

## COUNCIL DIRECTIVE

of 22 July 1991

laying down the health conditions for the production and the placing on the market of fishery products

(91/493/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposals from the Commission <sup>(1)</sup>,

Having regard to the opinions of the European Parliament <sup>(2)</sup>,

Having regard to the opinions of the Economic and Social Committee <sup>(3)</sup>,

Whereas, with a view to achieving the internal market and more especially to ensuring the smooth operation of the common organization of the market in fishery products established by Regulation (EEC) No 3796/81 <sup>(4)</sup>, as last amended by Regulation (EEC) No 2886/89 <sup>(5)</sup>, it is essential that the marketing of fish and fish products should no longer be hindered by disparities existing in the Member States in respect of health requirements; whereas this will enable production and placing on the market to be better harmonized and bring about competition on equal terms, whilst ensuring quality products for the consumer;

Whereas the European Parliament in its legislative resolution of 17 March 1989 <sup>(6)</sup> requested the Commission to come forward with comprehensive proposals on the hygienic production and placing on the market of fishery products, including solutions for the problem of nematodes;

Whereas fishery products freshly caught are in principle free of contamination with micro-organisms; whereas however contamination and subsequent decomposition may occur when handled and treated unhygienically;

Whereas therefore the essential requirements should be laid down for the correct hygienic handling of fresh and processed fishery products at all stages of production and during storage and transport;

Whereas it is appropriate to apply by analogy certain marketing standards which are laid down pursuant to Article 2 of Regulation (EEC) No 3796/81, in order to fix the health quality of these products;

Whereas it is the responsibility primarily of the fisheries industry to ensure that fishery products meet the health requirements laid down in this Directive;

Whereas the competent authorities of the Member States must, by carrying out checks and inspections, ensure that producers and manufacturers comply with the said requirements;

Whereas Community control measures should be introduced to guarantee the uniform application in all Member States of the standards laid down in this Directive;

Whereas, in order to ensure the smooth operation of the internal market, the measures should apply in an identical manner to trade within the Member States and to trade between the Member States;

Whereas in the context of intra-Community trade, the rules laid down in Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market <sup>(7)</sup> as amended by Directive 90/675/EEC <sup>(8)</sup> apply to fishery products;

Whereas fishery products from third countries intended to be placed on the market of the Community must not qualify for more favourable arrangements than those applied in the Community; whereas provision should therefore be made for a Community procedure for the inspection in third countries of the conditions of production and placing on the market in order to permit the application of a common import system based on conditions of equivalence;

Whereas the products in question are subject to the rules concerning checks and to safeguard measures covered by Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries;

Whereas, so that account may be taken of particular circumstances, derogations should be granted to some establishments already operating before 1 January 1993 so as to allow them to adapt to all the requirements laid down in this Directive;

<sup>(1)</sup> OJ No C 66, 11. 3. 1988, p. 2;

OJ No C 282, 8. 11. 1989, p. 7 and OJ No C 84, 2. 4. 1990, p. 56.

<sup>(2)</sup> OJ No C 96, 17. 4. 1989, p. 29 and OJ No C 183, 15. 7. 1991.

<sup>(3)</sup> OJ No C 134, 24. 5. 1988, p. 31 and OJ No C 332, 31. 12. 1990, p. 59.

<sup>(4)</sup> OJ No L 379, 31. 12. 1981, p. 1.

<sup>(5)</sup> OJ No L 282, 2. 10. 1989, p. 1.

<sup>(6)</sup> OJ No C 96, 17. 4. 1989, p. 199.

<sup>(7)</sup> OJ No L 395, 30. 12. 1989, p. 13.

<sup>(8)</sup> OJ No L 373, 31. 12. 1990, p. 1.

Whereas the Commission should be entrusted with the task of adopting certain measures for implementing this Directive; whereas, to that end, procedures should be laid down introducing close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee;

Whereas the essential requirements laid down in this Directive may need further specification,

HAS ADOPTED THIS DIRECTIVE

## CHAPTER I

### General provisions

#### Article 1

This Directive lays down the health conditions for the production and the placing on the market of fishery products for human consumption.

#### Article 2

For the purposes of this Directive, the following definitions shall apply:

1. *'fishery products'* means all seawater or freshwater animals or parts thereof, including their roes, excluding aquatic mammals, frogs and aquatic animals covered by other Community acts;
2. *'aquaculture products'* means all fishery products born and raised in controlled conditions until placed on the market as a foodstuff. However seawater or freshwater fish or crustaceans caught in their natural environment when juvenile and kept until they reach the desired commercial size for human consumption are also considered to be aquaculture products. Fish and crustaceans of commercial size caught in their natural environment and kept alive to be sold at a later date are not considered to be aquaculture products if they are merely kept alive without any attempt being made to increase their size or weight;
3. *'chilling'* means the process of cooling fishery products to a temperature approaching that of melting ice;
4. *'fresh products'* means any fishery product whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, which have not undergone any treatment to ensure preservation other than chilling;
5. *'prepared products'* means any fishery product which has undergone an operation affecting its anatomical wholeness, such as gutting, heading, slicing, filleting, chopping, etc.;
6. *'processed products'* means any fishery product which has undergone a chemical or physical process such as the heating, smoking, salting, dehydration or marinating, etc., of chilled or frozen products, whether or not associated with other foodstuffs, or a combination of these various processes;
7. *'preserve'* means the process whereby products are packaged in hermetically sealed containers and subjected to heat treatment to the extent that any micro-organisms that might proliferate are destroyed or inactivated, irrespective of the temperature at which the product is to be stored;
8. *'frozen products'* means any fishery product which has undergone a freezing process to reach a core temperature of  $-18^{\circ}\text{C}$  or lower after temperature stabilization;
9. *'packaging'* means the procedure of protecting fishery products by a wrapper, a container or any other suitable device;
10. *'batch'* means the quantity of fishery products obtained under practically identical circumstances;
11. *'consignment'* means the quantity of fishery products bound for one or more customers in the country of destination and conveyed by one means of transport only;
12. *'means of transport'* means those parts set aside for goods in automobile vehicles, rail vehicles and aircraft, the holds of vessels, and containers for transport by land, sea or air;
13. *'competent authority'* means the central authority of a Member State competent to carry out veterinary checks or any authority to which it has delegated that competence;
14. *'establishment'* means any premises where fishery products are prepared, processed, chilled, frozen, packaged or stored. Auction and wholesale markets in which only display and sale by wholesale takes place are not deemed to be establishments;
15. *'placing on the market'* means the holding or displaying for sale, offering for sale, selling, delivering or any other form of placing on the market in the Community, excluding retail sales and direct transfers on local markets of small quantities by fishermen to retailers or consumers, which must be subject to the health checks laid down by national rules for checking the retail trade;
16. *'importation'* means the introduction into the territory of the Community of fishery products from third countries;

17. 'clean seawater' means seawater or briny water which is free from microbiological contamination, harmful substances and/or toxic marine plankton in such quantities as may affect the health quality of fishery products and which is used under the conditions laid down in this Directive;
18. 'factory vessel' means any vessel on which fishery products undergo one or more of the following operations followed by packaging: filleting, slicing, skinning, mincing, freezing or processing.

The following are not deemed to be 'factory vessels':

- fishing vessels in which only shrimps and molluscs are cooked on board;
- fishing vessels on board which only freezing is carried out.

### Article 3

1. The placing on the market of fishery products caught in their natural environment shall be subject to the following conditions:

- (a) they must have:
- (i) been caught and where appropriate handled for bleeding, heading, gutting and the removal of fins, chilled or frozen, on board vessels in accordance with hygiene rules to be established by the Council acting by a qualified majority on a proposal from the Commission. The Commission shall submit proposals to that effect before 1 October 1992;
  - (ii) where appropriate, been handled in factory vessels approved in accordance with Article 7, and in accordance with the requirements of Chapter I of the Annex.

The cooking of shrimps and molluscs on board must comply with the provisions of Chapter III, section I(5), or Chapter IV, section IV(7), of the Annex. Such vessels shall be specifically registered by the competent authorities;

- (b) during and after landing they must have been handled in accordance with Chapter II of the Annex;
- (c) they must have been handled and, where appropriate, packaged, prepared, processed, frozen, defrosted or stored hygienically in establishments approved in accordance with Article 7, in compliance with the requirements of Chapters III and IV of the Annex.

The competent authority may, notwithstanding Chapter II, section 2 of the Annex, authorize the transfer of fishery products *ex quay* into containers for immediate delivery to an approved establishment or registered auction or wholesale market to be checked there;

- (d) they must have undergone a health check in accordance with Chapter V of the Annex;
- (e) they must have been appropriately packaged in accordance with Chapter VI of the Annex;
- (f) they must have been given an identification mark in accordance with Chapter VII of the Annex;
- (g) they must have been stored and transported under satisfactory conditions of hygiene, in accordance with Chapter VIII of the Annex.

2. Where gutting is possible from a technical and commercial viewpoint, it must be carried out as quickly as possible after the products have been caught or landed.

3. The placing on the market of aquaculture products shall be subject to the following conditions:

- (a) they must have been slaughtered under appropriate conditions of hygiene. They must not be soiled with earth, slime or faeces. If not processed immediately after having been slaughtered, they must be kept chilled;
- (b) they must, in addition, comply with the requirements laid down under 1 (c) to (g).

4. (a) The placing on the market of live bivalve molluscs shall be subject to the requirements laid down in Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs <sup>(1)</sup>.

- (b) When processed, bivalve molluscs must, in addition to the requirements in point (a), satisfy those of paragraph 1 (c) to (g).

### Article 4

Fishery products to be placed on the market alive shall at all times be kept under the most suitable survival conditions.

### Article 5

The placing on the market of the following products shall be forbidden:

- poisonous fish of the following families: *Tetraodontidae*, *Molidae*, *Diodontidae*, *Canthigasteridae*,
- fishery products containing biotoxins such as ciguatera toxins or muscle-paralysing toxins.

Detailed requirements concerning the species covered by this Article and concerning methods of analysis shall be laid down in accordance with the procedure prescribed in Article 15.

<sup>(1)</sup> See page 1 of this Official Journal.

### Article 6

1. Member States shall ensure that persons responsible for establishment take all necessary measures, so that, at all stages of the production of fishery products, the specifications of this Directive are complied with.

To that end, the said persons responsible must carry out their own checks based on the following principles;

- identification of critical points in their establishment on the basis of the manufacturing processes used;
- establishment and implementation of methods for monitoring and checking such critical points;
- taking samples for analysis in an approved laboratory by the competent authority for the purpose of checking cleaning and disinfection methods and for the purpose of checking compliance with the standards established by this Directive;
- keeping a written record or a record registered in an indelible fashion of the preceding points with a view to submitting them to the competent authority. The results of the different checks and tests will in particular be kept for a period of at least two years.

2. If the results of own checks or any information at the disposal of the persons responsible referred to in paragraph 1 reveal the risk of a health risk or suggest one might exist and without prejudice to the measures laid down in the fourth subparagraph of Article 3 (1) of Directive 89/662/EEC, the appropriate measures shall be taken, under official supervision.

3. Rules for the application of the second subparagraph of paragraph 1 shall be established in accordance with the procedure laid down in Article 15.

### Article 7

1. The competent authorities shall approve establishments once they have verified that these establishments meet the requirements of this Directive, with regard to the nature of the activities they carry out. The approval must be renewed if an establishment decides to carry out activities other than those for which it has received approval.

The competent authorities shall take the necessary measures if the requirements cease to be met. To this end, they shall take particular account of the conclusions of any check carried out in accordance with Article 8.

The competent authority shall register those auction and wholesale markets which are not subject to approval after verifying that such installations comply with the provisions of this Directive.

2. However, subject to the express condition that products coming from factory-vessels and establishments,

auction and wholesale markets meet the hygiene standards set by this Directive, Member States may, for the requirements relating to equipment and structures laid down in Chapters I to IV to the Annex, grant to factory-vessels and establishments, auction and wholesale markets a further period expiring on 31 December 1995 within which to comply with the conditions of approval set out in Chapter IX. Such derogations may be granted only to factory-vessels and establishments, auction and wholesale markets, already operating on 31 December 1991, which have, before 1 July 1992, submitted a duly justified application for derogation to the competent national authority. This application must be accompanied by a work plan and programme indicating the period within which it would be possible for them to comply with the requirements in question. Where financial assistance is requested from the Community, only requests in respect of projects complying with the requirements of this Directive can be accepted.

3. The competent authorities shall draw up a list of their approved establishments, each of which shall have an official number.

Each Member State shall notify the Commission of its list of approved establishments and of any subsequent amendment thereof. The Commission shall forward this information to the other Member States.

4. The inspection and monitoring of establishments shall be carried out regularly under the responsibility of the competent authority, which shall at all times have free access to all parts of establishments, in order to ensure compliance with the requirements of this Directive.

If such inspections and monitoring reveal that the requirements of this Directive are not being met, the competent authority shall take appropriate action.

5. Paragraphs 1, 3 and 4 shall also apply in respect of factory vessels.

6. Paragraphs 3 and 4 shall also apply to wholesale and auction markets.

### Article 8

1. Experts from the Commission may, in cooperation with the competent authorities of the Member States, make on-the-spot checks insofar as this is necessary to ensure the uniform application of this Directive. They may in particular verify whether establishments are in effect complying with the requirements of this Directive. A Member State in whose territory a check is being carried out shall give all necessary assistance to the experts in carrying out their duties. The Commission shall inform the Member States of the results of the investigations.

2. The arrangements for implementing paragraph 1 shall be adopted in accordance with the procedure laid down in Article 15.

*Article 9*

1. The rules laid down in Directive 89/662/EEC, as regards fishery products intended for human consumption, shall apply, in particular as regards the organization of and the action to be taken following the inspections to be carried out by the Member States of destination, and the protective measures to be implemented.

2. Directive 89/662/EEC shall be amended as follows:

(a) in Annex A the following indent shall be added:

‘— Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and placing on the market of fishery products (OJ No L 268, 24. 9. 1991, p. 15);’

(b) In Annex B the following indent shall be deleted:

‘— fishery products intended for human consumption’.

## CHAPTER II

**Imports from third countries***Article 10*

Provisions applied to imports of fishery products from third countries shall be at least equivalent to those governing the production and placing on the market of Community products.

Fishery products caught in their natural environment by a fishing vessel flying the flag of a third country must undergo the checks laid down in Article 18 (3) of Directive 90/675/EEC.

*Article 11*

1. For each third country or group of third countries, fishery products must fulfil the specific import conditions fixed in accordance with the procedure laid down in Article 15, depending on the health situation in the third country concerned.

2. In order to allow the import conditions to be fixed, and in order to verify the conditions of production, storage and dispatch of fishery products for consignment to the Community, inspections may be carried out on the spot by experts from the Commission and the Member States.

The experts of the Member States who are to be entrusted with these inspections shall be appointed by the Commission acting on a proposal from the Member States.

These inspections shall be made on behalf of the Community, which shall bear any expenditure incurred.

The frequency of and procedure for these inspections shall be determined in accordance with the procedure laid down in Article 15.

3. When fixing the import conditions of fishery products referred to in paragraph 1, particular account shall be taken of:

- (a) the legislation of the third country;
- (b) the organization of the competent authority of the third country and of its inspection services, the powers of such services and the supervision to which they are subject, as well as their facilities for effectively verifying the implementation of their legislation in force;
- (c) the actual health conditions during the production, storage and dispatch of fishery products intended for the Community;
- (d) the assurances which a third country can give on the compliance with the standards laid down in Chapter V of the Annex.

4. The import conditions referred to in paragraph 1 shall include:

- (a) the procedure for obtaining a health certificate which must accompany consignments when forwarded to the Community;
- (b) the placing of a mark identifying the fishery products, in particular with the approval number of the establishment of origin, except in the case of frozen fishery products, landed immediately for canning and bearing the certificate provided for under (a);
- (c) drawing up a list of approved establishments and auction or wholesale markets registered and approved by the Commission in accordance with the procedure laid down in Article 15;

For that purpose, one or more lists of such establishments shall draw up on the basis of a communication from the competent authorities of the third country to the Commission. An establishment may not appear on a list unless it is officially approved by the competent authority of the third country exporting to the Community. Such approval shall be subject to observance of the following requirements:

- compliance with requirements equivalent to those laid down in this Directive,
- monitoring by an official inspection service of the third country.

5. The conditions referred to in paragraph 4 (a) and (b) may be modified in accordance with the procedure laid down in Article 15.

The list referred to in paragraph 4 (c) may be amended by the Commission, in accordance with the rules established by Commission Decision 90/13/EEC <sup>(1)</sup>.

6. To deal with specific situations and in accordance with the procedure laid down in Article 15, imports may be authorized direct from an establishment or factory vessel of a third country where the latter is unable to provide the guarantees laid down in paragraph 3, provided that the establishment or factory vessel in question has received special approval following an inspection carried out in accordance with paragraph (2). The authorization decision shall fix the specific import conditions to be followed for products coming from that establishment or factory vessel.

7. Pending the fixing of the import conditions referred to in paragraph 1, the Member States shall ensure that the conditions applied to imports of fishery products from third countries shall be at least equivalent to those governing the production and placing on the market of Community products.

#### Article 12

1. The rules and principles laid down by Directive 90/675/EEC shall apply, notably as regards the organization of and follow up to the inspections to be carried out by the Member States.

2. Without prejudice to compliance with the rules and principles referred to in paragraph 1 of this Article and pending implementation of the decisions provided for in Article 8 (3) and Article 30 of Directive 90/675/EEC, and in Article 11 of this Directive the relevant national rules for applying Article 8 (1) and (2) of the said Directive shall continue to apply.

### CHAPTER III

#### Final provisions

#### Article 13

The Annexes shall be amended by the Council, acting by a qualified majority on a proposal from the Commission.

#### Article 14

The Commission, after consulting the Member States, shall by 1 July 1992 submit a report to the Council concerning the minimum structural and equipment requirements to be met by small establishments which distribute on the local market and are situated in regions subject to particular supply constraints, together with any proposals, on which the

<sup>(1)</sup> OJ No L 8, 11. 1. 1990, p. 70.

Council, acting under the voting procedure laid down in Article 43 of the Treaty, shall act before 31 December 1992.

#### Article 15

1. Where the procedure laid down in this Article is to be followed, the Chairman shall refer the matter to the Standing Veterinary Committee set up by Decision 68/361/EEC <sup>(2)</sup> hereafter referred to as the Committee, either on his own initiative or at the request of a Member State.

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

(b) If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

#### Article 16

In order to take into account the possible failure to take a decision on the detailed rules for applying this Directive by 1 January 1993, necessary transitional measures may be adopted in accordance with the procedure laid down in Article 15 for a period of two years.

#### Article 17

The provisions of this Directive shall be re-examined before 1 January 1998 by the Council, acting on proposals from the Commission, on the basis of experience gained.

<sup>(2)</sup> OJ No L 255, 18. 10. 1968, p. 23.

*Article 18*

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1993. They shall notify the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

*Article 19*

This Directive is addressed to the Member States.

Done at Brussels, 22 July 1991.

*For the Council*  
*The President*  
P. DANKERT

## ANNEX

## CHAPTER I

## CONDITIONS APPLICABLE TO FACTORY VESSELS

## I. Conditions concerning design and equipment

## 1. The minimum requirements for factory vessels are as follows:

- (a) a reception area set aside for taking fishery products on board, designed and arranged into pounds or pens that are large enough to allow each successive catch to be separated. The reception area and its movable parts must be easy to clean. It must be designed in such a way as to protect the products from the sun or the elements and from any source of dirt or contamination;
- (b) a system for conveying fishery products from the reception area to the work area that conforms with rules of hygiene;
- (c) work areas that are large enough for the preparation and processing of fishery products in proper conditions of hygiene. They must be designed and arranged in such a way as to prevent any contamination of the products;
- (d) storage areas for the finished products that are large enough and designed so that they are easy to clean. If a waste processing unit operates on board, a separate hold must be designated for the storage of these by-products;
- (e) a place for storing packaging materials that is separate from the product preparation and processing areas;
- (f) special equipment for pumping waste or fishery products that are unfit for human consumption either directly into the sea or, where circumstances so require, into a watertight tank reserved for that purpose. If waste is stored and processed on board with a view to cleaning, separate areas must be allocated for that purpose;
- (g) equipment providing a supply of potable water within the meaning of Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption <sup>(1)</sup> or pressurized clean seawater. The seawater intake must be situated in a position where it is not possible for the water being taken in to be affected by discharges into the sea of waste water, waste and engine coolant outlets;
- (h) a suitable number of changing rooms, wash basins and toilets, the latter not opening directly onto areas where fishery products are prepared, processed or stored. The wash basins must be equipped with appliances for washing and drying the hands that comply with hygiene requirements; the wash-basin taps must not be hand-operable.

## 2. Areas used for the preparation and processing or freezing/quick-freezing of fishery products must have:

- (a) a non-slip floor that is also easy to clean and disinfect and equipped for easy drainage of water. Structures and fixtures must have limber holds that are large enough not to be obstructed by fish waste and to allow water to drain freely;
- (b) walls and ceilings that are easy to clean, particularly where there are pipes, chains or electricity conduits;
- (c) the hydraulic circuits must be arranged or protected in such a way as to ensure that it is not possible for any leakage of oil to contaminate fishery products;
- (d) adequate ventilation and, where necessary, proper vapour extraction;
- (e) adequate lighting;
- (f) appliances for cleaning and disinfecting tools, equipment and fittings;
- (g) appliances for cleaning and disinfecting the hands with taps that are not hand-operable and with single use towels.

<sup>(1)</sup> OJ No L 229, 30. 9.1980, p. 11. Directive last amended by the 1985 Act of Accession (OJ No L 302, 15. 11. 1985, p. 218).



3. Equipment and tools such as cutting benches, containers, conveyors, gutting or filleting machines, etc., must be resistant to seawater corrosion, easy to clean and disinfect and well-maintained.
4. Factory vessels which freeze fishery products must have:
  - (a) a refrigeration plant sufficiently powerful to lower the temperature rapidly so as to achieve a core temperature that complies with the specifications of this Directive;
  - (b) refrigeration plants sufficiently powerful to keep fishery products in the storage holds at a temperature that complies with the specifications of this Directive. The storage holds must be equipped with a temperature recording system placed so that it can easily be consulted.

## II. Conditions of hygiene relating to on-board handling and storage of fishery products

1. A qualified person on board the factory vessel must be responsible for applying good fishery products manufacturing practices. That person shall have the authority to ensure that the provisions of this Directive are applied and shall make available to inspectors the programme for inspecting and checking critical points as applied on board, a register containing that person's comments and the temperature recordings that may be required.
2. The general conditions of hygiene applicable to areas and equipment shall be those laid down in Chapter III, section II (A), of this Annex.
3. The general conditions of hygiene applicable to staff shall be those laid down in Chapter III, section II (B), of this Annex.
4. Heading, gutting and filleting must be carried out under the conditions of hygiene laid down in Chapter IV, section I (2), (3) and (4) of this Annex.
5. On-board processing of fishery products must be carried out under the conditions of hygiene laid down in Chapter IV, sections III, IV and V of this Annex.
6. Fishery products must be wrapped and packaged under the conditions of hygiene laid down in Chapter VI of this Annex.
7. On-board storage of fishery products must be carried out under the conditions of hygiene laid down in Chapter VIII, points 1 and 2, of this Annex.

## CHAPTER II

### REQUIREMENTS DURING AND AFTER LANDING

1. Unloading and landing equipment must be constructed of material which is easy to clean and disinfect and must be kept in a good state of repair and cleanliness.
2. During unloading and landing, contamination of fishery products must be avoided. It must in particular be ensured that:
  - unloading and landing operations proceed rapidly;
  - fishery products are placed without unnecessary delay in a protected environment at the temperature required on the basis of the nature of the product and, where necessary, in ice in transport, storage or market facilities, or in an establishment;
  - equipment and handling practices that cause unnecessary damage to the edible parts of the fishery products are not authorized.
3. Parts of auction or wholesale markets where fishery products are displayed for sale must:
  - (a) be covered and have walls which are easy to clean;
  - (b) have waterproof flooring which is easy to wash and disinfect and laid in such a way as to facilitate the drainage of water and have a hygienic waste water disposal system;

- (c) be equipped with sanitary facilities with an appropriate number of wash basins and flush lavatories. Wash basins shall be supplied with materials for cleaning the hands and single use hand towels;
  - (d) be well lit to facilitate the inspection of fishery products provided for in Chapter V of this Annex;
  - (e) when they are used for display or storage of fishery products, not be used for other purposes; vehicles emitting exhaust fumes which may impair the quality of the fishery products not be admitted to markets; undesirable animals must not be admitted;
  - (f) be cleaned regularly and at least after each sale; crates must, after each sale, be cleaned and rinsed inside and outside with drinking water or clean seawater; where required, they must be disinfected;
  - (g) have displayed in a prominent position signs prohibiting smoking, spitting, eating and drinking;
  - (h) be closeable and be kept closed when the competent authority considers it necessary;
  - (i) have facilities to provide adequate water supplies satisfying the conditions laid down in Chapter III, section I, point 7 of this Annex;
  - (j) have special watertight receptacles made of corrosion-resistant materials for fishery products which are unfit for human consumption;
  - (k) insofar as they do not have their own premises on-the-spot or in the immediate vicinity on the basis of the quantities displayed for sale, have, for the purposes of the competent authority, an adequately equipped lockable room and the equipment necessary for carrying out inspections.
4. After landing or, where appropriate, after first sale, fishery products must be transported without delay, under the conditions laid down in Chapter VIII, of this Annex, to their place of destination.
5. However, if the conditions laid down in point 4 are not fulfilled, the markets in which fishery products may be stored before being displayed for sale or after being sold and pending transport to their place of destination must have sufficiently large cold rooms which satisfy the conditions laid down in Chapter III, section I, point 3 of this Annex. In such cases, fishery products must be stored at a temperature approaching that of melting ice.
6. The general conditions of hygiene laid down in Chapter III, section II — with the exception of point B 1(a) — of this Annex shall apply *mutatis mutandis* to the markets in which fishery products are displayed for sale or stored.
7. The wholesale markets in which fishery products are displayed for sale or stored shall be subject to the same conditions as those laid down in points 3 and 5 of this Chapter and to those set out in points 4, 10 and 11 of Chapter III, section I of this Annex.

The general conditions of hygiene laid down in Chapter III, section II of this Annex shall apply *mutatis mutandis* to wholesale markets.

### CHAPTER III

#### GENERAL CONDITIONS FOR ESTABLISHMENTS ON LAND

##### I. General conditions relating to premises and equipment

Establishment shall afford at least the following facilities:

- 1. working areas of sufficient size for work to be carried out under adequate hygienic conditions. Their design and layout shall be such as to preclude contamination of the product and keep quite separate the clean and contaminated parts of the building;
- 2. in areas where products are handled, prepared and processed:
  - (a) waterproof flooring which is easy to clean and disinfect and laid down in such a way as to facilitate the drainage of the water or provided with equipment to remove water;

- (b) walls which have smooth surfaces and are easy to clean, durable and impermeable;
  - (c) ceilings or roof linings which are easy to clean;
  - (d) doors in durable materials which are easy to clean;
  - (e) adequate ventilation and, where necessary, good steam and water-vapour extraction facilities;
  - (f) adequate natural or artificial lighting;
  - (g) an adequate number of facilities for cleaning and disinfecting hands. In work rooms and lavatories taps must not be hand-operable. These facilities must be provided with single use hand towels;
  - (h) facilities for cleaning plant, equipment and utensils;
3. in cold rooms where fishery products are stored:
    - the provisions set out under point 2 (a), (b), (c), (d) and (f);
    - where necessary, a sufficiently powerful refrigeration plant to keep products at temperatures prescribed in this Directive;
  4. appropriate facilities for protection against pests such as insects, rodents, birds, etc.;
  5. instruments and working equipment such as cutting tables, containers, conveyor belts and knives made of corrosion-resistant materials, easy to clean and disinfect;
  6. special watertight, corrosion-resistant containers for fishery products not intended for human consumption and premises for the storage of such containers if they are not emptied at least at the end of each working day;
  7. facilities to provide adequate supplies of drinking water within the meaning of Directive 80/778/EEC, or alternatively of clean seawater or seawater treated by an appropriate system, under pressure and in sufficient quantity. However, by way of exception, a supply of non-drinking water is permissible for the production of steam, fire-fighting and the cooling of refrigeration equipment, provided that the pipes installed for the purpose preclude the use of such water for other purposes and present no risk of contamination of the products. Non-drinking-water pipes must be clearly distinguished from those used for drinking water or clean seawater;
  8. hygienic waste water disposal system;
  9. an adequate number of changing-rooms with smooth, water-proof, washable walls and floors, wash basins and flush lavatories. The latter may not open directly onto the work rooms. The wash basins must have materials for cleaning the hands and disposable towels; the wash basin taps must not be hand-operable;
  10. if the volume of products treated requires regular or permanent presence an adequately equipped lockable room for the exclusive use of the inspection service;
  11. adequate facilities for cleaning and disinfecting means of transport. However, such facilities are not compulsory if there is a requirement for the means of transport to be cleaned and disinfected at facilities officially authorized by the competent authority;
  12. establishments keeping live animals such as crustaceans and fish must have appropriate fittings ensuring the best survival conditions provided with water of a quality such that no harmful organisms or substances are transferred to the animals.

## II. General conditions of hygiene

### A. *General conditions of hygiene applicable to premises and equipment*

1. Floors, walls and partitions, ceilings or roof linings, equipment and instruments used for working on fishery products must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the products.
2. Rodents, insects and any other vermin must be systematically exterminated in the premises or on the equipment; rodenticides, insecticides, disinfectants and any other potentially toxic substances must be stored in premises or cupboards which can be locked; their use must not present any risk of contamination of the products.

3. Working areas, instruments and working equipment must be used only for work on fishery products. However, following authorization by the competent authority they may be used at the same time or other times for work on other foodstuffs.
4. Drinking water, within the meaning of Directive 80/778/EEC, or clean seawater must be used for all purposes. However, by way of an exception, non-drinking water may be used for steam production, fire-fighting and the cooling of refrigeration equipment, provided that the pipes installed for the purpose preclude the use of such water for other purposes and present no risk of contamination of the products.
5. Detergents, disinfectants and similar substances must be approved by the competent authority and used in such a way that they do not have adverse effects on the machinery, equipment and products.

**B. General conditions of hygiene applicable to staff**

1. The highest possible standard of cleanliness is required of staff. More specifically:
  - (a) staff must wear suitable clean working clothes and headgear which completely encloses the hair. This applies particularly to persons handling exposed fishery products;
  - (b) staff assigned to the handling and preparation of fishery products must be required to wash their hand at least each time work is resumed; wounds to the hands must be covered by a waterproof dressing;
  - (c) smoking, spitting, eating and drinking in work and storage premises of fishery products must be prohibited.
2. The employer shall take all the requisite measures to prevent persons liable to contaminate fishery products from working on and handling them, until there is evidence that such persons can do so without risk.

When recruited, any person working on and handling fishery products shall be required to prove, by a medical certificate, that there is no impediment to such employment. The medical supervision of such a person shall be governed by the national legislation in force in the Member State concerned or in the case of third countries by specific guarantees to be fixed under the procedure set out in Article 15.

## CHAPTER IV

### SPECIAL CONDITIONS FOR HANDLING FISHERY PRODUCTS ON SHORE

**I. Conditions for fresh products**

1. Where chilled, unpackaged products are not dispatched, prepared or processed immediately after reaching the establishment, they must be stored or displayed under ice in the establishment's cold room. Re-icing must be carried out as often as is necessary; the ice used, with or without salt, must be made from drinking water or clean seawater and be stored under hygienic conditions in receptacles provided for the purpose; such receptacles must be kept clean and in a good state of repair. Prepacked fresh products must be chilled with ice or mechanical refrigeration plant creating similar temperature conditions.
2. If they are not carried out on board, operations such as heading and gutting must be carried out hygienically. The products must be washed thoroughly with drinking water or clean seawater immediately after such operations.
3. Operations such as filleting and slicing must be carried out in such a way as to avoid the contamination or spoilage of fillets and slices, and in a place other than that used for heading and gutting operations. Fillets and slices must not remain on work tables any longer than is necessary for their preparation. Fillets and slices to be sold fresh must be chilled as quickly as possible after preparation.
4. Guts and parts that may constitute a danger to public health must be separated from and removed from the vicinity of products intended for human consumption.
5. Containers used for the dispatch or storage of fresh fishery products must be designed in such a way as to ensure both their protection from contamination and their preservation under sufficiently hygienic conditions and, more particularly, they must provide adequate drainage of melt water.

6. Unless special facilities are provided for the continuous disposal of waste, the latter must be placed in leakproof, covered containers which are easy to clean and disinfect. Waste must not be allowed to accumulate in working areas. It must be removed either continuously or as soon as the containers are full and at least at the end of each working day in the containers or to the premises referred to in Chapter III, section I, paragraph 6 of this Annex. The containers, receptacles and/or premises set aside for waste must always be thoroughly cleaned and, if appropriate, disinfected after use. Waste stored there must not constitute a source of contamination for the establishment or of pollution of its surroundings.

## II. Conditions for frozen products

### 1. Plants must have:

- (a) freezing equipment sufficiently powerful to achieve a rapid reduction in the temperature so that the temperatures laid down in this Directive can be obtained in the product;
- (b) freezing equipment sufficiently powerful to keep products in storage rooms at a temperature not exceeding those laid down in this Directive, whatever the ambient temperature may be.

However, for technical reasons related to the method of freezing and to the handling of such products, for whole fish frozen in brine and intended for canning, higher temperatures than those laid down in this Directive are acceptable although they may not exceed  $-9^{\circ}\text{C}$ .

2. Fresh products to be frozen or quick-frozen must comply with the requirements of section I of this Chapter.
3. Storage rooms must have a temperature recording device in a place where it can easily be read. The temperature sensor of the recorder must be located in the area furthest away from the cold source, i.e. where the temperature in the storage room is the highest.

Temperature charts must be available for inspection by the supervisory authorities at least during the period in which the products are stored.

## III. Conditions for thawing products

Establishments that carry out thawing operations must comply with the following requirements:

1. fishery products must be thawed under hygienic conditions; their contamination must be avoided and there must be adequate drainage for any melt water produced.

During thawing, the temperature of the products must not increase excessively;

2. after thawing, fishery products must be handled in accordance with the requirements of this Directive. When they are prepared or processed, these operations must be carried out without delay. If they are put directly onto the market, particulars as to the thawed state of the fish must be clearly marked on the packaging in accordance with Article 5 (3) of Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs <sup>(1)</sup>.

## IV. Conditions for processed products

1. Fresh, frozen and thawed products used for processing must comply with the requirements of sections I or II of this Chapter.
2. Where the processing treatment is carried out to inhibit the development of pathogenic micro-organisms, or if it is a significant factor in the preservation of the product, the treatment must be scientifically recognized by the law in force, or in the case of a treatment of products referred to in Chapter I Section 1 (b) and (c) of Directive 91/492/EEC which have not been relayed or purified, such treatment must be approved, in accordance with the procedure laid down in Article 15 of this Directive, within four months of receipt of a request from a Member State.

The person responsible for an establishment must keep a register of the processing carried out. Depending on the type of process employed, heating time and temperature, salt content, pH, water content, etc., must be monitored and controlled. Records must be kept at least for the expected storage life of the products and be available to the competent authority.

<sup>(1)</sup> OJ No L 33, 8. 2. 1979, p. 1. Directive last amended by Directive 91/72/EEC (OJ No L 42, 16. 1. 1991, p. 22).

3. For products which are preserved for a limited period by a treatment such as salting, smoking, drying or marinating, the appropriate conditions for storage must be clearly marked on the packaging, in accordance with Directive 79/112/EEC.

In addition, the following conditions shall be complied with.

#### 4. *Canning*

In the case of fishery products which have been subjected to sterilization in hermetically sealed containers:

- (a) the water used for the preparation of cans must be drinking water;
- (b) the process used for the heat treatment must be appropriate, having regard to such major criteria as the heating time, temperature, filling, size of containers, etc., a record of which must be kept; the heat treatment must be capable of destroying or inactivating pathogenic organisms and the spores of pathogenic micro-organisms. The heating equipment must be fitted with devices for verifying whether the containers have in fact undergone appropriate heat treatment. Drinking water must be used to cool containers after heat treatment, without prejudice to the presence of any chemical additives used in accordance with good technological practice to prevent corrosion of the equipment and containers;
- (c) further checks must be carried out at random by the manufacturer to ensure that the processed products have undergone appropriate heat treatment, *viz.*:
  - incubation tests: incubation must be carried out at 37 °C for seven days or at 35 °C for ten days, or at any other equivalent combination;
  - microbiological examination of contents and containers in the establishment's laboratory or in another approved laboratory;
- (d) samples must be taken of production each day at predetermined intervals, to ensure the efficacy of sealing. For that purpose, appropriate equipment must be available for the examination of cross-sections of the can-seams;
- (e) checks are carried out in order to ensure that containers are not damaged;
- (f) all containers which have undergone heat treatment under practically identical conditions must be given a batch identification mark, in accordance with Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs <sup>(1)</sup>.

#### 5. *Smoking*

Smoking must be carried out in separate premises or a special place equipped, if necessary, with a ventilation system to prevent the smoke and heat from the combustion from affecting other premises or places where fishery products are prepared, processed or stored.

- (a) Materials used to produce smoke for the smoking of fish must be stored away from the place of smoking and must be used in such a way that they do not contaminate the products.
- (b) Materials used to produce smoke by burning wood that has been painted, varnished, glued or has undergone any chemical preservation treatment must be prohibited.
- (c) After smoking, products must be cooled rapidly to the temperature required for their preservation before being packaged.

#### 6. *Salting*

- (a) Salting operations must take place in different premises and sufficiently removed from the premises where the other operations are carried out.
- (b) Salt used in the treatment of fishery products must be clean and stored in such a way as to preclude contamination. It must not be re-used.
- (c) Any container used for salting or brining must be constructed in such a way as to preclude contamination during the salting or brining process.
- (d) Containers or areas used for salting or brining must be cleaned before use.

<sup>(1)</sup> OJ No L 186, 30. 6. 1989, p. 21.

#### 7. *Cooked crustacean and molluscan shellfish products*

Crustaceans and molluscan shellfish must be cooked as follows:

- (a) any cooking must be followed by rapid cooling. Water used for this purpose must be drinking water or clean seawater. If no other method of preservation is used, cooling must continue until the temperature approaching that of melting ice is reached;
- (b) shelling or shucking must be carried out under hygienic conditions avoiding the contamination of the product. Where such operations are done by hand, workers must pay particular attention to the washing of their hands and all working surfaces must be cleaned thoroughly. If machines are used, they must be cleaned at frequent intervals and disinfected after each working day.

After shelling or shucking, cooked products must immediately be frozen or kept chilled at a temperature which will preclude the growth of pathogens, and be stored in appropriate premises;

- (c) every manufacturer must carry out micro-biological checks on his production at regular intervals, complying with the standards to be fixed in accordance with Chapter V, Section 4 of this Annex.

#### 8. *Mechanically recovered fish flesh*

The mechanical recovery of fish flesh must be carried out under the following conditions:

- (a) mechanical recovery of gutted fish must take place without undue delay after filleting, using raw materials free of guts. Where whole fish are used, they must be gutted and washed beforehand;
- (b) the machinery must be cleaned at frequent intervals and at least every two hours;
- (c) after recovery, mechanically recovered flesh must be frozen as quickly as possible or incorporated in a product intended for freezing or stabilizing treatment.

### V. *Conditions concerning parasites*

1. During production and before they are released for human consumption, fish and fish products must be subject to a visual inspection for the purpose of detecting and removing any parasites that are visible.

Fish or parts of fish which are obviously infested with parasites, and which are removed, must not be placed on the market for human consumption.

The detailed rules for this inspection shall be adopted in accordance with the procedure laid down in Article 15 of this Directive, on a proposal from the Commission to be submitted before 1 October 1992.

2. The fish and fish products referred to in point 3 which are to be consumed as they are must, in addition, be subjected to freezing at a temperature of not more than  $-20\text{ }^{\circ}\text{C}$  in all parts of the product for not less than 24 hours. Products subjected to this freezing process must be either raw or finished.
3. Fish and products subject to the conditions in point 2:
  - (a) fish to be consumed raw or almost raw, e.g. raw herring 'maatje';
  - (b) the following species, if they are to undergo a cold smoking process at which the internal temperature of the fish is less than  $60\text{ }^{\circ}\text{C}$ :
    - herring,
    - mackerel,
    - sprat,
    - (wild) Atlantic and Pacific salmon;
  - (c) marinated and/or salted herring where this process is insufficient to destroy the larvae of nematodes.

This list may be amended, in the light of scientific data, in accordance with the procedure laid down in Article 15 of this Directive. In accordance with the same procedure, criteria will be laid down which must enable the processes which are deemed sufficient or insufficient to destroy nematodes to be defined.

4. Manufacturers must ensure that fish and fish products listed in point 3 or the raw materials for use in their manufacture are subjected to the treatment described in point 2, prior to their release for consumption.
5. The fishery products listed in point 3 must, when they are placed on the market, be accompanied by a document from the manufacturer stating the type of process they have undergone.

## CHAPTER V

### HEALTH CONTROL AND MONITORING OF PRODUCTION CONDITIONS

#### I. General monitoring

Arrangements for checking and monitoring must be made by the competent authorities in order to establish whether the requirements laid down in this Directive are complied with.

Such arrangements will include, in particular:

1. a check on the fishing vessels, on the understanding that such a check may be carried out during the stay in port;
2. a check on the conditions of landing and first sale;
3. an inspection at regular intervals of establishments to check, in particular:
  - (a) whether the conditions for approval are still fulfilled;
  - (b) whether the fishery products are handled correctly;
  - (c) the cleanliness of the premises, facilities and instruments and staff hygiene;
  - (d) whether identification marks are put on correctly;
4. an inspection of the wholesale and auction markets;
5. a check on storage and transport conditions.

#### II. Special checks

##### 1. *Organoleptic checks*

Without prejudice to the derogations provided for by Council Regulation (EEC) No 103/76 of 19 January 1976 laying down common marketing standards for certain fresh or chilled fish <sup>(1)</sup>, each batch of fishery products must be submitted for inspection by the competent authority at the time of landing or before first sale to check whether they are fit for human consumption. This inspection comprises an organoleptic check carried out by sampling.

Fishery products complying, as far as the freshness criteria are concerned, with the common marketing standards already laid down pursuant to Article 2 of Regulation (EEC) No 3796/81 are considered to fulfil the organoleptic requirements necessary for compliance with the provisions of this Directive.

The Commission may, where necessary, in accordance with the procedure referred to in Article 15 of this Directive, lay down specific organoleptic requirements for fishery products not harmonized under Regulation (EEC) No 3796/81.

The organoleptic examination must be repeated after the first sale of fishery products, if it is found that the requirements of this Directive have not been complied with or when considered necessary. After the first sale, fishery products must at least comply with the minimum freshness requirements of the aforementioned Regulation.

If the organoleptic examination reveals that the fishery products are not fit for human consumption, measures must be taken to withdraw them from the market and denature in such a way that they cannot be re-used for human consumption.

If the organoleptic examination reveals any doubt as to the freshness of the fishery products, use may be made of chemical checks or microbiological analyses.

##### 2. *Parasite checks*

Before they are released for human consumption, fish and fish products must be subject to a visual inspection, by way of sample, for the purpose of detecting any parasites that are visible.

<sup>(1)</sup> OJ No L 20, 28. 1. 1976, p. 29. Regulation last amended by Regulation (EEC) No 33/89 (OJ No L 5, 7. 1. 1989, p. 18).



Fish or parts of fish which are obviously infested with parasites, and which are removed, must not be placed on the market for human consumption.

The detailed rules for this inspection shall be established in accordance with the procedure laid down in Article 15.

### 3. *Chemicals checks*

A. Samples must be taken and subjected to laboratory analysis for the control of the following parameters:

(a) TVB-N (Total Volatile Basic Nitrogen) and TMA-N (Trimethylamine-Nitrogen)

The levels of these parameters must be specified for each category of species in accordance with the procedure laid down in Article 15 of this Directive.

(b) Histamine

Nine samples must be taken from each batch. These must fulfil the following requirements:

- the mean value must not exceed 100 ppm;
- two samples may have a value of more than 100 ppm but less than 200 ppm;
- no sample may have a value exceeding 200 ppm.

These limits apply only to fish species of the following families: Scombridae and Clupeidae. However, fish belonging to these families which have undergone enzyme ripening treatment in brine may have higher histamine levels but not more than twice the above values. Examinations must be carried out in accordance with reliable, scientifically recognized methods, such as high-performance liquid chromatography (HPLC).

B. Contaminants present in the aquatic environment

Without prejudice to the Community rules concerning water protection and management, and in particular those concerning pollution of the aquatic environment, fishery products must not contain in their edible parts contaminants present in the aquatic environment such as heavy metals and organochlorinated substances at such a level that the calculated dietary intake exceeds the acceptable daily or weekly intake for humans.

A monitoring system must be established by the Member States to check the level of contamination of fishery products.

C. In accordance with the procedure laid down in Article 15 of this Directive, the following shall be decided on by not later than 31 December 1992:

- (a) the methods of analysis to be used to check the chemical parameters, as well as the sampling plans;
- (b) the acceptable levels for the chemical parameters.

### 4. *Microbiological analyses*

In accordance with the procedure laid down in Article 15 of this Directive, microbiological criteria, including sampling plans and methods of analysis, may be laid down when there is a need to protect public health. The Commission will to this end submit appropriate proposals for measures by 1 October 1992.

## CHAPTER VI

### PACKAGING

1. Packaging must be carried out under satisfactory conditions of hygiene, to preclude contamination of the fishery products.
2. Packaging materials and products liable to enter into contact with fishery products must comply with all the rules of hygiene, and in particular:
  - they must not be such as to impair the organoleptic characteristics of the fishery products;
  - they must not be capable of transmitting to the fishery products substances harmful to human health;
  - they must be strong enough to protect the fishery products adequately.

3. With the exception of certain containers made of impervious, smooth and corrosion-resistant material which are easy to clean and disinfect, which may be re-used after cleaning and disinfecting, packaging materials may not be re-used. Packaging materials used for fresh products held under ice must provide adequate drainage for melt water.
4. Unused packaging materials must be stored in premises away from the production area and be protected from dust and contamination.

#### CHAPTER VII

##### IDENTIFICATION MARKS

Without prejudice to the requirements laid down in Directive 79/112/EEC, it must be possible to trace for inspection purposes the establishment of dispatch of consignments of fishery products, by means of either labelling or the accompanying documents. For that purpose, the following information must appear on the packaging or in the accompanying documents:

- the country of dispatch;
- identification of the establishment by its official approval number or, in the case of separate registering of auction or wholesale markets as laid down in Article 7 (1), third subparagraph of this Directive, the registration number of the auction or wholesale market.

#### CHAPTER VIII

##### STORAGE AND TRANSPORT

1. Fishery products must, during storage and transport, be kept at the temperatures laid down in this Directive and in particular:
  - fresh or thawed fishery products and cooked and chilled crustacean and molluscan shellfish products must be kept at the temperature of melting ice;
  - frozen fishery products, with the exception of frozen fish in brine intended for the manufacture of canned foods, must be kept at an even temperature of  $-18^{\circ}\text{C}$  or less in all parts of the product, allowing for the possibility of brief upward fluctuations of not more than  $3^{\circ}\text{C}$ , during transport;
  - processed products must be kept at the temperatures specified by the manufacturer, when the circumstances so require, prescribed in accordance with the procedure laid down in Article 15 of this Directive.
2. Where frozen fishery products are transported from a cold-storage plant to an approved establishment to be thawed on arrival for the purposes of preparation and/or processing and where the distance to be covered is short, not exceeding 50 km or one hour's journey, the competent authority may grant a derogation from the conditions laid down in point 1, second indent.
3. Products may not be stored or transported with other products which may contaminate them or affect their hygiene, unless they are packaged in such a way as to provide satisfactory protection.
4. Vehicles used for the transport of fishery products must be constructed and equipped in such a way that the temperatures laid down in this Directive can be maintained throughout the period of transport. If ice is used to chill the products, adequate drainage must be provided in order to ensure that water from melted ice does not stay in contact with the products. The inside surfaces of the means of transport must be finished in such a way that they do not adversely affect the fishery products. They must be smooth and easy to clean and disinfect.
5. Means of transport used for fishery products may not be used for transporting other products likely to impair or contaminate fishery products, except where the fishery products can be guaranteed uncontaminated as a result of such transport being thoroughly cleaned and disinfected.

6. Fishery products may not be transported in a vehicle or container which is not clean or which should have been disinfected.
7. The transport conditions of fishery products to be placed on the market alive must not adversely affect the products.

#### CHAPTER IX

#### POINTS OF ANNEX I WHICH MAY BE SUBJECT TO DEROGATIONS AND POSSIBLE CONDITIONS APPLICABLE IN THE CASE OF DEROGATIONS

##### Re Chapter I Part I of the Annex

1. *Point 1 (a)*

provided products are sheltered from the sun and the elements and from any source of dirt or contamination.

2. *Point 1 (c)*

provided any contamination of the products is prevented.

3. *Point 1 (d), first sentence*

provided the finished products are stored on board at the required temperature.

4. *Point 1 (g), last sentence*

provided products cannot be contaminated by waste water, waste or engine coolant.

5. *Point 1 (h)*

provided staff handling fishery products can wash their hands after using the toilet.

6. *Point 2 (a)*

provided floors are properly cleaned and disinfected.

7. *Point 2 (b), (c) and (d)*

8. *Point 2 (g) on taps and towels*

9. *Point 3*

provided equipment and tools are well maintained.

##### Re Chapter II of the Annex

10. *Point 3 (a)*

provided the walls are kept clean.

11. *Point 3 (b)*

provided the flooring is kept clean after every sale.

12. *Point 3 (c), first sentence*

13. *Point 3 (e): vehicles emitting exhaust fumes*

provided products contaminated by exhaust fumes are withdrawn from the market.

14. *Point 3 (j)*

provided that products which are not fit for human consumption cannot contaminate or be mixed with fishery products.

15. *Point 3 (k)*
16. *Point 7*  
insofar as it refers to point 3 of the same Chapter and point 10 of Chapter III, section I.

**Re Chapter III Part I of the Annex**

17. *Point 1*  
provided finished products cannot be contaminated by raw materials or waste.
18. *Point 2 (a)*  
provided the flooring is cleaned and disinfected accordingly.
19. *Point 2 (b)*  
provided the walls are kept clean.
20. *Point 2 (c)*  
provided the ceiling is not a source of contamination.
21. *Point 2 (d)*
22. *Point 2 (e)*  
provided products cannot be spoiled or contaminated by the steam.
23. *Point 2 (g)*  
provided there are facilities available for staff to wash their hands.
24. *Point 3*
25. *Point 5*  
insofar as it relates to corrosion-resistant materials provided instruments and working equipment are kept clean.
26. *Point 6*  
provided products cannot be contaminated by waste or leakage therefrom.
27. *Point 10*

**Re Chapter IV of the Annex**

28. *Part I, point 1*  
in respect of the requirement for products being held over to be put in the establishment's cold room provided the products are re-iced as often as necessary during a period not in excess of 12 hours or that a nearby cold room not belonging to the establishment can be used.
29. *Part I, point 6*  
in respect of the requirement for waste to be put in leakproof covered containers provided products cannot be contaminated by waste or leakage therefrom.
30. *Part IV, point 5, first paragraph*  
provided that every precaution is taken to prevent fishery products that are being prepared or stored from being affected by the smoke.
31. *Part IV, point 6 (a)*  
provided fishery products that are being prepared or stored are not affected by salting operations.