



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 28 September 2001

12259/01

**Interinstitutional Files:
2000/0178 (COD)
2000/0179 (COD)**

**DENLEG 45
AGRILEG 222
CODEC 937**

NOTE

From : Presidency
To : Working Party of Veterinary Experts (Public Health)

No. prev. doc. : SN 3725/01, 11017/01, 7959/01
No. Cion prop. : 10427/00 - COM(2000) 438 final

Subject : Proposals for Regulations:
- on the hygiene of foodstuffs
- laying down specific hygiene rules for food of animal origin

I. INTRODUCTION

On 19 and 20 July, the Working Party undertook a first reading of Sections VII and VIII of Annex II to the draft Regulation laying down specific hygiene rules for food of animal origin. Section VII deals with live bivalve molluscs and Section VIII with fishery products.

On 14 September, the Working Party re-examined the key issues identified at its first meeting and reached broad agreement on the principle of certain changes to the Commission's proposal.¹

¹ No representative of the L delegation attended either meeting. No representative of the I or A delegation attended the meeting on 14 September.

Annex A contains the Presidency's suggestions for modifications to the two Sections and related provisions in the light of the discussions to date and the suggestions of the informal drafting group that the Presidency convened on 19 September. **Annex B** contains the Presidency's suggestions for consequential changes to the Regulation on the hygiene of foodstuffs (which would lay down general hygiene rules for all foodstuffs).

II. KEY ISSUES

A. Scope of primary production

The Working Party agreed that it was necessary clearly to specify the point at which primary production ended. It reached broad consensus on what the cut-off point should be for live bivalve molluscs and fishery products. This would often, although not always, be the moment when they come ashore.

The most controversial issue concerned the cooking of molluscs and crustaceans. The Presidency and the representative of the Commission suggested that, when carried out on board fishing vessels with no further processing, these operations should remain part of primary production. However, several delegations believed that the rules applying to primary production would not be sufficient, and that the same rules should apply wherever cooking took place.

Annex B contains suggested text to clarify the scope of Annex I to the Regulation on the hygiene of foodstuffs, which lays down rules for primary production. The provision dealing with the cooking of molluscs and crustaceans appears between square brackets to reflect the absence of consensus.

B. Retail trade

The Working Party agreed that certain requirements set out in Sections VII and VIII of Annex II to the draft Regulation laying down specific hygiene rules for food of animal origin, particularly the health standards, should apply to retailers. The modified versions of these Sections contained in **Annex A** provide for this.

C. Direct sales by coastal fishermen

The Working Party considered whether Section VII ought to apply to coastal fishermen making direct sales of small quantities of live bivalve molluscs. The current legislation (Directive 91/492/EEC) does not apply to such sales.

Several delegations did not favour maintaining an exemption for coastal fishermen, while one delegation preferred to retain it. The Working Party also discussed two possible compromise solutions. An Article in the Regulation could provide for the granting of derogations, through comitology, to allow traditional methods of production to continue. Alternatively, Member States could have the option of banning or restricting direct sales under national law.

The opening paragraphs of the revised version of Section VII contained in **Annex A** include text between square to reflect the lack of consensus.

D. Wild pectinidae

The Working Party agreed that it would be desirable for the rules for wild pectinidae (scallops) to be more similar to those for farmed bivalve molluscs. The modified text of Section VII of Annex II to the draft Regulation laying down specific hygiene rules for food of animal origin contained in Annex A includes suggested provisions in a new Chapter IX.

No delegation disputed that the ban on the marketing of other wild products coming within the scope of Section VII should remain in force, since this allowed the Community to exercise some control over imports from third countries.

E. Checks and documentation

The Working Party agreed that live bivalve molluscs, with the possible exception of pectinidae fished outside classified production areas, should always pass through a dispatch centre before being placed on the market for retail sale. It also agreed that a registration document should accompany batches at all stages before retail (when the identification mark would replace it).

The modified text of Section VII of Annex II to the draft Regulation laying down specific hygiene rules for food of animal origin (contained in **Annex A** to this document) includes suggested provisions in a new Chapter I.

III. OTHER ISSUES

During the discussions on the Commission's proposals on live bivalve molluscs and fishery products, delegations also made several general points. In particular, some delegations:

- stressed the importance of establishing clear rules, to simplify enforcement;
 - asked what the Commission's timetable was for the adoption of further health standards;
 - regretted the absence of rules on toxic algae, viruses and the spread of fish parasites;
 - regretted the omission of certain provisions contained in the existing Directives, such as the rules on laboratories and record-keeping;
 - called for the establishment of a Community information system that would enable gatherers of live bivalve molluscs easily to obtain up-to-date information on the classification of production zones; and
 - requested the updating of certain rules, particularly the list of fish that undergo cold smoking and might contain harmful endo-parasites, and those relating to mechanically recovered fish flesh.

The representative of the Commission expressed the hope that his Institution would adopt new health standards before adoption of the hygiene Regulations, permitting their incorporation in the interests of transparency. He pointed out that certain specific rules that the current vertical directives contained would become unnecessary following the adoption of general rules of the proposed horizontal Regulation, which would set hygiene standards for all foodstuffs. He reminded delegations that his Institution proposed that it be possible to update the provisions in the Annexes to the Regulations through the comitology procedure in the light of technical developments and advances in scientific knowledge.

Suggested modifications to the draft Regulation laying down specific hygiene rules for food of animal origin ¹

[...] ²

Article B ³

Registration and approval of establishments

1. Food business operators shall place on the market only food prepared and handled exclusively in establishments that are registered with or, where required in accordance with paragraph 2, approved by the competent authority.
2. Food business operators shall ensure that the following establishments are approved:
 - (a) slaughterhouses;
 - (b) cutting plants;
 - (c) game handling establishments;
 - (d) establishments producing minced meat, meat preparations and mechanically separated meat;
 - (e) establishments manufacturing meat products;
 - (f) dispatch and purification centres handling live bivalve molluscs;*
 - (g) factory vessels and freezer vessels;* ⁴
 - (h) establishments on land handling fisheries products;*

¹ Underlining and italics indicate the changes compared to the previous version of the text (with the exception of Article B, this is the Commission's proposal).

² This represents provisions to which the Presidency is not suggesting any change at this time.

³ This Article derives from the Article B contained in Annex A to document 7959/01.

The Article consolidates all the provisions on approval and registration contained in Sections I to VIII of Annex II in the Commission's proposal, reflecting the Working Party's agreement that these provisions should appear in a single Article. The Working Party will discuss the content of the Article once it has examined all the Sections of Annex II.

⁴ A consequential amendment might be necessary, depending on the conclusion reached concerning the cooking of molluscs and crustaceans on board fishing vessels.

[...]

(-) wholesale markets where unprocessed or processed products of animal origin are handled [, *except for wholesale markets where fishery products are not worked upon but are only displayed for sale and auction halls*].¹

3. [However, the competent authority need only register an establishment referred to in paragraph 2(a), (b), (e) *or (h)* if it produces relatively small quantities of food and generally places it on the market locally.]

4. Regulation (EC) No .../... [on official controls] lays down rules on registration and approval.

[...]

ANNEX I

DEFINITIONS

For the purpose of this Regulation:

[...]

2. LIVE BIVALVE MOLLUSCS

2.1 “Bivalve molluscs” means filter-feeding lamellibranch molluscs [-].

2.2 “Marine biotoxins” means poisonous substances accumulated by bivalve molluscs, *in particular as a result of* feeding on plankton containing toxins.

2.3 “Conditioning” means the storage of live bivalve molluscs coming from class A areas in tanks or any other installation containing clean seawater, or in natural sites, to remove sand, mud or slime and to improve organoleptic qualities.²

2.4 “Gatherer” means any natural or legal person who collects live bivalve molluscs by any means from a harvesting area for the purpose of handling and placing on the market.

¹ Some delegations believe that approval ought to be mandatory for fish auctions, particularly if they handle wild pectinidae. A definition of “auction hall” might be helpful to clarify how such an establishment differs from a “wholesale market”. (The Commission’s proposal contains a definition for the latter term.)

² One delegation requested a definition of “conditioning area”. However, the suggested changes to Section VII (Chapter II, Part B) set out below might make this unnecessary.

- 2.5 “Production area” means any sea, estuarine or lagoon area containing either natural beds of bivalve molluscs, or sites used for the cultivation of bivalve molluscs, and from which live bivalve molluscs are taken.
- 2.6 “Relaying area” means any sea, estuarine or lagoon area approved by the competent authority, with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live bivalve molluscs.
- 2.7 “Dispatch centre” means any [-] on-shore or off-shore installation for the reception, conditioning, washing, cleaning, grading, *wrapping, re-wrapping and packaging* of live bivalve molluscs fit for human consumption.¹
- 2.8 “Purification centre” means an [-] establishment with tanks fed by clean seawater in which live bivalve molluscs are placed for the time necessary *to reduce contamination to make* them fit for human consumption.
- 2.9 “Relaying” means *the transfer of live bivalve molluscs* to [-] sea, lagoon or estuarine areas [-]² for the time necessary to remove contamination. This does not include the specific operation of transferring bivalve molluscs to areas more suitable for further growth or fattening.

[-]³

¹ It is not appropriate to require the approval of establishments in an Article.

In Directive 91/492/EC, the term “wrapping” covered both “wrapping” and “packaging” as defined in the draft Regulation on the hygiene of foodstuffs.

² It is not appropriate for a definition to require relaying to take place under the supervision of the competent authority. Moreover, the rules on relaying do not include any such requirement.

³ Section VII does not contain any reference to *faecal coliform* or *E. coli*. It would appear more logical to adopt the definitions at the same time as the related limit values. The draft Regulation on the hygiene of foodstuffs now contains a definition of clean seawater. (See Annex B.)

3. FISHERY PRODUCTS

3.1 “Fishery products” means all seawater or freshwater animals, wild or farmed, and parts of such animals, including roes and livers. It does not include live bivalve molluscs, live echinoderms, live tunicates, live marine gastropods, aquatic mammals and [reptiles, such as crocodiles and]¹ frogs.

[H]²

3.2 “Factory vessel” means any vessel, fishing or not, on which fishery products undergo one or more of the following operations followed by wrapping: filleting, slicing, skinning, mincing, or processing. Fishing vessels on board which crustaceans and molluscs are cooked, but no other form of processing takes place, are not factory vessels.

3.3 “Freezer vessel” means any vessel, fishing or not, on board which freezing of fishery products is carried out, where appropriate after preparatory work such as bleeding, heading, gutting and removal of fins and, where necessary, followed by wrapping and/or packaging.

3.4 “Mechanically recovered fish flesh” means flesh obtained by mechanical means from gutted whole fish or bones after filleting.

3.5 “Fresh products” means fishery products, whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, that have not undergone any treatment to ensure preservation other than chilling.

3.6 “Prepared products” means fishery products that have undergone an operation affecting their anatomical wholeness, such as gutting, heading, slicing, filleting, and chopping.³

[H]⁴

¹ If the definition of fishery products does not apply to reptiles, Annex II might need to contain appropriate provisions to make clear which rules apply to products derived from such animals. At present, there are only specific provisions for frogs’ legs. Alternatively, the general requirements of the Regulation on the hygiene of foodstuffs might suffice.

² The definition of “aquaculture products” appears superfluous. Directive 91/493/EEC only uses the definition to provide that the requirements relating to vessels and handling during and after landing do not apply. However, it is clear from Chapter I of Section VIII that the former requirements do not apply. The latter requirements in Chapter II would either be inapplicable or are so general that aquaculture products should comply with them anyway.

³ The new definitions of “fresh products” and “prepared products” reinstate those contained in Directive 91/493/EEC.

⁴ The suggestions concerning the draft Regulation on the hygiene of foodstuffs provide for definitions of both “clean seawater” and “clean water”. The latter term would cover river and lake water. (See Annex B.)

ANNEX II

SPECIFIC REQUIREMENTS

[...]

SECTION VII: LIVE BIVALVE MOLLUSCS

1. This Section applies to live bivalve molluscs. With the exception of the provisions on purification, it applies by analogy to echinoderms, tunicates and marine gastropods.¹
2. Chapters I to VIII apply to animals harvested from production areas that the competent authority has classified in accordance with Chapter II, Part A. Chapter IX applies to pectinidae harvested outside those areas.²
3. Chapters V, VI, VIII and IX, and paragraph 3 of Chapter VII, apply to retail trade.
- [4. This Section does not apply to coastal fishermen who make direct sales of small quantities of live bivalve molluscs under the control of the competent authority.]³

¹ This wording reflects the modified definition of “live bivalve molluscs”, which refers only to filter-feeding lamellibranch molluscs. One delegation argues that the rules on the classification of production areas are not applicable to marine gastropods.

² Chapter IX contains a provision providing explicitly for its extension to live bivalve molluscs other than pectinidae through comitology. However, should the Community decide to extend the scope of Chapter IX, in the interest of transparency this would no doubt take the form of the adoption of a modified version of Chapter IX and of a consequential amendment to this provision, through the same procedure.

³ If this provision remains in the Regulation, a recital could make clear that Member States could regulate such sales under national law (provided that national rules comply with other applicable Community law).

CHAPTER I: GENERAL REQUIREMENTS FOR THE PLACING ON THE MARKET OF LIVE BIVALVE MOLLUSCS

A SPECIFIC REQUIREMENTS FOR THE PLACING ON THE MARKET OF LIVE BIVALVE MOLLUSCS

1. Live bivalve molluscs may not be placed on the market for retail sale other than via a dispatch centre, where an identification mark must be applied in accordance with Chapter VII.
2. Food business operators may accept batches of live bivalve molluscs only if the documentary requirements of Part B have been complied with.

B DOCUMENTARY REQUIREMENTS

3. Whenever a food business operator sends a batch of live bivalve molluscs to another food business operator, up to and including the arrival of the batch at a dispatch centre, it must supply a registration document that conforms to a model laid down in accordance with the procedure referred to in Article 6(2).¹ The registration document must be in at least one official language of the Member State in which the receiving establishment is located.
4. Food business operators sending batches of live bivalve molluscs must complete the relevant sections of the registration document legibly and indelibly. Food business operators receiving batches must date-stamp the document on receipt of the batch.
5. Food business operators must keep a copy of the registration document relating to each batch sent and received for at least twelve months after its dispatch or receipt (or such longer period as the competent authority may specify).

¹ This requirement needs to be read together with the definition of retail trade, to check that it is not too wide.

6. However, registration documents are not necessary for batches transferred between two or more establishments of a single food business if procedures are in place to guarantee traceability and the competent authority:

(a) supervises all the establishments concerned; and

(b) provides the food business with a standing authorisation.

CHAPTER II: HYGIENE REQUIREMENTS FOR THE PRODUCTION AND HARVESTING OF LIVE BIVALVE MOLLUSCS

A. REQUIREMENTS FOR PRODUCTION AREAS

1. Gatherers may only harvest live bivalve molluscs from production areas with fixed locations and boundaries that the competent authority has classified - where appropriate, in co-operation with food business operators - as being of class A, B or C in accordance with Regulation (EC) No .../... [on official controls]..
2. Food business operators may place live bivalve molluscs collected from class A production areas on the market for direct human consumption if they meet the requirements of Chapter V.
3. Food business operators may place live bivalve molluscs collected from class B production areas on the market for human consumption only after treatment in a purification centre or after relaying.
4. Food business operators may place live bivalve molluscs collected from class C production on the market for human consumption only after relaying over a long period in accordance with Part C of this Chapter.¹

[H]²

5. After purification or relaying, live bivalve molluscs from class B or C production areas must meet all of the requirements of Chapter V. However, live bivalve molluscs from such areas that have not been submitted to purification or relaying may be sent to a processing establishment, where they must undergo treatment to inhibit the development of pathogenic microorganisms. The permitted treatment methods are:³

(a) sterilisation in hermetically sealed containers;

¹ One delegation argued that treatment in a purification centre should also be an option for live bivalve molluscs from class C production areas.

² It is not appropriate to refer to criteria for the classification of production areas here. The Regulation lays down requirements for food business operators. The competent authorities are responsible for classifying production areas.

³ The methods of treatment mentioned under subparagraphs (a) and (b) are those listed in the Annex to Commission Decision 93/25/EEC, as amended by Decision 97/275/EC.

(b) heat treatments involving:

(i) immersion in boiling water for the period required to raise the internal temperature of the mollusc flesh to not less than 90 °C and maintenance of this minimum temperature for a period of not less than 90 seconds,

(ii) cooking for three to five minutes in an enclosed space where the temperature is between 120 and 160 °C and the pressure is between 2 and 5 kg/cm², followed by shelling and freezing of the flesh to a core temperature of -20 °C, and

(iii) steaming under pressure in an enclosed space satisfying the requirements relating to cooking time and the internal temperature of the mollusc flesh mentioned under (i) and for which a validated methodology in the framework of an own-checks programme ensures the uniform distribution of heat; and

(c) any other treatment approved in accordance with the procedure referred to in Article 6(2), after consultation of the appropriate scientific committee.

6. Food business operators must not produce live bivalve molluscs in, or harvest them from, areas that the competent authority has not classified, or which are unsuitable for health reasons. Food business operators must take account of any relevant information concerning areas' suitability for production and harvesting, including information obtained from own-checks and the competent authority. They must use this information, particularly information on environmental and weather conditions, to determine the appropriate treatment to apply to harvested batches.¹

[H]²

B. REQUIREMENTS FOR HARVESTING AND HANDLING FOLLOWING HARVESTING

Food business operators harvesting live bivalve molluscs, or handling them immediately after harvesting, must ensure compliance with the following requirements.

1. Harvesting techniques and further handling must not cause additional contamination or excessive damage to the shells or tissues of the live bivalve molluscs or result in changes significantly affecting their suitability for treatment by purification, processing or relaying. Food business operators must in particular:

(a) adequately protect live bivalve molluscs from crushing, abrasion or vibration,

(b) not expose live bivalve molluscs to extreme temperatures,

¹ The new wording of this provision seeks to clarify that food business operators bear the primary responsibility for ensuring the safety of live bivalve molluscs.

² The provisions relating to pectinidae now appear in Chapter IX.

(c) not re-immerse live bivalve molluscs in water that could cause additional contamination, and

(d) if carrying out conditioning in natural sites, ensure that the area used meets the standards laid down for class A production areas.

2. Means of transport must permit adequate drainage, be equipped to ensure the best survival conditions possible and provide efficient protection against contamination.

[]¹

C. REQUIREMENTS FOR RELAYING LIVE BIVALVE MOLLUSCS

Food business operators relaying live bivalve molluscs must ensure compliance with the following requirements.

1. Food business operators may use only those areas that the competent authority has approved for relaying live bivalve molluscs. Buoys, poles or other fixed means must clearly identify the boundaries of the sites. There must be a minimum distance between relaying areas, and also between relaying areas and production areas, so as to minimise any risk of the spread of contamination.²

2. Conditions for relaying must ensure optimal conditions for purification. In particular, food business operators must:

(a) use techniques for handling live bivalve molluscs intended for relaying that permit the resumption of filter-feeding activity after immersion in natural waters;

(b) not relay live bivalve molluscs at a density that prevents purification;

(c) immerse live bivalve molluscs in seawater at the relaying area for an appropriate period, fixed depending on the water temperature and taking account of any directions that the competent authority may provide []³; and

[]⁴

(d) ensure sufficient separation of sites within a relaying area to prevent mixing of batches]; the ‘all in, all out’ system must be used, so that a new batch cannot be brought in before the whole of the previous batch has been removed].⁵

¹ All the provisions on registration documents now appear in the new Chapter I.

² Two delegations wish to retain the current requirement for a minimum distance of 300 metres.

³ The reference to the health standards laid down in Chapter V was superfluous. These standards always apply. Community standards for the relaying period could be laid down through the comitology procedure in the light of scientific advice.

⁴ All the provisions on registration documents now appear in the new Chapter I.

⁵ One delegation wants to keep the current requirement to use the “all in, all out” system.

3. *Food business operators managing relaying areas must keep* permanent records of the source of live bivalve molluscs, relaying periods, relaying areas *used* and the subsequent destination of the batch after relaying, for inspection by the competent authority.

[H]¹

CHAPTER *III*: *STRUCTURAL REQUIREMENTS FOR* DISPATCH AND PURIFICATION CENTRES

[H]

- 1.* The location of premises *on land* must not be subject to flooding by ordinary high tides or run-off from surrounding areas.²

[H]³

- 2.* *Tanks and water storage containers must meet the following requirements:*⁴

(a) *Internal surfaces must be smooth, durable, impermeable and easy to clean.*

(b) *They* must be constructed so as to allow complete draining of water.

(c) *Any water intake must be situated in a position that avoids contamination of the water supply.*⁵

- 3.* *In addition, in purification centres,* purification tanks must be *suitable* for the volume *and type* of products to be purified.⁶

[H]⁷

¹ All the provisions on registration documents now appear in the new Chapter I.

² The addition of the phrase “on land” makes clear that this requirement does not apply to dispatch centres on vessels and to natural sites used for conditioning.

³ The suggested modifications to Chapter VII of Annex II to the general Regulation would render the requirement for a supply of clean seawater superfluous. (See Annex B.)

⁴ In the Commission’s proposal, these requirements would have applied only to purification centres. However, those contained in this paragraph would seem to be appropriate for dispatch centres too.

⁵ This requirement appeared in the former Chapter III (now Chapter IV). However, as it is a structural rather than an operational requirement, it should appear in Chapter III (the former Chapter II). Its wording now follows that of Section VIII, Chapter I, Part B, paragraph 1(g).

⁶ The revised working of this wording seeks to state a general objective that is not specific to any particular type of purification system.

⁷ Again, the suggested modifications to the general Regulation would render the requirement for a supply of clean seawater superfluous.

CHAPTER IV: HYGIENE REQUIREMENTS FOR PURIFICATION AND DISPATCH CENTRES

A REQUIREMENTS FOR PURIFICATION CENTRES

Food business operators purifying live bivalve molluscs must ensure compliance with the following requirements.

1. Before purification commences, live bivalve molluscs must be washed free of mud and accumulated debris using pressurised clean seawater or potable water.

[H]¹

2. Operation of the purification system must allow live bivalve molluscs rapidly to resume filter-feeding activity, to eliminate sewage contamination, not to become re-contaminated and to be able to remain alive in a suitable condition after purification for wrapping, storage and transport before being placed on the market.

3. The quantity of live bivalve molluscs to be purified must not exceed the capacity of the purification centre. The live bivalve molluscs must be continuously purified for a period sufficient to allow the microbiological standards of Chapter V to be met.

4. Should a purification tank contain several *batches* of live bivalve molluscs, *they must be of the same species and* the length of the treatment must be based on the time required by the *batch* needing the longest period of purification.²

5. Containers used to hold live bivalve molluscs in purification systems must have a construction that allows seawater to flow through. The depth of layers of live bivalve molluscs must not impede the opening of shells during purification.

[H]³

6. No crustaceans, fish or other marine species may be kept in a purification tank in which live bivalve molluscs are undergoing purification.

[H]⁴

7. Every package containing purified live bivalve molluscs sent to a dispatch centre must be provided with a label certifying that all molluscs have been purified.

¹ This was a structural requirement. It now appears in Chapter III.

² The changes to this point reinstate requirements of Directive 91/492/EEC.

³ Since the new Chapter I makes clear that live bivalve molluscs placed on the market for retail sale must pass through a dispatch centre, the requirement for washing now appears in Part B.

⁴ All the provisions on registration documents now appear in the new Chapter IV.

B REQUIREMENTS FOR DISPATCH CENTRES

Food business operators operating dispatch centres must ensure compliance with the following requirements.

1. Handling of live bivalve molluscs, particularly conditioning, calibration and packing, must not cause contamination of the product or affect the viability of the molluscs.
2. Before dispatch, the shells of live bivalve molluscs must be washed thoroughly with clean seawater or potable water [-].¹
3. Live bivalve molluscs must come from:
 - (a) a class A production area;
 - (b) a relaying area;
 - (c) a purification centre; or
 - (d) from another dispatch centre (as a wholesale consignment).

[-]²

4. The requirements laid down in paragraphs 1 and 2 also apply to dispatch centres situated on board vessels. Molluscs handled in such centres must come from a class A production area or a relaying area. [-]³ Special requirements may be laid down in accordance with the procedure referred to in Article 6(2).

CHAPTER V: HEALTH STANDARDS FOR LIVE BIVALVE MOLLUSCS

Food business operators must ensure that live bivalve molluscs placed on the market for human consumption meet the standards laid down in this Chapter.

1. They must have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion and [-]⁴ normal amounts of intravalvular liquid.

¹ This requirement replaces separate, but broadly similar requirements, for purification and dispatch centres. It makes clear that washing must always take place before dispatch.

² The requirement to keep pests and domestic animals out of areas where food is prepared should appear in the general Regulation.

³ The previous requirement to comply with the provisions of Part A of Chapter II no longer makes sense. The one provision remaining in Part A applies only to establishments on land.

⁴ This deletion returns the text to its current formulation.

[1]¹

2. They must not contain:

(a) toxic or objectionable compounds [1] in such quantities that the calculated dietary intake exceeds the permissible daily intake (PDI); *or*

(b) higher levels of contaminants than those specified in Community legislation.

3. *Radionuclide levels must not exceed the limits for foodstuffs laid down in Community legislation.*

4. Limits for marine biotoxins:

(a) The total Paralytic Shellfish Poison (PSP) content in the edible parts of the molluscs (the whole body or any part edible separately) must not exceed 80 micrograms per 100 g of mollusc flesh in accordance with a method *recognised in accordance with the procedure referred to in Article 6(2).*

(b) The total Amnesic Shellfish Poison (ASP) content in edible parts of molluscs (the entire body or any edible part edible separately) must not exceed 20 micrograms of domoic acid per gram using the *high performance liquid chromatography (HPLC) method.*²

(c) The customary biological testing methods must not give a positive result to the presence of Diarrhoeic Shellfish Poison (DSP) in the edible parts of the molluscs (the whole body or any part edible separately).

6. *Additional requirements may be laid down in accordance with the procedure referred to in Article 6(2) in co-operation with the relevant Community Reference Laboratory and after consultation of the appropriate scientific committee, including:*

(a) limit values and analysis methods for other marine biotoxins [1];

(b) virus testing procedures and virological standards;

(c) sampling plans as well as the methods and analytical tolerances to be applied to check compliance with the health standards [1]; and

¹ The requirement to meet microbiological criteria was superfluous. Article 4(6) of the general Regulation contains such a requirement for all food business operators. If the Community adopts specific criteria for live bivalve molluscs before adoption of this Regulation, they could be included in this Chapter.

² It might be helpful to clarify “edible”. Are edible parts the parts that can be eaten or those that actually are eaten?

- (d) other health standards or checks, [-] where there is scientific evidence indicating that *they are necessary* to protect public health.

Pending the adoption of Community rules for methods for checking compliance with the health standards, the methods used must be scientifically recognised.

CHAPTER VI: **PACKAGING** OF LIVE BIVALVE MOLLUSCS ¹

1. Oysters must be *packaged* with the concave shell downwards.
2. *All consignments of live bivalve molluscs destined for retail sale must be closed and remain closed from the dispatch centre until presented for sale to the final consumer.*

[-] ²

CHAPTER VII: **IDENTIFICATION** MARKING AND LABELLING

1. The *identification mark* must be waterproof.
2. *In addition to the general requirements for identification marks contained in Section 0,* the following information must be present on the label:

(a) the species of bivalve mollusc (common name and scientific name); *and*

(b) the date of *packaging*, comprising at least the day and the month.

By way of derogation from Directive *2000/13/EC*, the date of *minimum* durability may be replaced by the entry ‘these animals must be alive when sold’.

3. The retailer must keep the label attached to the *packaging* of live bivalve molluscs which are not *packaged* in individual consumer-size parcels for at least 60 days after splitting up the contents.

CHAPTER VIII: **OTHER REQUIREMENTS**

1. *Food business operators storing and transporting live bivalve molluscs must ensure that they are* kept at a temperature that does not adversely affect their safety and viability.
2. *Live bivalve molluscs must not be re-immersed in, or sprayed with, water after they have been packaged for retail sale and left the dispatch centre.*

¹ The general Regulation defines “packaging” as including wrapping that provides sufficient protection to the wrapped product.

² The Working Party agreed that all the provisions on registration and approval should appear in a single Article. (See Article B, at the beginning of this Annex.)

CHAPTER IX: SPECIFIC REQUIREMENTS FOR PECTINIDAE HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS

Food business operators harvesting pectinidae outside classified production areas or handling such pectinidae must comply with the following requirements.

1. Pectinidae may not be placed on the market unless they are harvested and handled in accordance with Chapter II, Part B, and meet the standards laid down in Chapter V, as proved by a system of own-checks.
2. In addition, where data from official monitoring programmes enable the competent authority to classify fishing grounds - where appropriate, in co-operation with food business operators -, the provisions of Chapter II, Part A, apply by analogy to pectinidae.
3. Pectinidae may not be placed on the market for human consumption other than via a fish auction, a dispatch centre or a processing establishment. When they handle pectinidae, food business operators operating such establishments must inform the competent authority.
4. Food business operators handling pectinidae must comply with either the documentary requirements of Chapter I, Part B, or the requirements of Chapter VII concerning identification marking and labelling, as applicable.
5. This Chapter may be extended to live bivalve molluscs other than pectinidae in accordance with the procedure referred to in Article 6(2), after consultation of the appropriate scientific committee.

SECTION VIII: FISHERY PRODUCTS

1. This Section applies to both wild and, except for Chapter I, farmed fishery products.
2. Chapter III, Parts A, C, D and E, and Chapter IV apply to retail trade.¹

CHAPTER I: REQUIREMENTS FOR VESSELS

Food business operators must ensure that:

1. vessels used to harvest fishery products from their natural environment, or to handle or process them after harvesting, comply with the structural and equipment requirements laid down in Part I of this Chapter; and
2. operations carried out on board fishing vessels take place in accordance with the rules laid down in Part II.

I. STRUCTURAL AND EQUIPMENT REQUIREMENTS

A. Requirements applicable to all vessels

1. Vessels must be designed and constructed so as not to cause contamination of the products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances.
2. Surfaces with which fishery products come into contact must be of suitable corrosion-resistant material that is smooth and easy to clean. Surface coatings must be durable and non-toxic.
3. Equipment and material used for working on fishery products must be made of corrosion-resistant material that is easy to clean and disinfect.

¹ One delegation believed that Chapters V, VI and VII ought also to apply to retail trade. However, the Working Party needs first to decide on the scope of the definition of “retail”.

B. Factory vessels

1. Factory vessels must have at least:

- (a) a receiving area reserved for taking fishery products on board, designed to allow each successive catch to be separated. This area must be easy to clean and designed so as to protect the products from the sun or the elements and from any source of contamination;
- (b) a hygienic system for conveying fishery products from the receiving area to the work area;
- (c) work areas that are large enough for the hygienic preparation and processing of fishery products, easy to clean *and disinfect* and 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 such waste;
- (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 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 its sanitation, separate areas must be allocated for that purpose;
- (g) [-]¹ *a water intake* situated in a position *that avoids contamination of the water supply; and*
- (h) *hand-washing equipment for use by the staff engaged in handling exposed fishery products with taps designed to prevent the spread of contamination.*²

¹ The suggested modifications to Chapter VII of Annex II of the General Regulation would render the first part of this provision superfluous. (See Annex B.)

² The modified wording of this provision mirrors the changes made to the earlier Sections of Annex II. The General Regulation contains a requirement for a hygienic means of drying hands (Annex II, Chapter I, paragraph 4).

2. Factory vessels that freeze fishery products must have:
 - (a) freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of -18 °C or lower;
 - (b) refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at -18 °C or lower. Storage holds must be equipped with a temperature-recording device in a place where it can be easily read. The temperature sensor of the reader must be situated in the area where the temperature in the hold is the highest.

Whole frozen fish in brine intended for the manufacture of canned food may be kept at a temperature of -9 °C or lower.

C. Freezer vessels and vessels designed and equipped to preserve *fresh* fishery products for more than twenty-four hours

1. *Freezer vessels and vessels designed and equipped to preserve fishery products for more than twenty-four hours* must be equipped with holds, tanks or containers for the storage of refrigerated or frozen fishery products at the temperatures laid down in *Chapter VI*. The holds must be separated from the engine compartments and from the crew quarters by partitions which are sufficient to prevent any contamination of the stored fishery products. *Such vessels must have* freezing and refrigeration equipment, *as appropriate, that satisfies the requirements* laid down for factory vessels *in paragraph 2 of Part B*.
2. The holds must be designed to ensure that melt water cannot remain in contact with fishery products.
3. Containers used for the storage of *fishery* products must ensure their preservation under satisfactory conditions of hygiene [-]¹ and, *where necessary, provide adequate drainage to ensure that melt water does not remain in contact with the products.*²
4. In vessels equipped for chilling fishery products in cooled *clean water*, tanks must incorporate devices for achieving a uniform temperature throughout the tanks. *Such devices must achieve a chilling rate that* ensures that the mix of fish and *clean water* reaches 3 °C at the most 6 hours after loading and 0 °C at the most after 16 hours.

¹ The requirement for containers to be clean was out of place, since it was an operational requirement. It duplicated requirements in Part II of this Chapter and in the General Regulation (Annex II, Chapters IV and V).

² The wording of this paragraph is now consistent with the corresponding provisions in other Chapters.

II. HYGIENE REQUIREMENTS

1. When in use, the parts of fishing vessels or containers set aside for the storage of fishery products must be clean and, in particular, must not be [-] contaminated by fuel or bilge water.
2. As soon as possible after they are taken on board, fishery products must be protected from contamination and from the effects of the sun or any other source of heat. When they are washed, the water used must be either potable water or, where appropriate, clean water.
3. Fishery products must be handled and stored so as to prevent bruising. Handlers may use spiked instruments to move large fish or fish which might injure them, provided that the flesh of the products suffers no damage.
4. Fishery products other than those kept alive must undergo chilling as soon as possible after loading. However, when chilling is not possible, fishery products must be landed as soon as possible.
5. Ice used to chill fishery products must meet the requirements of Annex II, Chapter VII, of Regulation (EC) .../... [on the hygiene of foodstuffs].¹
6. Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after capture, and the products must be washed immediately and thoroughly with potable water or clean water. In that event, the viscera and parts that may constitute a danger to public health must be removed as soon as possible and kept apart from products intended for human consumption. Livers and roes intended for human consumption must be preserved under ice, at the temperature of melting ice, or be frozen.
7. Where freezing in brine of whole fish intended for canning is practised, a temperature of -9 °C must be achieved for the product. The brine must not be a source of contamination for the fish.

[-]²

¹ See Annex B for the new wording suggested for the general Regulation.

² This provision was superfluous. The rules of Chapter III, Part E, apply to operations on board vessels.

CHAPTER II: REQUIREMENTS DURING AND AFTER LANDING

1. Food business operators responsible for the unloading and landing of fishery products must:¹

(a) ensure that unloading and landing equipment that comes into contact with fishery products is constructed of material that is easy to clean and disinfect and maintained in a good state of repair and cleanliness; and

(b) avoid contamination of fishery products during unloading and landing, in particular by:

(i) carrying out unloading and landing operations rapidly,

(ii) placing fishery products without delay in a protected environment at the temperature required, and

(iii) not using equipment and practices that cause unnecessary damage to the edible parts of the fishery products.

2. Food business operators responsible for auction and wholesale markets or parts thereof where fishery products are displayed for sale must ensure that, at the time of display or storage of fishery products:

(a) the premises are not used for other purposes;

(b) vehicles emitting exhaust fumes likely to impair the quality of fishery products do not have access to the premises;

(c) persons having access to the premises do not introduce other animals, and

(d) the premises are well lit to facilitate official controls.

[]²

3. After landing or, where appropriate, after first sale, fishery products must be conveyed without delay to their place of destination, or else be chilled before being displayed for sale or after being sold and pending transport to their place of destination. In such cases, fishery products must be stored at a temperature approaching that of melting ice.

¹ Parts of this paragraph, particularly subparagraph (a), would be superfluous if there were agreement that the unloading and/or landing of fish is never part of primary production.

² The suggested modifications to Chapter VII of Annex II to the general Regulation would require there to be facilities for the supply of clean water. (See Annex B.)

CHAPTER III: REQUIREMENTS FOR ESTABLISHMENTS HANDLING FISHERY PRODUCTS

A REQUIREMENTS FOR FRESH PRODUCTS

1. Where chilled, unpackaged products are not distributed, dispatched, prepared or processed immediately after reaching an establishment on land, they must be stored under ice in a cold room. Re-icing must be carried out as often as necessary. [-] ¹ Packaged fresh products must be chilled to a temperature approaching that of melting ice.
2. Operations such as heading and gutting must be carried out hygienically. The products must be washed thoroughly with potable water or clean water immediately after these operations.
3. Operations such as filleting and cutting must be carried out so as to avoid contamination or spoilage of fillets and slices [-]. Fillets and slices must not remain on the worktables beyond the time necessary for their preparation and must be protected from contamination by suitable wrapping. Fillets and slices must be chilled as quickly as possible after their preparation.
4. Containers used for the dispatch or storage of unpackaged fresh fishery products must ensure that melt water does not remain in contact with the products.²

B REQUIREMENTS FOR FROZEN PRODUCTS

Establishments on land that freeze fishery products must have freezing equipment that satisfies the requirements laid down for factory vessels in Chapter I, Part I.B, paragraph 2.

C REQUIREMENTS FOR MECHANICALLY SEPARATED FISH FLESH

1. Mechanical separation of gutted fish must take place without undue delay after filleting, using raw materials free from guts. If whole fish are used, they must be gutted and washed beforehand.³
2. After production, mechanically recovered flesh must be frozen as quickly as possible or incorporated in a product intended for freezing or a stabilising treatment.

¹ The suggested amendment to the general Regulation would make it unnecessary to lay down any rules for the preparation and storage of ice in this chapter. Since the handling of fishery products on land is not primary production, the rules would apply automatically.

² This wording of this provision is now consistent with that of the equivalent provisions in other Chapters.

³ Some delegations advocate tighter rules on the raw material that can be used to produce mechanically separated fish flesh.

D REQUIREMENTS CONCERNING ENDO-PARASITES HARMFUL TO HUMAN HEALTH

1. The following fishery products must be frozen at a temperature of not more than -20 °C in all parts of the product for not less than 24 hours; this treatment must be applied to the raw product or the finished product:
 - (a) fish to be consumed raw or almost raw;
 - (b) the following species, if they are to undergo a cold smoking process in which the internal temperature of the fish is less than 60 °C:
 - (i) herring,
 - (ii) mackerel,
 - (iii) sprat,
 - (iv) (wild) Atlantic and Pacific salmon; and
 - (c) marinated and/or salted fish, if the processing is insufficient to destroy nematode larvae.
2. Food business operators need not carry out the treatment required under paragraph 1 if:
 - (a) epidemiological data are available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites; and
 - (b) the competent authority so authorises.
3. A document from the manufacturer, stating the type of process they have undergone, must accompany fishery products referred to in paragraph 1 when placed on the market.
4. Before placing them on the market, food business operators must subject fish and fish products to a visual examination for the purpose of detecting visible endo-parasites. They must not place fish or parts of fish that are obviously contaminated with parasites on the market for human consumption.

E COOKED CRUSTACEANS AND MOLLUSCS

Crustaceans and molluscs must be cooked as follows.

1. Rapid cooling must follow cooking. Water used for this purpose must be potable water or clean water. If no other method of preservation is used, cooling must continue until a temperature approaching that of melting ice is reached.
2. Shelling or shucking must be carried out hygienically, avoiding contamination of the product. Where such operations are done by hand, workers must pay particular attention to washing their hands. [-]¹
3. After shelling or shucking, cooked products must be frozen immediately, or kept chilled at a temperature that will preclude the growth of pathogens, and be stored in appropriate rooms allowing maintenance of the temperatures required.

CHAPTER IV: HEALTH STANDARDS FOR FISHERY PRODUCTS

Food business operators must ensure that fishery products placed on the market for human consumption meet the standards laid down in this Chapter.

A ORGANOLEPTIC PROPERTIES OF FISHERY PRODUCTS

Food business operators must carry out an organoleptic examination of fishery products. In particular, this examination must ensure that fishery products comply with any freshness criteria laid down in accordance with the procedure referred to in Article 6(2), after consultation of the appropriate scientific committee.

B HISTAMINE

1. If the organoleptic examination required under Part A reveals any doubt as to the freshness of fishery products, food business operators must check the level of histamine in fishery products before placing them on the market.
2. The histamine level must be within the following limits in [nine]² samples taken from a batch:
 - (a) the mean value must not exceed 100 ppm;
 - (b) two samples may have a value exceeding 100 ppm but not more than 200 ppm;
 - (c) no sample may have a value exceeding 200 ppm.

¹ The remainder of this provision duplicated requirements of the General Regulation (Annex II, Chapter V). If such operation remain part of primary production when carried out on board fishing vessels, a corresponding requirement could appear in Chapter I, Part II, paragraph 8.

² Some delegations question whether it is always necessary to take nine samples.

2. These limits apply only to fish species of the following families: Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae and Scombraesosidae. However, anchovy that has undergone enzyme maturation 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 methods, which are recognised scientifically, such as high performance liquid chromatography (HPLC).

C TOTAL VOLATILE NITROGEN (TVB-N)

Unprocessed fishery products must *not be placed on the market if*, organoleptic assessment having raised doubts as to their freshness, chemical tests reveal that the limits with regard to TVB-N *fixed* in accordance with the procedure referred to in Article 6(2) have been exceeded.

D CONTAMINANTS

Fishery products must not contain:

1. *toxic or objectionable compounds in such quantities that the calculated dietary intake exceeds the permissible daily intake (PDI); or*
2. *higher levels of contaminants than those specified in Community legislation.*

E TOXINS HARMFUL TO HUMAN HEALTH

The placing on the market of the following products is prohibited:

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

CHAPTER V: WRAPPING AND PACKAGING OF FISHERY PRODUCTS

1. *Receptacles* in which fresh fishery products are kept under ice must be water-resistant and *ensure that* melt water *does not remain in contact with the products.*¹
2. Frozen blocks prepared on board fisheries vessels must be adequately wrapped before landing.

¹ This wording of this provision is now consistent with that of the equivalent provisions in other Chapters.

CHAPTER VI: STORAGE OF FISHERY PRODUCTS

1. Fresh or thawed fishery products, and cooked and chilled products from crustaceans and molluscs must be maintained at the temperature of melting ice.
2. Frozen fishery products must be kept at a temperature of -18 °C or below in all parts of the product; however, whole frozen fish in brine intended for the manufacture of canned food may be kept at a temperature of -9 °C or less.

CHAPTER VII: TRANSPORT OF FISHERY PRODUCTS

1. During transport, fishery products must be maintained at the required temperature. In particular:
 - (a) fresh or thawed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at the temperature of melting ice;
 - (b) frozen fishery products, with the exception of frozen fish in brine intended for the manufacture of canned food, must be maintained during transport at an even temperature of -18 °C or below in all parts of the product, with possibly short upward fluctuations of not more than 3 °C.
2. When frozen fishery products are transported from a cold store to an approved establishment to be thawed on arrival for the purposes of preparation and/or processing, and where the journey is short, the competent authority may grant a derogation from the conditions laid down in paragraph 1(b).
3. If ice is used to chill *fishery* products, *melt water must* not remain in contact with the products.¹
4. Fishery products to be placed on the market live must be transported in such a way that the hygiene of the product is preserved.

[]²

¹ This wording of this provision is now consistent with that of the equivalent provisions in other Chapters.

² The Working Party agreed that all the provisions on registration and approval should appear in a single Article. (See Article B, at the beginning of this Annex.)

Suggested modifications to the draft Regulation on the hygiene of foodstuffs¹

1. ARTICLE 2 - DEFINITIONS

The definitions of “potable water” and “clean seawater” should read as follows. There should also be a new definition of “clean water”.

- “potable water” means water meeting the minimum requirements laid down in Directive 98/83/EC for water intended for human consumption;
- “clean seawater” means natural, artificial or purified seawater or brackish water that does not contain microbiological contamination, harmful substances or toxic marine plankton in quantities capable of affecting the health quality of the products with which it is in contact;
- “clean water” means clean seawater and fresh water of a similar quality.

2. ANNEX I - PRIMARY PRODUCTION

To clarify where primary production ends in relation to marine and aquatic products, Part A of Annex I should contain an additional sentence, as follows:

- “1. This Annex applies to primary production. This includes the handling of primary products at the place of production, provided that this does not substantially alter their nature. It therefore applies, for example, to the storage, wrapping and packaging of primary products at the place of production and associated transport operations.
2. In particular, as regards live bivalve molluscs, live echinoderms, live tunicates, live marine gastropods and fisheries products, primary production ends:
 - (a) on delivery to the first establishment on land; or
 - (b) on delivery to a factory or freezer vessel or an offshore dispatch centre.

¹ Underlining and italics indicate the changes compared to document 11017/01.

Primary production includes certain operations carried out on board fishing vessels that do not substantially alter the nature of fisheries products, namely bleeding, heading, gutting, removing fins, refrigeration and wrapping. Any other form of preparation, and any form of processing, carried out on board fishing vessels is not primary production.¹ [However, the cooking of crustaceans and molluscs on board fishing vessels without any further processing is part of primary production.]”²

3. ANNEX II, CHAPTER V - EQUIPMENT REQUIREMENTS

To clarify the requirement the Chapter should read as follows:

- “1. All articles, fittings and equipment with which food comes into contact *must*:
 - (a) *be effectively cleaned and, if necessary, disinfected. Cleaning and disinfection must take place at a frequency sufficient to avoid the risk of contamination;*
 - (b) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination of the food;
 - (c) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept *clean and, where necessary, disinfected; and*
 - (d) be installed in such a manner as to allow adequate cleaning of the surrounding area.
2. Where necessary, equipment must be fitted with any appropriate control device to guarantee fulfilment of this Regulation’s objectives.
3. Where chemical additives have to be used to prevent corrosion of equipment and containers, they must be used in accordance with good practices.”

¹ One delegation believed that freezing should also be part of primary production, if no processing takes place before freezing. Another delegation believed that both Annex I and parts of Annex II of the Regulation on the hygiene of foodstuffs should apply to fishing vessels to reflect their hybrid nature.

² Several delegations believe that the cooking of crustaceans and molluscs should not be part of primary production.

4. ANNEX II, CHAPTER VII - WATER SUPPLY

Paragraphs 1 and 4 should read as follows:

“1. There must be an adequate supply of *potable water, which* must be used whenever necessary to ensure that foodstuffs are not contaminated. *Clean water may be used with fishery products, and clean seawater with live bivalve molluscs, echinoderms, tunicates and marine gastropods. When such water is used, adequate facilities must be available for its supply.*”

[...]

“4. Ice which comes into contact with food or which may *contaminate* food must be made from *potable water or, when used to chill fishery products, clean water*. It must be made, handled and stored under conditions that protect it from contamination.”.

