

55. The treatment and management of hives should respect the principles of organic farming.

56. Collection areas must be large enough to provide adequate and sufficient nutrition and access to water.

57. The sources of natural nectar, honeydew and pollen shall consist essentially of organically produced plants and/or spontaneous (wild) vegetation.

58. The health of bees should be based on prevention such as adequate selection of breeds, favourable environment, balanced diet and appropriate husbandry practices.

59. The hives shall consist basically of natural materials presenting no risk of contamination to the environment or the bee products.

60. When bees are placed in wild areas, consideration should be given to the indigenous insect population.

#### Siting of hives

61. Hives for beekeeping shall be placed in areas where cultivated and/or spontaneous vegetation comply with the rules of production as set out in Section 4 of these Guidelines.

62. The official certification body or authority shall approve the areas which ensure appropriate sources of honeydew, nectar and pollen based on information provided by the operators and/or through the process of inspection.

63. The official certification body or authority may designate a specific radius from the hive within which the bees have access to adequate and sufficient nutrition that meets the requirements of these Guidelines.

64. The certification body or authority must identify zones where hives, that meet these requirements, should not be placed due to potential sources of contamination with prohibited substances, genetically modified organisms or environmental contaminants.

**Feed**

65. At the end of the production season hives must be left with reserves of honey and pollen sufficiently abundant for the colony to survive the dormancy period.

66. The feeding of colonies can be undertaken to overcome temporary feed shortages due to climatic or other exceptional circumstances. In such cases, organically produced honey or sugars should be used if available. However the certification body or authority may permit the use of non-organically produced honey or sugars. Time-limits should be set for such derogations. Feeding should be carried out only between the last honey harvest and the start of the next nectar or honeydew flow period.

**Conversion Period**

67. Bee products can be sold as organically produced when these Guidelines have been complied with for at least one year. During the conversion period the wax must be replaced by organically produced wax. In cases where all the wax cannot be replaced during a one-year period, the certification body or authority may extend the conversion period. By way of derogation when organically produced beeswax is not available, wax from sources not complying with these Guidelines may be authorized by the certification body or authority, provided it comes from the cap or from areas where no prohibited materials have been used.

68. Where no prohibited products have been previously used in the hive, replacement of wax is not necessary.

**Origin of bees**

69. Bee colonies can be converted to organic production. Introduced bees should come from organic production units when available.

70. In the choice of breeds, account must be taken of the capacity of bees to adapt to local conditions, their vitality and their resistance to disease.

**Health of the bees**

71. The health of bee colonies should be maintained by good agricultural practice, with emphasis on disease prevention through breed selection and hive management. This includes :

a) the use of hardy breeds that adapt well to the local conditions ;

b) renewal of queen bees if necessary ;

c) regular cleaning and disinfecting of equipment ;

d) regular renewal of beeswax ;

e) availability in hives of sufficient pollen and honey ;

f) systematic inspection of hives to detect any anomalies ;

g) systematic control of male broods in the hive ;

h) moving diseased hives to isolated areas, if necessary ; or

i ) destruction of contaminated hives and materials.

72. For pest and disease control the following are allowed :

- lactic, oxalic, acetic acid
- formic acid
- sulphur
- natural etheric oils (e.g. menthol, eucalyptol, camphor)
- *Bacillus thuringiensis*
- steam and direct flame.

73. Where preventative measures fail, veterinary medicinal products may be used provided that:

a) preference is given to phytotherapeutic and homeopathic treatment, and

b) if allopathic chemically synthesised medicinal products are used, the bee products must not be sold as organic. Treated hives must be placed in isolation and undergo a conversion period of one year. All the wax must be replaced with wax which is in accordance with these Guidelines, and

c) every veterinary treatment must be clearly documented.

74. The practice of destroying the male brood is permitted only to contain infestation with *Varroa jacobsoni*.

**Management**

75. The foundation comb shall be made from organically produced wax.

76. The destruction of bees in the combs as a method of harvesting of bee products is prohibited.

77. Mutilations, such as clipping of the wings of queen bees, are prohibited.

78. The use of chemical synthetic repellents is prohibited during honey extraction operations.

79. Smoking should be kept to a minimum. Acceptable smoking materials should be natural or from materials that meet the requirements of these Guidelines.

80. It is recommended that temperatures are maintained as low as possible during the extraction and processing of products derived from beekeeping.

**Record Keeping**

81. The operator should maintain detailed and up-to-date records as set out in Annex 3, paragraph 7. Maps should be maintained depicting the location of all hives.

## C. HANDLING, STORAGE, TRANSPORTATION, PROCESSING AND PACKAGING

82. The integrity of the organic product must be maintained throughout the processing phase. This is achieved by the use of techniques appropriate to the specifics of the ingredients with careful processing methods limiting refining and the use of additives and processing aids. Ionizing radiation should not be used on organic products for the purpose of pest control, food preservation, elimination of pathogens or sanitation. Ethylene may be used for ripening of kiwifruit and bananas.

**PEST MANAGEMENT**

83. For pest management and control the following measures, in order of preference, should be used:

a) Preventative methods, such as disruption and elimination of habitat and access to facilities by pest organisms, should be the primary methodology of pest management;

b) If preventative methods are inadequate, the first choice for pest control should be mechanical /physical and biological methods;

c) If mechanical/physical and biological methods are inadequate for pest control, pesticidal substances appearing in Annex 2 table 2 (or other substances allowed for use by a competent authority in accordance with Section 5.2) may be used provided that they are accepted for use in handling, storage, transportation or processing facilities by the competent authority and so that contact with organic products is prevented.

84. Pests should be avoided by good manufacturing practice. Pest control measures within storage areas or transport containers may include physical barriers or other treatments such as sound, ultra-sound, light, ultra-violet light, traps (pheromone traps and static bait traps) controlled temperature, controlled atmosphere (carbon dioxide, oxygen, nitrogen), and diatomaceous earth.

85. Use of pesticides not listed in Annex 2 for post harvest or quarantine purposes should not be permitted on products prepared in accordance with these guidelines and would cause organically produced foods to lose their organic status.

**PROCESSING AND MANUFACTURING**

86. Processing methods should be mechanical, physical or biological (such as fermentation and smoking) and minimize the use of non-agricultural ingredients and additives as listed in Annex 2, Tables 3 and 4.

**PACKAGING**

87. Packaging materials should preferably be chosen from bio-degradable, recycled or recyclable sources.

**STORAGE AND TRANSPORT**

88. Product integrity should be maintained during any storage and transportation and handling by use of the following precautions :

a) Organic products must be protected at all times from co-mingling with non-organic products; and

b) Organic products must be protected at all times from contact with materials and substances not permitted for use in organic farming and handling.

89. Where only part of the unit is certified, other product not covered by these guidelines should be stored and handled separately and both types of products should be clearly identified.

90. Bulk stores for organic product should be separate from conventional product stores and clearly labelled to that effect.

91. Storage areas and transport containers for organic product should be cleaned using methods and materials permitted in organic production. Measures should be taken to prevent possible contamination from any pesticide or other treatment not listed in Annex 2 before using a storage area or container that is not dedicated solely to organic products.

ANNEX 2

# PERMITTED SUBSTANCES FOR THE PRODUCTION OF ORGANIC FOODS

**Precautions**

1. Any substances used in an organic system for soil fertilization and conditioning, pest and disease control, for the health of livestock and quality of the animal products, or for preparation, preservation and storage of the food product should comply with the relevant national regulations.
2. Conditions for use of certain substances contained in the following lists may be specified by the certification body or authority, e.g. volume, frequency of application, specific purpose, etc.
3. Where substances are required for primary production they should be used with care and with the knowledge that even permitted substances may be subject to misuse and may alter the ecosystem of the soil or farm.
4. The following lists do not attempt to be all inclusive or exclusive, or a finite regulatory tool but rather provide advice to governments on internationally agreed inputs. A system of review criteria as detailed in Section 5 of these Guidelines for products to be considered by national governments should be the primary determinant for acceptability or rejection of substances.

TABLE 1 : SUBSTANCES FOR USE IN SOIL FERTILIZING AND CONDITIONING

| Substances | Description ; compositional requirements ; conditions of use |
|---|---|
| Farmyard and poultry manure | Need recognized by certification body or authority if not sourced from organic production systems. "Factory" farming[20] sources not permitted. |
| Slurry or urine | If not from organic sources, need recognized by inspection body. Preferably after controlled fermentation and/or appropriate dilution. "Factory" farming sources not permitted. |
| Composted animal excrements, including poultry | Need recognized by the certification body or authority |
| Manure and composted farmyard manure | "Factory" farming sources not permitted. |
| Dried farmyard manure and dehydrated poultry manure | Need recognized by the certification body or authority. "Factory" farming sources not permitted. |
| Guano | Need recognized by the certification body or authority. |
| Straw | Need recognized by the certification body or authority. |
| Compost and spent mushroom and Vermiculite substrate | Need recognized by the certification body or authority. The initial composition of the substrate must be limited to the products on this list |
| Sorted, composted or fermented home refuse | Need recognized by the certification body or authority. |
| Compost from plant residues | |
| Processed animal products from slaughterhouses & fish industries | Need recognized by the certification body or authority. |

20 "Factory" farming refers to industrial management systems that are heavily reliant on veterinary and feed inputs not permitted in organic agriculture.

| | |
|---|---|
| By-products of food & textile industries Not treated with synthetic additives. | Need recognized by the certification body or authority. |
| Seaweeds and seaweed products | Need recognized by the certification body or authority. |
| Sawdust, bark and wood waste | Need recognized by the certification body or authority, wood not chemically treated after felling. |
| Wood ash and wood charcoal | Need recognized by the certification body or authority, from wood not chemically treated after felling. |
| Natural phosphate rock. | Need recognized by the certification body or authority. Cadmium should not exceed 90mg/kg $P_2 0_5$ |
| Basic slag | Need recognized by the certification body or authority. |
| Rock potash, mined potassium salts (e.g. kainite, sylvinite) | Less than 60% chlorine |
| Sulphate of potash (e.g. patenkal i ) | Obtained by physical procedures but not enriched by chemical processes to increase its solubility. Need recognized by the certification body or authority. |
| Calcium carbonate of natural origin (e.g. chalk, marl, maerl, limestone, phosphate chalk) | |
| Magnesium rock | |
| Calcareous magnesium rock | |
| Epsom salt (magnesium-sulphate) | |
| Gypsum (calcium sulphate) | Only from natural sources/origin. |
| Stillage and stillage extract | Ammonium stillage excluded |
| Sodium chloride | Only mined salt |
| Aluminium calcium phosphate | Cadmium should not exceed 90mg/kg $P_2 0_5$ |
| Trace elements (e.g. boron, copper, iron, manganese, molybdenum, zinc) | Need recognized by the certification body or authority. |
| Sulphur | Need recognized by the certification body or authority. |
| Stone meal | |
| Clay (e.g. bentonite, perlite, zeolite) | |
| Naturally occurring biological organisms (e.g. worms) | |
| Vermiculite | |
| Peat | Excluding synthetic additives ; permitted for seed, potting module composts. Other use as recognized by certification body or authority. Not permitted as a soil conditioner. |
| Humus from earthworms and insects | |
| Chloride of lime | Need recognized by the certification body or authority. |
| Human excrements | Need recognized by the certification body or authority. The source is separated from household and industrial wastes that pose a risk of chemical contamination. It is treated sufficiently to eliminate risks from pests, parasites, pathogenic microorganisms, and is not applied to crops intended for human consumption or to the edible parts of plants. |

| | |
|---|---|
| By-products of the sugar industry (e.g. Vinasse) | Need recognized by the certification body or authority. |
| By-products from oil palm, coconut and cocoa (including empty fruit bunch, palm oil mill effluent (pome), cocoa peat and empty cocoa pods) | Need recognized by the certification body or authority. |
| By-products of industries processing ingredients from organic agriculture | Need recognized by the certification body or authority. |
| Calcium chloride solution | Leaf treatment in case of proven calcium deficiency. |

TABLE 2 : SUBSTANCES FOR PLANT PEST AND DISEASE CONTROL

| Substance | Description ; compositional requirements ; Conditions for use |
|---|---|
| ***I. Plant and Animal*** | |
| Preparations on basis of pyrethrins extracted from *Chrysanthemum cinerariaefolium,* containing possibly a synergist | Need recognized by the certification body or authority. Exclusion of Piperonyl butoxide after 2005 as a synergist. |
| Preparations of Rotenone from *Derris elliptica, Lonchocarpus, Thephrosia* spp. | Need recognized by the certification body or authority. |
| Preparations from *Quassia amara* | Need recognized by the certification body or authority. |
| Preparations from *Ryania speciosa* | Need recognized by the certification body or authority. |
| Commercial preparations/products of Neem (Azadirachtin) from *Azadirachta indica* | Need recognized by the certification body or authority. |
| Propolis | Need recognized by the certification body or authority. |
| Plant and animal oils | |
| Seaweed, seaweed meal, seaweed extracts, sea salts and salty water | Need recognised by the certification body or authority. Not chemically treated. |
| Gelatine | |
| Lecithin | Need recognized by the certification body or authority. |
| Casein | |
| Natural acids (e.g. vinegar) | Need recognized by the certification body or authority. |
| Fermented product from Aspergillus | |
| Extract from mushroom (Shiitake fungus) | Need recognized by certification body or authority |
| Extract from Chlorella | |
| Chitin nematicides | Natural origin |
| Natural plant preparations, excluding tobacco | Need recognized by certification body or authority. |
| Tobacco tea (except pure nicotine) | Need recognized by certification body or authority. |
| Sabadilla | |
| Beeswax | |
| ***II. Mineral*** | |
| Copper in the form of copper hydroxide, copper oxychloride, (tribasic) copper sulphate, cuprous oxide, Bordeaux mixture and Burgundy mixture | Need, prescription and application rates recognized by certification body or authority. As a fungicide on condition that the substance be used in such a way as to minimize copper accumulation in the soil. |
| Sulphur | Need recognized by certification body or authority. |
| Mineral powders (stone meal, silicates) | |
| Diatomaceous earth | Need recognized by certification body or authority. |
| Silicates, clay (bentonite) | |
| Sodium silicate | |
| Sodium bicarbonate | |

| | |
|---|---|
| Potassium permanganate | Need recognized by certification body or authority. |
| Iron phosphates | As molluscicide. |
| Paraffin oil | Need recognized by certification body or authority. |
| *III. Micro organisms used for biological pest controls* | |
| Micro-organisms (bacteria, viruses, fung i ) e.g. *Bacillus thuringiensis*, Granulosis virus,etc. | Need recognized by certification body or authority. |
| *IV. Other* | |
| Carbon dioxide and nitrogen gas | Need recognized by certification body or authority. |
| Potassium soap (soft soap) | |
| Ethyl alcohol | Need recognized by certification body or authority. |
| Homeopathic and Ayurvedic preparations | |
| Herbal and biodynamic preparations | |
| Sterilized insect males | Need recognized by certification body or authority. |
| Rodenticides | Products for pest control in livestock buildings and installations. Need recognized by certification body or authority. |
| *V. Traps* | |
| Pheromone preparations | |
| Preparations on the basis of metaldehyde containing a repellent to higher animal species and as far as applied in traps. | Need recognized by certification body or authority. |
| Mineral oils | Need recognized by the certification body or authority. |
| Mechanical control devices such as e.g., crop protection nets, spiral barriers, glue-coated plastic traps, sticky bands. | |

TABLE 3 : INGREDIENTS OF NON AGRICULTURAL ORIGIN REFERRED TO IN SECTION 3 OF THESE GUIDELINES

## 3.1 Additives Permitted for Use under Specified Conditions in Certain Organic Food Categories or Individual Food Items

The following table provides a list of those food additives including carriers which are allowed for use in organic food production. The functional uses and food categories and individual food items for each food additive in the following table are governed by the provisions in Tables 1-3 of the General Standard for Food Additives and other standards which have been adopted by the Codex Alimentarius Commission.

The table is an indicative list for the purpose of processing organic food only. Countries may develop a list of substances for national purposes that satisfy the requirements as recommended in Section 5.2 of these Guidelines.

Food additives in this Table can be used to perform the function indicated in the specified food products.

| INS No. | Additive Name | Functional Use Allowed in Organic Production | Permitted for Use In Food Categories | |
|---|---|---|---|---|
| | | | Food of Plant Origin | Food of Animal Origin |
| 170i | Calcium Carbonate | All | Permitted, although exclusions of the GSFA still apply. | 01.0 Dairy products and analogues, excluding products of food category 02.0 |
| 220 | Sulphur Dioxide | All | 14.2.2 Cider and perry<br>14.2.3 Grape wines<br>14.2.4 Wines (other than grapes) | 14.2.5 Mead |
| 270 | Lactic Acid (L- Dand DL-) | All | 04.2.2.7 Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes and aloe vera), and seaweed products, excluding fermented soybean products of food category 12.10 | 01.0 Dairy products and analogues, excluding products of food category 02.0<br>08.4 Edible casings (e.g. sausage casings) |
| 290 | Carbon Dioxide | All | Permitted, although exclusions of the GSFA still apply. | Permitted, although exclusions of the GSFA still apply. |
| 296 | Malic Acid (DL-) | All | Permitted, although exclusions of the GSFA still apply. | Not permitted. |
| 300 | Ascorbic Acid | All | Provided insufficient natural sources are available.<br>Permitted, although exclusions of the GSFA still apply. | Provided insufficient natural sources are available.<br>08.2 Processed meat, poultry, and game products in whole pieces or cuts<br>08.3 Processed comminuted meat, poultry, and game products<br>08.4 Edible casings (e.g., sausage casings) |
| 307 | Tocopherols (mixed natural concentrates) | All | Permitted, although exclusions of the GSFA still apply. | All mixed products allowed under the General Standard for Food Additives and Standards adopted by the Codex Alimentarius Commission |

| INS No. | Additive Name | Functional Use Allowed in Organic Production | Permitted for Use In Food Categories | |
|---|---|---|---|---|
| | | | Food of Plant Origin | Food of Animal Origin |
| 322 | Lecithins (Obtained without bleaches and organic solvents.) | All | Permitted, although exclusions of the GSFA still apply. | 01.0 Dairy products and analogues, excluding products of food category 02.0<br>02.0 Fats and oils, and fat emulsions<br>12.6.1 Emulsified sauces (e.g. mayonnaise, salad dressing)<br>13.1 Infant formulae and follow-on formulae<br>13.2 Complementary foods for infants and young children |
| 327 | Calcium Lactate | All | Not permitted. | 01.0 Dairy products and analogues, excluding products of food category 02.0 |
| 330 | Citric Acid | All | 04.0 Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds | As a coagulation agent for specific cheese products and for cooked eggs<br>01.6 Cheese and analogues<br>02.1 Fats and oils essentially free from water<br>10.0 Egg and egg products |
| 331i | Sodium Dihydrogen Citrate | All | Not permitted. | 01.1.1.2 Butter milk (plain) (Stabilizer only)<br>01.1.2 Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)<br>01.2.1.2 Fermented milks (plain), heat-treated after fermentation (Stabilizer only)<br>01.2.2 Renneted milk (Stabilizer only)<br>01.3 Condensed milk and analogues (plain) (Stabilizer only)<br>01.4 Cream (plain) and the like (Stabilizer only)<br>01.5.1 Milk powder and cream powder (plain) (Stabilizer only)<br>01.6.1 Unripened cheese (Stabilizer only)<br>01.6.4 Processed cheese (Emulsifier only)<br>01.8.2 Dried whey and whey products, excluding whey cheeses<br>08.3 Processed comminuted meat, poultry, and game products, restricted to sausages<br>To be used in pasteurization of egg whites only in the following :<br>10.2 Egg Products |

| INS No. | Additive Name | Functional Use Allowed in Organic Production | Permitted for Use In Food Categories | |
|---|---|---|---|---|
| | | | Food of Plant Origin | Food of Animal Origin |
| 332i | Potassium Dihydrogen Citrate | All | Not permitted. | Permitted, although exclusions of the GSFA still apply. |
| 333 | Calcium Citrates | All | Permitted, although exclusions of the GSFA still apply. | 01.0 Dairy products and analogues, excluding products of food category 02.0 |
| 334 | Tartaric Acid | All | Permitted, although exclusions of the GSFA still apply. | Not permitted. |
| 335i<br>335ii | Monosodium Tartrate<br>Disodium Tartrate | All | 05.0 Confectionery<br>07.2.1 Cakes | Not permitted. |
| 336i<br>336ii | Monopotassium Tartrate<br>Dipotassium Tartrate | All | 05.0 Confectionery<br>06.2 Flours and starches<br>07.2.1 Cakes | Not permitted. |
| 341i | Monocalcium Orthophosphate | All | 06.2.1 Flours | Not permitted. |
| 400 | Alginic Acid | All | Permitted, although exclusions of the GSFA still apply. | 01.0 Dairy products and analogues, excluding products of food category 02.0 |
| 401 | Sodium Alginate | All | Permitted, although exclusions of the GSFA still apply. | 01.0 Dairy products and analogues, excluding products of food category 02.0<br>All mixed products allowed under the General Standard for Food Additives and Standards adopted by the Codex Alimentarius Commission |
| 402 | Potassium Alginate | All | Permitted, although exclusions of the GSFA still apply. | 01.0 Dairy products and analogues, excluding products of food category 02.0<br>All mixed products allowed under the General Standard for Food Additives and Standards adopted by the Codex Alimentarius Commission |
| 406 | Agar | All | Permitted, although exclusions of the GSFA still apply. | Permitted, although exclusions of the GSFA still apply. |
| 407 | Carrageenan | All | Permitted, although exclusions of the GSFA still apply. | 01.0 Dairy products and analogues, excluding products of food category 02.0 |
| 410 | Carob Bean Gum | All | Permitted, although exclusions of the GSFA still apply. | 01.1 Milk and dairy-based drinks<br>01.2 Fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy-based drinks)<br>01.3 Condensed milk and analogues (plain)<br>01.4 Cream (plain) and the like |

| INS No. | Additive Name | Functional Use Allowed in Organic Production | Permitted for Use In Food Categories | |
|---|---|---|---|---|
| | | | Food of Plant Origin | Food of Animal Origin |
| | | | | 01.5 Milk powder and cream powder and powder analogues (plain)<br>01.6 Cheese and analogues<br>01.7 Dairy-based desserts (e.g. pudding, fruit or flavoured yoghurt)<br>01.8.1 Liquid whey and whey products, excluding whey cheeses<br>08.1.2 Fresh meat, poultry and game, comminuted<br>08.2 Processed meat, poultry, game products in whole pieces or cuts<br>08.3 Processed comminuted meat, poultry, and game products<br>08.4 Edible casings (e.g. sausage casings) |
| 412 | Guar Gum | All | Permitted, although exclusions of the GSFA still apply. | 01.0 Dairy products and analogues, excluding products of food category 02.0<br>8.2.2 Heat-treated processed meat, poultry, and game products in whole pieces or cuts<br>8.3.2 Heat-treated processed comminuted meat, poultry, and game products<br>10.2 Egg products |
| 413 | Tragacanth Gum | All | Permitted, although exclusions of the GSFA still apply. | Permitted, although exclusions of the GSFA still apply. |
| 414 | Gum Arabic | All | 02.0 Fats and oils, and fat emulsions<br>05.0 Confectionery | 01.0 Dairy products and analogues, excluding products of food category 02.0<br>02.0 Fats and oils, and fat emulsions<br>05.0 Confectionery |
| 415 | Xanthan Gum | All | 02.0 Fats and oils, and fat emulsions<br>04.0 Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds<br>07.0 Bakery wares<br>12.7 Salads (e.g. macaroni salad, potato salad) | Not permitted. |
| 416 | Karaya Gum | All | Permitted, although exclusions of the GSFA still apply. | Not permitted. |

| INS No. | Additive Name | Functional Use Allowed in Organic Production | Permitted for Use In Food Categories | |
|---|---|---|---|---|
| | | | Food of Plant Origin | Food of Animal Origin |
| 422 | Glycerol | All | Obtained from plant origin; used as a carrier for plant extracts<br>04.1.1.1 Untreated fresh fruit<br>04.1.1.2 Surface-treated fresh fruit<br>04.1.2 Processed fruit<br>04.2.1.2 Surface-treated fresh vegetables, (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds and nuts and seeds<br>04.2.2.2 Dried vegetables, (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds<br>04.2.2.3 Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soy sauce<br>04.2.2.4 Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds<br>04.2.2.5 Vegetable, (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)<br>04.2.2.6 Vegetable, (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5<br>04.2.2.7 Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweed products, excluding fermented soybean products of food category 12.10<br>12.2 Herbs, spices, seasonings, and condiments (e.g., seasoning for instant noodles) | Not permitted. |

| INS No. | Additive Name | Functional Use Allowed in Organic Production | Permitted for Use In Food Categories | |
|---|---|---|---|---|
| | | | Food of Plant Origin | Food of Animal Origin |
| 440 | Pectins (non-amidated) | All | Permitted, although exclusions of the GSFA still apply. | 01.0 Dairy products and analogues, excluding products of food category 02.0 |
| 500ii<br>500iii | Sodium hydrogen carbonate<br>Sodium Sesquicarbonate | All | 05.0 Confectionery<br>07.0 Bakery Wares | 01.0 Dairy products and analogues, excluding products of food category 02.0 |
| 501i | Potassium Carbonate | All | 05.0 Confectionery<br>06.0 Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses and legumes, excluding bakery wares of food category 07.0<br>07.2 Fine Bakery wares (sweet, salty, savoury) and mixes | Not permitted. |
| 503i<br>503ii | Ammonium carbonate<br>Ammonium Hydrogen Carbonate | Acidity Regulator Raising Agent | Permitted, although exclusions of the GSFA still apply. | Not permitted. |
| 504i<br>504ii | Magnesium Carbonate<br>Magnesium Hydrogen Carbonate | All | Permitted, although exclusions of the GSFA still apply. | Not permitted. |
| 508 | Potassium Chloride | All | 04.0 Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds<br>12.4 Mustards<br>12.6.2 Non-emulsified sauces (e.g. ketchup, cheese sauces, cream sauces, brown gravy) | Not permitted. |
| 509 | Calcium chloride | All | 04.0 Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds<br>06.8 Soybean products (excluding soybean products of food category 12.9 and fermented soybean products of food category 12.10)<br>12.9.1 Soybean protein products<br>12.10 Fermented soybean products | 01.0 Dairy products and analogues, excluding products of food category 02.0<br>08.2 Processed meat, poultry, and game products in whole pieces or cuts<br>08.3 Processed comminuted meat, poultry and game products<br>08.4 Edible casings (e.g. sausage casings) |
| 511 | Magnesium chloride | All | 06.8 Soybean products (excluding soybean products of food category 12.9 and fermented soybean products of food category 12.10)<br>12.9.1 Soybean protein products<br>12.10 Fermented soybean products | Not permitted. |

| INS No. | Additive Name | Functional Use Allowed in Organic Production | Permitted for Use In Food Categories | |
|---|---|---|---|---|
| | | | Food of Plant Origin | Food of Animal Origin |
| 516 | Calcium sulphate | All | 06.8 Soybean products (excluding soybean products of food category 12.9 and fermented soybean products of food category 12.10)<br>07.2.1 Cakes, cookies and pies (e.g. fruit-filled or custard type)<br>12.8 Yeast and like products<br>12.9.1 Soybean protein products<br>12.10 Fermented soybean products | Not permitted. |
| 524 | Sodium Hydroxide | All | 06.0 Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses and legumes, excluding bakery wares of food category 07.0<br>07.1.1.1 yeast-leavened breads and specialty breads | Not permitted. |
| 551 | Silicon Dioxide (Amorphous) | All | 12.2 Herbs, spices, seasonings, and condiments (e.g. seasonings for instant noodles) | Not permitted. |
| 941 | Nitrogen | All | Permitted, although exclusions of the GSFA still apply | Permitted, although exclusions of the GSFA still apply |

### 3.2 Flavourings

Substances and products labelled as natural flavouring substances or natural flavouring preparations are defined in the General Requirements for Natural Flavourings (CAC/GL 29-1987).

### 3.3 Water and Salts

Drinking water.

Salts (with sodium chloride or potassium chloride as basic components generally used in food processing).

### 3.4 Preparations of Microorganisms and Enzymes

Any preparation of microorganisms and enzymes normally used in food processing, with the exception of microorganisms genetically engineered/modified or enzymes derived from genetic engineering.

### 3.5 Minerals (including trace elements), Vitamins, Essential Fatty and Amino Acids, And Other Nitrogen Compounds

Only approved in so far as their use is legally required in the food products in which they are incorporated

TABLE 4 : PROCESSING AIDS WHICH MAY BE USED FOR THE PREPARATION OF PRODUCTS OF AGRICULTURAL ORIGIN REFERRED TO IN SECTION 3 OF THESE GUIDELINES

| Substance | Specific conditions |
|---|---|
| For plant products | |
| Water | |
| Calcium chloride | coagulation agent |
| Calcium carbonate | |
| Calcium hydroxide | |
| Calcium sulphate | coagulation agent |
| Magnesium chloride (or nigar i ) | coagulation agent |
| Potassium carbonate | drying of grape raisins |
| Carbon dioxide | |
| Nitrogen | |
| Ethanol | solvent |
| Tannic acid | filtration aid |
| Egg white albumin | |
| Casein | |
| Gelatine | |
| Isinglass | |
| Vegetable oils | greasing or releasing agent |
| Silicon dioxide | as gel or collodial solution |
| Activated carbon | |
| Talc | |
| Bentonite | |
| Kaolin | |
| Diatomaceous earth | |
| Perlite | |
| Hazelnut shells | |
| Beeswax | releasing agent |
| Carnauba wax | releasing agent |
| Sulphuric acid | pH adjustment of extraction water in sugar production |
| Sodium hydroxide | pH adjustment in sugar production |
| Tartaric acid and salts | |
| Sodium carbonate | sugar production |
| Preparations of bark components | |
| Potassium hydroxide | pH adjustment for sugar processing |
| Citric Acid | pH adjustment |

**Preparations of microorganisms and enzymes**

Any preparations of microorganisms and enzymes normally used as processing aids in food processing, with the exception of genetically engineered/modified organisms and enzymes derived from genetically engineered/modified organisms.

**For livestock and bee products**

The following is a provisional list for the purposes of processing livestock and bee products only. Countries may develop a list of substances for national purposes that satisfy the requirements of these Guidelines as recommended in Section 5.2.

| INS | Name | Specific conditions |
|---|---|---|
| | Calcium arbonates | |
| | Calcium Chloride | Firming, coagulation agent in cheese making. |
| | Kaolin | Extraction of propolis. |
| | Lactic acid | Milk products: coagulation agent, pH regulation of salt bath for cheese. |
| | Sodium carbonate | Milk products: neutralizing substance. |
| | Water | |

ANNEX 3

# MINIMUM INSPECTION REQUIREMENTS AND PRECAUTIONARY MEASURES UNDER THE INSPECTION OR CERTIFICATION SYSTEM

1. Inspection measures are necessary across the whole of the food chain to verify product labelled according to Section 3 of these guidelines conforms to internationally agreed practices. The official or officially recognized certification body or authority and the competent authority should establish policies and procedures in accordance with these guidelines.

2. Access by the inspection body to all written and/or documentary records and to the establishment under the inspection scheme is essential. The operator under an inspection should also give access to the competent or designated authority and provide any necessary information for third party audit purposes.

## A. PRODUCTION UNITS

3. Production according to these guidelines should take place in a unit where the land parcels, production areas, farm buildings and storage facilities for crop and livestock are clearly separate from those of any other unit which does not produce according to these guidelines ; preparation and/or packaging workshops may form part of the unit, where its activity is limited to preparation and packaging of its own agricultural produce.

4. When the inspection arrangements are first implemented, the operator and the official or officially recognized certification body or authority should draw up and sign a document which includes :

   a) a full description of the unit and/or collection areas, showing the storage and production premises and land parcels and, where applicable, premises where certain preparation and/or packaging operations take place ;

   b) and, in the case of collection of wild plants, the guarantees given by third parties, if appropriate, which the producer can provide to ensure that the provisions of Annex 1, para 10 are satisfied ;

   c) all the practical measures to be taken at the level of the unit to ensure compliance with these guidelines ;

   d) the date of the last application on the land parcels and/or collection areas concerned of products the use of which is not compatible with Section 4 of these guidelines ;

   e) an undertaking by the operator to carry out operations in accordance with Sections 3 and 4 and to accept, in event of infringements, implementation of the measures as referred to in Section 6, paragraph 9 of these guidelines.

5. Each year, before the date indicated by the certification body or authority, the operator should notify the official or officially recognized certification body or authority of its schedule of production of crop products and livestock, giving a breakdown by land parcel/herd, flock or hive.

6. Written and/or documentary accounts should be kept which enable the official or officially recognized certification body or authority to trace the origin, nature and quantities of all raw materials bought, and the use of such materials ; in addition, written and/or documentary accounts should be kept of the nature, quantities and consignees of all agricultural products sold. Quantities sold directly to the final consumer should preferably be accounted for on a daily basis. When the unit itself processes agricultural products, its accounts must contain the information required in B2, third dash point of this Annex.

7. All livestock should be identified individually or, in the case of small mammals or poultry, by herd or flock or in the case of bees by hive. Written and/or documentary accounts should be kept to enable tracking of livestock and bee colonies within the system at all times and to provide adequate traceback for audit purpose. The operator should maintain detailed and up-to-date records of :

   a) breeding and/or origins of livestock ;

   b) registration of any purchases ;

   c) the health plan to be used in the prevention and management of disease, injury and reproductive problems ;

   d) all treatments and medicines administered for any purpose, including quarantine periods and identification of treated animals or hives ;

   e) feed provided and the source of the feedstuffs ;

   f) stock movements within the unit and hive movements within designated forage areas as identified on maps ;

   g) transportation, slaughter and/or sales.

   h) extraction, processing and storing of all bee products.

8. Storage, on the unit, of input substances, other than those whose use is with paragraph 4.1(b) of these guidelines is prohibited.

9. The official or officially recognized certification body or authority should ensure that a full physical inspection is undertaken, at least once a year, of the unit. Samples for testing of products not listed in these guidelines may be taken where their use is suspected. An inspection report should be drawn up after each visit. Additional occasional unannounced visits should also be undertaken according to need or at random.

10. The operator should give the certification body or authority, for inspection purposes, access to the storage and production premises and to the parcels of land, as well as to the accounts and relevant supporting documents. The operator should also provide the inspection body with any information deemed necessary for the purposes of the inspection.

11. Products referred to in Section 1 of these guidelines which are not in their packaging for the end consumer should be transported in a manner which should prevent contamination or substitution of the content with substances or product not compatible with these guidelines and the following information, without prejudice to any other indications required by law :

   − the name and address of the person responsible for the production or preparation of the product ;

   − the name of the product ; and

   − that the product is of organic status.

12. Where an operator runs several production units in the same area (parallel cropping), units in the area producing crop, crop products not covered by Section 1 should also be subject to the inspection arrangements as regards the dash points of paragraph 4 and paragraphs 6 and 8 above. Plants of indistinguishable varieties as those produced at the unit referred to in paragraph 3 above should not be produced at these units :

   − If derogations are allowed by the competent authority, the authority must specify the types of production and circumstances for which derogations are granted and the supplementary inspection requirements, such as unannounced site visits; extra inspections during harvest; additional documentary requirements; assessment of an operation's ability to prevent co-mingling, etc., which are to be implemented.

   − Pending further review of these guidelines in accordance with Section 8, member countries can accept parallel cropping of the same variety, even if it is not distinguishable, subject to

adequate inspection measures being applied.

13. In organic livestock production, all livestock on one and the same production unit must be reared in accordance with the rules laid down in these Guidelines. However, livestock not reared in accordance with these Guidelines may be present on the organic holding provided that they are separated clearly from livestock produced in accordance with these Guidelines. The competent authority can prescribe more restrictive measures, such as different species.

14. The competent authority may accept that animals reared in accordance with the provisions of these Guidelines may be grazed on common land, provided that :

a) this land has not been treated with products other than those allowed in accordance with Section 4.1 (a) and (b) of these Guidelines, for at least three years ;

b) a clear segregation between the animals reared in accordance with the provisions of these Guidelines, and the other animals can be organized.

15. For livestock production, the competent authority should ensure, without prejudice to the other provisions in this Annex, that the inspections related to all stages of production and preparation up to the sale to the consumer ensure, as far as technically possible, the traceability of livestock and livestock products from the livestock production unit through processing and any other preparation until final packaging and/or labelling.

## B. PREPARATION AND PACKAGING UNITS

1. The producer and/or operator and should provide :

- a full description of the unit, showing the facilities used for the, preparation, packaging and storage of agricultural products before and after the operations concerning them ;
- all the practical measures to be taken at the level of the unit to ensure compliance these guidelines.

This description and the measures concerned should be signed by the responsible person of the unit and the certification body.

The report should include an undertaking by the operator to perform the operations in such a way as to comply with Section 4 of these guidelines and to accept, in the event of infringements, the implementation of measures as referred to in paragraph 6.9 of these guidelines and be countersigned by both parties.

2. Written accounts should be kept enabling the certification body or authority to trace:

- the origin, nature and quantities of agricultural products as referred to in Section 1 of these guidelines which have been delivered to the unit ;
- the nature, quantities and consignees of products as referred to in Section 1 of these guidelines which have left the unit ;
- any other information such as the origin, nature and quantities of ingredients, additives and manufacturing aids delivered to the unit and the composition of processed products, that is required by the certification body or authority for the purposes of proper inspection of the operations.

3. Where products not referred to in Section 1 of these guidelines are also processed, packaged or stored in the unit concerned :

- the unit should have separate areas within the premises for the storage of products as referred to in Section 1 of these guidelines, before and after the operations ;
- operations should be carried out continuously until the complete run has been dealt with, separated by place or time from similar operations performed on products not covered by Section 1 of these guidelines ;

- if such operations are not carried out frequently, they should be announced in advance, with a deadline agreed on with the certification body or authority ;
- every measure should be taken to ensure identification of lots and to avoid mixtures with products not obtained in accordance with the requirements of these guidelines.

4. The official or officially recognized certification body or authority should ensure that a full physical inspection, at least once a year, of the unit. Samples for testing of products not listed in these guidelines may be taken where their use is suspected. An inspection report must be drawn up after each visit countersigned by the person responsible for the unit inspected. Additional occasional unannounced visits should also be undertaken according to need or at random.

5. The operator should give the official or officially recognized certification body or authority or authority, for inspection purposes, access to the unit and to written accounts and relevant supporting documents. The operator should also provide the inspection body with any information necessary for the purposes of inspection.

6. The requirements in respect to the transport as laid down in paragraph A.10 of this Annex are applicable.

7. On receipt of a product referred to in Section 1 of these Guidelines, the operator shall check :

- the closing of the packaging or contained where it is required ;
- the presence of the indications referred to in A.10 of this Annex. The result of this verification shall be explicitly mentioned in the accounts referred to in point B.2. When there is any doubt that the product cannot be verified according to the production system provided for in Section 6 of this Guidelines, it must be placed on the market without indication referring to the organic production method.

## C. IMPORTS

Importing countries should establish appropriate inspection requirements for the inspection of importers and of imported organic products.

# GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS
# CAC / GL 23 - 1997

Nutrition claims should be consistent with national nutrition policy and support that policy. Only nutrition claims that support national nutrition policy should be allowed.

Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable. Health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim, provide truthful and non-misleading information to aid consumers in choosing healthful diets and be supported by specific consumer education. The impact of health claims on consumers' eating behaviours and dietary patterns should be monitored, in general, by competent authorities. Claims of the type described in section 3.4 of the Codex General Guidelines on Claims are prohibited.

## 1. SCOPE

1.1 These guidelines relate to the use of nutrition and health claims in food labelling and, where required by the authorities having jurisdiction, in advertising[1].

1.2 These guidelines apply to all foods for which nutrition and health claims are made without prejudice to specific provisions under Codex standards or Guidelines relating to Foods for Special Dietary Uses and Foods for Special Medical Purposes.

1.3 These guidelines are intended to supplement the *Codex General Guidelines on Claims* and do not supersede any prohibitions contained therein.

1.4 Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.

## 2. DEFINITIONS

2.1 ***Nutrition claim*** means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. The following do not constitute nutrition claims :

(a) the mention of substances in the list of ingredients ;

(b) the mention of nutrients as a mandatory part of nutrition labelling ;

(c) quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by national legislation.

2.1.1 ***Nutrient content claim*** is a nutrition claim that describes the level of a nutrient contained in a food. (Examples : "source of calcium" "high in fibre and low in fat".)

2.1.2 ***Nutrient comparative claim*** is a claim that compares the nutrient levels and/or energy value of two or more foods. (Examples : "reduced" "less than" "fewer" "increased" "more than".)

2.2 ***Health claim*** means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims include the following :

2.2.1 ***Nutrient function claims*** – a nutrition claim that describes the physiological role of the nutrient in

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1 Advertising means any commercial communication to the public, by any means other than labelling, in order to promote directly or indirectly, the sale or intake of a food through the use of nutrition and health claims in relation to the food and its ingredients.

growth, development and normal functions of the body.

**Example :**

"Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development). Food X is a source of/ high in nutrient A."

2.2.2 *Other function claims* – These claims concern specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.

**Examples :**

"Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains x grams of substance A."

2.2.3 *Reduction of disease risk claims* – Claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.

Risk reduction means significantly altering a major risk factor(s) for a disease or health-related condition. Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims.

**Examples :**

"A healthful diet low in nutrient or substance A may reduce the risk of disease D.
Food X is low in nutrient or substance A."

"A healthful diet rich in nutrient or substance A may reduce the risk of disease D.
Food X is high in nutrient or substance A."

## 3. NUTRITION LABELLING

Any food for which a nutrition or health claim is made should be labelled with a nutrient declaration in accordance with Section 3 of the Codex *Guidelines on Nutrition Labelling.*

## 4. NUTRITION CLAIMS

4.1 The only nutrition claims permitted shall be those relating to energy, protein, carbohydrate, and fat and components thereof, fibre, sodium and vitamins and minerals for which Nutrient Reference Values (NRVs) have been laid down in the Codex *Guidelines for Nutrition Labelling.*

## 5. NUTRIENT CONTENT CLAIMS

5.1 When a nutrient content claim that is listed in the Table to these Guidelines or a synonymous claim is made, the conditions specified in the Table for that claim should apply.

5.2 Where a food is by its nature low in or free of the nutrient that is the subject of the claim, the term describing the level of the nutrient should not immediately precede the name of the food but should be in the form "a low (naming the nutrient) food" or "a (naming the nutrient)-free food".

## 6. COMPARATIVE CLAIMS

Comparative claims should be permitted subject to the following conditions and based on the food as sold, taking into account further preparation required for consumption according to the instructions for use on the label :

6.1 The foods being compared should be different versions of the same food or similar foods. The foods being compared should be clearly identified.

6.2 A statement of the amount of difference in the energy value or nutrient content should be given. The following information should appear in close proximity to the comparative claim:

6.2.1 The amount of difference related to the same quantity, expressed as a percentage, fraction, or an absolute amount. Full details of the comparison should be given.

6.2.2 The identity of the food(s) to which the food is being compared. The food(s) should be described in such a manner that it (they) can be readily identified by consumers.

6.3 The comparison should be based on a relative difference of at least 25% in the energy value or nutrient content, except for micronutrients where a 10% difference in the NRV would be acceptable, between the compared foods and a minimum absolute difference in the energy value or nutrient content equivalent to the figure defined as "low" or as a "source" in the Table to these Guidelines.

6.4 The use of the word "light" should follow the same criteria as for "reduced" and include an indication of the characteristics which make the food "light".

## 7. HEALTH CLAIMS

7.1 Health claims should be permitted provided that all of the following conditions are met:

7.1.1 Health claims must be based on current relevant scientific substantiation and the level of proof must be sufficient to substantiate the type of claimed effect and the relationship to health as recognized by generally accepted scientific review of the data and the scientific substantiation should be reviewed as new knowledge becomes available.[2] The health claim must consist of two parts:

1) Information on the physiological role of the nutrient or on an accepted diet-health relationship; followed by

2) Information on the composition of the product relevant to the physiological role of the nutrient or the accepted diet-health relationship unless the relationship is based on a whole food or foods whereby the research does not link to specific constituents of the food.

7.1.2 Any health claim must be accepted by or be acceptable to the competent authorities of the country where the product is sold.

7.1.3 The claimed benefit should arise from the consumption of a reasonable quantity of the food or food constituent in the context of a healthy diet.

7.1.4 If the claimed benefit is attributed to a constituent in the food, for which a Nutrient Reference value is established, the food in question should be:

(i) a source of or high in the constituent in the case where increased consumption is recommended; or,

(ii) low in, reduced in, or free of the constituent in the case where reduced consumption is recommended.

Where applicable, the conditions for nutrient content claims and comparative claims will be used to determine the levels for "high", "low", "reduced", and "free".

7.1.5 Only those essential nutrients for which a Nutrient Reference Value (NRV) has been established in the Codex *Guidelines on Nutrition Labelling* or those nutrients which are mentioned in officially recognized dietary guidelines of the national authority having jurisdiction, should be the subject of a

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2 Reference to the Scientific Criteria for Health Related Claims being developed by the Codex Committee on Nutrition and Foods for Special Dietary Uses should be inserted here.

nutrient function claim.

7.2 Health claims should have a clear regulatory framework for qualifying and/or disqualifying conditions for eligibility to use the specific claim, including the ability of competent national authorities to prohibit claims made for foods that contain nutrients or constituents in amounts that increase the risk of disease or an adverse health-related condition. The health claim should not be made if it encourages or condones excessive consumption of any food or disparages good dietary practice.

7.3 If the claimed effect is attributed to a constituent of the food, there must be a validated method to quantify the food constituent that forms the basis of the claim.

7.4 The following information should appear on the label or labelling of the food bearing health claims:

7.4.1 A statement of the quantity of any nutrient or other constituent of the food that is the subject of the claim.

7.4.2 The target group, if appropriate.

7.4.3 How to use the food to obtain the claimed benefit and other lifestyle factors or other dietary sources, where appropriate.

7.4.4 If appropriate, advice to vulnerable groups on how to use the food and to groups, if any, who need to avoid the food.

7.4.5 Maximum safe intake of the food or constituent where necessary.

7.4.6 How the food or food constituent fits within the context of the total diet.

7.4.7 A statement on the importance of maintaining a healthy diet.

## 8. CLAIMS RELATED TO DIETARY GUIDELINES OR HEALTHY DIETS

Claims that relate to dietary guidelines or "healthy diets" should be permitted subject to the following conditions:

8.1 Only claims related to the pattern of eating contained in dietary guidelines officially recognized by the appropriate national authority.

8.2 Flexibility in the wording of claims is acceptable, provided the claims remain faithful to the pattern of eating outlined in the dietary guidelines.

8.3 Claims related to a "healthy diet" or any synonymous term are considered to be claims about the pattern of eating contained in dietary guidelines and should be consistent with the guidelines.

8.4 Foods which are described as part of a healthy diet, healthy balance, etc., should not be based on selective consideration of one or more aspects of the food. They should satisfy certain minimum criteria for other major nutrients related to dietary guidelines.

8.5 Foods should not be described as "healthy" or be represented in a manner that implies that a food in and of itself will impart health.

8.6 Foods may be described as part of a "healthy diet" provided that the label carries a statement relating the food to the pattern of eating described in the dietary guidelines.

Table of conditions for nutrient contents

| COMPONENT | CLAIM | CONDITIONS (not more than) |
|---|---|---|
| Energy | Low | 40 kcal (170 kJ) per 100 g (solids) or 20 kcal (80 kJ) per 100 ml (liquids) |
| | Free | 4 kcal per 100 ml (liquids) |
| Fat | Low | 3 g per 100 g (solids)<br>1.5 g per 100 ml (liquids) |
| | Free | 0.5 g per 100 g (solids) or 100 ml (liquids) |
| Saturated Fat | Low[3] | 1.5 g per 100 g (solids)<br>0.75 g per 100 ml (liquids)<br>and 10% of energy |
| | Free | 0.1 g per 100 g (solids)<br>0.1 g per 100 ml (liquids) |
| Cholesterol | Low | 0.02 g per 100 g (solids)<br>0.01 g per 100 ml (liquids) |
| | Free | 0.005 g per 100 g (solids)<br>0.005 g per 100 ml (solids)<br><br>and, for both claims, less than:1.5 g saturated fat per 100 g (solids)<br>0.75 g saturated fat per 100 ml (liquids)<br>and 10% of energy of saturated fat |
| Sugars | Free | 0.5 g per 100 g (solids)<br>0.5 g per 100 ml (liquids) |
| Sodium | Low | 0.12 g per 100 g |
| | Very Low | 0.04 g per 100 g |
| | Free | 0.005 g per 100g |
| Protein | Source | 10% of NRV per 100 g (solids)<br>5% of NRV per 100 ml (liquids)<br>or 5% of NRV per 100 kcal (12% of NRV per 1 MJ)<br>or 10% of NRV per serving |
| | High | 2 times the values for "source" |
| Vitamins and Minerals | Source | 15% of NRV per 100 g (solids)<br>7.5% of NRV per100 ml (liquids)<br>or 5% of NRV per 100 kcal (12% of NRV per 1 MJ)<br>or 15% of NRV per serving |
| | High | 2 times the value for "source" |

# ADVISORY LISTS OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN
# CAC / GL 10 - 1979

## 1. PREAMBLE

These lists include nutrient compounds, which may be used for nutritional purposes in foods for special dietary uses intended for infants and young children in accordance with 1) the criteria and conditions of use identified below and 2) other criteria for their use stipulated in the respective standards. In addition, the sources from which the nutrient compound is produced may exclude the use of specific substances where religious or other specific dietary restrictions apply. As noted in the respective standards, their use may either be essential or optional.

## 2. CRITERIA FOR THE INCLUSION AND DELETION OF NUTRIENT COMPOUNDS FROM THE ADVISORY LISTS

2.1 Nutrient compounds that are to be added for nutritional purposes to foods for infants and young children may be included in the Lists only if:

(a) they are shown to be safe and appropriate for the intended use as nutrient sources for infants and young children

(b) it is demonstrated by appropriate studies in animals and/or humans that the nutrients are biologically available

(c) the purity requirements of the nutrient compounds conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission, or in the absence of such specifications, with another internationally recognised specification. If there is no internationally recognised specification, national purity requirements that have been evaluated according to or similar to a FAO/WHO process may be considered

(d) the stability of nutrient compound(s) in the food(s) in which it is (they are) to be used can be demonstrated

(e) the fulfilment of the above criteria shall be demonstrated by generally accepted scientific criteria.

2.2 Nutrient compounds may be added to the Lists based on the criteria above. Nutrient compounds shall be deleted from the Lists if they are found no longer to meet the above criteria. If a country proposes to add or delete a nutrient compound to/from a list, the country should provide information that addresses how the nutrient compound satisfies/does not satisfy the criteria in Section 2.1.

## 3. Optional ingredients

The Optional Ingredients sections in Codex standards for foods for infants and young children do not identify all optional ingredients that may be considered for use in foods for special dietary uses intended for infants and young children. Optional ingredients added for nutritional purposes to foods for special dietary uses intended for infants and young children should meet the criteria specified in Section 2.1. They should also meet the provisions for optional ingredients in the respective Codex standard for foods for infants and young children.

A : ADVISORY LIST OF MINERAL SALTS AND TRACE ELEMENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

| Nutrient Source | Purity Requirements by | | Use in Codex Food Standards Applicable to Infants and Young Children | | | | | |
|---|---|---|---|---|---|---|---|---|
| | CAC[1] | internation al and/or national bodies | IF | | FUF[2] | PCBF[3] | CBF[4] | FSMP[5] for infants and young children |
| | | | Sec. A[6] | Sec. B[7] | | | | |
| 1. Source of Calcium (Ca) | | | | | | | | |
| 1.1 Calcium carbonate | ✔ (1981) | JECFA (1973), Ph Int, FCC, USP, NF, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 1.2 Calcium chloride | ✔ (1979) | JECFA (1975), FCC, USP, Ph Eur, JP, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 1.3 Tricalcium dicitrate (Calcium citrate) | ✔ (1979) | JECFA (1975), FCC, USP, DAC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 1.4 Calcium gluconate | ✔ (1999) | JECFA (1998), Ph Int, FCC, USP, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 1.5 Calcium glycerophosphate | | FCC, Ph Eur, Ph Franc | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 1.6 Calcium L - lactate | ✔ (1978) | JECFA (1974), FCC, USP, Ph Eur (triand pentahydrate), BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 1.7 Calcium hydroxide | ✔ (1979) | JECFA (1975), FCC, USP, Ph Eur, BP | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 1.8 Calcium oxide | ✔ (1979) | JECFA (1975), FCC, DAC | - | ✔ | - | ✔ | ✔ | ✔ |
| 1.9 Calcium dihydrogen phosphate (Calcium phosphate, monobasic) | ✔ (1997) | JECFA (1996), Ph Int, FCC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 1.10 Calcium hydrogen phosphate (Calcium phosphate, dibasic) | ✔ (1979) | JECFA (1975), FCC, USP, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |

1 CAC = Codex Alimentarius Commission

2 FUF = Follow-up Formula

3 PCBF = Processed Cereal Based Food for Infants and Young Children

4 CBF = Canned Baby Food

5 FSMP = Food for Special Medical Purposes other than Infant Formula

6 IF Sect. A = Section A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants

7 IF Sect. B = Section B of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1.11 Tricalcium diphosphate (Calcium phosphate, tribasic) | | JECFA (1973), Ph Int, FCC, BP | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 1.12 Calcium sulphate | ✔ (1979) | JECFA (1975), Ph Int, FCC, Ph Eur (dihydrate), DAB | - | ✔ | - | - | - | ✔ |
| 2. Source of Iron (Fe) | | | | | | | | |
| 2.1 Ferrous carbonate, stabilised with saccharose | | DAB | - | ✔ | - | ✔ | ✔ | ✔ |
| 2.2 Ferrous fumarate | | Ph Int, FCC, USP, Ph Eur, BP | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 2.3 Ferrous gluconate | ✔ (2001) | JECFA (1999), FCC, USP, Ph Eur, DAB, BP | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 2.4 Ferrous lactate | ✔ (1991) | JECFA (1989), FCC, NF | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 2.5 Ferrous sulphate | ✔ (2001) | JECFA (1999), Ph Int, FCC, USP, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 2.6 Ferric ammonium citrate | ✔ (1987) | JECFA (1984), FCC, DAC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 2.7 Ferric citrate | | FCC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 2.8 Ferric diphosphate (pyrophosphate) | | FCC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 2.9 Hydrogen reduced iron | | FCC, DAB | - | ✔ | - | ✔ | ✔ | ✔ |
| 2.10 Electrolytic iron | | FCC | - | ✔ | - | ✔ | ✔ | ✔ |
| 2.11 Carbonyl iron | | FCC | - | ✔ | - | ✔ | ✔ | ✔ |
| 2.12 Ferric saccharate | | Ph Helv, DAB, ÖAB | - | ✔ | - | ✔ | ✔ | ✔ |
| 2.13 Sodium ferric diphosphate | | FCC | - | ✔ | - | ✔ | ✔ | ✔ |
| 2.14 Ferrous citrate | | FCC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 2.15 Ferrous succinate | | MP, MI | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 2.16 Ferrous bisglycinate | | JECFA (2003) | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 2.17 Ferric orthophosphate | | FCC | - | - | - | ✔ | - | - |
| 3. Source of Magnesium (Mg) | | | | | | | | |
| 3.1 Magnesium hydroxide carbonate | | JECFA (1979), USP, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 3.2 Magnesium chloride | ✔ (1979) | JECFA (1979), FCC, USP, Ph Eur (- 4,5-hydrate), BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 3.3 Magnesium gluconate | ✔ (2001) | JECFA (1998), FCC, DAC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 3.4 Magnesium glycerophosphate | | Ph Eur, BPC | - | ✔ | - | ✔ | ✔ | ✔ |
| 3.5 Magnesium hydroxide | ✔ (1979) | JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 3.6 Magnesium lactate | ✔ (1987) | JECFA (1983) (Mg-DLLactate, Mg-LLactate) | - | ✔ | - | ✔ | ✔ | ✔ |
| 3.7 Magnesium oxide | | JECFA (1973), Ph Int, FCC, USP, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 3.8 Magnesium hydrogen phosphate (Magnesium phosphate, dibasic) | ✔ (1985) | JECFA (1982), FCC, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 3.9 Trimagnesium phosphate (Magnesium phosphate, tribasic) | ✔ (1981) | JECFA (1982), FCC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 3.10 Magnesium sulphate | | Ph Eur (heptahy drate), FCC, USP, JP, BP, DAB, DAC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 3.11 Magnesium acetate | | Ph Eur, DAC | - | ✔ | - | - | - | ✔ |
| 3.12 Magnesium salts of citric acid | | USP, DAC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 3.13 Magnesium carbonate | | JECFA (1973), FCC, USP, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 4. Source of Sodium (Na) | | | | | | | | |
| 4.1 Sodium carbonate | ✔ (1979) | JECFA (1975), FCC, USP, NF, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | - | - | ✔ |
| 4.2 Sodium hydrogen carbonate (Sodium bicarbonate) | ✔ (1979) | JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | - | - | ✔ |
| 4.3 Sodium chloride | | Ph Int, FCC, USP, Ph Eur, JP, BP, DAB | ✔ | ✔ | ✔ | - | - | ✔ |
| 4.4 Trisodium citrate (Sodium citrate) | | JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | - | - | ✔ |
| 4.5 Sodium gluconate | ✔ (1999) | JECFA (1998), FCC, USP, DAC | ✔ | ✔ | ✔ | - | - | ✔ |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4.6 Sodium L-lactate | ✔ (1978) | JECFA (1974), FCC, USP, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | - | - | ✔ |
| 4.7 Sodium dihydrogen phosphate (Sodium phosphate, monobasic) | ✔ (1995) | JECFA (1963), FCC, USP, Ph Eur (dihydrate) | ✔ | ✔ | ✔ | - | - | ✔ |
| 4.8 Disodium hydrogen phosphate (Sodium phosphate, dibasic) | | JECFA (1975), Ph Int, FCC, USP, BP | ✔ | ✔ | ✔ | - | - | ✔ |
| 4.9 Trisodium phosphate (Sodium phosphate, tribasic) | | JECFA (1975), FCC, DAC | ✔ | ✔ | ✔ | - | - | ✔ |
| 4.10 Sodium hydroxide | ✔ (1979) | JECFA (1975), Ph Int, FCC, USP, NF, Ph Eur, JP, BP, DAB | ✔ | ✔ | ✔ | - | - | ✔ |
| 4.11 Sodium sulphate | | JECFA (2000), Ph Int, FCC, USP, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | - | - | ✔ |
| 5. Source of Potassium (K) | | | | | | | | |
| 5.1 Potassium carbonate | ✔ (1979) | JECFA (1975), FCC, USP, Ph Eur, DAC | ✔ | ✔ | ✔ | - | - | ✔ |
| 5.2 Potassium hydrogen carbonate (Potassium bicarbonate) | ✔ (1979) | JECFA (1975), FCC, USP, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | - | - | ✔ |
| 5.3 Potassium chloride | ✔ (1983) | JECFA (1979), Ph Int, FCC, USP, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 5.4 Tripotassium citrate (Potassium citrate) | | JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 5.5 Potassium gluconate | ✔ (1999) | JECFA (1998), FCC, USP, DAC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 5.6 Potassium glycerophosphate | | FCC | - | ✔ | - | ✔ | ✔ | ✔ |
| 5.7 Potassium L-lactate | ✔ (1978) | JECFA (1974), FCC, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 5.8 Potassium dihydrogen phosphate (Potassium phosphate, monobasic) | ✔ (1979) | JECFA (1982), FCC, NF, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | - | - | ✔ |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 5.9 Dipotassium hydrogen phosphate (Potassium phosphate, dibasic) | ✔ (1979) | JECFA (1982), FCC, BP | ✔ | ✔ | ✔ | - | - | ✔ |
| 5.10 Potassium phosphate, tribasic | ✔ (1979) | JECFA (1982) | ✔ | ✔ | ✔ | - | - | ✔ |
| 5.11 Potassium hydroxide | ✔ (1979) | JECFA (1975), FCC, NF, Ph Eur, JP, BP, DAC | ✔ | ✔ | ✔ | - | - | ✔ |
| 6. Source of Copper (Cu) | | | | | | | | |
| 6.1 Cupric gluconate (Copper gluconate) | | FCC, USP | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 6.2 Cupric sulphate (Copper sulphate) | ✔ (1981) | JECFA (1973), FCC, USP, Ph Eur, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 6.3 Cupric carbonate | | MI | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 6.4 Cupric citrate | | FCC, USP | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 7. Source of Iodine ( I ) | | | | | | | | |
| 7.1 Potassium iodide | | Ph Int, FCC, USP, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 7.2 Sodium iodide | | Ph Eur, USP, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 7.3 Potassium iodate | ✔ (1991) | JECFA (1988), FCC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 7.4 Sodium iodate | | FCC | - | ✔ | - | ✔ | ✔ | ✔ |
| 8. Source of Zinc (Zn) | | | | | | | | |
| 8.1 Zinc acetate | | USP, Ph Eur (dihydrate) | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 8.2 Zinc chloride | | USP, Ph Eur, JP, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 8.3 Zinc gluconate | | FCC, USP, DAC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 8.4 Zinc lactate | | FCC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 8.5 Zinc oxide | | Ph Int, FCC, USP, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 8.6 Zinc sulphate | | FCC, USP, Ph Eur, BP | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 8.7 Zinc carbonate | | USP, BP (hydroxide carbonate) | - | ✔ | - | - | - | ✔ |
| 9. Source of Manganese (Mn) | | | | | | | | |
| 9.1 Manganese (II) chloride | | FCC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 9.2 Manganese (II) citrate | | FCC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 9.3 Manganese (II) glycero - phosphate | | FCC | - | ✔ | - | ✔ | ✔ | ✔ |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9.4 Manganese (II) sulphate | | FCC, USP, Ph Eur (monohydr ate) | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 9.5 Manganese (II) gluconate | | FCC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 9.6 Manganese (II) carbonate | | MI | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 10. Source of Selenium (Se) | | | | | | | | |
| 10.1 Sodium selenate | | MI | ✔ | ✔ | ✔ | ✔ | - | ✔ |
| 10.2 Sodium selenite | | Ph Eur, USP, MP, MI | ✔ | ✔ | ✔ | ✔ | - | ✔ |
| 10.3 Sodium hydrogen selenite | | DVFA | - | ✔ | - | - | - | ✔ |
| 11. Chromium (Cr Ⅲ) | | | | | | | | |
| 11.1 Chromium (III) sulphate | | USP, MI | - | ✔ | - | - | - | ✔ |
| 11.2 Chromium (III) chloride | | USP, MI | - | ✔ | - | - | - | ✔ |
| 12. Molybdenum (Mo Ⅵ) | | | | | | | | |
| 12.1 Sodium molybdate | | Ph Eur (dihydrate), BP, DAB | - | ✔ | - | - | - | ✔ |
| 12.2 Ammonium molybdate | | FCC, USP | - | ✔ | - | - | - | ✔ |
| 13. Fluoride (F) | | | | | | | | |
| 13.1 Sodium fluoride | | FCC, USP, Ph Eur, BP, DAB | - | ✔ | - | - | - | ✔ |
| 13.2 Potassium fluoride | | FCC, DAB | - | ✔ | - | - | - | ✔ |
| 13.3 Calcium fluoride | | DAB | - | ✔ | - | - | - | ✔ |

B : ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

| Nutrient Source | Purity Requirements by | | Use in Codex Food Standards Applicable to Infants and Young Children | | | | | |
|---|---|---|---|---|---|---|---|---|
| | CAC[1] | internation al and/or national bodies | IF | | FUF[2] | PCBF[3] | CBF[4] | FSMP[5] for infants and young children |
| | | | Sec. A[6] | Sec. B[7] | | | | |
| 1. Vitamin A | | | | | | | | |
| 1.1 all trans Retinol | | FCC (vitamin A), USP, Ph Eur (vitamin A) | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 1.2 Retinyl acetate | | FCC (vitamin A), USP, Ph Eur (vitamin A), Jap Food Stan | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 1.3 Retinyl palmitate | | FCC (vitamin A), USP, Ph Eur (vitamin A), Jap Food Stan | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 2. Provitamin A | | | | | | | | |
| 2.1 Beta-Carotene | ✔ (1991) | JECFA (1987), FCC, USP, Ph Eur, Jap Food Stan | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 3. Vitamin D | | | | | | | | |
| 3.1 Vitamin $D_2$ = Ergocalciferol | | Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 3.2 Vitamin $D_3$ = Cholecalcifer ol | | Ph Int, FCC, USP, Jap Food Stan, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 4. Vitamin E | | | | | | | | |
| 4.1 D-alpha-Tocopher ol | ✔ (2001) | JECFA (2000), FCC, USP, NF, Ph Eur | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 4.2 DL-alpha-Tocophe rol | ✔ (1989) | JECFA (1986), FCC, USP, NF, Ph Eur, Jap Food Stan | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 4.3 D-alpha-Tocopher yl acetate | | FCC, USP, NF, Ph Eur | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |

1 CAC = Codex Alimentarius Commission

2 FUF = Follow-up Formula

3 PCBF = Processed Cereal Based Food for Infants and Young Children

4 CBF = Canned Baby Food

5 FSMP = Food for Special Medical Purposes other than Infant Formula

6 IF Sect. A = Section A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants

7 IF Sect. B = Section B of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4.4 DL-alpha-Tocopheryl acetate | | FCC, USP, NF, Ph Eur, BP | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 4.5 D-alpha-Tocopheryl acid succinate | | FCC, USP, Ph Eur | - | ✔ | - | - | - | ✔ |
| 4.6 DL-alpha-Tocopheryl acid succinate | | NF, MP, MI, USP, Ph Eur | - | ✔ | - | - | - | ✔ |
| 4.7 DL-alpha-Tocopheryl polyethylene glycol 1000 succinate | | FCC, USP | - | ✔ | - | - | - | ✔ |
| 5. Vitamin C | | | | | | | | |
| 5.1 L-Ascorbic acid | ✔ (1981) | JECFA (1973), Ph Int, FCC, USP, Ph Eur, JP, Jap Food Stan, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 5.2 Calcium-L-ascorbate | ✔ (1983) | JECFA (1981), FCC, USP, Ph Eur | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 5.3 6-Palmitoyl-L-ascorbic acid (Ascorbyl palmitate) | | JECFA (1973), FCC, USP, NF, Ph Eur, Jap Food Stan, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 5.4 Sodium-L-ascorbate | | JECFA (1973), FCC, USP, Ph Eur, Ph Franc, Jap Food Stan, DAC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 5.5 Potassium-L-ascorbate | | FCC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 6. Vitamin $B_1$ | | | | | | | | |
| 6.1 Thiaminchloride hydrochloride | | Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 6.2 Thiamin mononitrate | | Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 7. Vitamin $B_2$ | | | | | | | | |
| 7.1 Riboflavin | ✔ (1991) | JECFA (1987), Ph Int, FCC, USP, Ph Eur, JP, Jap Food Stan, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 7.2 Riboflavin-5'-phosphate sodium | ✔ (1991) | JECFA (1987), USP, Ph Eur, JP, Jap Food Stan, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 8. Niacin | | | | | | | | |
| 8.1 Nicotinic acid amide (Nicotinamide) | | Ph Int, FCC, USP, Ph Eur, Jap Food Stan, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 8.2 Nicotinic acid | | Ph Int, FCC, USP, Ph Eur, Jap Food Stan, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9. Vitamin $B_6$ | | | | | | | | |
| 9.1 Pyridoxine hydrochloride | | Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 9.2 Pyridoxal 5-phosphate | | MI, FCC, USP | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 10. Folic acid | | | | | | | | |
| 10.1 N-Pteroyl-L-glutamic acid | | Ph Int, FCC, USP, Ph Eur, Jap Food Stan | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 10.2 Calcium-L-methyl-folate | | JECFA (2005) | - | ✔ | - | - | - | ✔ |
| 11. Pantothenic acid | | | | | | | | |
| 11.1 Calcium-D-pantothenate | | FCC, USP, Ph Eur, Jap Food Stan, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 11.2 Sodium-D-pantothenate | | Jap Food Stan, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 11.3 D-Panthenol/ | | FCC, USP, Ph Eur | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 11.4 DL-Panthenol | | FCC, USP, Ph Eur | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 12. Vitamin $B_{12}$ | | | | | | | | |
| 12.1 Cyanocobalamin | | Ph Int, FCC, USP, Ph Eur, BP, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 12.2 Hydroxocobalamin | | Ph Int, USP, NF, Ph Eur (hydrochloride) | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 13. Vitamin $K_1$ | | | | | | | | |
| 13.1 Phytomenadione (2-Methyl-3-phytyl-1,4-naphthoquinone/Phylloquinone/Phytonadione) | | Ph Int, FCC (vitamin K), USP, Ph Eur, BP | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 14. Biotin | | | | | | | | |
| 14.1 D-Biotin | | FCC, USP, Ph Eur | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |

C : ADVISORY LIST OF AMINO ACIDS AND OTHER NUTRIENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

| Nutrient Source | Purity Requirements by | | Use in Codex Food Standards Applicable to Infants and Young Children | | | | | |
|---|---|---|---|---|---|---|---|---|
| | CAC[1] | internation al and/or national bodies | IF | | FUF[2] | PCBF[3] | CBF[4] | FSMP[5] for infants and young children |
| | | | Sec. A[6] | Sec. B[7] | | | | |
| 1. Amino acids[8] | | | | | | | | |
| 1.1 L-Arginine | | FCC, USP, Ph Eur, BP, DAB | only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use) | ✔ | only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use) | | | ✔ |
| 1.2 L-Arginine hydrochloride | | FCC, USP, Ph Eur, BP, DAB | | ✔ | | | | ✔ |
| 1.3 L-Cystine | | FCC, USP, Ph Eur | | ✔ | | | | ✔ |
| 1.4 L-Cystine dihydrochloride | | MI | | ✔ | | | | ✔ |
| 1.5 L-Cysteine | | DAB | | ✔ | | | | ✔ |
| 1.6 L-Cysteine hydrochloride | | FCC, Ph Eur | | ✔ | | | | ✔ |
| 1.7 L- Histidine | | FCC, USP, Ph Eur, DAB | | ✔ | | | | ✔ |
| 1.8 L- Histidine hydrochloride | | FCC, Ph Eur, DAB | | ✔ | | | | ✔ |
| 1.9 L-Isoleucine | | FCC, USP, Ph Eur, DAB | | ✔ | | | | ✔ |
| 1.10 L-Isoleucine hydrochloride | | FCC, USP | | | | | | |
| 1.11 L-Leucine | | FCC, USP, Ph Eur, DAB | | ✔ | | | | ✔ |
| 1.12 L-Leucine hydrochloride | | MI, FCC, USP | | ✔ | | | | ✔ |

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2 FUF = Follow-up Formula

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6 IF Sect. A = Section A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants

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8 As far as applicable, also the free, hydrated and anhydrous forms of amino acids, and the hydrochloride, sodium, and potassium salts of amino acids may be used for FSMP.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1.13 L-Lysine | | USP | only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use) | ✔ | only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use) | | | ✔ |
| 1.14 L-Lysine monohydrochlor ide | | FCC, USP, Ph Eur, DAB | | ✔ | | | | ✔ |
| 1.15 L-Methionine | | Ph Int, FCC, USP, Ph Eur, DAB | | ✔ | | | | ✔ |
| 1.16 L-Phenylalanine | | FCC, USP, Ph Eur | | ✔ | | | | ✔ |
| 1.17 L-Threonine | | FCC, USP, Ph Eur, DAB | | ✔ | | | | ✔ |
| 1.18 L-Tryptophan | | FCC, USP, Ph Eur, DAB | | ✔ | | | | ✔ |
| 1.19 L-Tyrosine | | FCC, USP, Ph Eur, DAB | | ✔ | | | | ✔ |
| 1.20 L-Valine | | FCC, USP, Ph Eur, DAB | | ✔ | | | | ✔ |
| 1.21 L-Alanine | | FCC, USP, Ph Eur, DAB | - | ✔ | - | - | - | ✔ |
| 1.22 L-Arginine-L-aspartate | | Ph Eur | - | ✔ | - | - | - | ✔ |
| 1.23 L-Aspartic acid | | FCC, USP, Ph Eur | - | ✔ | - | - | - | ✔ |
| 1.24 L-Citrulline | | USP, DAC | - | ✔ | - | - | - | ✔ |
| 1.25 L-Glutamic acid | | JECFA (1987), FCC, USP, Ph Eur | - | ✔ | - | - | - | ✔ |
| 1.26 L-Glutamine | | FCC, USP, DAB | - | ✔ | - | - | - | ✔ |
| 1.27 Glycine | | FCC, USP, Ph Eur | - | ✔ | - | - | - | ✔ |
| 1.28 L-Ornithine | | MI, FCC | - | ✔ | - | - | - | ✔ |
| 1.29 L-Ornithine monohydrochlor ide | | DAB | - | ✔ | - | - | - | ✔ |
| 1.30 L-Proline | | FCC, USP, Ph Eur, DAB | - | ✔ | - | - | - | ✔ |
| 1.31 L-Serine | | USP, Ph Eur, DAB | - | ✔ | - | - | - | ✔ |
| 1.32 N-Acetyl-L-cysteine | | USP, Ph Eur, DAB | - | ✔ | - | - | - | ✔ |
| 1.33 N-Acetyl-L-methionine | | FCC | - | - | - | - | - | ✔ not for infants |
| 1.34 L-Lysine acetate | | FCC, USP, MP ; Ph Eur | - | ✔ | - | - | - | ✔ |
| 1.35 L-Lysine L-Aspartate | | Jap Food Stan | - | ✔ | - | - | | ✔ |
| 1.36 L-Lysine L-glutamate dihydrate | | Jap Food Stan | - | ✔ | - | - | - | ✔ |
| 1.37 Magnesium L- aspartate | | Ph Eur | - | ✔ | - | - | - | ✔ |
| 1.38 Calcium L-glutamate | ✔ 1991 | JECFA, FCC, Jap Food Stan | - | ✔ | - | - | - | ✔ |
| 1.39 Potassium L-glutamate | | JECFA, FCC, Jap Food Stan | - | ✔ | - | - | - | ✔ |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2. Carnitine | | | | | | | | |
| 2.1 L-Carnitine | | FCC, USP, Ph Eur | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 2.2 L-Carnitine hydrochloride | | FCC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 2.3 L-Carnitine tartrate | | FCC, Ph Eur | ✔ | ✔ | ✔ | - | - | ✔ |
| 3. Taurine | | | | | | | | |
| 3.1 Taurine | | USP, JP | ✔ | ✔ | ✔ | - | - | ✔ |
| 4. Choline | | | | | | | | |
| 4.1 Choline | | FCC, USP | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 4.2 Choline chloride | | FCC, DAC, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 4.3 Choline citrate | | NF | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 4.4 Choline hydrogen tartrate | | DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 4.5 Choline bitartrate | | FCC, NF, DAB | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 5. Inositols | | | | | | | | |
| 5.1 Myo-Inositol (=meso-Inositol) | | FCC, DAC | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 6. Nucleotides | | | | | | | | |
| 6.1 Adenosine 5-monophosphate (AMP) | | FSANZ | ✔ | ✔ | ✔ | - | - | ✔ |
| 6.2 Cytidine 5-monophosphate (CMP) | | FSANZ, Jap Food Stan | ✔ | ✔ | ✔ | - | - | ✔ |
| 6.3 Guanosine 5-monophosphate (GMP) | | JECFA (1985) | ✔ | ✔ | ✔ | - | - | ✔ |
| 6.4 Inosine 5-monophosphate (IMP) | | JECFA (1974) | ✔ | ✔ | ✔ | - | - | ✔ |
| 6.5 Disodium Uridine 5-monophosphate salt | | FSANZ, Jap Food Stan | ✔ | ✔ | ✔ | - | - | ✔ |
| 6.6 Disodium Guanosine 5-monophosphate salt | | FCC, JECFA, FSANZ, Jap Food Stan | ✔ | ✔ | ✔ | - | - | ✔ |
| 6.7 Disodium Inosine 5-monophosphate salt | | FCC, JECFA, FSANZ, Jap Food Stan | ✔ | ✔ | ✔ | - | - | ✔ |

D : ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT FORMS

For reasons of stability and safe handling, some vitamins and other nutrients have to be converted into suitable preparations, e.g. gum arabic coated products, dry rubbed preparations. For this purpose, the food additives included in the respective specific Codex standard may be used. In addition, the following food additives may be used as nutrient carriers :

| | INS no. | Additive / Carrier | Maximum Level in Ready-to-use Food for infants and young children (mg/kg) |
|---|---|---|---|
| (a) | 551 | Silicon dioxide | 10 |
| (b) | 421 | Mannitol (for vitamin B12 dry rubbing, 0,1% only) | 10 |
| (c) | 1450 | Starch sodium octenyl succinate | 100 |
| (d) | 301 | Sodium L-ascorbate (in coating of nutrient preparations containing polyunsaturated fatty acids) | 75 |

**Abbreviations :**

| | | |
|---|---|---|
| BP | = | British Pharmacopoeia |
| BPC | = | British Pharmaceutical Codex |
| DAB | = | Deutsches Arzneibuch |
| DAC | = | Deutscher Arzneimittel-Codex |
| DVFA | = | Danish Veterinary and Food Administration |
| FCC | = | Food Chemicals Codex |
| FSANZ | = | Food Standards Australia New Zealand |
| FU | = | Farmacopoea Ufficiale della Republica Italiana |
| JP | = | The Pharmacopeia of Japan |
| Jap Food Stan | = | Japanese Food Standard |
| MI | = | Merck Index |
| MP | = | Martindale Pharmacopoeia |
| ÖAB | = | Österreichisches Arzneibuch |
| Ph Eur | = | Pharmacopoeia Europaea |
| Ph Franç | = | Pharmacopée Française |
| Ph Helv | = | Pharmacopoeia Helvetica |
| Ph Int | = | International Pharmacopoeia |
| USP | = | The United States Pharmacopoeia |

# RECOMMENDED INTERNATIONAL CODE OF PRACTICE FOR THE PROCESSING AND HANDLING OF QUICK FROZEN FOODS (CAC / RCP 8 - 1976)

## 1. SCOPE AND OBJECTIVE

This Code applies to the receiving, preparation, processing, handling, storage, transport, distribution, and retailing of all quick frozen foods such as cereals, fruits and vegetables, fish, meat, poultry and their products, bakery and pastry products. The Code does not apply to edible ices, ice creams and milk.

The objective of this Code is to provide guidance for the processing and handling of quick frozen food to help ensure product safety and other aspects of the production of quick frozen foods including, as appropriate, essential quality provisions, composition and labelling provisions of pertinent Codex commodity standards. The guidance, emphasizing proper cold chain management, incorporates good hygienic and good manufacturing practices and the application of the Hazard Analysis and Critical Control Point (HACCP) approach described in the HACCP Annex to the *Recommended International Code of Practice : General Principles of Food Hygiene* (CAC/RCP 1-1969). A prerequisite programme is described in the Code, covering

essential requirements of hygiene in the production of quick frozen foods that should be in place prior to the application of HACCP.

The food hygiene provisions of this document are supplemental to, and must be used in conjunction with the *General Principles of Food Hygiene*. The Code should also, as appropriate, be used in conjunction with other Codex texts, including the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985), codes of hygienic practice (e.g. *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food* (CAC/RCP 47-2001), *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005)), codes of practice (e.g. *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003)) as well as the *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69-2008). Reference can also be made, as appropriate, to Codex quick frozen food standards and/or provisions in relevant Codex texts.

This Code including its Annex is intended to assist all those who are engaged in the processing and handling of quick frozen foods and/or are concerned with their storage, transportation, export, import and sale in attaining safe food products of appropriate quality.

In addition, the Code may be used for training of employees of the quick frozen food industry. The application of this Code by countries is likely to require modifications and amendments, taking into account local conditions and specific consumer requirements.

## 2. DEFINITIONS

The definitions listed below are for the purpose of this Code only :

| | |
|---|---|
| Blanching | A heat process typically applied to a food for the purpose of inactivating enzymes and/or fixing the product colour. |
| Cold chain | A term embracing the continuity of successively employed means to maintain the temperature of foods, as appropriate, from receiving through processing, transport, storage and retailing. |
| Prerequisite programme | Programme required prior to the application of the HACCP system to ensure that any component of the cold chain is operating according to the *Recommended International Code of Practice : General Principles of Food Hygiene* appropriate Codex codes of practice, and other appropriate food safety legislation. |

| | |
|---|---|
| Quick freezing process | A process which is carried out in such a way that the range of temperature of maximum ice crystallization is passed as quickly as possible. |
| Quick frozen food | Food which has been subjected to a quick freezing process, and maintained at -18℃ or colder at all points in the cold chain, subject to permitted temperature tolerances. |
| Thermal centre | The point within a piece of food which has the highest temperature at the end of a quick freezing process.<br>Tolerances Short term fluctuations of temperature of the product in the cold chain, within limits permitted in this Code and which do not affect safety and quality. |

## 3. PREREQUISITE PROGRAMME

In conjunction with the application of HACCP to any segment of the quick frozen food chain, that segment should be supported by prerequisite programmes based on good hygienic practice and good manufacturing practice. Prerequisite programmes should be specific within an individual establishment, and should be periodically evaluated to ensure their continued effectiveness.

While prerequisite programmes are usually associated with food safety, properly operating prerequisite programmes will also contribute to product quality.

Reference should be made to the *Recommended International Code of Practice : General Principles of Food Hygiene* and relevant Codex codes of hygienic practice and codes of practice including the *Guidelines for the Validation of Food Safety Control Measures* for further information to assist with the design of the prerequisite programmes for a processing facility.

In addition to the provisions of the *Recommended International Code of Practice : General Principles of Food Hygiene* following additional prerequisite provisions should apply :

### 3.1 ESTABLISHMENT : DESIGN AND FACILITIES

#### 3.1.1 Location

Processing facilities should, to the extent possible, be located close to the source of raw materials so as to minimize changes that might lead to quality or safety concerns for raw materials of quick frozen foods prior to freezing.

#### 3.1.2 Process Plant Design

The food processing facility should be designed for the rapid processing, freezing and storage of food products. The processing facility should include a product flow that is designed to minimize process delays and prevent cross-contamination that could affect food quality and safety.

#### 3.1.3 Cold Store Design

The cold store walls, floor, ceiling, and doors should be properly insulated in order to help maintain appropriate product temperatures. It is important that the design of the cold store ensures that :

- adequate refrigeration capacity provides and maintains a product temperature of -18℃ or colder ;
- there is adequate air flow around the stored foods ;
- storage areas are provided with a capability to control and record temperatures on a regular basis ;
- loss of cold air and introduction of warm and humid air are avoided ; and
- leaks of any refrigerant are prevented. In case of a leak, immediate corrective action ought to be applied in order to eliminate the problem.

#### 3.1.4 Equipment Design and Construction

The equipment should be designed and constructed in such a manner that physical damage to the raw materials and product is minimized, e.g. by ensuring there are no sharp inside corners or projections and that physical, chemical or biological hazards are not introduced into the product. Freezers should be designed and constructed so that, when properly operated, they meet the requirements of a quick freezing process.

#### 3.1.5 Facilities

In the case of power losses or equipment failure, a contingency plan should be in place in order to maintain the product temperature.

### 3.2 CONTROL OF OPERATION

#### 3.2.1 Recall Procedures

Recall procedures should be in place to ensure timely withdrawal of products that may pose a risk to human health.

##### 3.2.1.1 Traceability/Product Tracing[1]

The traceability/product tracing system should be designed and implemented according to the *Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System* (CAC/GL 60-2006), especially to enable the withdrawal of the product, where necessary.

### 3.3 ESTABLISHMENT: MAINTENANCE AND SANITATION

#### 3.3.1 Maintenance Regimes

Proper maintenance and repair of any damage to the cold store and its infrastructure (e.g. prevention of rust, water leaks, ice accumulation, etc.) should be ensured so that insulation and refrigeration performance is maintained.

### 3.4 TRAINING

Staff should have the skills and knowledge appropriate to their work to ensure that safety and quality of foods is not adversely affected during handling. Staff should also be aware of the importance of maintaining temperature control for frozen foods to maintain the quality and safety of the foods. Training programs should be in place (either formal training courses or training provided whilst working) to ensure that staff have these skills and knowledge.

## 4. COLD CHAIN CONTROL

As appropriate, both safety and quality aspects should be considered for each operation of the cold chain.

With respect to fo od safety, a HACCP plan should be developed, as appropriate, for each operation in the cold chain.

Cold chain control is also important with respect to food quality. Essential quality provisions[2] can apply at various points in the processing and handling system. While control of essential quality provisions may be considered optional, control of food safety hazards through prerequisite programs and a HACCP plan should be used, as appropriate, to ensure safety.

### 4.1 RAW MATERIALS

Raw materials used should be safe, sound and suitable for further processing.

Procedures should be in place to ensure quality and safety of incoming materials. Freezing cannot improve quality, and it is necessary to use raw materials of optimum quality. Many raw materials

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1 See Definitions for the Purposes of the Codex Alimentarius, Procedural Manual of the Codex Alimentarius Commission.

2 Essential quality provision is a provision which should be applied to ensure the specified quality of the product.

and food products are highly perishable and should be handled carefully to maintain their quality until the freezing process is initiated.

Initial microbial levels in raw materials to be frozen should be kept as low as possible, both for food safety and quality reasons. Temperatures and duration of storage should be appropriately and regularly controlled to minimize adverse microbial effects. Most quality deterioration, including the development of off odours and flavours and changes in colours and texture are due to microbial growth or enzymatic activity.

Producers of quick frozen food should as far as practicable implement measures to control physical, biological and chemical hazards in raw materials to levels that do not present a threat to human health according to the recommendations of the relevant sections of the *Recommended International Code of Practice : General Principles of Food Hygiene* and other relevant Codex texts.

Appropriate procedures should be in place for sorting and segregating raw materials that are unsuitable for further processing. Raw materials for processing and quick freezing should be prepared without delay and appropriate temperature control should be applied in order to minimize possible microbiological, chemical or biochemical changes that might affect safety and quality. To minimize deterioration, raw materials should be cooled and stored under appropriate conditions (e.g. pre-cooling) or transported and frozen in the shortest time possible.

For highly perishable products, product temperature control at receiving may be considered a critical control point (CCP)[3]. Additionally, the receipt temperature may also be considered an essential quality provision.

## 4.2 PROCESSING BEFORE FREEZING

Raw materials may be processed in many ways before freezing, e.g. cleaning, sorting, cutting, slicing, blanching, conditioning, ageing, scalding, filleting and heating. Whether such processes should be regarded as CCPs depends on the type of raw materials and the actual conditions, especially on how much time the raw materials and the resulting product spend at temperatures that could result in pathogen growth. It is particularly important that the time spent in the critical temperature zone (i.e. between 10℃ and 60℃) be as short as possible. Consideration should also be given to any of these processes as to whether or not they should be regarded as an essential quality provision.

Blanching is often used in the production of frozen vegetables and other products to inactivate enzymes that would cause quality problems (taste, colour) during frozen storage. The blanching schedule should be determined to ensure the desired quality outcome, and may be an essential quality provision.

If storage of intermediate ingredients (e.g. a quick frozen vegetable that is to be combined with other quick frozen vegetables or other ingredients into a final product) is necessary prior to further processing, the storage conditions, especially temperature, should be appropriate to the foodstuff concerned and if necessary, take into account future use or further processing of the food.

The heat treatment of many pre-cooked foods, e.g. prepared meals, should be sufficient to ensure inactivation of pathogens of concern. In certain cases, based on the hazards and controls specified for an operation, the time-temperature treatment and subsequent cooling may be considered as CCPs.

If frozen raw materials are used and a thawing process is included, the thawing method should be clearly defined and the thawing schedule (time and temperature parameters) should be carefully monitored.

Selection of the thawing method should take into account the thickness and uniformity of size of the products in particular. Thawing should be done in such a manner that the growth of microorganisms is controlled.

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3 See HACCP Annex to the *Recommended International Code of Practice : General Principles of Food Hygiene.*

Thawing time and temperature parameters may be a CCP and/or an essential quality provision.

## 4.3 QUICK FREEZING PROCESS

The quick freezing process should be performed in such a manner as to minimize physical, biochemical and microbiological changes, by taking into account the freezing system or process and its capacity, nature of the product (thermal conductivity, thickness, form, initial temperature) and volume of production. This is best achieved by ensuring that the product passes quickly through the temperature range of maximum ice crystallization. This temperature range varies among different types of products. The quick freezing process step may be considered an essential quality provision.

During freezing operation it is important to provide spaces or channels permitting air circulation between the cartons or the pieces of food, respectively. This is especially the case when large lots of food are frozen or where the food consists of large pieces (e.g. whole turkeys). If such air channels are not provided, the mass of the food may be such that in spite of rapid air blast and low air temperatures, the inner parts of the lot chill and freeze slowly. It is important that the thermal centre of the product is chilled as quickly as possible to prevent the outgrowth of pathogenic microorganisms or the production of microbial toxins. Freezing may be a CCP.

The quick freezing process should not be regarded as complete until and unless the product temperature has reached -18℃ or colder at the thermal centre, after the stabilization of the temperature. On exit from the freezing apparatus, the product should be moved to a cold store as quickly as possible in order to minimise exposure to warm temperatures and high humidity and to maintain the product temperature at -18℃ or colder. The same applies to products that are retail packed after the quick freezing process (see Section 4.8).

### 4.3.1 Impact of Quick Freezing on Microorganisms and Parasites

Freezing should not be considered as a lethal treatment for microbiological contamination in foods. However, freezing may result in the death of certain microorganisms and will inhibit the growth of others.

In products intended for raw consumption or not fully cooked prior to consumption, freezing can be used to control live helminth parasites, such as *Anisakis* spp. and *Trichinella spiralis*. Freezing may serve as a control mechanism when developing HACCP plans for marinating, pickling, or other final preparations which do not supply sufficient heat from cooking to inactivate any potentially harmful parasites. The conditions required for effective parasite control using freezing include the final temperature and time of holding in the frozen state. These parameters vary depending on a number of factors which may include the type of commodity, species of parasite, thickness of the product, and arrangement of product in the freezer.

The use of freezing as a food safety control measure should, as with all food safety control measures, be appropriately validated to ensure that the measure is capable of controlling the hazard[4].

## 4.4 PROCESSING AFTER FREEZING

Glazing[5] may be used to limit dehydration during frozen storage. Such dehydration may affect the appearance and other quality parameters of the food. The application of glazing should be properly controlled.

## 4.5 PACKAGING AND LABELLING

### 4.5.1 Packaging

In general, the packaging should:

- protect the food against dehydration;

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4 See *Guidelines for the Validation of Food Safety Control Measures*.

5 The application of a protective layer of ice formed on the surface of a frozen product by spraying it with, or dipping it into, potable water, or potable water with additives adopted by the Codex Alimentarius Commission, as appropriate.

- protect the food against microbial and other contamination that could adversely affect safety and quality ;
- protect the sensory and other quality characteristics of the food ; and
- not add to the food any substance that may influence the safety and quality of the food.

The packaging or re-packing of quick frozen foods should be carried out in such a manner that an increase in temperature, within the permitted tolerances of the quick frozen foods, does not adversely affect the safety and quality of the product.

### 4.5.2 Labelling

The labelling of packaged quick frozen foods should comply with the requirements of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) and the relevant Codex standards for quick frozen foods.

## 4.6 FROZEN STORAGE

Cold stores should be designed and operated so as to maintain a product temperature of -18℃ or colder with a minimum of fluctuation (see Section 3.1.3). The temperature of the cold store may be an essential quality provision and/or a CCP to avoid a critical temperature abuse situation that may jeopardize food safety.

Stock should be placed in the cold room in such a manner that the circulation of cold air is not impeded to the extent that the product temperature is adversely affected.

Stocks should be rotated to ensure that the products leave the cold store on a "First in-First out" basis or shortest durability date. In no case, should products be stored beyond their specified shelf-life.

## 4.7 TRANSPORT AND DISTRIBUTION

The product temperature during transport and distribution may be an essential quality provision and/or a CCP to avoid a critical temperature abuse situation that may jeopardize food safety. The transport of quick frozen foods (e.g. from cold storage warehouse to cold storage warehouse) should be carried out in suitably insulated equipment that ideally maintains a product temperature of -18℃ or colder. The product temperature should be at -18℃ or colder at the beginning of the transport.

Vehicle compartments or containers should be pre-cooled prior to loading. Care should be taken not to impair the efficiency of temperature control or reduce the refrigeration capacity.

The user of the vehicle or container should ensure :

- adequate supervision of product temperatures at the moment of loading ;
- effective stowage of the load in the vehicle or the container to protect the cargo against heat entering from outside ;
- efficient operation of the refrigerating unit during transit, including the correct thermostat setting ;
- an appropriate method of unloading at the points of arrival (particularly the frequency and duration of door openings) ;
- proper maintenance of the insulated body and the refrigeration system ; and
- proper cleaning of the vehicle or container.

Distribution of quick frozen foods should be carried out in such a way that any rise in product temperature warmer than -18℃ be kept to a minimum within, as appropriate, the limit set by competent authorities and should not in any case be warmer than -12℃ in the warmest package to ensure quality of the products. After delivery, the product temperature should be reduced to -18℃ as soon as possible.

Loading into and unloading from vehicles and loading into and unloading from cold stores should be as fast as practicable and the methods used should minimize product temperature rise.

### 4.8 TRANSFER POINTS

Attention should be paid to moving quick frozen foods as rapidly as is reasonably practicable from cold store to vehicle/container or from vehicle/container to holding store or from holding store to display cabinets. Often, transfer of responsibility occurs at the same time.

- Quick frozen foods should not be left for any significant length of time at ambient temperature.
- Procedures should be established for dispatching loads and for immediate storage of food upon arrival, in order to minimize exposure to humidity, elevated temperatures or other adverse conditions.
- It should be established that all personnel are following such procedures.
- The product temperature should be checked as necessary, as the product is received or dispatched and a record of these measurements retained for a period that exceeds the shelf-life of the product.
- Operations (such as casing, order assembly, palletizing, etc.) should be carried out in the cold store or in a suitably temperature-controlled area.

### 4.9 RETAIL SALE

Quick frozen foods should be offered for sale from freezer cabinets designed for the purpose. Cabinets should be capable of maintaining and be so operated as to maintain a product temperature of -18℃. A rise in product temperature may be tolerated for short periods, with any rise warmer than -18℃ kept to a minimum, within, as appropriate, the limit set by competent authorities, and should not in any case be warmer than -12℃ in the warmest package.

Temperature in the cabinet may be an essential quality provision and/or a CCP to avoid a critical temperature abuse situation that may jeopardize food safety.

Display cabinets should:

- be equipped with an appropriate temperature measuring device (see Annex, Section 2.4);
- be located so that the open display area is not subject to draughts or abnormal radiant heat (e.g. direct sunlight, strong artificial light or in direct line with heat sources); and
- never be stocked beyond the load line.

Cabinets requiring defrosting should have the defrost cycle programmed in such a way that, to the extent possible, defrosting takes place outside peak shopping periods. If necessary to avoid detrimental effects due to warming or thawing, quick frozen foods should be moved during defrost cycles to a suitable cold store.

Stocks should be rotated to ensure that the products are sold on a "First in-First out" basis or shortest durability date. In no case, should products be stored beyond their specified shelf-life.

The retail establishment should have an appropriate back-up storage for quick frozen foods that allows products to be kept at a temperature of -18℃.

## 5. TEMPERATURE MANAGEMENT IN THE COLD CHAIN

Inadequate food temperature control is one of the most common causes of food borne illness. Inadequate food temperature control may also result in an adverse effect on product quality, including food spoilage. Temperature management systems should be in place to ensure that the temperature along the cold chain is controlled and monitored effectively. Details on temperature control and temperature monitoring are provided below and in the Annex, which provides additional guidance and explanation on currently available technology on temperature monitoring

and control in the cold chain.

## 5.1 TEMPERATURE MONITORING

Operators should ensure that appropriate systems are in place to monitor air temperatures during the freezing process and to monitor temperature along the cold chain in order to ensure that the product temperature is maintained at -18℃ or colder within the permitted tolerances set by competent authorities.

In general, operators have a choice of monitoring systems for quick frozen products, which either include measurement of operating air temperatures of the refrigerating systems or direct/indirect measurement of product temperature. Additional approaches also exist (see Section 5.1.3).

### 5.1.1 Air Temperature Monitoring

In air temperature monitoring, fixed temperature sensors are used to monitor the air temperature in the refrigerated system. The sensors are normally protected from damage during commercial activity.

Air temperature monitoring permits :

- diagnosis of problems occurring in the system ; and
- process management using data storage on computers, which can be linked to other operating information such as defrost cycles, door openings, energy consumption and production batch codes.

### 5.1.2 Product Temperature Monitoring

Product temperature may be measured directly or indirectly. Direct measurements of product temperature may be undertaken destructively or non-destructively.

Although product temperature measurement can give more confidence than air temperature monitoring that temperature requirements are being complied with, this approach is often not practical during busy production and distribution periods.

### 5.1.3 Additional Approaches

Additional approaches to temperature monitoring include :

- use of a simulated food product ;
- use of temperature probes and/or recorders, as appropriate, placed between packages or in a load ;
- use of a non-contact thermometer ; and
- use of temperature indicators and time-temperature indicators.

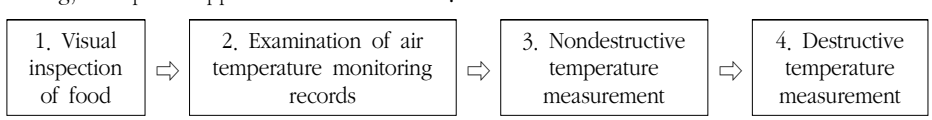
### 5.1.4 Temperature monitoring equipment

The selection of temperature monitoring equipment should take into account:

- appropriate accuracy and resolution (depends on the construction of the equipment and its use) ;
- ability to withstand vibrations, shocks or movement (for mobile system) ;
- coverage of temperature range adequate for quick frozen foods ; and
- need for calibration and periodic checks to ensure proper functioning.

## 5.2 STEPWISE APPROACH TO TEMPERATURE CONTROL

When quick frozen foods are being inspected in the cold chain, either before loading or during unloading, a stepwise approach is recommended.



1. First, before loading and during unloading, a visual inspection is recommended in order to verify the condition of the foods (e.g. for signs of damage, abuse, defrosting).

2. Second, the air temperature monitoring records and other temperature readings noted in the documentation following the foods should be examined. If the loading temperature was correct and the refrigeration system functioning correctly, and there are no irregularities in the temperature difference between the air leaving the refrigeration unit and the air return, no further action need be taken.

3. A non-destructive product temperature measurement should be carried out, especially if there is a doubt about any of the above aspects or no records are available. This should involve a between carton or between package temperature reading (see Annex, Section 3.1.3). If the non-destructive measurement indicates that the product temperature is within the permitted tolerances set by competent authorities, the inspection may stop at this point.

4. If the non-destructive product measurement indicates that the product temperature is outside the permitted tolerances, a destructive temperature measurement should be undertaken (see Annex, Section 3.1.4). This operation must be carried out after placing the cargo in refrigerated environments or after protecting the load in order to avoid increasing the temperature of the food.

Whenever this stepwise approach indicates a temperature violation, the procedure in Section 5.3 should be followed.

## 5.3 TEMPERATURE VIOLATION

Loads or parts of loads that are warmer than the temperature required for quick frozen food should be identified and sorted immediately. Delivery, and sale of these loads or parts of loads should be suspended. It is the responsibility of the person in possession of the food to ensure the food safety of the product. Any measures necessary for preserving the food should be taken, including bringing down the temperature immediately. An assessment should be made as to whether the safety or the quality of the product has been compromised and action taken accordingly. Destruction of the product may be necessary, especially if safety provisions are compromised. In cases of compromised safety or quality, the supplier, as well as other relevant parties in the supply chain should be informed of the incident. In the case of compromised safety the competent authorities should also be notified.

## 5.4 RECORD KEEPING

Records of these measurements should be kept for a period that exceeds the shelf-life of the product or as required by competent authorities.

ANNEX

# SPECIFIC INFORMATION ON TEMPERATURE MONITORING AND CONTROL IN THE COLD CHAIN

## 1. INTRODUCTION

This Annex provides additional guidance and explanation on currently available technology on temperature monitoring in the cold chain. New temperature measuring and recording devices may be developed and should be used as appropriate.

## 2. AIR TEMPERATURE MONITORING

### 2.1 AIR TEMPERATURE MONITORING EQUIPMENT

Temperature measurement and recording devices consist of a sensor (placed in the cold air), and a read-out or recording system. The sensor can be located far from the read-out or recording system or incorporated in it. A recorder is able to store the data, usually electronically, although chart recorders are still widely used for cold stores and containers.

- Air temperature measurement and recording devices should be accurate to within ± 2℃ and have a resolution of 1℃. The response time, i.e. the time taken for readings to stabilize, depends on the construction of the equipment and its use. Also if the system is mobile, it should be able to withstand vibrations, shocks or movement.
- The sensor may consist of a thermocouple (e.g. Type K, Type T), thermistor or platinum resistance device. All of these will provide an acceptable performance and cover a temperature range adequate for quick frozen foods.
- Systems are checked and calibrated during manufacture. It is important that once installed, periodic checks are carried out to ensure proper functioning. This is normally undertaken by checking against a calibrated thermometer placed in an equilibrated ice bath.

### 2.2 AIR TEMPERATURE MONITORING OF COLD STORES

Sensors should be placed high up, in relevant locations within the cold store, away from all positions causing uncontrolled temperature fluctuations such as cooler fans, the entrance or the exit (if different from the entrance) in order to enable precise recording. The position of the sensors should be chosen taking into account the cold air circulation and in such a manner to give an accurate recording of the temperature conditions. Recorders are recommended to be placed outside the cold stores in a convenient location selected for this purpose.

As far as the number of sensors concerned, each food business operator should evaluate its processes and make a documented decision on the number of sensors required. As indicative figures, small cold stores (less than 500 $m^3$) may need only one sensor, those with a volume of less than 30,000 $m^3$ may require two sensors, those with a volume from 30,000 $m^3$ -60,000 $m^3$ may require four sensors, and those with a volume greater than 60,000 $m^3$ may require 6 sensors. Retail stores with a volume less than 10 $m^3$ can be equipped with only a visible thermometer.

### 2.3 AIR TEMPERATURE MONITORING DURING TRANSPORT

Measurement of the return air temperature to the cooling unit will give a good indication of the load temperature, provided adequate air flow is achieved throughout the length of the vehicle.

In long vehicles (above 6 m), air ducting is recommended to ensure that sufficient cold air reaches the rear of the vehicle. Two sensors are recommended to be fitted in the compartment: one measures the return air temperature, and the other is placed two thirds to three quarters the length

of the vehicle mounted in the ceiling ducts. The difference between these two temperatures should be an indication of how well the refrigeration is functioning. If the difference is large or variable it may indicate insufficient pre-cooling, incorrect stowage of pallets, or unnecessary delay in closing the doors.

The recorder can be placed in the vehicle cabin or mounted on the outside, usually near the refrigeration controls.

### 2.4 AIR TEMPERATURE MONITORING IN DISPLAY CABINETS

Display cabinets should be equipped with an accurate thermometer or temperature measuring device that is easily readable. In open cabinets, the temperature should be measured in the return air, at the load line level, or at the warmest place.

## 3. PRODUCT TEMPERATURE MONITORING

### 3.1 DIRECT TEMPERATURE MEASUREMENT

#### 3.1.1 Specification of Measuring System

The temperature measuring device used to measure product temperature should be of better accuracy than that used for air temperature monitoring. The following specifications are recommended for the system, i.e. sensor and read-out :

- the system should have an accuracy of ± 0.5℃ within the measuring range -20℃ to +30℃ ;
- the response time should achieve 90% of the difference between initial and final readings within three minutes ;
- the display resolution of the read-out should be 0.1℃ ;
- the measuring accuracy should not change by more than 0.3℃ during operation in the ambient range -20℃ to +30℃ ;
- the system should be calibrated or otherwise verified prior to use and at specified intervals against measurement standards traceable to international or national measurement standards ;
- the accuracy of the system should be checked at regular intervals ;
- the system should be robust and the device and equipment should be shock-proof ; and
- the electrical components of the system should be protected against undesirable effects due to condensation of moisture.

#### 3.1.2 Pre-cooling of the Probe

The probe should be pre-cooled to a temperature as close to the product temperature as possible before measurement. After inserting the probe, the temperature should be read when it has reached a stable value.

#### 3.1.3 Non-destructive Temperature Measurement

Non-destructive testing is rapid and can be done without unduly disturbing the load. However, because the outside temperature of the package or carton is being measured this may result in up to 2℃ difference between the true product temperature and the reading obtained.

Product surface temperature measurement undertaken non-destructively should :

- measure the temperature between cases on a pallet or between packages inside a carton ;
- use sufficient pressure to give good thermal contact, and sufficient length of probe inserted to minimize conductivity errors ; and
- use a probe with a flat surface to give good surface thermal contact, low thermal mass, and high thermal conductivity.

### 3.1.4 Destructive Temperature Measurement

Temperature probes are not designed to penetrate quick frozen foods. Therefore it is necessary to make a hole in the product in which to insert the probe. The hole is made by using a pre-cooled sharp pointed metallic device such as an ice punch, hand drill or an auger. The diameter of the hole should provide a close fit to that of the probe. The depth to which the probe is inserted will depend on the type of product :

- where product dimensions allow, insert the probe to a minimum depth of 2.5 cm from the surface of the product.
- where this is not possible because of the size of the product, the probe should be inserted to a minimum depth from the surface of 3 or 4 times the diameter of the probe.
- where it is not possible or practical to make a hole in certain foods because of their size or composition, e.g. diced vegetables, the internal temperature of the food package should be determined by insertion of a suitable sharp-stemmed probe to the centre of the package to measure the temperature in contact with the food.
- in order to measure the centre temperature in large products after the quick freezing process it may be necessary to insert the probe to a depth of more than 2.5 cm.

## 3.2 SAMPLING OF PRODUCTS FOR TEMPERATURE MEASUREMENT

### 3.2.1 During Transport

A non-destructive temperature measurement should be taken of the product being loaded into the vehicle and a record entered in the documents.

A destructive product temperature measurement should be made if there appears to be a problem. If it is necessary to measure product temperatures during transport whilst the vehicle is loaded, samples should be selected from the top and bottom of the consignment adjacent to the opening edge of each door or pair of doors (see Figure 1).

If product temperature measurement is necessary, after the vehicle is unloaded and the cargo placed in a properly cooled environment, four samples should be selected from within the transport vehicle from amongst the following points, carefully noting the location of the load within the transport vehicle (see Figure 2).

When samples are selected, a non-destructive temperature measurement should in general be carried out first before deciding whether a destructive measurement should be carried out. A total tolerance of 2.8℃ should be applied (2℃ for limitations of methodology and 0.8℃ tolerance for the system). If a destructive measurement is carried out, the tolerance of 2.8℃ is not applicable.

### 3.2.2 At Retail

If it is necessary to measure the temperature of quick frozen foods in retail display cabinets, one sample should be selected from each of three locations representative of the warmest points in the cabinets. The positions will vary with the different types of retail display cabinets used.

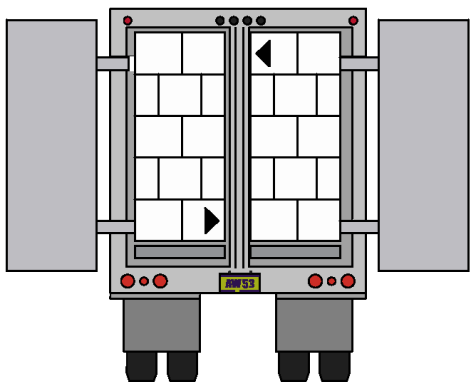


Figure 1 - Sampling positions for a loaded vehicle (◀)

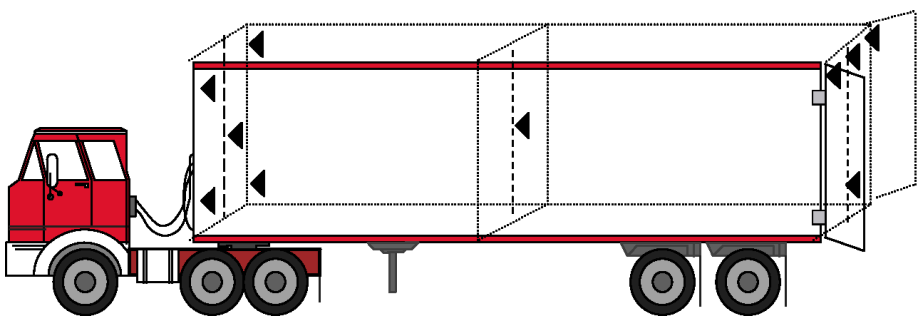


Figure 2 - Sampling positions for an unloaded vehicle (◀)

- o top and bottom of the consignment adjacent to the opening edge of the doors ;
- o top and far corners of the consignment (as far from the refrigeration unit as possible) ;
- o centre of the consignment ;
- o centre of the front surface of the consignment (as close to the refrigeration unit as possible) ;
- o top and bottom corners of the front surface of the consignment (as close as possible to the air return inlet).

## 4. OPTIONAL APPROACHES TO TEMPERATURE MONITORING : Indirect Temperature Measurement

### 4.1 SIMULATED PRODUCT

When air temperature monitoring is difficult, e.g. during the freezing process, it is possible to use a simulated food sample. This is a device that has a similar shape and is made of a material that has similar thermal properties and gives a similar cooling factor to the food being monitored. Materials such as nylon, polystyrene, polyvinyl chloride, perspex and polytetrafluorethylene have thermal properties similar to certain foods. Sensors can be embedded permanently into such a device and it can be packed along with the food packages and measured when required. The simulant may also be incorporated into a temperature recording device.

### 4.2 RECORDERS BETWEEN PACKAGES

Small temperature recorders may be placed between packages or in a load, e.g. in cartons, in order to record the temperature over long periods. Such recorders may be programmed and the measurements retrieved by means of computerized devices.

### 4.3 NON-CONTACT THERMOMETERS

These devices measure the temperature of the food by sensing the infrared radiation emitted by the food. The amount of radiation varies with different materials, which absorb and reflect and transmit radiation differently. Infrared thermometers can be portable and are usually "pistol shaped" sometimes with a laser sighting aid. Target size can be important, since the instrument averages all the radiation in its field of vision. Care must be taken in interpreting results from these devices with quick frozen foods because a package rapidly picks up radiation from its surroundings, there can be a difference between surface temperature and interior temperature. In addition the type of packaging will affect the radiation. Laminated foil packaging in particular can give large errors because it reflects radiation more efficiently than cardboard. Also available are devices which compensate for this type of error and measure the radiation through a window.

Fixed video camera-type infrared thermometers are also used. These can give thermal images, which permit industrial control of heating or cooling processes to ensure even processing. This is also true of the freezing process. Therefore it is possible to scan large numbers of products and pick out "hot-spots", followed up by more accurate temperature measurements.

### 4.4 TEMPERATURE INDICATORS (TIS) AND TIME-TEMPERATURE INDICATORS (TTIS)

These devices give a colour change, either when a specific temperature has been exceeded (TIs), or when the integrated exposure to a temperature over a period of time has been exceeded (TTIs). There has been a reluctance to use TIs and TTIs on retail packages for a number of reasons, in particular because of their current limitations and because they are on the surface of packages and not inside the package, and because of their possible conflict with durability dates. However, TIs and TTIs may be used on the outside of cartons or pallets to detect temperature abuse during distribution from cold stores to holding stores at retail, and they can monitor transfer of quick frozen foods where monitoring records may not be available.

# GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS CODEX STAN 1-1985

## 1. SCOPE

This standard applies to the labelling of all prepackaged foods to be offered as such to the consumer or for catering purposes and to certain aspects relating to the presentation thereof.

## 2. DEFINITION OF TERMS

For the purpose of this standard:

*"Claim"* means any representation which states, suggests or implies that a food has particular qualities relating to its origin, nutritional properties, nature, processing, composition or any other quality.

*"Consumer"* means persons and families purchasing and receiving food in order to meet their personal needs.

*"Container"* means any packaging of food for delivery as a single item, whether by completely or partially enclosing the food and includes wrappers. A container may enclose several units or types of packages when such is offered to the consumer.

For use in *Date Marking* of prepackaged food:

*"Date of Manufacture"* means the date on which the food becomes the product as described.

*"Date of Packaging"* means the date on which the food is placed in the immediate container in which it will be ultimately sold.

*"Sell-by-Date"* means the last date of offer for sale to the consumer after which there remains a reasonable storage period in the home.

*"Date of Minimum Durability"*( "best before" ) means the date which signifies the end of the period under any stated storage conditions during which the product will remain fully marketable and will retain any specific qualities for which tacit or express claims have been made. However, beyond the date the food may still be perfectly satisfactory.

*"Use-by Date"*(Recommended Last Consumption Date, Expiration Date) means the date which signifies the end of the estimated period under any stated storage conditions, after which the product probably will not have the quality attributes normally expected by the consumers. After this date, the food should not be regarded as marketable.

*"Food"* means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drinks, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs.

*"Food Additive"* means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include "contaminants" or substances added to food for maintaining or improving nutritional qualities.

*"Ingredient"* means any substance, including a food additive, used in the manufacture or preparation of a food and present in the final product although possibly in a modified form.

*"Label"* means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of food.

*"Labelling"* includes any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.

*"Lot"* means a definitive quantity of a commodity produced essentially under the same conditions.

*"Prepackaged"* means packaged or made up in advance in a container, ready for offer to the consumer, or for catering purposes.

*"Processing Aid"* means a substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.

*"Foods for Catering Purposes"* means those foods for use in restaurants, canteens, schools, hospitals and similar institutions where food is offered for immediate consumption.

## 3. GENERAL PRINCIPLES

3.1 Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.[1]

3.2 Prepackaged food shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.

## 4. MANDATORY LABELLING OF PREPACKAGED FOODS

The following information shall appear on the label of prepackaged foods as applicable to the food being labelled, except to the extent otherwise expressly provided in an individual Codex standard:

4.1 The name of the food

4.1.1 The name shall indicate the true nature of the food and normally be specific and not generic:

4.1.1.1 Where a name or names have been established for a food in a Codex standard, at least one of these names shall be used.

4.1.1.2 In other cases, the name prescribed by national legislation shall be used.

4.1.1.3 In the absence of any such name, either a common or usual name existing by common usage as an appropriate descriptive term which was not misleading or confusing to the consumer shall be used.

4.1.1.4 A "coined", "fanciful", "brand" ame, or "trade mark" may be used provided it accompanies one of the names provided in Subsections 4.1.1.1 to 4.1.1.3.

4.1.2 There shall appear on the label either in conjunction with, or in close proximity to, the name of the food, such additional words or phrases as necessary to avoid misleading or confusing the consumer in regard to the true nature and physical condition of the food including but not limited

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1 Examples of descriptions or presentations to which these General Principles refer are given in the Codex General Guidelines on Claims.

to the type of packing medium, style, and the condition or type of treatment it has undergone ; for example : dried, concentrated, reconstituted, smoked.

4.2 List of ingredients

4.2.1 Except for single ingredient foods, a list of ingredients shall be declared on the label.

4.2.1.1 The list of ingredients shall be headed or preceded by an appropriate title which consists of or includes the term 'ingredient'.

4.2.1.2 All ingredients shall be listed in descending order of ingoing weight (m/m) at the time of the manufacture of the food.

4.2.1.3 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the food, the ingredients, other than food additives which serve a technological function in the finished product, need not be declared.

4.2.1.4 The following foods and ingredients are known to cause hypersensitivity and shall always be declared :[2]

- Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these ;
- Crustacea and products of these ;
- Eggs and egg products ;
- Fish and fish products ;
- Peanuts, soybeans and products of these ;
- Milk and milk products (lactose included) ;
- Tree nuts and nut products ; and
- Sulphite in concentrations of 10 mg/kg or more.

4.2.1.5 Added water shall be declared in the list of ingredients except when the water forms part of an ingredient such as brine, syrup or broth used in a compound food and declared as such in the list of ingredients. Water or other volatile ingredients evaporated in the course of manufacture need not be declared.

4.2.1.6 As an alternative to the general provisions of this section, dehydrated or condensed foods which are intended to be reconstituted by the addition of water only, the ingredients may be listed in order of proportion (m/m) in the reconstituted product provided that a statement such as "ingredients of the product when prepared in accordance with the directions on the label" is included.

4.2.2 The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in Section 4.2.1.4 shall be declared.

When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

4.2.3 A specific name shall be used for ingredients in the list of ingredients in accordance with the provisions set out in Section 4.1 (Name of the Food) except that :

4.2.3.1 Except for those ingredients listed in section 4.2.1.4, and unless a general class name would be more informative, the following class names may be used :

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2 Future additions to and/or deletions from this list will be considered by the Codex Committee on Food Labelling taking into account the advice provided by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

| NAME OF CLASSES | CLASS NAMES |
|---|---|
| Refined oils other than olive | 'Oil' together with either the term 'vegetable' or 'animal', qualified by the term 'hydrogenated' or 'partially-hydrogenated', as appropriate |
| Refined fats | 'Fat' together with either, the term 'vegetable' or 'animal', as appropriate |
| Starches, other than chemically modified starches | 'Starch' |
| All species of fish where the fish constitutes an ingredient of another food and provided that the labelling and presentation of such food does not refer to a specific species of fish | 'Fish' |
| All types of poultrymeat where such meat constitutes an ingredient of another food and provided that the labelling and presentation of such a food does not refer to a specific type of poultrymeat | 'Poultrymeat' |
| All types of cheese where the cheese or mixture of cheeses constitutes an ingredient of another food and provided that the labelling and presentation of such food does not refer to a specific type of cheese | 'Cheese' |
| All spices and spice extracts not exceeding 2% by weight either singly or in combination in the food | 'Spice', 'spices', or 'mixed spices', as appropriate |
| All herbs or parts of herbs not exceeding 2% by weight either singly or in combination in the food | 'Herbs' or 'mixed herbs', as appropriate |
| All types of gum preparations used in the manufacture of gum base for chewing gum | 'Gum base' |
| All types of sucrose | 'Sugar' |
| Anhydrous dextrose and dextrose monohydrate | 'Dextrose' or 'glucose' |
| All types of caseinates | 'Caseinates' |
| Milk products containing a minimum of 50% of milk protein (m/m) in dry matter* | 'Milk Protein' |
| Press, expeller or refined cocoa butter | 'Cocoa butter' |
| All crystallized fruit not exceeding 10% of the weight of the food | 'Crystallized fruit' |

* Calculation of milk protein content : Kjeldahl nitrogen × 6.38

4.2.3.2 Notwithstanding the provision set out in Section 4.2.3.1, pork fat, lard and beef fat shall always be declared by their specific names.

4.2.3.3 For food additives falling in the respective classes and appearing in lists of food additives permitted for use in foods generally, the following class titles shall be used together with the specific name or recognized numerical identification as required by national legislation.

- Acidity Regulator
- Acids
- Anticaking Agent
- Antifoaming Agent
- Antioxidant
- Bulking Agent
- Colour
- Colour Retention Agent
- Emulsifier
- Emulsifying Salt
- Firming Agent
- Flour Treatment Agent
- Flavour Enhancer
- Foaming Agent
- Gelling Agent
- Glazing Agent
- Humectant
- Preservative
- Propellant
- Raising Agent
- Stabilizer
- Sweetener
- Thickener

4.2.3.4 The following class titles may be used for food additives falling in the respective classes and appearing in lists of food additives permitted generally for use in foods:

- Flavour(s) and Flavouring(s)
- Modified Starch(es)

The expression "flavours" may be qualified by "natural", "nature identical", "artificial" or a combination of these words as appropriate.

4.2.4 Processing aids and carry-over of food additives

4.2.4.1 A food additive carried over into a food in a significant quantity or in an amount sufficient to perform a technological function in that food as a result of the use of raw materials or other ingredients in which the additive was used shall be included in the list of ingredients.

4.2.4.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additives and processing aids listed in section 4.2.1.4.

4.3 Net contents and drained weight

4.3.1 The net contents shall be declared in the metric system ("Systèeme International" units).[3]

4.3.2 The net contents shall be declared in the following manner:

(i) for liquid foods, by volume;

(ii) for solid foods, by weight;

(iii) for semi-solid or viscous foods, either by weight or volume.

4.3.3 In addition to the declaration of net contents, a food packed in a liquid medium shall carry a declaration in the metric system of the drained weight of the food. For the purposes of this requirement, liquid medium means water, aqueous solutions of sugar and salt, fruit and vegetable juices in canned fruits and vegetables only, or vinegar, either singly or in combination.[4]

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3 The declaration of net contents represents the quantity at the time of packaging and is subject to enforcement by reference to an average system of quantity control.

4.4 Name and address

The name and address of the manufacturer, packer, distributor, importer, exporter or vendor of the food shall be declared.

4.5 Country of origin

4.5.1 The country of origin of the food shall be declared if its omission would mislead or deceive the consumer.

4.5.2 When a food undergoes processing in a second country which changes its nature, the country in which the processing is performed shall be considered to be the country of origin for the purposes of labelling.

4.6 Lot identification

Each container shall be embossed or otherwise permanently marked in code or in clear to identify the producing factory and the lot.

4.7 Date marking and storage instructions

4.7.1 If not otherwise determined in an individual Codex standard, the following date marking shall apply:

(i) The "date of minimum durability" shall be declared.

(ii) This shall consist at least of:

- the day and the month for products with a minimum durability of not more than three months;
- the month and the year for products with a minimum durability of more than three months. If the month is December, it is sufficient to indicate the year.

(iii) The date shall be declared by the words:

- "Best before ..." where the day is indicated;
- "Best before end ..." in other cases.

(iv) The words referred to in paragraph (iii) shall be accompanied by:

- either the date itself; or
- a reference to where the date is given.

(v) The day, month and year shall be declared in uncoded numerical sequence except that the month may be indicated by letters in those countries where such use will not confuse the consumer.

(vi) Notwithstanding 4.7.1(i) an indication of the date of minimum durability shall not be required for:

- fresh fruits and vegetables, including potatoes which have not been peeled, cut or similarly treated;
- wines, liqueur wines, sparkling wines, aromatized wines, fruit wines and sparkling fruit wines;
- beverages containing 10% or more by volume of alcohol;
- bakers' or pastry-cooks' wares which, given the nature of their content, are normally consumed within 24 hours of their manufacture;
- vinegar;
- food grade salt;

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4 The declaration of drained weight is subject to enforcement by reference to an average system of quantity control.

- solid sugars ;
- confectionery products consisting of flavoured and/or coloured sugars ;
- chewing gum.

4.7.2 In addition to the date of minimum durability, any special conditions for the storage of the food shall be declared on the label if the validity of the date depends thereon.

4.8 Instructions for use

Instructions for use, including reconstitution, where applicable, shall be included on the label, as necessary, to ensure correct utilization of the food.

## 5. ADDITIONAL MANDATORY REQUIREMENTS

5.1 Quantitative ingredients declaration

5.1.1 The ingoing percentage of an ingredient (including compound ingredients[5] or categories of ingredients[6]), by weight or volume as appropriate, at the time of manufacture, shall be disclosed for foods sold as a mixture or combination where the ingredient :

(a) is emphasised as present on the label through words or pictures or graphics ; or

(b) is not within the name of the food, is essential to characterise the food and is expected to be present in the food by consumers in the country where the food is sold if the omission of the quantitative ingredient declaration would mislead or deceive the consumer.

Such disclosure is not required :

(c) where the ingredient is used in small quantities for the purpose of flavouring ; or

(d) where commodity specific standards of Codex Alimentarius conflict with the requirements described here.

With respect to 5.1.1(a) :

(e) a reference in the name of the food to an ingredient or category of ingredients shall not of itself require quantitative ingredient declaration if :

- that reference would not mislead or deceive or would not be likely to create an erroneous impression to the consumer regarding the character of the food in the country of marketing because the variation in quantity of the ingredient(s) between products is not necessary to characterise the food or distinguish it from similar foods.

5.1.2 The information required in Section 5.1.1 shall be declared on the product label as a numerical percentage. The ingoing percentage, by weight or volume as appropriate, of each such ingredient shall be given on the label in close proximity to the words or pictures or graphics emphasising the particular ingredient, or beside the percentage where emphasis is on the presence of the ingredient and a maximum percentage where emphasis is on the low level of the ingredient.

For foodstuffs which have lost moisture following heat or other treatment, the percentage (by weight or by volume) shall correspond to the quantity of the ingredient(s) used, related to the finished product.

When the quantity of an ingredient or the total quantity of all ingredients expressed on the labelling exceeds 100%, the percentage may be replaced by the declaration of the weight of the ingredient(s) used to prepare 100g of finished product.

5.2 Irradiated foods

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5 For compound ingredients the ingoing percentage means the ingoing percentage of the compound ingredient as a whole.

6 For the purposes of Quantitative Ingredient Declaration, "category of ingredients" means the generic term which refers to the class name of an ingredient and/or any similar common term(s) which are used in reference to the name of a food.

5.2.1 The label of a food which has been treated with ionizing radiation shall carry a written statement indicating that treatment in close proximity to the name of the food. The use of the international food irradiation symbol, as shown below, is optional, but when it is used, it shall be in close proximity to the name of the food.

5.2.2 When an irradiated product is used as an ingredient in another food, this shall be so declared in the list of ingredients.

5.2.3 When a single ingredient product is prepared from a raw material which has been irradiated, the label of the product shall contain a statement indicating the treatment.

## 6. EXEMPTIONS FROM MANDATORY LABELLING REQUIREMENTS

With the exception of spices and herbs, small units, where the largest surface area is less than 10 $cm^2$ , may be exempted from the requirements of paragraphs 4.2 and 4.6 to 4.8.

## 7. OPTIONAL LABELLING

7.1 Any information or pictorial device written, printed, or graphic matter may be displayed in labelling provided that it is not in conflict with the mandatory requirements of this standard and those relating to claims and deception given in Section 3 – General Principles.

7.2 If grade designations are used, they shall be readily understandable and not be misleading or deceptive in any way.

## 8. PRESENTATION OF MANDATORY INFORMATION

8.1 General

8.1.1 Labels in prepackaged foods shall be applied in such a manner that they will not become separated from the container.

8.1.2 Statements required to appear on the label by virtue of this standard or any other Codex standards shall be clear, prominent, indelible and readily legible by the consumer under normal conditions of purchase and use.

8.1.3 Where the container is covered by a wrapper, the wrapper shall carry the necessary information or the label on the container shall be readily legible through the outer wrapper or not obscured by it.

8.1.4 The name and net contents of the food shall appear in a prominent position and in the same field of vision.

8.2 Language

8.2.1 If the language on the original label is not acceptable, to the consumer for whom it is intended, a supplementary label containing the mandatory information in the required language may be used instead of relabelling.

8.2.2 In the case of either relabelling or a supplementary label, the mandatory information provided shall be fully and accurately reflect that in the original label.

CODEX, WTO-SPS, IPPC 2008년 채택기준

국제기준 협정관리 자료집

# WTO-SPS(2008)

농림수산식품부

한국농림수산정보센터

# RECOMMENDED PROCEDURES FOR IMPLEMENTING THE TRANSPARENCY OBLIGATIONS OF THE SPS AGREEMENT (ARTICLE 7)

## AS OF 1 DECEMBER 2008

**Revision**[1]

1. The term transparency in the context of the World Trade Organization (WTO) is used to signify one of the fundamental principles of its agreements: the aim is to achieve a greater degree of clarity, predictability and information about trade policies, rules and regulations of Members. In implementing this concept Members use notifications. Under the SPS Agreement, notifications are used to inform other Members about new or changed regulations that may significantly affect their trading partners.[2] Transparency under the SPS Agreement also includes answering reasonable questions, and publishing regulations.

2. These procedures have been developed to assist Members fulfil their transparency obligations under Article 7 and Annex B of the SPS Agreement regarding the notification of SPS regulations, answering information requests under the National Enquiry Point system and publishing regulations.

3. These guidelines do not add to nor detract from the existing rights and obligations of Members under the SPS Agreement nor any other WTOAgreement. These guidelines do not provide any legal interpretation or modification to the SPS Agreement itself.

### IDENTIFICATION OF THE NATIONAL NOTIFICATION AUTHORITY AND OF THE NATIONAL ENQUIRY POINT

4. In accordance with paragraph 10 of Annex B of the SPS Agreement, Members are obliged to designate "a single central government authority" as responsible for the implementation at the national level of the provisions concerning notification procedures. Paragraph 3 of Annex B of the SPS Agreement indicates that each Member "shall ensure that one enquiry point exists" which is responsible for the provision of answers to all reasonable questions as well as the provision of relevant documents.[3]

5. When a Member's National Notification Authority or National Enquiry Point has been designated, or changed, the WTO Secretariat should be informed. The Secretariat regularly circulates a list of all Members' National Notification Authorities and National Enquiry Points, and this information is also available through the WTO's SPS web page (www.wto.org) and through the SPS Information Management System (http://spsims.wto.org). The National Enquiry Points are listed in the G/SPS/

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1 At its meeting of 2-3 April 2008, the SPS Committee adopted the revised Recommended Procedures for Implementing the Transparency Obligations of the SPS Agreement (Article 7) on an ad referendum basis. Members who objected to the adoption of the guidelines were asked to make this known by 30 May 2008. No objections were raised by that date. In light of the required modifications to the SPS Information Management System (SPS IMS), which the Secretariat uses to generate and report on SPS notifications, these procedures, including the revised notification formats, will take effect as of 1 December 2008.

2 The SPS Agreement uses the terms 'measures' and 'regulations' somewhat interchangeably when referring to any sanitary or phytosanitary measure such as laws, decrees, or ordinances applied to protect human, animal or plant life or health as defined under paragraph 1 of Annex A to the SPS Agreement.

3 In practice, a number of Members have decided to designate the same entity as the Enquiry Point and the National Notification Authority while others have found it more functional to establish more than one Enquiry Point to cover the areas of food safety, animal and plant health.

ENQ/ document series of the WTO, and the notification authorities are listed in the G/SPS/NNA/ series. It is useful to provide the following contact information so that they can be included in the lists :

- Contact name
- Name of institution
- Postal address / physical address
- Phone
- Fax
- E-mail
- Website address

**RECOMMENDED NOTIFICATION PROCEDURES**

6. Members should follow these procedures when notifying regulations as required in paragraphsor 6 of Annex B of the SPS Agreement. The form for routine notifications (see Annex A-1 of these procedures) should be used for notifications in accordance with paragraph 5 of Annex B of the SPS Agreement, whereas the form for emergency notifications (see Annex B-1 of these procedures) should be used for notifications as provided for in paragraph 6 of Annex of the SPS Agreement.

A. APPLICATION OF ANNEXPARAGRAPH 5 (PREAMBULAR PART) OF THE SPS AGREEMENT

7. In accordance with Article 7 and paragraph 5 of Annex B of the SPS Agreement, Members are required to notify all regulations the content of which is "not substantially the same as the content of an international standard, guideline or recommendation", if such regulations are expected to have a significant effect on trade of other Members.

8. Members are encouraged to notify all regulations that are based on, conform to, or are substantially the same as an international standard, guideline or recommendation, if they are expected to have a significant effect on trade of other Members.[4]

9. For the purposes of Annexparagraphs 5 and 6 of the SPS Agreement, the concept of "significant effect on trade of other Members" may refer to the effect on trade :

   - of one sanitary or phytosanitary regulation only or of various sanitary or phytosanitary regulations in combination ;
   - in a specific product, group of products or products in general ; and
   - between two or more Members.

10. To assess whether the sanitary or phytosanitary regulation may have a significant effect on trade, the Member concerned should consider relevant available information such as : the value or other importance of imports to the importing and/or exporting Members concerned, whether from other Members individually or collectively ; the potential development of such imports ; and difficulties for producers in other Members, particularly in developing country Members, to comply with the proposed sanitary or phytosanitary regulations. The concept of a significant effect on trade of other Members should include both import-enhancing and import-reducing effects on the trade of other Members, as long as such effects are significant.

B. TIMING OF NOTIFICATIONS

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4 The Secretariat should provide an annual report on the level of implementation of the transparency provisions of the SPS Agreement and of the recommended transparency procedures contained in this document, including, *inter alia*, an overview of those notifications which relate to the adoption of international standards, guidelines and recommendations by Members.

11. Paragraph 5(a) of Annex B of the SPS Agreement obliges Members to publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with a proposal to introduce a particular regulation. This is useful so that other Members are better able to assess and if necessary, comment on the proposed measures. Members may wish to provide information to the SPS Committee regarding expected modifications to their national regulatory systems.

12. Paragraph 5(b) of Annex B of the SPS Agreement obliges Members to submit a notification at an early stage when amendments can still be introduced and comments taken into account. This should be donewhen a draft of the complete text of a regulation is available.

13. Paragraph 5(d) of Annex B of the SPS Agreement obliges Members to allow a reasonable period of time for submission, discussion and consideration of comments. Members should normally allow a period of at least sixty calendar days for comments, except for proposed measures which facilitate trade[5] and those which are substantially the same as an international standard, guideline, or recommendation. Where domestic regulatory mechanisms allow, the 60-day comment period should normally begin with the circulation of the notification by the WTO Secretariat. Any Member which is able to provide a time-limit beyond sixty days is encouraged to do so.

14. A notification should be made well before the entry into force of the relevant measure, except when urgent problems of health protection arise or threaten to arise for the Member concerned. In accordance with paragraph 6(a)of Annex B of the SPS Agreement, any regulation brought into force in urgent circumstances is required to be notified immediately and a rationale for the urgent action provided.

15. The late notification of a measure already in force does not in and of itself constitute sufficient reason for theuse of the emergency format. When urgent problems of health protection are not involved, late notifications should be made using the regular format and consideration should still be given to all comments received, in accordance with paragraph 5(d) of Annex B of the SPS Agreement.

C. REQUESTING DOCUMENTS RELATED TO A NOTIFICATION

16. Members requesting documents related to a notification should provide all the information necessary to identify the documents and in particular the WTO SPS notification number to which the requests refer.

17. When requesting an electronic transmission of documents from another Member, Members should indicate which electronic formats they are able to receive, including compatible versions.

D. PROVIDING DOCUMENTS RELATED TO A NOTIFICATION

*Address of body supplying the documents*

18. Members should indicate under point 13 of the WTO notification format the full address of the body responsible for supplying the relevant documents if that body is not the National Notification Authority or the National Enquiry Point. Where the relevant documents are also available from a website, the website address or a specific hyperlink to these documents should be provided.

*Responding to requests*

19. Members are obliged to provide upon request to other Members copies of the proposed regulation in accordance with paragraph 5(c) of Annex B of the SPS Agreement. Documents requested should normally be provided within five working days. If this is not possible, the request for documentation or information should be acknowledged within that period and an estimate given of the time required to provide the requested documentation. With a view to facilitating the timely provision of comments on notifications, Members are strongly encouraged to comply with the five-day deadline.

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5 Trade facilitating measures could include, *inter alia*, the raising of the level of maximum residue limits of certain pesticides in certain products, the lifting of a ban on imports, or the simplification or elimination of certain certification/ approval procedures.

20. Documents supplied in response to a request should be identified with the WTO SPS notification number to which the request refers.

21. Members should use fax and E-mail facilities to the extent possible in responding to requests for documentation or information. Members are encouraged to publish their sanitary or phytosanitary measures on the Internet, to facilitate the supply of documents, and to provide the address of relevant websites.

22. Members may also submit an electronic version of the text of the notified draft regulation together with the notification format. These texts are stored on a WTO server and are accessible through a hyperlink in the notification format.[6] Information about the provision, storage, and language of attachments to SPS notifications is contained in Annex C of these procedures.

*Acknowledging receipt of documents*

23. The Member requesting documents relating to a notification should acknowledge receipt of the documents provided.

*Translation of documents*

24. When a translation of a relevant document exists or is planned, this fact should be indicated on the WTO notification form next to the title of the document. If only a translated summary exists, the fact that such a summary is available should be similarly indicated.

25. If a translation of a document or summary exists in the language of the requesting Member, or, as the case may be, in the WTO working language used by the requesting Member, it should be automatically sent with the original of the document requested.

26. Where documents are not available in a WTO working language, developed country Members shall, upon request, supply a translation of the document, or in case of voluminous documents, a translation of a summary of the document, in a WTO working language in accordance with paragraph8 of Annex B of the SPS Agreement.

27. When a Member seeks a copy of a document relating to a notification which does not exist in that Member's WTO working language, the notifying Member should advise the requesting Member of other Members that have requested, as of that date, a copy of the document. The Member seeking a copy of a document relating to a notification may contact other Members in order to determine whether the latter are prepared to share any translation that they have or will be making.

28. Any Member possessing an unofficial translation of a document relating to a notification should inform the notifying Member of the existence of the unofficial translation and should submit to the Secretariat a supplement to the original notification submitted by a Member. The supplement should indicate the address for requesting a copy or the website address where the unofficial translation can be found. The format of the supplement can be found in Annex D of these procedures. Neither the Secretariat nor the Member providing the unofficial translation can be held responsible for the accuracy or quality of these translations.[7]

## E. HANDLING OF COMMENTS ON NOTIFICATIONS

29. Each Member should notify the WTOSecretariat of the authority or agency (e.g. its National Notification Authority) which it has designated to be in charge of handling comments received, and of any change and/or modification of such authority or agency.

30. Members submitting comments on a notified draft regulation should provide them without unnecessary delay to the authority designated to handle the comments, or to the National Notification Authority if no other designation is made.

31. A Member receiving comments through the designated body should, without further request :

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6 See G/SPS/GEN/818.

7 See G/SPS/GEN/487 for further information on this mechanism.

(i) acknowledge the receipt of such comments;

(ii) explain within a reasonable period of time, and at the earliest possible date before the adoption of the measure, to any Member from which it has received comments, how it will take these comments into account and, where appropriate, provide additional relevant information on the proposed sanitary or phytosanitary regulations concerned;

(iii) provide to any Member from which it has received comments, a copy of the corresponding sanitary or phytosanitary regulations as adopted or information that no corresponding sanitary or phytosanitary regulations will be adopted for the time being.

32. A Member receiving comments through the designated body may consider making available to other Members, where possible, non-confidential comments and questions it has received and answers it has provided, or summaries thereof, preferably via electronic means.

33. Members should grant requests for extension of the comment period wherever practicable, in particular with regard to notifications relating to products of particular interest to developing country Members, where there have been delays in receiving and translating the relevant documents or where there is a need for further clarification of the measure notified. A 30-day extension should normally be provided and notified to the WTO (see section below on Addenda).

34. Members are also encouraged to use the "Procedure to Enhance Transparency of Special and Differential Treatment in Favour of Developing Countries" (G/SPS/33).

F. ADDENDA, REVISIONS AND CORRIGENDA

35. In addition to their original notifications, Members can also provide supplementary information in three different forms:

- An addendum is used to provide additional information or changes to an original notification. A Member may wish to indicate on the addendum if the final regulation has been substantially modified from the notified proposal.
- A corrigendum is used to correct an error in an original notification such as an incorrect address detail.
- A revision is used to replace an existing notification.

Any addendum or corrigendum should be read in conjunction with the original notification.

**Addenda**

36. Members should notify changes in the status of a notified SPS regulation. The issuance of an addendum allows Members to track the status of an SPS regulation via its unique notification number. Addenda to SPS notifications should be made in a number of circumstances, such as:

(a) if the comment period has been extended;

(b) when a proposed regulation is either adopted, published or comes into force, if the relevant dates have not been provided in the original notification or have been changed. Members are strongly encouraged to follow this recommendation and inform other Members in a timely manner. A Member may wish to indicate on the addendum if the final regulation has been substantially modified from the notified proposal;

(c) if the content of a previously notified draft regulation ispartially changed, or if the scope of application of the existing notification is modified, either in terms of Members affected or products covered. Such an addendum should provide for a new 60-day comment period unless the notified change is of a trade-facilitating nature or is negligible. Where domestic regulatory mechanisms allow, the 60-day comment period should normally begin with the circulation of the notification by the WTO Secretariat

(d) if a proposed regulation is withdrawn;

(e) in the case of an emergency notification, an addendum should also be submitted if the period of application of the existing notification is extended.

37. An addendum should:

- briefly recap what was notified, when and what it was about - this is a practical requirement, and reduces the need for Members to have to go back to the original notification to check what it was about;
- specify what change has been made and why - briefly state why the information, dates, etc. have been changed; and
- restate the comments deadline, even if it has not been changed - as a reminder to Members that if they wish to comment it must be done by this date.

38. A form for making an addendum is available in Annex A-2 of these procedures for routine notifications and in Annex B-2 for notifications of emergency measures.

**Revisions**

39. Revisions **replace** an existing notification. Revisions should be submitted, for example, if a notified draft regulation was substantially redrafted or if a notification contained a large number of errors. A Member should provide a further period for comments on the revised notification, normally 60 calendar days, unless the notified change is of a trade-facilitating nature or would have a negligible effect on trade. Where domestic regulatory mechanisms allow, the 60-day comment period should normally begin with the circulation of the revised notification by the WTO Secretariat.

40. A form for making a revision is available in Annex A-3 of these procedures for routine notifications and Annex B-3 for notifications of emergency measures.

**Corrigenda**

41. Members should inform the Secretariat of any error(s) contained in their original notification. The Secretariat will issue a corrigendum accordingly.

42. A form for making a corrigendum is available in Annex A-4 of these procedures for routine notifications and Annex B-4 for notifications of emergency measures.

G. REGULATIONS THAT CONTAIN BOTH SPS AND TBT MEASURES

43. When a regulation contains both SPS and TBT measures, it should be notified according to both the SPS and TBT Agreements, preferably with an indication of which parts of the regulation fall under the SPS Agreement (e.g., a food safety measure) and which parts fall under the TBT Agreement (e.g., quality or compositional requirements).

H. NOTIFICATION OF DETERMINATION OF THE RECOGNITION OF EQUIVALENCE OF SANITARY OR PHYTOSANITARY MEASURES[8]

44. In accordance with the Decision on Equivalence (G/SPS/19/Rev.2), a Member which has made a determination recognizing the equivalence of sanitary or phytosanitary measures of another Member or Members shall notify other Members through the Secretariat of the measure(s) recognized to be equivalent and of the products affected by this recognition.

45. For the purposes of this notification, equivalence is defined to be the state wherein sanitary or

8 AT ITS MEETING OF 25-26 JUNE 2002, THE COMMITTEE ADOPTED A FORMAT AND RECOMMENDED PROCEDURES FOR THE NOTIFICATION OF DETERMINATION OF THE RECOGNITION OF EQUIVALENCE OF SANITARY OR PHYTOSANITARY MEASURES WHICH CAN BE FOUND IN G/SPS/7/REV.2/ADD.1. THIS DOCUMENT HAS BEEN INCORPORATED INTO THIS REVISION.

phytosanitary measures applied in an exporting Member, though different from the measures applied in an importing Member, achieve, as demonstrated by the exporting Member and recognized by the importing Member, the importing Member's appropriate level of sanitary or phytosanitary protection. A determination of the recognition of equivalence may be with respect to a specific measure or measures related to a certain product or categories of products, or on a systems-wide basis.

46. Notification should also be made of significant variations to existing equivalence arrangements, including their suspension or rescission.

47. See Annex E of these procedures for further information on the format for the Notification of Determination of the Recognition of Equivalence of Sanitary or Phytosanitary Measures.

### I. completed notifications

48. Notifications should be sent, preferably by E-mail, but if notby fax or air mail, from the National Notification Authority to the central registry of notifications (CRN) at the WTO. The address is:

Central Registry of Notifications
World Trade Organization
Rue de Lausanne 154
1211 Geneva 21
Switzerland
Fax: (+41 22) 739 5638
E-mail: crn@wto.org

49. Electronic copies of all notification formats can be downloaded from the WTO website at: http://www.wto.org/english/tratop_e/sps_e/sps_e.htm

50. Members may submit electronic copies, in PDF format, of proposed regulations along with the corresponding notifications to the WTO Secretariat. These texts will be accessible, in the format and language provided, through a hyperlink in the notification format (see paragraph 22).

51. In addition, Members are encouraged to provide a website address or a specific hyperlink, if available, for the relevant documents in the appropriate section of the notification format.

## GUIDELINES FOR NATIONAL ENQUIRY POINTS

52. The National Enquiry Point system established in paragraph 3 of Annex B of the SPS Agreement is an effective avenue for obtaining information regarding SPS systems and measures from other Members.

53. The National Enquiry Point handles on a routine basis:

- document and information requests;
- general enquiries; and
- delivery and charging of documents.

54. National Enquiry Points should also provide, upon request, information on participation in any bilateral or multilateral equivalence agreements and arrangements in accordance with paragraph 3(d) of Annex B of the SPS Agreement.

55. While the mode of delivery is at the discretion of the Member concerned, it is recommended that delivery of documents should be by the fastest means possible. In the first instance, if the Member has such facilities, the documents should be made accessible through a website or sent by E-mail or by fax. Alternatively, a Member can send the documents by post or via a requesting Member's diplomatic mission in their territory.

56. A Member may only charge the same cost for the documents as it would for its own nationals

plus the cost of delivering the documents in accordance with paragraph 4 of Annex B of the SPS Agreement.

57. Members should also refer to the guidelines on transparency contained in the handbook *How to apply the transparency provisions of the SPS Agreement* (November 2000), when notifying regulations and operating National Enquiry Points in accordance with Article 7 and Annex B of the SPS Agreement.[9]

## PUBLICATION OF REGULATIONS

58. The publication of regulations is a fundamental component of transparency under the SPS Agreement. This is a general obligation on Members, and does not relate specifically to the work of either the National Notification Authority or National Enquiry Point.

59. In accordance with paragraphs 1 and 2 of Annex B of the SPS Agreement, Members are obliged to:

(a) ensure that all SPS regulations which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them. Regulations to be published include laws, decrees or ordinances which are applicable generally;

(b) except in urgent circumstances, allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting Members and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member.

60. As agreed in the Doha Decision on Implementation-Related Issues and Concerns (WT/MIN(01)/17, para. 3.2):

Subject to the conditions specified in paragraph 2 of Annex B to the Agreement on the Application of Sanitary and Phytosanitary Measures,the phrase "reasonable interval" shall be understood to mean normally a period of not less than 6 months. It is understood that timeframes for specific measures have to be considered in the context of the particular circumstances of the measure and actions necessary to implement it. The entry into force of measures which contribute to the liberalization of trade should not be unnecessarily delayed.

61. The reasonable interval specified above between the publication and entry into force of new regulations should be provided, including when these are based on, conform to, or are substantially the same as an international standard, guideline, or recommendation.

62. Members are encouraged to publish SPS regulations on the Internet where possible. Publication on the Internet has a number of advantages and benefits to Members over more traditional methods. It:

(a) allows for greater transparency;

(b) makes it easier for Members to obtain documents; and

(c) reduces the amount of work involved in processing and fulfilling document requests.

### ACCESS to international electronicresources related to SPS notifications and other SPS INFOrmation

63. There are a number of international resources on the Internet which could facilitate Members' access to SPS-related information. These include the WTOSecretariat's Documents Online Facility and SPS Information Management System (SPS IMS) (http://spsims.wto.org) as well as the FAO's International Portal on Food Safety, Animal and Plant Health (http://www.ipfsaph.org).

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9 A practical procedural manual on the operation of National Enquiry Points and Notification Authorities is under preparation. Once it is finalized, the manual will be posted on the WTO website for access by all interested parties.

64. Members are encouraged to provide the WTO Secretariat up-to-date information regarding SPS-related websites within their territory for inclusion on the WTO's SPS web page.Official national SPS-related documentation and information can also be provided to the FAO's International Portal on Food Safety, Animal and Plant Health for publication.

# COMPLETION OF FORMATS - ROUTINE NOTIFICATIONS (ANNEX B, PARAGRAPH OF THE SPS AGREEMENT)

Information contained in the notifications should be as complete as possible and no section should be left blank. Where necessary, "not known" or "not stated" should be indicated.

| Item | Description |
|---|---|
| 1. Member notifying | Government, including the competent authorities of the European Communities, which is making the notification. |
| 2. Agency responsible | Body elaborating a proposal for or promulgating a sanitary or phytosanitary regulation. |
| 3. Products covered | Tariff item number(s) (normally HS, chapter or heading and number) as contained in national schedules deposited with the WTO. ICS numbers should be provided in addition, where applicable. A clear description is important for an understanding of the notification by delegations and translators. Abbreviations should be avoided. |
| 4. Regions or countries likely to be affected | The geographical regions or countries likely to be affected by the notified regulation should be identified to the extent relevant or practicable. Members are encouraged to be as specific as possible in identifying regions or countries likely to be affected. |
| 5. Title, language and number of pages of the notified document | Title of the proposed or adopted (in the case of late submissions) sanitary or phytosanitary regulation. Number of pages in the notified document. Languages in which the notified document is available.<br><br>If a translation of the whole document or its summary exists, indicate this here.<br><br>If a Member submits the text of the draft regulation or a summary or translation thereof in PDF format along with the notification, the WTO Secretariat will facilitate access to this text through a hyperlink in the notification format. |
| 6. Description of content | A summary of the proposed or adopted (in the case of late submissions) sanitary or phytosanitary regulation clearly indicating its content and health protection objective. The summary should be as complete and accurate as possible to allow the full understanding of the proposed regulation. To the extent possible, likely effects on trade should be described. Abbreviations should be avoided. Where practicable it should also include an outline of the specific sanitary measures the regulation will apply. The summary should enable trading partners to determine whether thenotified measure is likely to have an impact on products they wish to export to the notifying Member.<br><br>When a regulation contains both SPS and TBT measures, it should be notified according to both the SPS and TBT Agreements, preferably with an indication of which parts of the regulation fall under the SPS Agreement and which parts fall under the TBT Agreement. |
| 7. Objective and rationale | State whether objective is : protection of human health from food-borne risks ; or protection of human health from plant-or animal-carried diseases ; or protection of animal health from pests or diseases ; or protection of animal health from contaminated feed; or protection of plant health from pests or diseases ; or prevention of other damage from entry, establishment or spread of pests. |

| Item | Description |
|---|---|
| 8. Existence of international standard, guideline or recommendation | If a relevant international standard, guideline or recommendation exists, put a cross in the box provided for the appropriate standard-setting organization and give the appropriate reference of the existing standard, guideline or recommendation, e.g., Codex standard number, ISPM number, OIE Code chapter. Indicate whether the proposed regulation conforms to the relevant international standard and if not, describe, whenever possible,how and whythe proposed regulation deviates from the international standard, guideline or recommendation.<br><br>If no international standard, guideline or recommendation exists, put a cross in the box "none". |
| 9. Other relevant documents and language(s) in which these are available | Documents referenced here are different from those listed in box 5.<br>Documents which should be referenced include :<br>(a) Publication where notice of the proposed regulation appears, including date and reference numbers ;<br>(b)oposal and basic document to which proposal refers (with specific reference number or other identification), and the language(s) in which the notified documents and any summary of these are available ;<br>(c) Publication in which proposal will appear when adopted.<br>If it is necessary to charge for documents supplied, the amount of the charge should be indicated.<br>Provide the website address and hyperlink for these documents where available.<br>If a Member submits texts of referenced documents in PDF format along with the notification to the WTO Secretariat, hyperlinks to these texts will be made available under this item. |
| 10. Proposed date of adoption and of publication | The date when the sanitary or phytosanitary regulation is expected to be adopted. Also provide where possible the proposed date of publication of the final measure if this differs from the date of adoption. |
| 11. Proposed date of entry into force | The date from which the requirements in the regulation are proposed or decided to enter into force shall normally be at least six months following the above date of adoption and/or publication.<br><br>Where appropriate, Members should accord longer time-frames for compliance on products of interest to developing country Members. This shall normally be a period of not less than six months.[10]<br><br>Put a cross in the box if the proposed measure contributes to the liberalization of trade. In this case,the implementation of the measure should not be unnecessarily delayed and no comment period need be provided. |
| 12. Final date for comments and agency or authority handling comments | The date by which Members may submit comments in accordance with Annex B, Paragraph 5(b) of the SPS Agreement. A Member should normally allow a period of at least sixty calendar days for comments. Check the box if this is 60 calendar days following the date of circulation of the notification as a WTOdocument, the Secretariat will indicate the corresponding date. If not, a specific date should be indicated. Any Member which is able to provide a time limit beyond 60 days is encouraged to do so. |

10 Doha Decision on Implementation-Related Issues and Concerns (WT/MIN/(01)/17, para.3.1).

| Item | Description |
|---|---|
| | The agency or authority which has been designated to handle the comments should be indicated. If this is the National Notification Authority or the National Enquiry Point, put a cross in the box provided. If another agency or authority has been designated, provide its name, address, fax and (if available) E-mail address.<br><br>For proposed measures which facilitate trade or those which are substantially the same as an international standard, guideline or recommendation, Members may reduce or eliminate the period for receiving comments. |
| 13. Texts available from | If available from the National Notification Authority or the National Enquiry Point, put a cross in the respective box. If available from another body, give its address, fax number and (if available) E-mail address. Such indications do not in any way discharge the relevant National Enquiry Point of its responsibilities under the provisions of Annex B, Paragraphs 3 and 4 of the SPS Agreement.<br>Provide the website address and specific hyperlink of the document notified, if available.<br>If a Member submits the text of the draft regulation in PDF format along with the notification, a hyperlink to this text will be made available under this item. |

# World Trade Organization

**G/SPS/N/COUNTRY/**
date of distribution
(##-####)

**Committee on Sanitary and Phytosanitary Measures** Original:

## NOTIFICATION

| | |
|---|---|
| 1. | Notifying Member :<br>If applicable, name of local government involved : |
| 2. | Agency responsible : |
| 3. | Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO ; ICS numbers should be provided in addition, where applicable) : |
| 4. | Regions or countries likely to be affected, to the extent relevant or practicable : [specific regions or countries] or [ ] all trading partners |
| 5. | Title, language and number of pages of the notified document : |
| 6. | Description of content : |
| 7. | Objective and rationale : [ ] food safety [ ] animal health [ ] plant protection<br>[ ] protect humans from animal/plant pest or disease<br>[ ] protect territory from other damage from pests |
| 8. | Is there a relevant international standard? If so, identify the standard :<br>[ ] Codex Alimentarius Commission<br>[(e.g., title or serial number of Codex standard or related text)]<br>[ ] World Organization for Animal Health (OIE)<br>[(e.g., Terrestrial or Aquatic Animal Health Code, chapter number)]<br>[ ] International Plant Protection Convention<br>[(e.g., ISPM N° )]<br>[ ] None<br>Does this proposed regulation conform to the relevant international standard? [ ] Yes [ ] No<br>If no, describe, whenever possible, how and why it deviates from the international standard : |
| 9. | Other relevant documents and language(s) in which these are available : |
| 10. | Proposed date of adoption (dd/mm/yy) :<br>Proposed date of publication (dd/mm/yy) : |
| 11. | Proposed date of entry into force (dd/mm/yy) : [ ] Six months from date of publication<br>and/or [DATE : dd/mm/yy]<br>[ ] Trade facilitating measure |
| 12. | Final date for comments : [ ] Sixty days from the date of circulation of the notification ([DATE])<br>or [DATE : dd/mm/yy]<br>Agency or authority designated to handle comments : [Notification Authority, [ ] National Enquiry Point, or address, fax number and E-mail address (if available) of other body : |
| 13. | Texts available from : [ ] National Notification Authority, [ ] National Enquiry Point, or address, fax number and E-mail address (if available) of other body : |

# World Trade Organization

**G/SPS/N/COUNTRY/**
date of distribution
(##-####)

**Committee on Sanitary and Phytosanitary Measures**

Original:

## NOTIFICATION

Addendum

The following communication, received on # Month Year, is being circulated at the request of the Delegation of [Member].

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Title outlining what the SPS measure or product is

[Text]

This addendum concerns a :

[ ] Modification of final date for comments

[ ] Notification of adoption, publication, or entry into force of regulation

[ ] Modification of content and/or scope of previously notified draft regulation

[ ] Withdrawal of proposed regulation

[ ] Change in proposed date of adoption, publication, or date of entry into force

[ ] Other [provide brief description]

Commentperiod: [If the addendum extends the scope of the previously notified measure in terms of products and/or potentially affected Members, a new deadline for receipt of comments should be provided, normally of at least 60 calendar days. Under other circumstances, such as extension of originally announced final date for comments, the comment period provided in the Addendum may vary.]

[ ] Sixty days from the date of circulation of the addendum to the notification ([DATE])

or [DATE : dd/mm/yy]

Agency or authority designated to handle comments : [ ] National Notification Authority, [ ] National Enquiry Point, or address, fax number and E-mail address (if available) of other body :

Text available from : [ ] National Notification Authority, [ ] National Enquiry Point, or address, fax number and E-mail address (if available) of other body :

# World Trade Organization

**G/SPS/N/COUNTRY/**
date of distribution
(##-####)

**Committee on Sanitary and Phytosanitary Measures**

Original:

## NOTIFICATION

**Revision**

| | |
|---|---|
| 1. | Notifying Member :<br>If applicable, name of local government involved : |
| 2. | Agency responsible : |
| 3. | Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO ; ICS numbers should be provided in addition, where applicable) : |
| 4. | Regions or countries likely to be affected, to the extent relevant or practicable : [specific regions or countries] or [ ] all trading partners |
| 5. | Title, language and number of pages of the notified document : |
| 6. | Description of content : |
| 7. | Objective and rationale : [ ] food safety [ ] animal health [ ] plant protection<br>[ ] protect humans from animal/plant pest or disease<br>[ ] protect territory from other damage from pests |
| 8. | Is there a relevant international standard? If so, identify the standard :<br>[ ] Codex Alimentarius Commission<br>[(e.g. title or serial number of Codex standard or related text)]<br>[ ] World Organization for Animal Health (OIE)<br>[(e.g., Terrestrial or Aquatic Animal Health Code, chapter number)]<br>[ ] International Plant Protection Convention<br>[(e.g., ISPM N° )]<br>[ ] None<br>Does this proposed regulation conform to the relevant international standard? [ ] Yes [ ] No<br>If no, describe, whenever possible, how and why it deviates from the international standard : |
| 9. | Other relevant documents and language(s) in which these are available : |
| 10. | Proposed date of adoption (dd/mm/yy) :<br>Proposed date of publication (dd/mm/yy) : |
| 11. | Proposed date of entry into force (dd/mm/yy) : [ ] Six months from date of publication and/or [DATE : dd/mm/yy]<br>[ ] Trade facilitating measure |
| 12. | Final date for comments : [ ] Sixty days from the date of circulation of the notification ([DATE]) or [DATE : dd/mm/yy]<br>Agency or authority designated to handle comments : [ ] National Notification Authority, [ ] National Enquiry Point, or address, fax number and E-mail address (if available) of other body : |
| 13. | Texts available from : [ ] National Notification Authority, [ ] National Enquiry Point, or address, fax number and E-mail address (if available) of other body : |

# World Trade Organization

**G/SPS/N/COUNTRY/#/Corr.#**
date of distribution
(##-####)

**Committee on Sanitary and Phytosanitary Measures** Original:

## NOTIFICATION

Corrigendum

The following communication, received on # Month Year, is being circulated at the request of the Delegation of [Member].

---

Title outlining what the SPS measure or product is

[Text]

Text available from : [Notification Authority, [ ] National Enquiry Point, or address, fax number and E-mail address (if available) of other body :

# COMPLETION OF FORMATS - EMERGENCY NOTIFICATIONS (ANNEX B, PARAGRAPH 6 OF THE SPS AGREEMENT)

Information contained in the notification form should be as complete as possible and no section should be left blank. Where necessary, "not known" or "not stated" should be indicated.

| Item | Description |
|---|---|
| 1. Member notifying | Government, including the competent authorities of the European Communities, which is making the notification. |
| 2. Agency responsible | Body elaborating a proposal for or promulgating a sanitary or phytosanitary regulation. |
| 3. Products covered | Tariff item number(s) (normally HS, chapter or heading and number) as contained in national schedules deposited with the WTO. ICS numbers should be provided in addition, where applicable. A clear description is important for an understanding of the notification by delegations and translators. Abbreviations should be avoided. |
| 4. Regions or countries likely to be affected | The geographical regions or countries likely to be affected by the notified regulation should be identified to the extent relevant or practicable. Members are encouraged to be as specific as possible in identifying regions or countries likely to be affected. |
| 5. Title, language and number of pages of the notified document | Title of the proposed or adopted (in the case of late submissions)sanitary or phytosanitary regulation. Number of pages in the notified document. Languages in which the notified document is available.<br><br>If a translation of the whole document or its summary exists, indicate this here.<br><br>If a Member submits the text of the draft regulation or a summary or translation thereof in PDFformat along with the notification, the WTO Secretariat will facilitate access to this text through a hyperlink in the notification format. |
| 6. Description of content | Asummary of the proposed or adopted sanitary or phytosanitary regulation clearly indicating its content and health protection objective. The summary should be as complete and accurate as possible to allow the full understanding of the proposed regulation. To the extent possible, likely effects on trade should be described. Abbreviations should be avoided. Where practicable it should also include an outline of the specific sanitary measures the regulation will apply. The summary should enable trading partners to determine whether the notified measure is likely to have an impact on products they wish to export to the notifying Member.<br>When a regulation contains both SPS andTBT measures, it should be notified according to both the SPS and TBT Agreements, preferably with an indication of which parts of the regulation fall under the SPS Agreement and which parts fall under the TBT Agreement. |
| 7. Objective and rationale | State whether objective is : protection of human health from food-borne risks ; or protection of human health from plant- or animal-carried diseases ; or protection of animal health from pests or diseases ; or protection of animal health from contaminated feed ; or protection of plant health from pests or diseases ; or prevention of other damage from entry, establishment or spread of pests. |

| Item | Description |
|---|---|
| 8. Natureofproblem(s) and reason for urgent action | Indication of the underlying reasons for resorting to emergency action, e.g., incursion of pests associated with imports, outbreak of a disease in supplying areas, etc. |
| 9. Existenceinternational standard, guideline or recommendation | If a relevant international standard, guideline or recommendation exists, put a cross in the box provided for the appropriate standard-setting organization and givethe appropriate reference of the existing standard, guideline or recommendation, e.g., Codex standard number, ISPM number, OIE Code chapter. Indicate whether the proposed regulation conforms to the relevant international standard and if not, describe, whenever possible,how and why the proposed regulation deviates from the international standard, guideline or recommendation.<br><br>If no international standard, guideline or recommendation exists, put a cross in the box "none". |
| 10. Other relevant documents and language(s) in which these are available | Documents referenced here are different from those listed in box 5.<br>Documents which should be referenced include :<br>(a) Measure(s) taken and basic regulation which was modified (with specific reference number or otheridentification), and the language(s) in which the notified documents and any summary of these are available;<br>(b) Publication in which regulation will appear.<br>If it is necessary to charge for documents supplied, the amount of the charge should be indicated.<br>Provide the website address and hyperlink for these documents where available.<br>If a Member submits texts of referenced documents in PDF format along with the notification to the WTO Secretariat, hyperlinks to these texts will be made available under this item. |
| 11. Date of entry into force and period of application | The date from which the requirements entered into force, and, if applicable, the period of time during which they will apply. (For example : immediate entry into force [date], duration of two months.)<br>Put a cross in the box if the proposed measure contributes to the liberalization of trade. |
| 12. Agency or authority handling comments | The agency or authority which has been designated to handle the comments should be indicated. If this is the National Notification Authority or the National Enquiry Point, put a cross in the box provided. If another agency or authority has been designated, provide its name, address, fax and (if available) E-mail address. |
| 13. Texts available from | If available from the National Notification Authority or National Enquiry Point, put a cross in the respective box. If available from another body, give its address, fax number and (if available) E-mail address. Such indications do not in any way discharge the relevant National Enquiry Point of its responsibilities under the provisions of AnnexParagraphs 3 and 4 of the SPS Agreement.<br><br>Provide the website address and specific hyperlink of the document notified, if available.<br><br>If a Member submits the text of the draft regulation in PDFformat along with the notification, a hyperlink to this text will be made available under this item. |

# World Trade Organization

**G/SPS/N/COUNTRY/**
date of distribution
(##-####)

**Committee on Sanitary and Phytosanitary Measures** Original:

## NOTIFICATION OF EMERGENCY MEASURES

| | |
|---|---|
| 1. | Notifying Member :<br>If applicable, name of local government involved : |
| 2. | Agency responsible : |
| 3. | Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO ; ICS numbers should be provided in addition, where applicable) : |
| 4. | Regions or countries likely to be affected, to the extent relevant or practicable: : [specific regions or countries] or [ ] all trading partners |
| 5. | Title, language and number of pages of the notified document : |
| 6. | Description of content : |
| 7. | Objective and rationale : [ ] food safety [ ] animal health [ ] plant protection<br>[ ] protect humans from animal/plant pest or disease<br>[ ] protect territory from other damage from pests |
| 8. | Nature of the urgent problem(s) and reason for urgent action : |
| 9. | Is there a relevant international standard? If so, identify the standard :<br>[ ] Codex Alimentarius Commission<br>[(e.g., title or serial number of Codex standard or related text)]<br>[ ] World Organization for Animal Health (OIE)<br>[(e.g., Terrestrial or Aquatic Animal Health Code, chapter number)]<br>[ ] International Plant Protection Convention<br>[(e.g., ISPM N° )]<br>[ ] None<br>Does this proposed regulation conform to the relevant international standard? [ ] Yes [ ] No<br>If no, describe, whenever possible, how and why it deviates from the international standard : |
| 10. | Other relevant documents and language(s) in which these are available : |
| 11. | Date of entry into force (dd/mm/yy)/period of application (as applicable) :<br>[ ] Trade facilitating measure |
| 12. | Agency or authority designated to handle comments : [ ] National Notification Authority, [ ] National Enquiry Point, or address, fax number and E-mail address (if available) of other body : |
| 13. | Texts available from : [ ] National Notification Authority, [ ] National Enquiry Point, or address, fax number and E-mail address (if available) of other body : |

# World Trade Organization

**G/SPS/N/COUNTRY/#/Add.#**
date of distribution
(##-####)

**Committee on Sanitary and Phytosanitary Measures** Original:

## NOTIFICATION OF EMERGENCY MEASURES

Addendum

The following communication, received on # Month Year, is being circulated at the request of the Delegation of [Member].

---

Title outlining what the SPS measure or product is

[Text]

This addendum concerns a :

[ ] Modification of final date for comments
[ ] Modification of content and/or scope of previously notified draft regulation
[ ] Withdrawal of proposed regulation
[ ] Change in period of application of measure
[ ] Other [provide brief description]

Agency or authority designated to handle comments: [ ]Notification Authority, [ ] National Enquiry Point, or address, fax number and E-mail address (if available) of other body :

Text available from: [ ]Notification Authority, [ ] National Enquiry Point, or address, fax number and E-mail address (if available) of other body :

# World Trade Organization

**G/SPS/N/COUNTRY/#/Rev.#**
date of distribution
(##-####)

**Committee on Sanitary and Phytosanitary Measures** Original:

## NOTIFICATION OF EMERGENCY MEASURES

**Revision**

| | |
|---|---|
| 1. | Notifying Member :<br>If applicable, name of local government involved : |
| 2. | Agency responsible : |
| 3. | Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO ; ICS numbers should be provided in addition, where applicable) : |
| 4. | Regions or countries likely to be affected, to the extent relevant or practicable: : [specific regions or countries] or [ ] all trading partners |
| 5. | Title, language and number of pages of the notified document : |
| 6. | Description of content : |
| 7. | Objective and rationale : [ ] food safety [ ] animal health [ ] plant protection<br>[ ] protect humans from animal/plant pest or disease<br>[ ] protect territory from other damage from pests |
| 8. | Nature of the urgent problem(s) and reason for urgent action : |
| 9. | Is there a relevant international standard? If so, identify the standard :<br>[ ] Codex Alimentarius Commission<br>[(e.g. title of serial number of Codex standard or related text)]<br>[ ] World Organization for Animal Health (OIE)<br>[(e.g., Terrestrial or Aquatic Animal Health Code, chapter number)]<br>[ ] International Plant Protection Convention<br>[(e.g., ISPM number)]<br>[ ] None<br>Does this proposed regulation conform to the relevant international standard? [ ] Yes [ ] No<br>If no, describe, whenever possible how and why it deviates from the international standard : |
| 10. | Other relevant documents and language(s) in which these are available : |
| 11. | Date of entry into force (dd/mm/yy)/period of application (as applicable) :<br>[ ] Trade facilitating measure |
| 12. | Agency or authority designated to handle comments : [ ] National Notification Authority, [ ] National Enquiry Point, or address, fax number and E-mail address (if available) of other body : |
| 13. | Texts available from : [ ] National Notification Authority, [ ] National Enquiry Point, or address, fax number and E-mail address (if available) of other body : |

# World Trade Organization

**G/SPS/N/COUNTRY/#/Corr.#**
date of distribution
(##-####)

**Committee on Sanitary and Phytosanitary Measures** Original:

## NOTIFICATION OF EMERGENCY MEASURES

Corrigendum

The following communication, received on # Month Year, is being circulated at the request of the Delegation of [Member].

---

Title outlining what the SPS measure or product is

[Text]

Text available from : [ ]Notification Authority, [ ] National Enquiry Point, or address, fax number and E-mail address (if available) of other body :

# Attachments submitted together with WTO SPS Notifications Guidelines

## 1. General

(a) An "attachment" is a draft regulatory text or a translation or a summary thereof referred to in a WTO SPS notification.

(b) An attachment will not be considered as a WTO document.

(c) The Secretariat cannot be held responsible for the content of attachments.

## 2. Provision of attachments to the WTO

(a) Attachments shouldbe provided electronically to the Central Registry of Notifications (crn@wto.org), in conjunction with the corresponding WTO SPS notification.

(b) Attachments will not be scanned by the WTO Secretariat if submitted in hard copy.

(c) Attachments should be provided in PDF format only. Notifications should continue to be submitted in Word.

(d) Individual attachments should not exceed 4MB in size ; multiple attachments may be provided.

## 3. Storage of attachments

(a) Attachments will be stored on a WTO central server.

(b) Attachments stored on the WTO central server will be viewable online by clicking on the hyperlink in the notification form.

(c) Attachments can also be downloaded directly by the user.

(d) Attachments will not be circulated in hard copy form.

## 4. Language of attachments

(a) Attachments may be provided in their original language.

(b) If available, Members may also provide translations.

(c) Attachments will not be translated by the Secretariat.

# AVAILABILITY OF TRANSLATIONS

**Supplement**

The Secretariat has been informed that an unofficial translation into [one of the WTO working languages or another language] of the document referenced in this notification is available for consultation at :

http://www. .....

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Comité des mesures sanitaires et phytosanitaires

# TRADUCTIONS DISPONIBLES

**Supplément**

Le Secrétariat a été informé qu'une traduction non officielle en [l'une des langues de travail de l' OMC ou une autre langue] du document auquel renvoie la présente notification pouvait être consultée à l' adresse suivante :

http://www. .....

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Comité de Medidas Sanitarias y Fitosanitarias

# ACCESO A TRADUCCIONES

**Suplemento**

Se ha comunicado a la Secretaría que en la dirección:

http://www. .....

se puede consultar una traducción no oficial al [uno de los idiomas de trabajo de la OMC u otro idioma] del documento a que se hace referencia en la presente notificación.

# RECOMMENDED PROCEDURES FOR THE COMPLETION OF THE NOTIFICATION FORMAT

In accordance with the Decision on Equivalence (G/SPS/19), a Member which has made a determination recognizing the equivalence of sanitary or phytosanitary measures of another Member or Members shall notify other Members through the Secretariat of the measure(s) recognized to be equivalent and of the products affected by this recognition.

For the purposes of this notification, equivalence is defined to be the state wherein sanitary or phytosanitary measures applied in an exporting Member, though different from the measures applied in an importing Member, achieve, as demonstrated by the exporting Member and recognized by the importing Member, the importing Member's appropriate level of sanitary or phytosanitary protection. A determination of the recognition of equivalence may be with respect to a specific measure or measures related to a certain product or categories of products, or on a systems-wide basis.

Notification should also be made of significant variations to existing equivalence arrangements, including their suspension or rescission.

| Item | Description |
|---|---|
| 1. Member notifying | Government, including the competent authorities of the European Communities, which is making the notification. |
| 2. Title of the text stating determination of the recognition of equivalence | Title of any formal or informal agreement, Memorandum of Understanding or other document establishing the determination of recognition of equivalence. |
| 3. Parties involved | Name of the exporting Member or Members whose measure has been determined to be equivalent. |
| 4. Date of entry into force of the determination of the recognition of equivalence and any associated procedures or regulations | Date from which procedures, regulations or other measures based on the determination of recognition of equivalence took effect. |
| 5. Products covered (HS or CCCN where applicable, otherwise national tariff heading) | Tariff item number(s) (normally HS, chapter or heading and number) as contained in national schedules deposited with the WTO of the product(s) which are imported on the basis of the determination of the recognition of equivalence. |
| 6. Brief description of the measure(s) recognized to be equivalent | Clearly indicate the nature of the recognition of equivalence, including which measure(s) of the exporting Member have been determined to be equivalent and which elements of the importing Member's usual requirements are met by these equivalent measures. |
| 7. Further information available from: | The agency or authority from which an interested Member may request further information regarding the specific determination of equivalence being notified. If this is the National Enquiry Point, check the box provided. If available from another body, give its address, fax number and (if available) E-mail address. Provide the website address of the document, if available. |

# World Trade Organization

**G/SPS/N/EQV/#**
Date of circulation
(00-0000)

**Committee on Sanitary and Phytosanitary Measures**

Original:

## NOTIFICATION OF DETERMINATION OF THE RECOGNITION OF EQUIVALENCE OF SANITARY OR PHYTOSANITARY MEASURES

The following notification of determination of the recognition of equivalence has been received.

| | |
|---|---|
| 1. | Member notifying: |
| 2. | Title of the text stating the determination of the recognition of equivalence: |
| 3. | Parties involved: |
| 4. | Date of entry into force of the determination of the recognition of equivalence and any associated procedures or regulations (dd/mm/yy): |
| 5. | Products covered (HS or CCCN where applicable, otherwise national tariff heading): |
| 6. | Description of measures recognized to be equivalent: |
| 7. | Further information available from:<br>[ ] National Enquiry Point [ ] Other (specify) |

# World Trade Organization

**G/SPS/48**
16 May 2008
(08-2302)

**Committee on Sanitary and Phytosanitary Measures**

## GUIDELINES TO FURTHER THE PRACTICAL IMPLEMENTATION OF ARTICLEOF THE AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES

At its meeting of 2-3 April 2008, the Committee adopted[1] the following guidelines to further the practical implementation of Article 6.

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The Committee on Sanitary and Phytosanitary Measures ( "the Committee" ),

Having regard to paragraph 1 of Article 12 of the Agreement on the Application of Sanitary and Phytosanitary Measures ( "the Agreement" ) ;

*Recalling* that in its first review of the operation and implementation of the Agreement, concluded in 1999, the Committee, while notingthat adaptation to regional conditions, including the recognition of pest- or disease-free areas or areas of low pest or disease prevalence, was of significant importance for trade in agricultural products, also noted that Members faced difficulties in the implementation of Article 6 of the Agreement ;

*Recalling* that at its June 2003 meeting the Committee initiated substantive discussion of problems linked with the implementation of the provisions for recognition of pest- or disease-free areas and areas of low pest or disease prevalence in Article 6 ;

Recallingthat in its second review of the operation and implementation of the Agreement, concluded at its June 2005 meeting, the Committee agreed that it should develop a proposal for a decision on the effective application of Article 6, taking as the point of departure the various proposals submitted by Members and the discussions in the Committee ;

*Taking into account* the work of the OIE and the IPPC in developing international standards, guidelines and recommendations to further the practical implementation of Article 6 ;

*Recognizing* the constructive manner in which the OIE and IPPC have responded to requests from the Committee for technical and administrative guidance ;

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1 At its meeting, the Committee adopted the guidelines on an ad referendum basis. Members who objected to the adoption of the guidelines were asked to make this known by 15 May 2008. No objections were raised by that date.

*Decides as follows:*

1. These guidelinesare intended to provide assistance to Members in the practical implementation of Article 6 by improving transparency, exchange of information, predictability, confidence and credibility between importing and exporting Members. These guidelines are not intended to duplicate the technical and administrative guidance provided to Members by the IPPC and OIE.

2. These guidelines do not add to nor detract from the existing rights and obligations of Members under the Agreement nor any other WTO Agreement. These guidelines do not provide any legal interpretation or modification to the Agreement itself. These guidelines are without prejudice to the right of a Member to determine its appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health.

3. These guidelines will be reviewed periodically and revised as necessary by the Committee in light of experience gained through the implementation of the Agreement and the use of these guidelines themselves. The Committee should undertake a first review of these guidelines within 36 months of their adoption by the Committee and thereafter as the need arises.

## I. General considerations

4. Importing Members should publish the basis for recognition of pest- or disease-free areas and areas of low pest or disease prevalence and a description of the general process used, including the information generally required to evaluate such requests and a contact point responsible for requests for recognition of pest-or disease-free areas or areas of low pest or disease prevalence.

5. Members should proceed with a recognition process without undue delay.

6. The process should be applied without discrimination between Members.

7. Members should endeavour to maintain transparency in all aspects of the recognition process.

8. Any determination under Article 6 should consider the strength and credibility of the veterinary or phytosanitary infrastructure of the exporting Member in accordance with the importing Member's appropriate level of sanitary or phytosanitary protection. The veterinary or phytosanitary authorities of the exporting Member should be able to demonstrate their ability to maintain freedom from specified pests or diseases to encourage confidence on the part of the importing Member.

9. The importing Member should take into account any relevant knowledge of and prior experience with the authorities of the exporting Member.

10. Where an exporting Member resubmits a request for recognition of pest- or disease-free areas or areas of low pest or disease prevalence, the importing Member should take into consideration all information previously provided, if verification has been provided by the exporting Member that the information remains valid.

11. If an exporting Member submits multiple requests tothe importing Member, the exporting Member should identify its priority among these requests and this will be taken into account by the importing Member.

12. Uponrequest from the exporting Member, an importing Member should provide information on the stage of the exporting Member's request within its evaluation process.

## II. InITIAL Discussions

13. The importing Member should, upon request, enter into discussions with the exporting Member with the aim of clarifying the importing Member's general process and the information generally required to facilitate a request for the recognition of a pest- or disease-free area or area of low pest or disease prevalence.

14. In this regard, the discussions should, *inter alia* clarify:

(a) the general process used by the importing Member in the evaluation of requests for the recognition of pest- or disease-free areas and areas of low pest or disease prevalence ;

(b) the general information required to evaluate the request ;

(c) the process for the exchange of information relating to the request, including a contact point, and a language or languages to be used, which should include at least one of the official languages of the WTO ; and

(d) if possible, an anticipated timeframe for completion of the recognition process.

15. The discussions should be undertakenwithin a reasonable period of time, and normally within 90 days of a request or as otherwise mutually decided.

16. The clarification(s) made in the course of the discussions should, if necessary, be appropriately recorded by the importing Member and transmitted to the exporting Member to avoid any misunderstandings of the general process.

17. When an importing Member has limited resources to undertake work on new requests for recognition, discussions may be postponed for a reasonable period of time. In deciding whether to postpone discussions, the importing Member should take into account as relevant factors, *inter alia* :

(a) the numberof requests for recognition of pest- or disease-freeareas or areas of low pest or disease prevalence it has received ;

(b) the priority of the exporting Member in situations where it has submitted multiple requests, and

(c) capacity to undertake work on new requests.

18. When an importing Member has postponed discussions in accordance with paragraph 17 of this decision, it should inform the exporting Member and provide an explanation in writing for the delay.

## III. TYPICAL ADMINISTRATIVE STEPS IN THE RECOGNITION Process

19. While Members have the sovereign right to determine their own processes for the evaluation of requests for recognition of pest- or disease-free areas or areas of low pest or disease prevalence, a process for making a determination under Article 6 typically involves a number of steps such as the following.

*Step A : Exporting Member requests information about procedures and/or recognition*

20. Theexporting Member requests information about the importing Member's requirements and procedures for the evaluation of requests for recognition of pest- or disease-free areas or areas of low pest or disease prevalence. An exporting Member may either request information about an importing Member's requirements and procedures prior to formally requesting recognition of an area as a pest- or disease-free area or an area of low pest or disease prevalence, or at the time it requests such recognition. In the latter case, the exporting Member at the same time communicates its sanitary or phytosanitary status to relevant trading partners along with a copy of its request for recognition of an area as a pest- or disease-free area or an area of low pest or disease prevalence.

21. The requestfor the recognition of a pest- or disease-free area or an area of low pest or disease prevalence may be accompanied by supporting scientific and technical information, including reference to relevant international recognition of the area as a pest- or disease-free area or an area of low pest or disease prevalence.In the interests of transparency, the exporting Member should indicate the organization and an individual within the organizationto act as a contact point for the request, and request that the importing Member do the same.

*Step B : Importing Member explains requirements*

22. The importing Member explains its requirements and procedures for the evaluation of requests for recognition of pest- or disease-free areas or areas of low pest or disease prevalence. The importing Member may, for example, request answers to a specific questionnaire.

*Step C : Exporting Member provides documentation*

23. The exporting Member sends the documentation demonstrating compliance with the requirements laid down by the importing Member. Where applicable, the exporting Member provides supporting information showing that the procedures it used to identify that area as pest- or disease-free or of low pest or disease prevalence are based on an international standard, guidelineor recommendation. The exporting Member also supplies any further information that could help the importing Member to make a determination.

*Step D : Importing Member evaluates the documentation and, if necessary, requests additional information*

24. The importing Member acknowledges the receipt of documentation provided by the exporting Member. The importing Member evaluates the documentation provided by the exporting Member and provides feedback to the exporting Member regarding whether the documentation is in order. In addition, the importing Member may indicate the necessity of additional information or an on-site verification, where justified, based on the results of the ongoing evaluation.

*Step E : Exporting Member responds to feedback*

25. The exporting Member provides any clarifications, additions or modifications requested by the importing Member.

*Step F : Importing Member evaluates any additional information and, if required, seeks further clarifications*

26. The importing Member evaluates any additional information provided by the exporting Member and provides further feedback to the exporting Member in accordance with step D. If further clarification is needed steps D and E are repeated.

*Step G : Importing Member conducts on- site verification*

27. If applicable, the importing Member carries out on-site verification in order to verify the information provided in support of the request for recognition of a pest- or disease-free area or an area of low pest or disease prevalence. Such inspections may consider, *inter alia*, the administrative structure of the regulatory bodies concerned and the programmes they implement with a view to prevention, control and eradication of pests and diseases. The strength and credibility of the veterinary or phytosanitary infrastructure of the exporting region(s) would also be part of this evaluation.

28. The importing Member provides a report on the on-site verification to the exporting Member.

*Step H : Exporting Member responds to inspection report*

29. If the inspection report so requests, the exporting Member provides further clarifications, additions or modifications.

*Step I : Importing Member makes a determination*

30. Where its evaluation of the evidence provided by the exporting Member results in a decision by the importing Member not to recognizethe pest- or disease-free area or area of low pest or disease prevalence, the importing Member provides to the exporting Member the technical grounds for the determination, so that, if appropriate, the exporting Member may modify and adapt its system with a view to future requests for recognition of pest- or disease-free areas or areas of low pest or disease prevalence.

31. Where its evaluation of the evidence provided by the exporting Member results in recognition of the pest- or disease-free area or area of low pest or disease prevalence, the importing Member takes the necessary administrative or legal steps to facilitate trade from the exporting Member.If necessary, the importing Member modifies existing sanitary or phytosanitaryregulations or elaborates new ones to support its recognition of the area in question as a pest- or disease-free area or an area of low pest or disease prevalence. In addition, the importing Member may circulate any modified or new regulation for public comment.

## IV. Expedited process

32. The importing Member may determine that an expedited process can be used to evaluate a request for recognition of pest- or disease-free areas or areas of low pest or disease prevalence. An expedited process may involve exclusion of one or more stages or some parts of a stage of the importing Member's general process for the recognition of pest- or disease-free or areas of low pest or disease prevalence. In determining the possibility of applying an expedited process, the importing Member should take into account factors including *inter alia*:

(a) when there has been official recognition of an area as a pest- or disease-free area or an area of low pest of disease prevalence by a relevant international organization; or

(b) when there has been an outbreak in an area previously recognized, and suspended, by the importing Member as a pest- or disease-free area or an area of low pest or disease prevalence and which has been restored to its former status as determined by the importing Member in accordance with the relevant international standards, guidelines or recommendations; or

(c) when the infrastructureand operation of the responsible veterinary or phytosanitary service of the exporting Member are familiar to the importing Member as a result of existing trade relations; or

(d) when there has been no previously notified occurrence of the pest or disease and the importing Member agrees that the surveillance procedures and activities implemented by the exporting Member have shown the non-existence thereof, the territory of the Member in question shall be considered free of that pest or disease.

## V. monitoring

33. The Committee will monitor the implementation of Article 6 under the standing agenda item at its regular meetings. In this regard, Members are encouraged to inform the Committee when:

(a) a request for recognition of pest- or disease-free area or area of low pest or disease prevalence is made and/or,

(b) a determination on whether to recognize a pest- or disease-free areas or areas of low pest or disease prevalence is made.

34. Members are also encouraged to provide information on their experiences in the implementation of Article 6 and to provide relevant background information on their decisions to other interested Members upon request.

35. The Secretariat should prepare an annual report to the Committee on implementation of Article 6 based on the information provided by Members under paragraphs 33 and 34.

CODEX, WTO-SPS, IPPC 2008년 채택기준
국제기준 협정관리 자료집

# IPPC(2008)

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# INTRODUCTION

## SCOPE

This standard provides guidelines for the establishment and maintenance of areas of low pest prevalence for fruit flies (FF-ALPPs) by a National Plant Protection Organization (NPPO). Such areas may be utilised as official pest risk management measures alone, or as part of a systems approach, to facilitate trade of fruit fly host products, or to minimize the spread of regulated fruit flies within an area. This standard applies to fruit flies (Tephritidae) of economic importance.

## REFERENCES

*Agreement on the Application of Sanitary and Phytosanitary Measures*, 1994. World Trade Organization, Geneva.

*Determination of pest status in an area*, 1998. ISPM No. 8, FAO, Rome.

*Establishment of pest free areas for fruit flies (Tephritidae)*, 2006. ISPM No. 26, FAO, Rome.

*Glossary of phytosanitary terms*, 2008. ISPM No. 5, FAO, Rome.

*Guidelines for surveillance*, 1997. ISPM No. 6, FAO, Rome.

I*nternational Plant Protection Convention*, 1997. FAO, Rome.

*Pest reporting*, 2002. ISPM No. 17, FAO, Rome.

*Recognition of pest free areas and areas of low pest prevalence*, 2007. ISPM No. 29, FAO, Rome.

*Requirements for the establishment of areas of low pest prevalence*, 2005. ISPM No. 22, FAO, Rome.

*The use of integrated measures in a systems approach for pest risk management*, 2002. ISPM No. 14, FAO, Rome.

## DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

## OUTLINE OF REQUIREMENTS

The general requirements for establishment and maintenance of an area of low pest prevalence for fruit flies (FF-ALPP) include :

- confirming the operational and economic feasibility of the FF-ALPP
- describing the purpose of the area
- listing the target fruit fly species(s) for the FF-ALPP
- operational plans
- determination of the FF-ALPP
- documentation and record keeping
- supervision activities.

For the establishment of the FF-ALPP, parameters used to estimate the level of fruit fly prevalence and the efficacy of trapping devices for surveillance should be determined as stated in Annex 1. Surveillance, control measures and corrective action planning are required for both establishment

and maintenance. Corrective action planning is described in Annex 2.

Other specific requirements include phytosanitary procedures, as well as suspension, loss and reinstatement of the status of the FF-ALPP.

## BACKGROUND

The International Plant Protection Convention (IPPC, 1997) contains provisions for areas of low pest prevalence (ALPPs), as does the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (Article VI of the WTO-SPS Agreement). ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*) describes different types of ALPPs and provides general guidance on the establishment of ALPPs. ALPPs may also be used as part of a systems approach (ISPM No. 14 : The use of *integrated measures in a systems approach for pest risk management*).

Fruit flies are a very important group of pests for many countries because of their potential to cause damage to fruits and restrict national and international trade for plant products that are hosts of fruit flies.

The high probability of introduction of fruit flies associated with a wide range of hosts results in restrictions imposed by many importing countries and the need for phytosanitary measures to be applied in exporting countries related to movement of host material or regulated articles to ensure that the risk of introduction is appropriately mitigated.

This standard provides guidance for the establishment and maintenance by the NPPO of FF-ALPPs with the aim to facilitate trade by minimizing the risk of introduction or spread of regulated fruit flies.

FF-ALPPs are generally used as buffer zones for fruit fly-pest free areas (FF-PFAs), fruit fly free places of production or fruit fly free production sites (either as a permanent buffer zone or as part of an eradication process), or for export purposes, usually in conjunction with other risk mitigation measures as a component of a systems approach (this may include all or part of an FF-ALPP that acts as a buffer zone).

They may occur naturally (and subsequently be verified, declared and monitored or otherwise managed) ; they may occur as a result of pest control practices during crop production that suppress the population of fruit flies in an area to limit their impact on the crop ; or they may be established as a result of control practices that reduce the number of fruit flies in the area to a specified low level.

The decision to establish an FF-ALPP may be closely linked to market access as well as to economic and operational feasibility.

If an FF-ALPP is established for export of fruit fly host commodities, the parameters for establishment and maintenance of the FF-ALPP should be determined and agreed to in conjunction with the importing country and in consideration of the guidelines presented in this standard and in accordance with ISPM No. 29 (*Recognition of pest free areas and areas of low pest prevalence*).

The requirements for the establishment of FF-ALPPs in this standard can also be applied for movement of fruit between ALPPs within a country.

The target pests for which this standard was developed include insects of the order Diptera, family Tephritidae, of the genera *Anastrepha, Bactrocera, Ceratitis, Dacus, Rhagoletis* and *Toxotrypana*.

## REQUIREMENTS

### 1. General Requirements

The concepts and provisions of ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*) apply to the establishment and maintenance of ALPPs for a specified pest, or a

group of pests including fruit flies, and therefore ISPM No. 22 should be referred to in conjunction with this standard.

An FF-ALPP may be established in accordance with this standard under a variety of situations. Some may require the application of the full range of elements provided by this standard, whereas others may require the application of only some of those elements.

Phytosanitary measures and specific procedures as further described in this standard may be required for the establishment and maintenance of an FF-ALPP by the NPPO. The decision to establish an official FF-ALPP may be based on all or some of the technical factors provided in this standard, as appropriate. They include components such as pest biology and control methods, which will vary according to the species of fruit fly for which the FF-ALPP is being established.

The establishment of an official FF-ALPP should be considered against the overall operational and economic feasibility of establishing a programme to meet and maintain the low pest level and the objectives of the FF-ALPP.

An FF-ALPP may be applied to facilitate the movement of fruit fly hosts from one FF-ALPP to another of the same fruit fly pest status to protect areas endangered by a regulated fruit fly pest.

The essential prerequisite for establishment of an FF-ALPP is an area that exists naturally, or that can be established, and that can be delimited, monitored and verified by the NPPO to be of a specified fruit fly prevalence level. The area may be in place to protect an FF-PFA or support sustainable crop production, or may have developed in response to suppression or eradication actions. It may occur naturally as a result of climatic, biological or geographical factors that reduce or limit the fruit fly population through all or part of the year.

An area can be defined as an FF-ALPP for one or more target fruit fly species. However, for an FF-ALPP covering multiple target fruit fly species, trapping devices and their deployment densities and locations should be specified, and low pest prevalence levels determined for each target fruit fly species.

FF-ALPPs should include public awareness programmes of a similar nature as outlined in section 1.1 of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*).

### 1.1 Operational plans

An official operational plan is needed to specify the phytosanitary procedures required to establish and maintain an FFALPP.

The operational plan should describe the main procedures to be carried out such as surveillance activities, procedures to maintain the specified level of low pest prevalence, the corrective action plan and any other procedures that are required to achieve the objective of the FF-ALPP.

### 1.2 Determination of an FF-ALPP

Elements to be considered in the determination of an FF-ALPP are as follows :

- delimitation of the area (size of location, detailed maps including an accurate description of the boundaries or Global Positioning System (GPS) coordinates showing the boundaries, natural barriers, entry points, location of commercial and, as appropriate, non-commercial hosts of the target fruit fly and urban areas)
- target fruit fly species and its/their seasonal and spatial distribution within the area
- location, abundance and seasonality of hosts, including wherever possible specifying primary (biologically preferred) hosts
- climatic characteristics, including rainfall, relative humidity, temperature, and prevailing wind speed and direction
- identification of factors limiting and keeping fruit fly population at low levels.

In areas where prevalence of fruit flies is naturally at a low level because of climatic, geographical or other reasons (e.g. natural enemies, availability of suitable hosts, host seasonality), the target fruit

fly population may already be below the specified level of low pest prevalence without applying any control measures. In such cases, surveillance should be undertaken over an appropriate length of time to validate the low prevalence status and this status may be recognized in accordance with the examples listed in section 3.1.1 of ISPM No. 8 (*Determination of pest status in an area*). If, however, the fruit flies are detected above the specified level of low pest prevalence (e.g. because of extraordinary climatic conditions) corrective actions should be applied. Guidelines for corrective action plans are provided in Annex 2.

## 1.3 Documentation and record keeping

The phytosanitary procedures used for the determination, establishment, verification and maintenance of an FF-ALPP should be adequately documented. These procedures should be reviewed and updated regularly, including the corrective actions if required (as described in ISPM No. 22: *Requirements for the establishment of areas of low pest prevalence*). It is recommended that a manual of procedures relating to the operational plan be prepared for the FF-ALPP.

Documentation for determination and establishment may include:

- list of fruit fly hosts known to occur in the area, including seasonality and commercial fruit production in the area
- delimitation records: detailed maps showing the boundaries, natural barriers and points where fruits may enter the area; description of agro-ecological features such as soil type, the location of main host areas of target fruit fly, and marginal and urban host areas; and climatic conditions, for example rainfall, relative humidity, temperature, and prevailing wind speed and direction
- surveillance records:
  - trapping: types of surveys, number and type of traps and lures, frequency of trap inspection, trap density, trap array, trapping time and duration, number of target fruit flies captured by species for each trap, trap servicing
  - fruit sampling: type, quantity, date, frequency and result
- record of control measures used for fruit flies and other pests that may have an effect on fruit fly populations: type(s) and locations.

For verification and maintenance, documentation should include the data recorded to demonstrate the population levels of the target fruit fly species are below the specified level of low pest prevalence. The records of surveys and results of other operational procedures should be retained for at least 24 months. If the FF-ALPP is being used for export purposes, records should be made available to the NPPO of the relevant importing country on request and verification may take place if necessary.

Corrective action plans should also be developed and maintained (see section 2.4).

## 1.4 Supervision activities

The FF-ALPP programme, including applicable domestic regulations, surveillance procedures (e.g. trapping, fruit sampling) and corrective action plans, should comply with officially approved procedures. These procedures may include official delegation of responsibility assigned to key personnel, for example:

- a person with defined authority and responsibility to ensure that the systems/procedures are implemented and maintained appropriately
- entomologist(s) with responsibility for the identification of fruit flies to species level.

The NPPO should evaluate and audit the operation of the procedures for establishment and maintenance of the FFALPP to ensure that effective management is maintained even where the responsibility to carry out specific activities has been delegated to outside the NPPO. Supervision of operational procedures include:

- operation of surveillance procedures
- surveillance capability
- trapping materials (traps, attractants) and procedures
- identification capability
- application of control measures
- documentation and record keeping
- implementation of corrective actions.

## 2. Specific Requirements

### 2.1 Establishment of the FF-ALPP

Elements for consideration when establishing an FF-PFA are described in sections 2.1 and 2.2 of ISPM No. 26

(*Establishment of pest free areas for fruit flies (Tephritidae)*) and may also be applied to an FF-ALPP as defined in following subsections.

#### 2.1.1 Determination of the specified level of low pest prevalence

Specified levels of low pest prevalence will depend on the level of risk associated with the target fruit fly species-host-area interaction. These levels should be established by the NPPO of the country where the FF-ALPP is located and with sufficient precision to allow assessment of whether surveillance data and protocols are adequate to determine that pest prevalence is below these levels.

Individual NPPOs may draw on a variety of different factors when determining exactly what an appropriate level of pest prevalence should be for a given FF-ALPP. Some commonly considered factors include the following :

- levels stipulated by trading partners in order for trade to proceed
- levels in use by other NPPOs for the same or similar fruit fly species, hosts and agro-ecological conditions (including experience and historical data gained from the operation of other FF-ALPPs as to what levels are required to be maintained to achieve pest free fruits).

Establishment of the parameters used to estimate the level of fruit fly prevalence is described in Annex 1.

#### 2.1.2 Geographical description

The NPPO defines the limits of a proposed FF-ALPP. Isolation of the area (physical or geographical) is not necessarily required for establishment of FF-ALPPs.

Boundaries used to describe the delimitation of the FF-ALPP should be established and closely related to the relative presence of hosts of the target fruit fly species or adjusted to readily recognizable boundaries.

#### 2.1.3 Surveillance activities prior to establishment

Prior to the establishment of an FF-ALPP, surveillance to assess the presence and level of prevalence of the target fruit fly species should be undertaken for a period determined by its biology, behaviour, climatic characteristics of the area, host availability and appropriate technical considerations. This surveillance should continue for at least 12 consecutive months.

### 2.2 Phytosanitary procedures

#### 2.2.1 Surveillance activities

Surveillance systems based on trapping are similar in any type of ALPP. The surveillance used in an FF-ALPP may include those processes described in ISPM No. 6 (*Guidelines for surveillance*), section 2.2.2.1 on trapping procedures

of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*) and any other relevant scientific information.

Fruit sampling as a routine surveillance method is not widely used for monitoring fruit flies in low prevalence areas except in areas where sterile insect technique (SIT) is applied, where it may be a major tool.

The NPPO may complement trapping for adults with fruit sampling for larvae. Fruit sampling may be especially useful for surveillance for fruit flies when no traps are available. If larvae are detected in fruit sampling, it may be necessary to rear the larvae to adults in order to identify them. This is the case particularly if multiple species of fruit flies may be present. However, fruit sampling alone will not provide sufficient accuracy for describing the size of the population and should not be solely relied on to validate or verify the FF-ALPP status. Surveillance procedures may include those described in section 2.2.2.2 on fruit sampling procedures of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*).

The presence and distribution of fruit fly hosts should be recorded separately identifying commercial and noncommercial hosts. This information will help in planning the trapping and host sampling activities and may help in anticipating the potential ease or difficulty of establishing and maintaining the phytosanitary status of the area.

The NPPO should have, or have access to, appropriate identification capabilities for identification of the target fruit fly species detected during the surveys (whether adult or larvae). This capability should also exist for the ongoing verification of FF-ALPP status for the target fruit fly species.

### 2.2.2 Reduction and maintenance of target fruit fly species population level

Specific control measures may be applied to reduce fruit fly populations to or below the specified level of low pest prevalence. Suppression of fruit fly populations may involve the use of more than one control option; some of these are described in section 3.1.4.2 of ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*) and Annex 1 of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*).

Since the target fruit fly species are either endemic or established in the area, preventive control measures to maintain fruit fly populations at or below the specified level of low pest prevalence are nearly always necessary (some FF-ALPPs may occur naturally). Efforts should be made by NPPOs to select those measures with least environmental impact.

Available methods may include :

- chemical control (e.g. selective insecticide bait, aerial and ground spraying, bait stations and male annihilation technique)
- physical control (e.g. fruit bagging)
- use of beneficial organisms (e.g. natural enemies, SIT)
- cultural control (e.g. stripping and destruction of mature and fallen fruit, elimination or replacement of other host plants by non-host plants where appropriate, early harvesting, discouraging intercropping with fruit fly host plants, pruning before the fruiting period, use of perimeter trap hosts).

### 2.2.3 Phytosanitary measures related to movement of host material or regulated articles

Phytosanitary measures may be required to reduce the risk of entry of the specified pests into the FF-ALPP. These are outlined in section 3.1.4.3 of ISPM No. 22 (Requirements for the establishment of areas of low pest prevalence) and 2.2.3 of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*).

### 2.2.4 Domestic declaration of an FF-ALPP

The NPPO should verify the status of the FF-ALPP (in accordance with ISPM No. 8 : *Determination of pest status in an area*) specifically by confirming compliance with the procedures established in

accordance with this standard (surveillance and controls). The NPPO should declare and notify the establishment of the FF-ALPP, as appropriate.

To verify the status of the FF-ALPP and for purposes of internal management, the continuing FF-ALPP status should be verified after it has been established and any phytosanitary measures for the maintenance of the FF-ALPP have been put in place.

### 2.3 Maintenance of the FF-ALPP

Once the FF-ALPP is established, the NPPO should maintain the relevant documentation and verification procedures (auditable), and continue the application of phytosanitary procedures as described in section 2.2 of this standard.

#### 2.3.1 Surveillance

In order to maintain the FF-ALPP status, the NPPO should continue surveillance, as described in section 2.2.1 of this standard.

#### 2.3.2 Measures to maintain low prevalence levels of target fruit fly species

In most cases the control measures as identified in section 2.2.2 may be applied to maintain the FF-ALPP, since the target fruit flies are still present in the established area.

If the monitored fruit fly prevalence level is observed to be increasing (but remains below the specified level for the area), a threshold set by the NPPO for the application of additional control measures may be reached. At this point the NPPO may require implementation of such measures (e.g. as described in section 3.1.4.2 of ISPM No. 22 : *Requirements for the establishment of areas of low pest prevalence*). This threshold should be set to provide adequate warning of potentially exceeding the specified level of low pest prevalence and avert suspension.

### 2.4 Corrective action plans

A corrective action plan for the FF-ALPP should be applied by the NPPO when the population level of the target fruit fly exceeds the specified level of low pest prevalence. Annex 2 provides guidelines on corrective action plans for FFALPPs.

### 2.5 Suspension, reinstatement and loss of FF-ALPP status

#### 2.5.1 Suspension of FF-ALPP status

If the specified level of low pest prevalence of the target fruit fly species is exceeded either throughout the whole FFALPP area or within a part of the FF-ALPP, the entire FF-ALPP is normally suspended. However, where the affected area within the FF-ALPP can be identified and clearly delimited, then the FF-ALPP may be redefined to suspend only that area.

Relevant importing NPPOs should be notified without undue delay of these actions (further information on pest reporting requirements is provided in ISPM No. 17 : *Pest reporting*).

Suspension may also apply if faults in the application of the procedures are found (for example, inadequate trapping, pest control measures or documentation).

If an FF-ALPP is suspended, an investigation by the NPPO should be initiated to determine the cause of the failure and introduce measures to prevent such failures from reoccurring.

When an FF-ALPP is suspended, the criteria for reinstatement should be made clear.

#### 2.5.2 Reinstatement of FF-ALPP status

Reinstatement of FF-ALPP status applies only to suspended areas and may take place when :

- the population level no longer exceeds the specified level of low pest prevalence and this is maintained for a period determined by the biology of the target fruit fly species and the prevailing environmental conditions ; and/or
- faulty procedures have been corrected and verified.

Once the specified level of low prevalence has been achieved and maintained as required above or procedural faults have been rectified through the application of corrective actions contained in the plan, the FF-ALPP status can be reinstated. If the FF-ALPP is established for export of host fruits, records regarding the reinstatement should be made available to the NPPO of the relevant importing country(ies) on request and verification may take place if necessary.

### 2.5.3 Loss of FF-ALPP status

Loss of FF-ALPP status should occur after suspension if reinstatement has failed to take place within a justifiable time frame, taking into account the biology of the fruit fly target species. Relevant importing NPPOs should be notified without undue delay of the change in status of the FF-ALPP (further information on pest reporting requirements is provided in ISPM No. 17 : *Pest reporting*).

In the event that FF-ALPP status is lost, the procedures for establishment and maintenance outlined in this standard should be followed to achieve the FF-ALPP status again, and should take into account all background information related to the area.

ANNEX 1

# PARAMETERS USED TO ESTIMATE THE LEVEL OF FRUIT FLY PREVALENCE[1]

Parameters used to determine the level of fruit fly prevalence in the FF-ALPP are defined by the NPPO. The most widely used parameter is flies per trap per day (FTD). More precise spatial data may be presented on the basis of trap density (i.e. FTD per unit area) or temporally for each trap present in an area over time.

The FTD is an index used to estimate the population by averaging the number of flies captured by one trap in one day.

This parameter estimates the relative number of fruit fly adults in a given time and space. It provides baseline information to compare fruit fly populations among different places and/or time.

The FTD is the result of dividing the total number of captured flies by the product obtained from multiplying the total number of inspected traps by the average number of days the traps were exposed. The formula is as follows:

$$\text{FTD} = \frac{F}{T \times D}$$

Where
F = total number of flies captured
T = number of inspected traps
D = number of days traps were exposed in the field.

In cases where traps are regularly inspected on a weekly basis, or longer in the case of winter surveillance operations, the parameter may be "flies per trap per week"(FTW). It estimates the number of flies captured by one trap in one week. Thus, FTD can be obtained from FTW by dividing by 7. Any significant changes in the status of any parameters critical to the efficacy of the FF-ALPP should be reviewed and modified, as appropriate.

Specified levels of low pest prevalence, as expressed in FTD values, should be established in relation to the risk of infestation of the fruits that are intended to be protected by the FF-ALPP, and in relation to any specific related objectives of the FF-ALPP (e.g. fruit-fly free commodities for export). In situations where a single FF-ALPP contains more than one host species (i.e. the ALPP is intended to protect more than one target fruit fly host), the specified level of low pest prevalence should be based on scientific information relating to each host of the fruit fly species, the risks of infestation and comparative preferences of the target fruit fly species for the different hosts. However, in situations where the FF-ALPP is established to protect only one type of host, consideration should be given to the level of infestation expected on that host. In such situations, lower specified levels of low pest prevalence are usually established for the primary host(s) of the target fruit fly species and comparatively higher levels for secondary hosts.

The biology of the target fruit flies (including number of generations per year, host range, host species present in the area, temperature thresholds, behaviour, reproduction and dispersion capacity) plays a major role in establishing appropriate specified levels of low pest prevalence. For an FF-ALPP with several hosts present, the established specified levels of low pest prevalence should reflect host diversity and abundance, host preference and host sequence for each target fruit fly species present. Although an FF-ALPP may have different specified levels of low pest prevalence for each relevant fruit fly target species, those levels should remain fixed for the whole area and duration of the FF-ALPP operation.

Efficiency of the types of traps and attractants used to estimate the levels of the pest population and the procedures applied for servicing the traps should be taken into consideration. The rationale is that different

1 This annex is an official part of the standard.

trap efficiencies could lead to different FTD results at the same location for a given population, so they have a significant effect in measuring the prevalence level of the target fruit fly species. Thus, when specifying the level of low pest prevalence accepted in terms of an FTD value, the efficacy of the trapping system should be stated as well.

Once a specified level of low pest prevalence has been established for a given situation using a specific lure/attractant, the lure/attractant used in the FF-ALPP must not be changed or modified until an appropriate specified level of low pest prevalence is determined for the new formulation. For FF-ALPPs with multiple target fruit fly species present that are attracted to different lures/attractants, trap placement should take into consideration possible interactive effects between lures/attractants.

Fruit sampling can be used as a complementary surveillance method to trapping to assess the profile of the fruit fly population levels, particularly if traps are not available for target species. Fruit sampling should be done on known hosts. It should be taken into account that efficacy of fruit sampling depends on sample size, frequency and timing.

Fruit sampling may include rearing larvae to identify the fruit fly species. If fruit cutting is done, the efficacy of visually detecting larvae should be considered. However, fruit sampling will not provide sufficient accuracy for describing the size of the population and should not be solely relied on to validate or verify the FF-ALPP status.

ANNEX 2

# GUIDELINES ON CORRECTIVE ACTION PLANS FOR FRUIT FLIES IN AN FF-ALPP[2]

Faults in the procedures or their application (e.g. inadequate trapping or pest control measures, inadequate documentation) or the detection of a population level exceeding the specified level of low pest prevalence for the target fruit fly species in the FF-ALPP should trigger the application of a corrective action plan. The objective of the corrective action plan is to ensure procedures and their applications are adequate and suppression of the fruit fly population to below the specified level for low pest prevalence is achieved as soon as possible. It is the responsibility of the NPPO to ensure that appropriate corrective action plans are developed. Corrective action plans should not be repeatedly implemented because this may lead to a loss of FF-ALPP status and the need to re-establish the area in accordance with the guidelines of this standard.

The corrective action plan should be prepared taking into account the biology of the target fruit fly species, the geography of the FF-ALPP, climatic conditions, phenology, and host abundance and distribution within the area.

The elements required for implementation of a corrective action plan include :

- declaration of suspension of FF-ALPP of status, where appropriate
- legal framework under which the corrective action plan can be applied
- time scales for the initial response and follow-up activities
- delimiting survey (trapping and fruit sampling) and application of the suppression actions
- identification capability
- availability of sufficient operational resources
- effective communication within the NPPO and with the NPPO(s) of the relevant importing country(ies), including provision of contact details of all parties involved
- a detailed map and definition of the suspension area
- revision and rectification of operational procedures, or
- range of control measures available e.g. pesticides.

**Application of the corrective action plan**

1. Notice to implement corrective actions

   The NPPO notifies interested stakeholders and parties, including relevant importing countries, when initiating the application of a corrective action plan. The NPPO is responsible for supervising the implementation of corrective measures.

   Notification should include the reason for initiating the plan i.e. faulty procedures or exceeding the specified level of low pest prevalence.

2. Determination of the phytosanitary status

   Immediately after detecting a population level higher than the specified level of low pest prevalence, a delimiting survey (which may include the deployment of additional traps, fruit sampling of host fruits and increased trap inspection frequency) should be implemented to determine the size of the affected area and more precisely gauge the level of the fruit fly prevalence.

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2 This annex is an official part of the standard.

3. Suspension of FF-ALPP status

If the specified level of low pest prevalence of the target fruit fly species is exceeded or faulty procedures are found, the FF-ALPP status should be suspended as stated in section 2.5.1 of this standard.

4. Rectification of procedural faults

Faulty procedures and associated documentation should be immediately reviewed to identify the source of the fault(s). The source and corrective action taken should be documented and the modified procedures monitored to ensure compliance with the objectives of the FF-ALPP.

5. Implementation of control measures in the affected area

Specific suppression actions should immediately be implemented in the affected area(s). Available methods include:

- selective insecticide-bait treatments (aerial and/or ground spraying and bait stations)
- sterile insect technique
- male annihilation technique
- collection and destruction of affected fruit
- stripping and destruction of host fruits, if possible
- insecticide treatments (ground, cover).

6. Notification of relevant agencies

Relevant NPPOs and other agencies should be kept informed of corrective actions. Information on pest reporting requirements under the IPPC is provided in ISPM No. 17 (*Pest reporting*).

**APPENDIX 1**

# GUIDELINES ON TRAPPING PROCEDURES[3]

Information about trapping is available in the following publication of the International Atomic Energy Agency (IAEA) : T*rapping Guidelines for area-wide fruit fly programmes*, IAEA/FAO-TG/FFP, 2003. IAEA, Vienna.

This publication is widely available, easily accessible and generally recognized as authoritative.

3 This appendix is not an official part of the standard. It is provided for information only.

**APPENDIX 2**

# TYPICAL APPLICATIONS OF AN FF-ALPP[4]

## 1. An FF-ALPP as a buffer zone

In cases where the biology of the target fruit fly species is such that it is likely to disperse from an infested area into a protected area, it may be necessary to define a buffer zone with a low fruit fly prevalence (as described in ISPM No. 26: *Establishment of pest free areas for fruit flies (Tephritidae)*). Establishment of the FF-ALPP and FF-PFA should occur at the same time, enabling the FF-ALPP to be defined for the purpose of protecting the FF-PFA.

### 1.1 Determination of an FF-ALPP as a buffer zone

Determination procedures draw upon those listed in section 1.2 of this standard. In addition, in delimiting the buffer zone, detailed maps may be included showing the boundaries of the area to be protected, distribution of hosts, host location, urban areas, entry points and control checkpoints. It is also relevant to include data related to natural biogeographical features such as prevalence of other hosts, climate, and location of valleys, plains, deserts, rivers, lakes and sea, as well as other areas that function as natural barriers. The size of the buffer zone in relation to the size of the area being protected will depend on the biology of the target fruit fly species (including behaviour, reproduction and dispersal capacity), the intrinsic characteristics of the protected area, and the economic and operational feasibility of establishing the FF-ALPP.

### 1.2 Establishment of an FF-ALPP as a buffer zone

The establishment procedures are described in section 2.1 of this standard. The movement of relevant fruit fly host commodities into the area may need to be regulated. Additional information can be found in section 2.2.3 of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*).

### 1.3 Maintenance of an FF-ALPP as a buffer zone

Maintenance procedures include those listed in section 2.3 of this standard. Since the buffer zone has features similar to the area or place of production it protects, procedures for maintenance may include those listed for the FF-PFA as described in section 2.3 of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*) and sections 3.1.4.2, 3.1.4.3 and 3.1.4.4 of ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*). The importance of information dissemination may also be considered in the maintenance of an FF-ALPP as a buffer zone.

## 2. FF-ALPPs for export purposes

FF-ALPPs may be used to facilitate fruit exports from the area. In most cases the FF-ALPP is the main component of a systems approach as a pest risk mitigation measure. Examples of measures and/or factors used in conjunction with FFALPPs include:

- pre- and post-harvest treatments
- production of secondary hosts or non-hosts in preference to primary hosts
- export of host material to areas not at risk during particular seasons
- physical barriers (e.g. pre-harvest bagging, insect-proof structures).

### 2.1 Determination of an FF-ALPP for export purposes

4 This appendix is not an official part of the standard. It is provided for information only.

Determining procedures may include those listed in section 1.2 of this standard. In addition, the following elements should be considered for the determination of an FF-ALPP :

- a list of products (hosts) of interest
- a list of other commercial and non-commercial hosts of the target fruit fly species present but not intended for export and their level of occurrence, as appropriate
- additional information such as any historical records in connection with biology, occurrence and control of the target fruit fly species or any other fruit fly species that may be present in the FF-ALPP.

## 2.2 Maintenance of an FF-ALPP for export purposes

Maintenance procedures may include those described in section 2.3.2 of this standard and should be applied if hosts are available. If appropriate, surveillance may continue at a lower frequency during the off-season period. This will depend on the biology of the target fruit fly species and its relationship with hosts present during the off-season period.

# INTRODUCTION

## SCOPE

This standard provides guidance to National Plant Protection Organizations (NPPOs) in selecting appropriate sampling methodologies for inspection or testing of consignments to verify compliance with phytosanitary requirements.

This standard does not give guidance on field sampling (for example, as required for surveys).

## REFERENCES

Cochran, W.G. 1977. *Sampling techniques*. 3rd edn. New York, John Wiley & Sons. 428 pp.

*Glossary of phytosanitary terms*, 2008. ISPM No. 5, FAO, Rome.

*Guidelines for inspection*, 2005. ISPM No. 23, FAO, Rome.

*Guidelines for phytosanitary import regulatory systems*, 2004, ISPM No. 20, FAO Rome.

*Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, ISPM No. 11, 2004, FAO, Rome.

*Pest risk analysis for regulated non-quarantine pests*, 2004. ISPM No. 21, FAO, Rome.

*Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*, 2006. ISPM No. 1, FAO, Rome.

## DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

## OUTLINE OF REQUIREMENTS

The sampling methodologies used by NPPOs in selecting samples for the inspection of consignments of commodities moving in international trade are based on a number of sampling concepts. These include parameters such as acceptance level, level of detection, confidence level, efficacy of detection and sample size.

The application of statistically based methods, such as simple random sampling, systematic sampling, stratified sampling, sequential sampling or cluster sampling, provides results with a statistical confidence level. Other sampling methods that are not statistically based, such as convenience sampling, haphazard sampling or selective sampling, may provide valid results in determining the presence or absence of a regulated pest(s) but no statistical inference can be made on their basis. Operational limitations will have an effect on the practicality of sampling under one or another method.

In using sampling methodologies, NPPOs accept some degree of risk that non-conforming lots may not be detected.

Inspection using statistically based methods can provide results with a certain level of confidence only and cannot prove the absence of a pest from a consignment.

## BACKGROUND

This standard provides the statistical basis for, and complements, ISPMs No. 20 (*Guidelines for*

*phytosanitary import regulatory systems*) and No. 23 (*Guidelines for inspection*). Inspection of consignments of regulated articles moving in trade is an essential tool for the management of pest risks and is the most frequently used phytosanitary procedure worldwide to determine if pests are present and/or the compliance with phytosanitary import requirements.

It is usually not feasible to inspect entire consignments, so phytosanitary inspection is performed mainly on samples obtained from a consignment. It is noted that the sampling concepts presented in this standard may also apply to other phytosanitary procedures, notably selection of units for testing.

Sampling of plants, plant products and other regulated articles may occur prior to export, at the point of import, or other points as determined by NPPOs.

It is important that sampling procedures established and used by NPPOs are documented and transparent, and take into account the principle of minimum impact (ISPM No. 1 : *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*), particularly because inspection based on sampling may lead to the refusal to issue a phytosanitary certificate, refusal of entry, or treatment or destruction of a consignment or part of a consignment.

Sampling methodologies used by NPPOs will depend on the sampling objectives (for example, sampling for testing) and may be solely statistically based or developed noting particular operational constraints. Methodologies developed to achieve the sampling objectives, within operational constraints, may not yield the same statistical confidence levels in the results as fully statistically based methods, but such methods may still give valid results depending on the desired sampling objective. If the sole purpose of sampling is to increase the chance of finding a pest, selective or targeted sampling is also valid.

## OBJECTIVES OF SAMPLING OF CONSIGNMENTS

Sampling of consignments is done for inspection and/or testing in order to :

- detect regulated pests
- provide assurance that the number of regulated pests or infested units in a consignment does not exceed the specified tolerance level for the pest
- provide assurance of the general phytosanitary condition of a consignment
- detect organisms for which a phytosanitary risk has not yet been determined
- optimize the probability of detecting specific regulated pests
- maximize the use of available sampling resources
- gather other information such as for monitoring of a pathway
- verify compliance with phytosanitary requirements
- determine the proportion of the consignment infested.

It should be noted that inspection and/or testing based on sampling always involves a degree of error. The acceptance of some probability that the pests are present is inherent in the use of sampling procedures for inspection and/or testing.

Inspection and/or testing using statistically based sampling methods can provide a level of confidence that the incidence of a pest is below a certain level, but it does not prove that a pest is truly absent from a consignment.

## REQUIREMENTS

### 1. Lot Identification

A consignment may consist of one or more lots. Where a consignment comprises more than one lot, the inspection to determine compliance may have to consist of several separate visual

examinations, and therefore the lots will have to be sampled separately. In such cases, the samples relating to each lot should be segregated and identified in order that the appropriate lot can be clearly identified if subsequent inspection or testing reveals non-compliance with phytosanitary requirements. Whether or not a lot will be inspected should be determined using factors stated in ISPM No. 23 (*Guidelines for inspection*, section 1.5).

A lot to be sampled should be a number of units of a single commodity identifiable by its homogeneity in factors such as :

- origin
- grower
- packing facility
- species, variety, or degree of maturity
- exporter
- area of production
- regulated pests and their characteristics
- treatment at origin
- type of processing.

The criteria used by the NPPO to distinguish lots should be consistently applied for similar consignments.

Treating multiple commodities as a single lot for convenience may mean that statistical inferences can not be drawn from the results of the sampling.

## 2. Sample Unit

Sampling first involves the identification of the appropriate unit for sampling (for example, a fruit, stem, bunch, unit of weight, bag or carton). The determination of the sample unit is affected by issues related to homogeneity in the distribution of pests through the commodity, whether the pests are sedentary or mobile, how the consignment is packaged, intended use, and operational considerations. For example, if determined solely on pest biology, the appropriate sample unit might be an individual plant or plant product in the case of a low-mobility pest, whereas in the case of mobile pests, a carton or other commodity container may be the preferred sample unit. However, when inspection is to detect more than one type of pest, other considerations (for example, practicality of using different sample units) may apply. Sample units should be consistently defined and independent from each other. This will allow NPPOs to simplify the process of making inferences from the sample to the lot or consignment from which the sample was selected.

## 3. Statistical and Non-Statistical Sampling

The sampling method is the process approved by the NPPO to select units for inspection and/or testing. Sampling for phytosanitary inspection of consignments or lots is done by taking units from the consignment or lot without replacement of the units selected[1]. NPPOs may choose either a statistically based or non-statistical sampling methodology.

Sampling based on statistical or targeted methods is designed to facilitate the detection of a regulated pest(s) in a consignment and/or lot.

### 3.1 Statistically based sampling

Statistically based sampling methods involve the determination of a number of interrelated parameters and the selection of the most appropriate statistically based sampling method.

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1 Sampling without replacement is selecting a unit from the consignment or lot without replacing the unit before the next units are selected. Sampling without replacement does not mean that a selected item cannot be returned to a consignment (except for destructive sampling) ; it means only that the inspector should not return it before selecting the remainder of the sample.

### 3.1.1 Parameters and related concepts

Statistically based sampling is designed to detect a certain percentage or proportion of infestation with a specific confidence level, and thus requires the NPPO to determine the following interrelated parameters: acceptance number, level of detection, confidence level, efficacy of detection and sample size. The NPPO may also establish a tolerance level for certain pests (for example, regulated non-quarantine pests).

#### 3.1.1.1 Acceptance number

The acceptance number is the number of infested units or the number of individual pests that are permissible in a sample of a given size before phytosanitary action is taken. Many NPPOs determine this number to be zero for quarantine pests. For example, if the acceptance number is zero and an infested unit is detected in the sample then phytosanitary action will be taken. It is important to appreciate that a zero acceptance number within a sample does not imply a zero tolerance level in the consignment as a whole. Even if no pests are detected in the sample there remains a probability that the pest may be present in the remainder of the consignment, albeit at a very low level.

The acceptance number is linked to the sample. The acceptance number is the number of infested units or the number of individual pests that are permissible in the sample whereas the tolerance level (see section 3.1.1.6) refers to the status of the entire consignment.

#### 3.1.1.2 Level of detection

The level of detection is the minimum percentage or proportion of infestation that the sampling methodology will detect at the specified efficacy of detection and level of confidence and which the NPPO intends to detect in a consignment.

The level of detection may be specified for a pest, a group or category of pests, or for unspecified pests. The level of detection may be derived from:

- a decision based on pest risk analysis to detect a specified level of infestation (the infestation determined to present an unacceptable risk)
- an evaluation of the effectiveness of phytosanitary measures applied before inspection
- an operationally based decision that inspection intensity above a certain level is not practical.

#### 3.1.1.3 Confidence level

The confidence level indicates the probability that a consignment with a degree of infestation exceeding the level of detection will be detected. A confidence level of 95% is commonly used. The NPPO may choose to require different confidence levels depending on the intended use of the commodity. For example, a higher confidence level for detection may be required for commodities for planting than for commodities for consumption, and the confidence level may also vary with the strength of the phytosanitary measures applied and historical evidence of non-compliance. Very high confidence level values quickly become difficult to achieve, and lower values become less meaningful for decisionmaking. A 95% confidence level means that the conclusions drawn from the results of sampling will detect a noncompliant consignment, on average, 95 times out of 100, and therefore, it may be assumed that, on average, 5% of noncompliant consignments will not be detected.

#### 3.1.1.4 Efficacy of detection

The efficacy of detection is the probability that an inspection or test of an infested unit(s) will detect a pest. In general the efficacy should not be assumed to be 100%. For example, pests may be difficult to detect visually, plants may not express symptoms of disease (latent infection), or efficacy may be reduced as a result of human error. It is possible to include lower efficacy values (for instance, an 80% chance of detecting the pest

when an infested unit is inspected) in the determination of sample size.

3.1.1.5 Sample size

The sample size is the number of units selected from the lot or consignment that will be inspected or tested. Guidance on determining the sample size is provided in Section 5.

3.1.1.6 Tolerance level

Tolerance level refers to the percentage of infestation in the entire consignment or lot that is the threshold for phytosanitary action.

Tolerance levels may be established for regulated non-quarantine pests (as described in ISPM No. 21 : *Pest risk analysis for regulated non-quarantine pests*, section 4.4) and may also be established for conditions related to other phytosanitary import requirements (for example, bark on wood or soil on plant roots).

Most NPPOs have a zero tolerance level for all quarantine pests, taking into account probabilities of pest presence in the non-sampled units as described in section 3.1.1.1. However, an NPPO may determine to establish a tolerance level for a quarantine pest based on pest risk analysis (as described in ISPM No. 11 : *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, section 3.4.1) and then determine sampling rates from this. For example, NPPOs may determine a tolerance level that is greater than zero because small numbers of the quarantine pest may be acceptable if the establishment potential of the pest is considered low or if the intended end use of the product (for example, fresh fruit and vegetables imported for processing) limits the potential of entry of the pest into endangered areas.

### 3.1.2 Links between the parameters and tolerance level

The five parameters (acceptance number, level of detection, confidence level, efficacy of detection and sample size) are statistically related. Taking into account the established tolerance level, the NPPO should determine the efficacy of the detection method used and decide upon the acceptance number in the sample ; any two of the remaining three parameters can also be chosen, and the remainder will be determined from the values chosen for the rest.

If a tolerance level greater than zero has been established, the level of detection chosen should be equal to (or less than, if the acceptance number is greater than zero) the tolerance level to ensure that consignments having an infestation level greater than the tolerance level will be detected with the specified confidence level.

If no pests are detected in the sample unit, then the percentage of infestation in the consignment can not be stated beyond the fact that it falls below the level of detection at the stated confidence level. If the pest is not detected with the appropriate sample size, the confidence level gives a probability that the tolerance level is not exceeded.

### 3.1.3 Statistically based sampling methods

3.1.3.1 Simple random sampling

Simple random sampling results in all sample units having an equal probability of being selected from the lot or consignment. Simple random sampling involves drawing the sample units in accordance with a tool such as a random numbers table. The use of a predetermined randomization process is what distinguishes this method from haphazard sampling (described in section 3.2.2).

This method is used when little is known about the pest distribution or rate of infestation. Simple random sampling can be difficult to apply correctly in operational situations. To use this method, each unit should have an equal probability of selection. In cases where a pest is not distributed randomly through the lot, this method may not be optimal. Simple random sampling may require greater resources than other sampling methods. The application can be dependent on the type and/or configuration of the consignment.

3.1.3.2 Systematic sampling

Systematic sampling involves drawing a sample from units in the lot at fixed, predetermined intervals. However, the first selection must be made at random through the lot. Biased results are possible if pests are distributed in a manner similar to the interval chosen for sampling.

Two advantages of this method are that the sampling process may be automated through machinery and that it requires the use of a random process only to select the first unit.

3.1.3.3 Stratified sampling

Stratified sampling involves separating the lot into separate subdivisions (that is, strata) and then drawing the sample units from each and every subdivision. Within each subdivision, sample units are taken using a particular method (systematic or random). Under some circumstances, different numbers of sample units may be taken from each subdivision - for instance, the number of sample units may be proportional to the size of the subdivision, or based on prior knowledge concerning the infestation of the subdivisions.

If at all feasible, stratified sampling will almost always improve detection accuracy. The smaller variation associated with stratified sampling yields more accurate results. This is especially true when infestation levels may vary across a lot depending on packing procedures or storage conditions. Stratified sampling is the preferred choice when knowledge about the pest distribution is presumed and operational considerations will allow it.

3.1.3.4 Sequential sampling

Sequential sampling involves drawing a series of sample units using one of the above methods. After each sample (or group) is drawn, the data are accumulated and compared with predetermined ranges to decide whether to accept the consignment, reject the consignment or continue sampling.

This method can be used when a tolerance level greater than zero is determined and the first set of sample units does not provide sufficient information to allow a decision to be made on whether or not the tolerance level is exceeded. This method would not be used if the acceptance number in a sample of any size is zero. Sequential sampling may reduce the number of samples required for a decision to be made or reduce the possibility of rejecting a conforming consignment.

3.1.3.5 Cluster sampling

Cluster sampling involves selecting groups of units based on a predefined cluster size (for example, boxes of fruit, bunches of flowers) to make up the total number of sample units required from the lot. Cluster sampling is simpler to evaluate and more reliable if the clusters are of equal size. It is useful if resources available for sampling are limited and works well when the distribution of pests is expected to be random.

Cluster sampling can be stratified, and can use either systematic or random methods for selecting the groups. Of the statistically based methods, this method is often the most practical to implement.

3.1.3.6 Fixed proportion sampling

Sampling a fixed proportion of the units in the lot (for example, 2%) results in inconsistent levels of detection or confidence levels when lot size varies. As shown in Appendix 5, fixed proportion sampling results in changing confidence levels for a given level of detection, or in changing levels of detection for a given confidence level.

## 3.2 Non-statistically based sampling

Other sampling methods that are not statistically based, such as convenience sampling, haphazard sampling or selective or targeted sampling, may provide valid results in determining the presence or

absence of a regulated pest(s). The following methods may be used based on specific operational considerations or when the goal is purely detection of pests.

### 3.2.1 Convenience sampling

Convenience sampling involves selecting the most convenient (for example, accessible, cheapest, fastest) units from the lot, without selecting units in a random or systematic manner.

### 3.2.2 Haphazard sampling

Haphazard sampling involves selecting arbitrary units without using a true randomization process. This may often appear to be random because the inspector is not conscious of having any selection bias. However, unconscious bias may occur, so that the degree to which the sample is representative of the lot is unknown.

### 3.2.3 Selective or targeted sampling

Selective sampling involves deliberately selecting samples from parts of the lot most likely to be infested, or units that are obviously infested, in order to increase the chance of detecting a specific regulated pest. This method may rely on inspectors who are experienced with the commodity and familiar with the pest's biology. Use of this method may also be triggered through a pathway analysis identifying a specific section of the lot with a higher probability of being infested (for example, a wet section of timber may be more likely to harbour nematodes). Because the sample is targeted, and hence statistically biased, a probabilistic statement about the infestation level in the lot can not be made. However, if the sole purpose of sampling is to increase the chance of finding a regulated pest(s), this method is valid. Separate samples of the commodity may be required to meet general confidence in detection of other regulated pests. The use of selective or targeted sampling may limit the opportunities to derive information about the overall pest status of the lot or consignment, because sampling is focused on where specific regulated pests are likely to be found not on the remainder of the lot or consignment.

## 4. Selecting a Sampling Method

In most cases the selection of an appropriate sampling method is necessarily dependent on information available about pest incidence and distribution in the consignment or lot as well as the operational parameters associated with the inspection situation in question. In most phytosanitary applications operational limitations will dictate the practicality of sampling under one or another method. Subsequently determining the statistical validity of practical methods will narrow the field of alternatives.

The sampling method that is ultimately selected by the NPPO should be operationally feasible and be the most appropriate to achieve the objective and be well documented for transparency. Operational feasibility is clearly linked to judgements concerning situation-specific factors, but should be consistently applied.

If sampling is undertaken to increase the chance of detecting a specific pest targeted sampling (described in section 3.2.3) may be the preferred option as long as the inspectors can identify the section(s) of the lot with a higher probability of being infested. Without this knowledge, one of the statistically based methods will be more appropriate. Non-statistically based sampling methods do not result in each unit having an equal probability of being included in the

sample and do not allow for quantification of a confidence level or level of detection.

Statistically based methods will be appropriate if sampling is undertaken to provide information about the general phytosanitary condition of a consignment, to detect multiple quarantine pests or to verify compliance with phytosanitary requirements.

In selecting a statistically based method, consideration may be given to how the consignment has been treated in harvesting, sorting and packing, and the likely distribution of the pest(s) in the lot. Sampling methods may be combined: for instance, a stratified sample may have either random or

systematic selection of sample units (or clusters) within strata.

If sampling is undertaken to determine whether a specific non-zero tolerance level has been exceeded, a sequential sampling method may be appropriate.

Once a sampling method has been selected and correctly applied, repeating the sampling with the aim of achieving a different result is unacceptable. Sampling should not be repeated unless considered necessary for specific technical reasons (for example, suspected incorrect application of sampling methodology).

## 5. Sample Size Determination

To determine the number of samples to be taken, the NPPO should select a confidence level (for example, 95%), a level of detection (for example, 5%) and an acceptance number (for example, zero), and determine the efficacy of detection (for example, 80%). From these values and the lot size, a sample size can be calculated. Appendices 2-5 set out the mathematical basis for sample size determination. Section 3.1.3 of this standard provides guidance on the most appropriate statistical based sampling method when considering the distribution of the pest in the lot.

### 5.1 Pests distribution unknown in the lot

Because sampling is done without replacement and the population size is finite, the hypergeometric distribution should be used to determine the sample size. This distribution gives a probability of detecting a certain number of infested units in a sample of a given size drawn from a lot of a given size, when a specific number of infested units exist in the lot (see Appendix 2). The number of infested units in the lot is estimated as the level of detection multiplied by the total number of units in the lot.

As lot size increases, the sample size required for a specific level of detection and confidence level approaches an upper limit. When the sample size is less than 5% of the lot size, the sample size can be calculated using either the binomial or Poisson distribution (see Appendix 3). All three distributions (hypergeometric, binomial and Poisson) give almost identical sample sizes for specific confidence and detection levels with large lot sizes, but binomial and Poisson distributions are easier to calculate.

### 5.2 Pest distribution aggregated in the lot

Most pest populations are aggregated to some degree in the field. Because commodities may be harvested and packed in the field without being graded or sorted, the distribution of infested units in the lot may be clustered or aggregated.

Aggregation of infested units of a commodity will always lower the likelihood of finding an infestation. However, phytosanitary inspections are aimed at detection of infested units and/or pest(s) at a low level. The effect of aggregation of the infested units on the efficacy of detection of a sample and on the required sample size is small in most cases.

When NPPOs identify that there is a high likelihood that there will be aggregation of infested units in the lot a stratified sampling method may help increase the chance of detecting an aggregated infestation.

When pests are aggregated, the calculation of sample size should ideally be performed using a beta-binomial distribution (see Appendix 4). However, this calculation requires knowledge of the degree of aggregation, which is generally not known and therefore this distribution may not be practical for general use. One of the other distributions (hypergeometric, binomial or Poisson) can be used ; however, the confidence level of the sampling will decline as the degree of aggregation increases.

## 6. Varying Level of Detection

The choice of a constant level of detection may result in a varying number of infested units

entering with imported consignments because lot size varies (for example, a 1% infestation level of 1000 units corresponds to 10 infested units, while a 1% infestation level of 10,000 units corresponds to 100 infested units). Ideally the selection of a level of detection will reflect in part the number of infested units entering on all consignments within a particular period of time.

If NPPOs want to manage the number of infested units entering with each consignment as well, a varying level of detection may be used. A tolerance level would be specified in terms of a number of infested items per consignment, and the sample size would be set in order to give the desired confidence and detection levels.

## 7. Outcome of Sampling

The outcome of activities and techniques related to sampling may result in phytosanitary action being taken (further details can be found in ISPM No. 23 : *Guidelines for inspection*, section 2.5).

**APPENDIX 1**

# FORMULAE USED IN APPENDICES 2-5[2]

| Formula No. | Purpose | Appendix No. |
|---|---|---|
| 1 | Probability of detecting *i* infested units in a sample. | 2 |
| 2 | Approximation for calculating the probability of finding no infested units. | 2 |
| 3 | Probability of detecting *i* infested units in a sample of n units (sample size is less than 5% of the lot size). | 3 |
| 4 | Binomial distribution probability of not observing an infested unit in a sample of n units. | 3 |
| 5 | Binomial distribution probability of observing at least one infested unit. | 3 |
| 6 | Binomial distribution formulae 5 and 6 rearranged to determine *n*. | 3 |
| 7 | Poisson distribution version of binomial formula 6 | 3 |
| 8 | Poisson distribution probability of finding no infested units (simplified). | 3 |
| 9 | Poisson distribution probability of finding at least one infested unit (the confidence level). | 3 |
| 10 | Poisson distribution to determine the sample size for *n*. | 3 |
| 11 | Beta-binomial based sampling for aggregated spatial distribution | 4 |
| 12 | Beta-binomial - probability of not observing an infested unit after inspecting several lots (for a single lot) | 4 |
| 13 | Beta-binomial - probability of observing one or more infested units | 4 |
| 14 | Beta-binomial formulae 12 and 13 rearranged to determine m. | 4 |

2 This appendix is not an official part of the standard. It is provided for information only.

APPENDIX 2

# CALCULATING SAMPLE SIZES FOR SMALL LOTS : HYPERGEOMETRIC-BASED SAMPLING (SIMPLE RANDOM SAMPLING)[3]

The hypergeometric distribution is appropriate to describe the probability of finding a pest in a relatively small lot. A lot is considered as small when the sample size is more than 5% of the lot size. In this case, sampling of one unit from the lot affects the probability of finding an infested unit in the next unit selected. Hypergeometric-based sampling is based on sampling without replacement.

It is also assumed that the distribution of the pest in the lot is not aggregated and that random sampling is used. This methodology can be extended for other schemes such as stratified sampling (further details can be found in Cochran, 1977).

The probability of detecting i infested units in a sample is given by

$$P(X = i) = \frac{\binom{A}{i}\binom{N-A}{n-i}}{\binom{N}{n}} \quad \text{Formula 1}$$

Where:

$$\binom{a}{b} = \frac{a!}{b!(a-b)!} \text{ where a!= a(a-1)(a-2)….. 1 and 0!=1}$$

P(X = i) = is the probability of observing i infested units in the sample, where i = 0, ……, *n*.

The confidence level corresponds to : 1- P(X = i)

A = number of infested units in the lot that could be detected if every unit in the lot was inspected or tested, given the efficacy of detection (level of detection × N × efficacy, truncated to an integer)

i = number of infested units in the sample

N = number of units in the lot (size of the lot)

*n* = number of units in the sample (sample size)

In particular the approximation that can be used for the probability of finding no infested units is

$$P(X=0) = \left(\frac{N-A-u}{N-u}\right)^n \quad \text{Formula 2}$$

where u = (n-1)/2 (from Cochran, 1977).

Solving the equation to determine n is difficult arithmetically but can be done with approximation or through maximum likelihood estimation.

Tables 1 and 2 show sample sizes calculated for different lot sizes, levels of detection and confidence levels, when the acceptance number is 0.

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3 This appendix is not an official part of the standard. It is provided for information only.

Table 1. Table of minimum sample sizes for 95% and 99% confidence levels at varying levels of detection according to lot size, hypergeometric distribution

| Number of units in lot | P = 95% (confidence level)<br>% level of detection × efficacy of detection | | | | | P = 99% (confidence level)<br>% level of detection × efficacy of detection | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 5 | 2 | 1 | 0.5 | 0.1 | 5 | 2 | 1 | 0.5 | 0.1 |
| 25 | 24* | - | - | - | - | 25* | - | - | - | - |
| 50 | 39* | 48 | - | - | - | 45* | 50 | - | - | - |
| 100 | 45 | 78 | 95 | - | - | 59 | 90 | 99 | - | - |
| 200 | 51 | 105 | 155 | 190 | - | 73 | 136 | 180 | 198 | - |
| 300 | 54 | 117 | 189 | 285* | - | 78 | 160 | 235 | 297* | - |
| 400 | 55 | 124 | 211 | 311 | - | 81 | 174 | 273 | 360 | - |
| 500 | 56 | 129 | 225 | 388* | - | 83 | 183 | 300 | 450* | - |
| 600 | 56 | 132 | 235 | 379 | - | 84 | 190 | 321 | 470 | - |
| 700 | 57 | 134 | 243 | 442* | - | 85 | 195 | 336 | 549* | - |
| 800 | 57 | 136 | 249 | 421 | - | 85 | 199 | 349 | 546 | - |
| 900 | 57 | 137 | 254 | 474* | - | 86 | 202 | 359 | 615* | - |
| 1 000 | 57 | 138 | 258 | 450 | 950 | 86 | 204 | 368 | 601 | 990 |
| 2 000 | 58 | 143 | 277 | 517 | 1553 | 88 | 216 | 410 | 737 | 1800 |
| 3 000 | 58 | 145 | 284 | 542 | 1895 | 89 | 220 | 425 | 792 | 2353 |
| 4 000 | 58 | 146 | 288 | 556 | 2108 | 89 | 222 | 433 | 821 | 2735 |
| 5 000 | 59 | 147 | 290 | 564 | 2253 | 89 | 223 | 438 | 840 | 3009 |
| 6 000 | 59 | 147 | 291 | 569 | 2358 | 90 | 224 | 442 | 852 | 3214 |
| 7 000 | 59 | 147 | 292 | 573 | 2437 | 90 | 225 | 444 | 861 | 3373 |
| 8 000 | 59 | 147 | 293 | 576 | 2498 | 90 | 225 | 446 | 868 | 3500 |
| 9 000 | 59 | 148 | 294 | 579 | 2548 | 90 | 226 | 447 | 874 | 3604 |
| 10 000 | 59 | 148 | 294 | 581 | 2588 | 90 | 226 | 448 | 878 | 3689 |
| 20 000 | 59 | 148 | 296 | 589 | 2781 | 90 | 227 | 453 | 898 | 4112 |
| 30 000 | 59 | 148 | 297 | 592 | 2850 | 90 | 228 | 455 | 905 | 4268 |
| 40 000 | 59 | 149 | 297 | 594 | 2885 | 90 | 228 | 456 | 909 | 4348 |
| 50 000 | 59 | 149 | 298 | 595 | 2907 | 90 | 228 | 457 | 911 | 4398 |
| 60 000 | 59 | 149 | 298 | 595 | 2921 | 90 | 228 | 457 | 912 | 4431 |
| 70 000 | 59 | 149 | 298 | 596 | 2932 | 90 | 228 | 457 | 913 | 4455 |
| 80 000 | 59 | 149 | 298 | 596 | 2939 | 90 | 228 | 457 | 914 | 4473 |
| 90 000 | 59 | 149 | 298 | 596 | 2945 | 90 | 228 | 458 | 915 | 4488 |
| 100 000 | 59 | 149 | 298 | 596 | 2950 | 90 | 228 | 458 | 915 | 4499 |
| 200 000+ | 59 | 149 | 298 | 597 | 2972 | 90 | 228 | 458 | 917 | 4551 |

Values in table 1 marked with an asterisk (*) have been rounded down to a whole number because scenarios resulting in a fraction of a unit being infested (for example, 300 units with 0.5% infestation corresponds to 1.5 infested units in the shipment) are not possible. This means that the sampling intensity increases slightly, and may be greater for a shipment size where the number of infested units is rounded down than for a larger shipment where a larger number of infested units are calculated (for example, compare results for 700 and 800 units in the lot). It also means that a slightly lower proportion of infested units might be detected than the proportion indicated by the table, or that such infestation is more likely to be detected than the confidence level shown.

Values in table 1 marked with a dash (-) refer to scenarios presented that are not possible (less than one unit infested).

Table 2 : Table of sample sizes for 80% and 90% confidence levels at varying levels of detection according to lot size, hypergeometric distribution

| Number of units in lot | P = 80% (confidence level) % level of detection × efficacy of detection | | | | | P = 90% (confidence level) % level of detection × efficacy of detection | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 5 | 2 | 1 | 0.5 | 0.1 | 5 | 2 | 1 | 0.5 | 0.1 |
| 100 | 27 | 56 | 80 | - | - | 37 | 69 | 90 | - | - |
| 200 | 30 | 66 | 111 | 160 | - | 41 | 87 | 137 | 180 | - |
| 300 | 30 | 70 | 125 | 240* | - | 42 | 95 | 161 | 270* | - |
| 400 | 31 | 73 | 133 | 221 | - | 43 | 100 | 175 | 274 | - |
| 500 | 31 | 74 | 138 | 277* | - | 43 | 102 | 184 | 342* | - |
| 600 | 31 | 75 | 141 | 249 | - | 44 | 104 | 191 | 321 | - |
| 700 | 31 | 76 | 144 | 291* | - | 44 | 106 | 196 | 375* | - |
| 800 | 31 | 76 | 146 | 265 | - | 44 | 107 | 200 | 350 | - |
| 900 | 31 | 77 | 147 | 298* | - | 44 | 108 | 203 | 394* | - |
| 1 000 | 31 | 77 | 148 | 275 | 800 | 44 | 108 | 205 | 369 | 900 |
| 2 000 | 32 | 79 | 154 | 297 | 1106 | 45 | 111 | 217 | 411 | 1368 |
| 3 000 | 32 | 79 | 156 | 305 | 1246 | 45 | 112 | 221 | 426 | 1607 |
| 4 000 | 32 | 79 | 157 | 309 | 1325 | 45 | 113 | 223 | 434 | 1750 |
| 5 000 | 32 | 80 | 158 | 311 | 1376 | 45 | 113 | 224 | 439 | 1845 |
| 6 000 | 32 | 80 | 159 | 313 | 1412 | 45 | 113 | 225 | 443 | 1912 |
| 7 000 | 32 | 80 | 159 | 314 | 1438 | 45 | 114 | 226 | 445 | 1962 |
| 8 000 | 32 | 80 | 159 | 315 | 1458 | 45 | 114 | 226 | 447 | 2000 |
| 9 000 | 32 | 80 | 159 | 316 | 1474 | 45 | 114 | 227 | 448 | 2031 |
| 10 000 | 32 | 80 | 159 | 316 | 1486 | 45 | 114 | 227 | 449 | 2056 |
| 20 000 | 32 | 80 | 160 | 319 | 1546 | 45 | 114 | 228 | 455 | 2114 |
| 30 000 | 32 | 80 | 160 | 320 | 1567 | 45 | 114 | 229 | 456 | 2216 |
| 40 000 | 32 | 80 | 160 | 320 | 1577 | 45 | 114 | 229 | 457 | 2237 |
| 50 000 | 32 | 80 | 160 | 321 | 1584 | 45 | 114 | 229 | 458 | 2250 |
| 60 000 | 32 | 80 | 160 | 321 | 1588 | 45 | 114 | 229 | 458 | 2258 |
| 70 000 | 32 | 80 | 160 | 321 | 1591 | 45 | 114 | 229 | 458 | 2265 |
| 80 000 | 32 | 80 | 160 | 321 | 1593 | 45 | 114 | 229 | 459 | 2269 |
| 90 000 | 32 | 80 | 160 | 321 | 1595 | 45 | 114 | 229 | 459 | 2273 |
| 100 000 | 32 | 80 | 160 | 321 | 1596 | 45 | 114 | 229 | 459 | 2276 |
| 200 000 | 32 | 80 | 160 | 321 | 1603 | 45 | 114 | 229 | 459 | 2289 |

Values in table 2 marked with an asterisk (*) have been rounded down to a whole number because scenarios resulting in a fraction of a unit being infested (for example, 300 units with 0.5% infestation corresponds to 1.5 infested units in the shipment) are not possible. This means that the sampling intensity increases slightly, and may be greater for a shipment size where the number of infested units is rounded down than for a larger shipment where a larger number of infested units are calculated (for example, compare results for 700 and 800 units in the lot). It also means that a slightly lower proportion of infested units might be detected than the proportion indicated by the table, or that such infestation is more likely to be detected than the confidence level shown.

Values in table 2 marked with a dash (-) refer to scenarios presented that are not possible (less than one unit infested).

**APPENDIX 3**

# SAMPLING OF LARGE LOTS : BINOMIAL OR POISSON BASED SAMPLING[4]

For large lots sufficiently mixed, the likelihood of finding an infested unit is approximated by simple binomial statistics.

The sample size is less than 5% of the lot size. The probability of observing i infested units in a sample of *n* units is given by :

$$P(X=i) = \binom{n}{i} \phi p^{\,i} (1-\phi p)^{n-i} \qquad \text{Formula 3}$$

p is the average proportion of infested units (infestation level) in the lot and f represents the percentage inspection efficacy divided by 100.

P(X = i) is the probability of observing i infested units in the sample. The confidence level corresponds to: 1- P(X = i), i = 0, 1, 2, ⋯, n.

For phytosanitary purposes, the probability of not observing a pest specimen or symptom in the sample is determined. The probability of not observing an infested unit in a sample of n units is given by

$$P(X=0) = (1 - \phi p)^n \qquad \text{Formula 4}$$

The probability of observing at least one infested unit is then:

$$P(X>0) = 1 - (1 - \phi p)^n \qquad \text{Formula 5}$$

This equation can be rearranged to determine n

$$n = \frac{\ln[1 - P(X > 0)]}{\ln(1 - \phi p)} \qquad \text{Formula 6}$$

The sample size n can be determined with this equation when the infestation level (p), efficacy (f)and the confidence level (1- P (X 〉 0)) are determined by the NPPO.

The binomial distribution can be approximated with the Poisson distribution. *As n* increases and p decreases, the binomial distribution equation given above tends to the Poisson distribution equation given below,

$$P(X=i) = \frac{(n\phi p)^i e^{-n\phi p}}{i!} \qquad \text{Formula 7}$$

where *e* is the base-value of the natural logarithm.

The probability of finding no infested units simplifies to

$$P(X=0) = e^{-n\phi p} \qquad \text{Formula 8}$$

The probability of finding at least one infested unit (the confidence level) is calculated as

$$P(X>0) = 1 - e^{-n\phi p} \qquad \text{Formula 9}$$

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4 This appendix is not an official part of the standard. It is provided for information only.

Solving for n gives the following, which can be used to determine the sample size :

$$n = -\ln[1 - P(X>0)]/\phi p \qquad \text{Formula 10}$$

Tables 3 and 4 show sample sizes when the acceptance number is 0, calculated for different levels of detection, efficacy and confidence levels with the binomial and Poisson distributions, respectively. A comparison of the case for 100% efficacy with the sample sizes in Table 1 (see Appendix 2) shows that the binomial and Poisson give very similar results to the hypergeometric distribution when n is large and p is small.

Table 3 : Table of sample sizes for 95% and 99% confidence levels at varying levels of detection, according to efficacy values where lot size is large and sufficiently mixed, binomial distribution

| % efficacy | P = 95% (confidence level) % level of detection | | | | | P = 99% (confidence level) % level of detection | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 5 | 2 | 1 | 0.5 | 0.1 | 5 | 2 | 1 | 0.5 | 0.1 |
| 100 | 59 | 149 | 299 | 598 | 2995 | 90 | 228 | 459 | 919 | 4603 |
| 99 | 60 | 150 | 302 | 604 | 3025 | 91 | 231 | 463 | 929 | 4650 |
| 95 | 62 | 157 | 314 | 630 | 3152 | 95 | 241 | 483 | 968 | 4846 |
| 90 | 66 | 165 | 332 | 665 | 3328 | 101 | 254 | 510 | 1022 | 5115 |
| 85 | 69 | 175 | 351 | 704 | 3523 | 107 | 269 | 540 | 1082 | 5416 |
| 80 | 74 | 186 | 373 | 748 | 3744 | 113 | 286 | 574 | 1149 | 5755 |
| 75 | 79 | 199 | 398 | 798 | 3993 | 121 | 305 | 612 | 1226 | 6138 |
| 50 | 119 | 299 | 598 | 1197 | 5990 | 182 | 459 | 919 | 1840 | 9209 |
| 25 | 239 | 598 | 1197 | 2396 | 11982 | 367 | 919 | 1840 | 3682 | 18419 |
| 10 | 598 | 1497 | 2995 | 5990 | 29956 | 919 | 2301 | 4603 | 9209 | 46050 |

Table 4 : Table of sample sizes for 95% and 99% confidence levels at varying levels of detection, according to efficacy values where lot size is large and sufficiently mixed, Poisson distribution

| % efficacy | P = 95% (confidence level) % level of detection | | | | | P = 99% (confidence level) % level of detection | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 5 | 2 | 1 | 0.5 | 0.1 | 5 | 2 | 1 | 0.5 | 0.1 |
| 100 | 60 | 150 | 300 | 600 | 2996 | 93 | 231 | 461 | 922 | 4606 |
| 99 | 61 | 152 | 303 | 606 | 3026 | 94 | 233 | 466 | 931 | 4652 |
| 95 | 64 | 158 | 316 | 631 | 3154 | 97 | 243 | 485 | 970 | 4848 |
| 90 | 67 | 167 | 333 | 666 | 3329 | 103 | 256 | 512 | 1024 | 5117 |
| 85 | 71 | 177 | 353 | 705 | 3525 | 109 | 271 | 542 | 1084 | 5418 |
| 80 | 75 | 188 | 375 | 749 | 3745 | 116 | 288 | 576 | 1152 | 5757 |
| 75 | 80 | 200 | 400 | 799 | 3995 | 123 | 308 | 615 | 1229 | 6141 |
| 50 | 120 | 300 | 600 | 1199 | 5992 | 185 | 461 | 922 | 1843 | 9211 |
| 25 | 240 | 600 | 1199 | 2397 | 11983 | 369 | 922 | 1843 | 3685 | 18421 |
| 10 | 600 | 1498 | 2996 | 5992 | 29958 | 922 | 2303 | 4606 | 9211 | 46052 |

**APPENDIX 4**

# SAMPLING FOR PESTS WITH AN AGGREGATED DISTRIBUTION: BETA-BINOMIAL BASED SAMPLING[5]

In the case of aggregated spatial distribution, sampling can be adjusted to compensate for aggregation. For this adjustment to apply, it should be assumed that the commodity is sampled in clusters (for example, boxes) and that each unit in a chosen cluster is examined (cluster sampling). In such cases, the proportion of infested units, *f*, is no longer constant across all clusters but will follow a beta density function.

$$P(X=i) = \binom{n}{i} \frac{\prod_{j=0}^{i-1} (f + j\theta) \prod_{j=0}^{n-i-1} (1 - f + j\theta)}{\prod_{j=0}^{n-1} (1 + j\theta)} \qquad \text{Formula 11}$$

f is the average proportion of infested units (infestation level) in the lot.

P(X = i) is the probability of observing i infested units in a lot.

n = number of units in a lot.

$\prod$ is the product function

$\theta$ provides a measure of aggregation for the jth lot where $\theta$ is $0 < \theta < 1$.

Phytosanitary sampling is often more concerned with the probability of not observing an infested unit after inspecting several batches. For a single batch, the probability that $X > 0$ is

$$P(X>0) = 1 - \prod_{j=0}^{n-1} (1 - f + j\theta)/(1 + j\theta) \qquad \text{Formula 12}$$

and the probability that each of several lots has no infested unit equals $P(X=0)^m$, where m is the number of lots. When f is low, equation 1 can be estimated by

$$\Pr(X=0) \approx (1 + n\theta)^{-(mf/\theta)} \qquad \text{Formula 13}$$

The probability of observing one or more infested units is given by 1- Pr (X=0).

This equation can be rearranged to determine *m*

$$m = \frac{-\theta}{f}\left[\frac{\ln(1 - P(x>0))}{\ln(1 + n\theta)}\right] \qquad \text{Formula 14}$$

Stratified sampling offers a way of reducing the impact of aggregation. Strata should be chosen so that the degree of aggregation within the strata is minimized.

When the degree of aggregation and the confidence level are fixed, the size of the sample can be determined. Without the degree of aggregation, the sample size can not be determined.

Efficacy ($\phi$ values of less than 100% can be included by substituting $\phi$f for f in the equations.

5 This appendix is not an official part of the standard. It is provided for information only.

APPENDIX 5

# COMPARISON OF HYPERGEOMETRIC AND FIXED PROPORTION SAMPLING RESULTS[6]

Table 5 : Confidence in the results of different sampling schemes for a 10% level of detection

| | Hypergeometric-based sampling (random sampling) | | Fixed proportion sampling (2%) | |
|---|---|---|---|---|
| Lot size | sample size | confidence level | sample size | confidence level |
| 10 | 10 | 1 | 1 | 0.100 |
| 50 | 22 | 0.954 | 1 | 0.100 |
| 100 | 25 | 0.952 | 2 | 0.191 |
| 200 | 27 | 0.953 | 4 | 0.346 |
| 300 | 28 | 0.955 | 6 | 0.472 |
| 400 | 28 | 0.953 | 8 | 0.573 |
| 500 | 28 | 0.952 | 10 | 0.655 |
| 1 000 | 28 | 0.950 | 20 | 0.881 |
| 1 500 | 29 | 0.954 | 30 | 0.959 |
| 3 000 | 29 | 0.954 | 60 | 0.998 |

Table 6 : Minimum levels that can be detected with 95% confidence using different sampling schemes

| | Hypergeometric-based sampling (random sampling) | | Fixed proportion sampling (2%) | |
|---|---|---|---|---|
| Lot size | sample size | minimum level of detection | sample size | minimum level of detection |
| 10 | 10 | 0.10 | 1 | 1.00 |
| 50 | 22 | 0.10 | 1 | 0.96 |
| 100 | 25 | 0.10 | 2 | 0.78 |
| 200 | 27 | 0.10 | 4 | 0.53 |
| 300 | 28 | 0.10 | 6 | 0.39 |
| 400 | 28 | 0.10 | 8 | 0.31 |
| 500 | 28 | 0.10 | 10 | 0.26 |
| 1 000 | 28 | 0.10 | 20 | 0.14 |
| 1 500 | 29 | 0.10 | 30 | 0.09 |
| 3 000 | 29 | 0.10 | 60 | 0.05 |

6 This appendix is not an official part of the standard. It is provided for information only.