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of :	Working Party of Veterinary Experts (Public Health/Third Countries)
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No. Cion prop.:	10427/00 – COM(2000) 438 final
Subject:	Proposals for Regulations of the European Parliament and of the Council: - on the hygiene of foodstuffs - laying down specific hygiene rules for food of animal origin

The Commission presented the above-mentioned proposals to the Council in July 2000. Since then, the Working Party of Veterinary Experts (Public Health) has met on many occasions during the French, Swedish and Belgian Presidencies to discuss the proposals, most recently on 28 November 2001.

In addition, the Working Party of Veterinary Experts (Third Countries) met on two occasions during the Belgian Presidency, on 21 October and 27 November 2001, to discuss the provisions of the second proposal relating to imports.

This document summarises the outcome of the discussion within both formations of the Working Party. It complements document 11017/01, which contains a consolidated and annotated text of the first proposal.

Annex A to this document contains revised text for the proposed Regulation laying down specific hygiene rules for food of animal origin reflecting the outcome of the discussions carried out to date.

Annex B sets out possible consequential amendments to the proposed general rules of the Regulation on the hygiene of foodstuffs that have come to light during the discussion of the specific rules for food of animal origin.

Annex C indicates the derivation of the provisions contained in Annexes A and B.

Revised draft Regulation of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Regulation lays down specific rules for food business operators on the hygiene of food of animal origin. These rules supplement those laid down by Regulation (EC) No …/… [*on the hygiene of foodstuffs*]. They apply to unprocessed and processed products of animal origin.

2. This Regulation shall not apply to:

   (a) retail outlets delivering food of animal origin directly to the final consumer[1], unless expressly indicated to the contrary;

   (b) the primary production[2] of food for private domestic use;

   (c) the domestic preparation of foodstuffs for private consumption; and

   (d) products containing both processed products of animal origin and products of plant origin. However, processed products of animal origin used to prepare such products must be obtained and handled in accordance with the requirements of this Regulation.[3]

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[1] While accepting that the scope of this exclusion must be appropriate, the representative of the Commission has reserved his Institution's position on its restriction to retail outlets delivering food of animal origin directly to the final consumer. Some delegations want the Regulation to enable Member States to exclude from its scope retail outlets that sell a limited amount of products of animal origin to other retailers, who process it and supply it to the final consumer.

[2] Primary production includes hunting. There is therefore no need for Section V to contain a specific rule excluding wild game not intended for commercial purposes from its scope.

[3] Most delegations support the exclusion of "composite products" from the scope of the Regulation provided for in this subparagraph. However, some delegations have suggested that the Regulation needs also to clarify: (a) the position of products composed of different processed products of animal origin; (b) the position of certain products prepared from unprocessed products of animal origin and products of plant origin; and (c) that checks must be carried out on imports to ensure that products of animal origin used to manufacture composite products meet Community requirements.

3. This Regulation shall apply without prejudice to relevant animal and public health rules, including more stringent rules laid down for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

Article 2

Definitions

The following definitions shall apply for the purposes of this Regulation:

1. the definitions laid down in Regulation (EC) …/2002 [*laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*];

2. the definitions laid down in Regulation (EC) …/… [*on the hygiene of foodstuffs*]; and

3. the definitions laid down in Annex I.

CHAPTER II

FOOD BUSINESS OPERATORS' OBLIGATIONS [1]

Article 3

General obligations

1. Food business operators shall comply with the provisions of Annex II.

2. Food business operators shall not apply any substance other than potable water to products for hazard reduction unless its use has been approved in accordance with the procedure referred to in Article 19(2). Food business operators shall also comply with any conditions for use that may be adopted under the same procedure. The use of an approved substance shall not affect the food business operator's duty to comply with the requirements of the present Regulation.

[1] The recitals should contain a reminder of Member States' duty, under Article 10 of the EC Treaty, to take all appropriate measures to ensure food business operators' compliance with these obligations (since they will form part of Community law).

[Article 4

Registration and approval of establishments

1. Food business operators shall place products of animal origin manufactured in the Community on the market only if they have been prepared and handled exclusively in establishments:

   (a) that meet the requirements of Annex II; and

   (b) that the competent authority has registered or, where required in accordance with paragraph 2, approved.

2. Without prejudice to Article 6(2) of Regulation (EC) No …/… [*on the hygiene of foodstuffs*], establishments handling products of animal origin for which Annex II lays down requirements, except for establishments performing only primary production or transport operations, shall not operate unless the competent authority has approved them in accordance with paragraph 3.

3. The competent authority shall approve establishments only if an on-site visit prior to the start-up of any activity has demonstrated that they meet the relevant requirements of this Regulation. However, the competent authority may provide an establishment with provisional approval to operate:

   (a) after an initial on-site visit has demonstrated that the establishment meets the structural requirements laid down in this Regulation, but pending a second on-site visit to verify compliance with the operational requirements; or

   (b) in the case of an establishment producing relatively small quantities of food and generally placing it on the market locally, pending an on-site visit.

4. Regulation (EC) No …/… [*on official controls*] lays down detailed rules on registration and approval.] [1]

[1] This Article it seeks to reflect the emerging consensus with the Working Party. It appears between square brackets, because the Working Party has not yet concluded its discussions on the issue of approval.
The Working Party has agreed that approval should imply an on-site visit by the competent authority to inspect the establishment before it starts operating. It has also agreed that the Regulation should lay down minimum standards regarding approval, but permit Member States to go further.
A majority of delegations believes that approval should be a requirement for all establishments that fall within the scope of the Regulation, except for establishments that carry out primary production or transport operations. However, some delegations doubt whether such a wide requirement for approval is appropriate, preferring a risk-based approach.

Article 5

Health and identification marking

Food business operators shall not place a product of animal origin on the market unless it has either:

1. a health mark applied in accordance with Regulation (EC) No …/… [*on official controls*]; or

2. when that Regulation does not provide for the application of a health mark, an identification mark applied in accordance with Annex II, Section I.

Article 6

Importation

1. Food business operators importing products of animal origin from third countries [1] shall ensure that importation takes place only in accordance with paragraph 2, 3 or 4.

2. Importation may take place if:

   (a) the third country of dispatch appears on a list, drawn up in accordance with Article 8, of third countries from which imports of that product are permitted;

   (b) the establishment of dispatch [2] appears on a list, drawn up in accordance with Article 9, of establishments from which imports of that product are permitted. With the exception of live bivalve molluscs, this subparagraph does not apply to primary products dispatched from the establishment of production. Live bivalve molluscs must come from a production area appearing on a list drawn up in accordance with Article 10;

   (c) the product, and any raw material of animal origin used in its manufacture, were obtained or prepared in:

      (i) the establishment of dispatch,

      (ii) another establishment appearing on a list referred to in subparagraph (b), or

      (iii) the Community;

[1] It might be desirable to define the term "third country" to clarify that it covers territories (including Member States' territories that are not part of the Community customs zone).

[2] One delegation suggests that this provision and subparagraph (c)(i) refer to the establishment of *origin or* dispatch.

(d) the product satisfies the requirements laid down for such products:

(i) under this Regulation, including the requirements on identification marking contained in Annex II, Section I;

(ii) under Regulation (EC) …/… [*on the hygiene of foodstuffs*]; and

(iii) in accordance with Article 11; and

(e) a certificate meeting the requirements of Article 12 accompanies the consignment.

3. Importation may take place in accordance with Article 13.

4. [In the case of fishery products,] Importation may take place in accordance with Article 14. [1]

5. Food business operators importing products of animal origin shall also ensure that:

(a) products are made available for control upon importation in accordance with Directive 97/78/EC; and

(b) operations that take place after importation are carried out in accordance with the requirements of Annex II.

CHAPTER III

PROCEDURES CONCERNING IMPORTS [2]

Article 7

General provisions

1. The provisions applicable to the importation of products of animal origin from third countries shall be the same as, or equivalent to, those applicable to the production and placing of the market of Community products.

2. To ensure the uniform application of the principle lain down in paragraph 1, the procedures laid down in this Chapter shall apply.

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[1] Some delegations favour the deletion of this paragraph and Article 14. Other delegations believe that the paragraph should maintain the status quo; and, therefore, that its scope should not extend beyond fishery products. Yet other delegations believe that the procedure provided for in Article 14 should be available for all products of animal origin, to provide flexibility for developing countries in exceptional cases.

[2] The representative of the Commission reserved his Institution's position on the transfer of these provisions from Annex III to the Articles. Some delegations believe that these procedural provisions ought to appear in the Regulation on official controls.

Article 8

Lists of third country and parts of third countries from which imports of specified products of animal origin are permitted

1. Products of animal origin shall come from a third country or a part of third country that appears on a list drawn up and updated in accordance with the procedure referred to in Article 19(2).

2. A third country shall appear on such lists only if a Community audit of that country has taken place and demonstrates that the competent authority provides appropriate guarantees as regards compliance with food law. However, a Community audit is not necessary if:

   (a) the permitted imports from the third country consist solely of fisheries products handled on board factory or freezer vessels flying its flag; or

   (b) the risk (in particular, in terms of the type of products of animal origin to be imported and their likely volume) does not warrant it and other information indicates that the competent authority provides the necessary guarantees. [1]

3. Lists draw up in accordance with this Article may be combined with other lists drawn up for public and animal health purposes.

4. When drawing up or updating lists, particular account shall be taken of:

   (a) the legislation of the third country;

   (b) the organisation of the competent authority of the third country and of its inspection services, of the powers of these services and the supervision to which they are subject, as well as the authority that these services have to monitor effectively the application of their legislation;

   (c) the hygiene conditions of production, manufacture, handling, storage and dispatch actually applied to products of animal origin destined for the Community;

   (d) assurances which the competent authority of the third country can give regarding compliance or equivalence with the relevant health conditions;

[1] This paragraph gives effect to the Presidency compromise suggested at the end of the Working Party's meeting on 27 November 2001. The suggestion received a generally favourable initial reaction, but delegations and the representative of the Commission indicated that they would need time to consider its implications.

(e) any experience of marketing of the product from the third country and the results of any import controls carried out;

(f) the results of Community inspection and/or audits carried out in the third country, in particular the results of the assessment of the competent authorities;

(g) the state of health of the livestock, other domestic animals and wildlife in the third country and the general health situation in the country, which might endanger public health in the Community;

(h) the regularity and rapidity of the information supplied by the third country relating to the presence of hazards, including the presence of marine biotoxins in fishing or aquaculture zones;

(i) the existence, implementation and communication of a zoonoses control programme.

(j) the legislation of the third country on the use of veterinary medicinal products, including rules on their prohibition or authorisation, their distribution, their marketing and the rules covering administration and inspection;

(k) the existence, implementation and communication of a residue control programme;

(l) the legislation of the third country on the preparation and use of feedingstuffs, including the procedures for using additives and the preparation and use of medicated feedingstuffs, as well as the hygiene quality of the raw materials used for preparing feedingstuffs and of the final product; and

(m) compliance with other relevant provisions of food law.

4. The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this Article to be available to the public.

Article 9

List of establishments from which imports of specified products of animal origin are permitted

1. Products of animal origin, except for primary products dispatched from the establishment of production, shall come from establishments that appear on lists drawn up and updated in accordance with this Article.

2. Lists may be drawn up, in accordance with the procedure referred to in Article 19(2), on the basis of a communication from the competent authority of the third country to the Commission.

3. (a) An establishment shall be placed on such a list only if the competent authority of the third country of origin declares that:

   (i) the establishment complies with Community requirements laid down in accordance with this Regulation;

   (ii) an official inspection service in that third country supervises the establishment; and

   (iii) it has real powers to stop the establishment from exporting to the Community in the event that the establishment fails to meet the requirements referred to under (i).

   (b) In the case of factory vessels and freezer vessels, "third country of origin" shall mean either:

   (i) the third country the flag of which the vessels is flying; or

   (ii) [another third country, on condition that:

   — that third country appears on the Community list of third countries authorised to import fishery products to the Community,

   — fishery products from the vessel are landed regularly on the territory of that third country and inspected by its competent authority, and

   — the competent authority of that third country issues certificates in accordance with Article 12.] [1]

[1] Several delegations have a reservation on this provision. The Commission's proposal envisages that a Member State may also make the declaration provided for in subparagraph (a).

4. Lists drawn up in accordance with paragraph 2 shall be updated as follows:

(a) The Commission shall notify Member States when it considers that the modification of a list is necessary in the light of a request from a third country or other information, such as Community inspection reports.

(b) If no Member State objects to the proposed modifications within a week of this notification, imports shall be authorised from establishments appearing on the modified list a month from the day on which the Commission notified Member States of the proposed modifications.

(c) When at least one Member State makes written comments, the Commission shall inform all Member States and include the point on agenda of the next meeting of the Standing Committee on the Food Chain and Animal Health for decision in accordance with the procedure referred to in Article 19(2).

5. The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this Article to be available to the public.

Article 10

Live bivalve molluscs

1. Live bivalve molluscs shall come from production areas in third countries that appear on lists drawn up in accordance with Article 9(2) and (3) and updated in accordance with Article 9(4).

2. Before such lists are drawn up:

(a) an Community inspection visit on-the-spot must take place; and

(b) particular account shall be taken of the guaranties that the competent authority of the third country can give concerning respect for the requirements of this Regulation and Regulation (EC) …/… [*on official controls*] on the classification and control of production zones.

3. The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this Article to be available to the public.

Article 11

Special import requirements

1. Where necessary to ensure compliance with Article 7(1), special import requirements shall be laid down, in accordance with the procedure referred to in Article 19(2), for products of animal origin or groups of such products.

2. Such import conditions may be laid down for an individual third country, for group of third countries, or for all third countries from which imports are permitted.

Article 12

Certificates [1]

1. A certificate meeting the requirements set out in Annex III shall accompany consignments of products of animal origin on entry into the Community.

2. The certificate shall certify that the products satisfy:

   (a) the requirements laid down for such products under this Regulation and Regulation (EC) …/… [*on the hygiene of foodstuffs*], or provisions that are equivalent to those requirements; and

   (b) any special import conditions established in accordance with Article 11.

3. Certificates may include details required in accordance with other Community legislation on public and animal health matters.

4. In accordance with the procedure referred to in Article 19(2):

   (a) provision may be made for electronic certificates;

   (b) model certificates may be laid down;

   (b) the provisions of Annex III may be repealed, amended, adapted or supplemented.

Article 13

Equivalence procedure

1. A decision may be taken, in accordance with the procedure referred to in Article 19(2), recognising that the health and hygiene measures applied by a third country, a group of third countries or a region of a third country to the production, manufacture, handling, storage and transport of one or more categories of products of animal origin offer guarantees equivalent to those applied in the Community, if the third country supplies objective proof in this respect.

   The decision shall set out the conditions governing the importation of products of animal from that region, country or group of countries.

[1] Some delegations suggested that this Article refer to "certificates or other documents issued by the competent authority".

2. The conditions referred to in paragraph 1 shall include:

(a) the nature and content of the health certificate that must accompany the product;

(b) specific requirements applicable to importation into the Community; and

(c) where necessary, procedures for drawing up and amending lists of regions or plants from which imports are permitted.

3. Detailed rules for the application of this Article shall be adopted in accordance with the procedure referred to in Article 19(2).

Article 14

Case-by-case procedure

1. Imports [of fishery products] [1] from an establishment in a third country that does not appear on the lists provided for in Article 9 may be authorised following a Commission inspection.

2. Specific import conditions shall be laid down for products coming from each establishment authorised in accordance with paragraph 1.

3. The authorisation of establishment in accordance with paragraph 1 and the laying down of special import conditions in accordance with paragraph 2 shall take place in accordance with the procedure referred to in Article 19(2).

Article 15

Interim measures [2]

1. Pending the compilation of the lists provided for in Articles 8 and 9, any reference to such lists shall be interpreted as reference to the lists established on the basis of the Directives referred to in Article 1 of Directive …/…/EC [*repealing certain Directives on the hygiene of foodstuffs and the health conditions for the placing on the market certain products of animal origin intended for human consumption and amending Directives 89/662/EEC and 91/67/EEC*].

2. Pending the adoption of model certificates in accordance with Article 12, certificates shall correspond to models established on the basis of the Directives referred to in Article 1 of Directive …/…/EC [*repealing certain Directives on the hygiene of foodstuffs and the health conditions for the placing on the market certain products of animal origin intended for human consumption and amending Directives 89/662/EEC and 91/67/EEC*].

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[1] See the footnote setting out delegations' positions on Article 6(4).

[2] Arguably, this Article should also provide for current import requirements to remain in force. However, this perhaps follows more directly from Article 3 of the proposed Directive.

Article 16

Community inspections and audits [1]

1. Experts from the Commission, where appropriate accompanied by experts from the Member States, may carry out on-the-spot checks with a view to:

   (a) drawing up the list of third countries or parts thereof and determining conditions for importation;

   (b) verifying compliance with:

      (i) the conditions for inclusion in a Community list of third countries,

      (ii) import conditions,

      (iii) the conditions for recognising equivalence of measures,

      (iv) any emergency measures applied under Community legislation.

   The Commission shall appoint experts from the Member States responsible for these checks.

2. The checks referred to in paragraph 1 shall be carried out on behalf of the Community, which shall meet the costs incurred.

3. The frequency of and the procedure for the checks referred to in paragraph 1 may be specified in accordance with the procedure referred to in Article 19(2).

4. If a check referred to in paragraph 1 reveals a serious infringement of the health rules, the Commission shall immediately take emergency measures in accordance with Regulation (EC) …/2002 [*laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*].

[1] Some delegations advocate clarification of this Article, in particular as regards the distinction between audits and targeted inspections. The representative of the Commission explained that Article used standard wording and that the forthcoming proposals on official controls might render it superfluous.

CHAPTER V

SPECIAL GUARANTEES

Article 17

Special guarantees

1. In respect of salmonella, the rules laid down by paragraph 2 shall apply to the following foodstuffs intended for placing on the market in Sweden or Finland:

   (a) meat from bovine and porcine animals [and minced meat prepared therefrom];

   (b) meat from poultry and ratites [and minced meat prepared therefrom]; and

   (c) eggs.

2. (a) In the case of meat from bovine and porcine animals and meat from poultry and ratites, samples of consignments shall have been taken in the dispatching establishment and been subjected to a microbiological test with negative results in accordance with Community legislation.

   (b) In the case of eggs, packing centres shall provide a guarantee that consignments originate from flocks that have been subjected to a microbiological test with negative results in accordance with Community legislation.

   (c) In the case of meat from bovine and porcine animals, the test provided for in subparagraph (a) need not be carried out for consignments intended for an establishment for the purposes of pasteurisation, sterilisation or treatment having a similar effect. In the case of eggs, the test provided for in subparagraph (b) need not be carried out for consignments intended for the manufacture of processed products by a process that guarantees the elimination of salmonella.

   (d) The tests provided for in subparagraphs (a) and (b) need not be carried out for foodstuffs originating in an establishment that is subject to an operational control programme recognised, in accordance with the procedure referred to in Article 19(2), as equivalent to that approved for Sweden and Finland.

   (e) In the case of meat from bovine and porcine animals and meat from poultry and ratites, a trade document or certificate conforming to a model laid down by Community legislation shall accompany the food and state that:

      (i) the checks referred to in subparagraph (a) have been carried out with negative results; or

(ii) the meat is intended for one of the purposes referred to in subparagraph (c); or

(iii) the meat comes from an establishment covered by subparagraph (d). [1]

(f) In the case of eggs, a certificate stating that the tests referred to in subparagraph (b) have been carried out with negative results, or that the eggs are destined to be used in the manner referred to in subparagraph (c), must accompany consignments.

3. In accordance with the procedure referred to in Article 19(2):

(a) the operational programmes referred to in paragraph 2(c) may be amended and updated at the request of the Member State concerned; and

(b) the rules laid down by paragraph 2 in respect of the foodstuffs referred to in paragraph 1 may be extended to any Member State, or any region of a Member State, that has an operational control programme recognised as equivalent to that approved for Sweden and Finland.

CHAPTER V

FINAL PROVISIONS

Article 18

Amendment of Annex II and adoption of implementing measures, exemptions, transitional measures and national adaptations

1. The provisions of Annex II may be repealed, amended, adapted or supplemented, in accordance with the procedure referred to in Article 19(2), to take account of:

(a) the development of codes of good practice;

(b) food business operators' implementation of food safety programmes;

(c) technological developments;

(d) scientific advice, particularly new risk assessments; and

(e) the setting of food safety targets.

2. Implementing measures may be adopted, in accordance with the procedure referred to in Article 19(2), to ensure the uniform implementation of this Regulation.

[1] A recital should refer to the legislation laying down the current requirements.

3. Exemptions from provisions of Annex II may be granted, and any appropriate transitional measures adopted, in accordance with the procedure referred to in Article 19(2), provided that such exemptions or measures do not affect the achievement of the objectives of this Regulation. [1]

[4. Member States may, without compromising food hygiene objectives, adapt the requirements [laid down in Section I, Chapters I and II, and Section II, Chapters II and III,] of Annex II [concerning the construction, layout and equipment of establishments]:

(a) to accommodate the needs of food businesses that generally place food on the market locally and are situated in regions suffering from special geographical constraints or affected by supply difficulties; or

(b) to take account of traditional methods of production or distribution.

5. Any Member State wishing to take advantage of the possibility referred to in paragraph 4 shall first notify the Commission and other Member States. Other Member States shall have three months from the receipt of the notification to send written comments to the Commission. The Commission may - and, when it receives written comments from one or more Member States, shall - propose a decision to be adopted in accordance with the procedure referred to in Article 19(2).

6. A Member State may adapt the requirements of Annex II in accordance with paragraph 4 only in compliance with a decision adopted in accordance with paragraph 5 or if, after the expiry of the three month period referred to in that paragraph, the Commission informs that Member State that it has received no written comments from other Member States and does not intend to propose such a decision.] [2]

Article 19

Standing Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Regulation (EC) No …/2002.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, in compliance with Article 8 thereof.

The period provided for in Article 5(6) of that Decision shall be three months.

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[1] A reference to transitional measures has been added, to clarify that exemptions need not be permanent.

[2] Some delegations support the procedure provided for in paragraphs 4 to 6, which seeks to provide flexibility in a transparent manner. Other delegations believe that the Regulation should lay down rules that are applicable to all Member States or that, special conditions should only be granted at the initiative of the Commission (for example, in accordance with paragraph 3).

3. The Committee shall adopt its rules of procedure.

Article 20

Consultation of the European Food Safety Authority

The European Food Safety Authority shall be consulted on any matter within the scope of this Regulation that could have an impact on public health.

Article 21

Report to Council and Parliament

The Commission shall, within [seven] years of this Regulation entering into force, submit a report to the European Parliament and the Council reviewing the experience gained from the implementation of this Regulation and accompanied, where appropriate, by relevant proposals.

Article 22

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

It shall apply [one year after its entry into force].[1]

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at …

For the European Parliament	*For the Council*
For the President	*The President*

[1] A recital should explain that the year-long delay between the dates of entry into force and application is to give all those involved in applying or enforcing the new rules time to adapt.

ANNEX I

DEFINITIONS

For the purpose of this Regulation:

1. MEAT

1.1 "Meat" means edible parts of the animals referred to in paragraphs 1.2 to 1.8.

1.2 "Domestic ungulates" means domestic bovine (including Bubalus and Bison species), porcine, ovine and caprine animals, and domestic solipeds.

1.3 "Poultry" means farmed birds, including birds that are not considered as domestic but which are farmed as domestic animals, with the exception of ratites.

1.4 "Lagomorphs" means rabbits, hares and rodents.

1.5 "Wild game" means:

– wild land mammals that are hunted, including mammals living in enclosed territory under conditions of freedom similar to those of wild game; and

– wild birds that are hunted.

1.6 "Farmed game" means farmed ungulates and ratites.

1.7 "Small wild game" means wild game birds and lagomorphs living freely in the wild.

1.8 "Large wild game" means wild mammals living freely in the wild and not classified as small wild game.

1.9 "Carcase" means the body of an animal after slaughter and dressing.

1.10 "Fresh meat" means meat that has not undergone any preserving process other than chilling, freezing or quick-freezing, including meat that is vacuum-wrapped or wrapped in a controlled atmosphere.

1.11 "Offal" means fresh meat other than that of the carcase.

1.12 "Viscera" means offal from the thoracic, abdominal and pelvic cavities, as well as the trachea and oesophagus and, in birds, the crop.

1.13 "Minced meat" means boned meat that has been minced into fragments and contains less than 1% salt.

1.14 ["Mechanically separated meat" means the product resulting from the mechanical separation of meat left on bones after boning, or on poultry carcases, so that the cellular structure of the meat is broken.] [1]

1.15 "Meat preparations" means fresh meat, including minced meat, which has had foodstuffs, seasonings or additives added to it or which has undergone a treatment insufficient to modify the internal cellular structure of the meat and thus to eliminate the characteristics of fresh meat.

1.16 "Slaughterhouse" means an establishment used for slaughtering and dressing animals, the meat of which is intended for human consumption.

1.17 "Cutting plant" means an establishment used for boning and/or cutting up meat.

1.18 "Game handling establishment" means any establishment in which game and game meat obtained after hunting are prepared for placing on the market.

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.

2.4 "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.

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 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.

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[1] The Presidency has suggested deleting this definition and placing the rules in Annex II, Section VI. The definition contains implicit rules on the raw material that can be used to produce mechanically separated meat. It would be more appropriate for any rules to appear in Annex II. This would also enable their updating in the light of technological definitions or scientific advice. Some delegations have reserved their position on the Presidency's suggestion.

2.7 "Dispatch centre" means any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs fit for human consumption.

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 for the time necessary to reduce contamination to make them fit for human consumption. This does not include the specific operation of transferring bivalve molluscs to areas more suitable for further growth or fattening.

3. FISHERY PRODUCTS

3.1 "Fishery products" means live seawater or freshwater animals, wild or farmed, and parts and products of such animals, including roes and livers.

3.2 "Factory vessel" means any vessel on board which fishery products undergo one or more of the following operations followed by wrapping or packaging and chilling or freezing: filleting, slicing, skinning, shelling, shucking, 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 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 or packaging.

3.4 ["Mechanically recovered fish flesh" means flesh obtained by mechanical means from gutted whole fish or bones after filleting.] [1]

3.5 "Fresh fishery products" means unprocessed 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 fishery products" means unprocessed fishery products that have undergone an operation affecting their anatomical wholeness, such as gutting, heading, slicing, filleting, and chopping.

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[1] The Presidency has suggested deleting this definition and placing the rules in Annex II, Section IX. The definition contains implicit rules on the raw material that can be used to produce mechanically separated meat. It would be more appropriate for any rules to appear in Annex II. This would also enable their updating in the light of technological definitions or scientific advice. Some delegations have reserved their position on the Presidency's suggestion.

4. MILK

4.1 "Raw milk" means milk produced by the secretion of the mammary gland of farmed animals that has not been heated to more than 40 ºC or undergone any treatment that has an equivalent effect.

4.2 "Milk production holding" means an establishment where one or more farmed animals are kept to produce milk with a view to placing it on the market as food.

5. EGGS

5.1 "Eggs" means eggs in shell - other than broken, incubated or cooked eggs - produced by farmed birds and that are fit for direct human consumption or for the preparation of processed egg products.

5.2 "Liquid egg" means unprocessed egg contents after removal of the shell.

5.3 "Cracked eggs" means eggs with a damaged, but unbroken, shell and intact membranes.

5.4 "Packing centre" means an establishment where eggs are graded by quality and weight.

6. FROGS' LEGS AND SNAILS

6.1 "Frogs' legs" means the posterior part of the body divided by a transverse cut behind the front limbs, eviscerated and skinned, of the species Rana (family Ranidae).

6.2 "Snails" means terrestrial gastropods of the species Helix pomatia Linné, Helix aspersa Muller, Helix lucorum and species of the family Achatinidae.

7. PROCESSED PRODUCTS

7.1 "Processing" means an action that substantially alters the initial product by heating, smoking, curing, maturing, drying, marinating, extraction, extrusion, or a combination of those processes, with the exception of slicing, freezing and thawing.

7.2 "Unprocessed products" means foodstuffs which have not undergone processing, including products that have been divided, parted, severed, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen or deep-frozen.

7.3 "Processed products" means foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients necessary for their manufacture in order to give them specific characteristics.

7.4 "Meat products" means products that have been prepared from meat, or with meat that has undergone processing, so that the cut surface shows that the product no longer has the characteristics of fresh meat.

7.5 "Processed dairy products" means processed products resulting from the processing of raw milk or from the further processing of such processed products.

7.6 "Processed egg products" means processed products resulting from the processing of eggs, or of various components or mixtures of eggs, or from the further processing of such processed products.

7.7 "Rendered animal fat" means fat derived from rendering meat, including bones, and intended for human consumption.

7.8 "Greaves" means the protein-containing residue of rendering, after partial separation of fat and water.

7.9 "Gelatine" means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals (including fish and poultry).

7.10 "Treated stomachs, bladders and intestines" means stomachs, bladders and intestines that have been submitted to a treatment such as salting, heating or drying after they have been obtained and after cleaning.

8. OTHER DEFINITIONS

8.1 "Products of animal origin" means foodstuffs obtained from animals, including honey.

8.2 "Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms.

ANNEX II

SPECIFIC REQUIREMENTS

SECTION I: IDENTIFICATION MARKING

When required in accordance with Articles 5 or 6, and subject to the provisions of the subsequent Sections of this Annex, food business operators handling a product of animal origin at any stage of production, processing and distribution after primary production must ensure that it has an identification mark that meets the following requirements.

1. The mark must be applied before the product leaves the establishment.

2. The mark must be legible and indelible, and the characters easily decipherable. It must be clearly displayed for the competent authorities.

3. The mark must indicate the name of the country in which the establishment is located, which may be written out in full or shown as a two-letter code in accordance with the relevant ISO standard.

   In the case of Member States, these codes are AT, BE, DE, DK, ES, FI, FR, GR, IE, IT, LU, NL, PT, SE and GB. [1]

4. The mark must indicate the registration or approval number of the establishment. [2]

5. When applied in an establishment located within the Community, the mark must be oval in shape [and include the abbreviation CE, EC, EF, EG, EK or EY].

6. The mark may, depending on the presentation of different products of animal origin, be applied directly to the product, the wrapping or the packaging, or be printed on a label affixed to the product, the wrapping or the packaging. The mark may also be an irremovable tag made of a resistant material.

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[1] While no delegation opposed the use of the ISO country codes, several have scrutiny reserves.

[2] The Working Party may wish to discuss the position of establishments that produce composite products. The current drafting of this Regulation and the general hygiene Regulation could result in an establishment having to apply an identification mark indicating its approval number to some products but to have different packaging indicating a registration number for composite products. Food business operators may find it more practical to be able to apply an identification mark to all their products.

7. For products of animal origin that are placed in transport containers or large packages and intended for further handling, processing or wrapping in another establishment, the mark may be applied to the external surface of the container or packaging.

8. The marking of individual products of animal origin destined for the final consumer and contained in a common external packaging is not necessary if the mark is applied to the external surface of that packaging.

9. When the mark is applied directly to products of animal origin, the colours used must be authorised in accordance with Community rules on the use of colouring substances in foodstuffs.

10. A new mark need not be applied to a product unless its packaging and/or wrapping is removed or it is further processed in another establishment, in which case the new mark must indicate the registration or approval number of the establishment where these operations take place.

SECTION II: MEAT OF DOMESTIC UNGULATES

CHAPTER I: REQUIREMENTS FOR SLAUGHTERHOUSES

Food business operators must ensure that the construction, layout and equipment of slaughterhouses in which domestic ungulates are slaughtered meet the following requirements.

1. (a) Slaughterhouses must have adequate and hygienic lairage facilities or, climate permitting, waiting pens that are easy to clean and disinfect. These facilities must be equipped for watering the animals and, if necessary, feeding them. The drainage of the wastewater must not compromise food safety.

   (b) They must also have separate lockable facilities or, climate permitting, pens for sick or suspect animals with separate draining and sited in such a way as to avoid contamination of other animals, unless the competent authority considers that such facilities are unnecessary.

   (c) The size of the lairage facilities must ensure the respect of the welfare of the animals. Their layout must facilitate ante-mortem inspections, including the identification of the animals or groups of animals.

2. To avoid contaminating meat, they must:

   (a) have a sufficient number of rooms, appropriate to the operations being carried out;

   (b) have a separate room for the emptying and cleaning of stomachs and intestines, unless the competent authority authorises the separation in time of these operations within a specific slaughterhouse on a case by case basis;

   (c) ensure separation in space or time of the following operations, if carried out in the slaughterhouse:

      (i) stunning and bleeding,

      (ii) in the case of porcine animals, scalding, depilation, scraping and singeing,

      (iii) handling clean guts and tripe,

      (iv) preparation and cleaning of other offal, particularly the handling of skinned heads if it does not take place at the slaughter line,

      (v) packaging offal, and

      (vi) dispatching meat;

(d) have installations that prevent contact between the meat and the floors, walls and fixtures; and

(e) have slaughter lines (where operated) that are designed to allow a constant progress of the slaughter process and to avoid cross-contamination between the different parts of the slaughter line. Where more than one slaughter line is operated in the same premises, there must be adequate separation of the lines to prevent cross-contamination. [1]

3. They must have facilities for disinfecting tools with hot water supplied at not less than 82 ºC, or an alternative system having an equivalent effect.

4. The equipment for washing hands used by the staff engaged in handling exposed meat must have taps designed to prevent the spread of contamination.

5. There must be lockable facilities for the refrigerated storage of detained meat and separate lockable facilities for the storage of meat declared unfit for human consumption.

6. There must be a separate place with appropriate facilities for the cleaning, washing and disinfection of means of transport. These places and facilities are not compulsory if officially authorised places and facilities exist nearby. [2]

7. They must have lockable facilities reserved for the slaughter of sick and suspect animals. This is not essential if this slaughter takes place in other establishments authorised by the competent authority for this purpose, or at the end of the normal slaughter period. [3]

8. If manure or domestic tract gut content is stored in the slaughterhouse, there must be a special area or place for that purpose.

9. They must have an adequately equipped lockable facility or, where needed, room for the exclusive use of the veterinary service.

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[1] One delegation reserved its position on the removal of the current requirement for a minimum separation of 5 metres. It could agree to its removal only if the Regulation as a whole did not represent a step backwards compared to current requirements.

[2] Some delegations have a reservation on the second sentence of this paragraph, because of animal health concerns. One delegation believed that the deletion of the sentence could be a problem for small slaughterhouses.

[3] One delegation favours the deletion of the second sentence.

10. All operations for the slaughter of reindeer destined for intra-Community trade may be carried out in mobile slaughter units equipped in accordance with this Chapter.
The conditions under which mobile slaughterhouses may be used for the slaughter of other species may be laid down in accordance with the procedure referred to in Article 19(2).

CHAPTER II: REQUIREMENTS FOR CUTTING PLANTS

Food business operators must ensure that cutting plants handling meat of domestic ungulates:

(a) are constructed so as:

(i) to allow constant progress of the operations, and [1]

(ii) to ensure separation between the different production batches;

(b) have rooms for the separate storage of packaged and exposed meat, unless stored at different times; [2]

(c) have cutting rooms equipped to ensure compliance with the requirements laid down in Chapter IV;

(d) have equipment for washing hands with taps designed to prevent the spread of contamination, for use by staff engaged in handling exposed meat; and

(e) have facilities for disinfecting tools with hot water supplied at not less than 82 ºC, or an alternative system having an equivalent effect.

[1] The representative of the Commission prefers retaining the conjunction "or", as proposed by his Institution.

[2] One delegation expressed a reservation on this provision.

CHAPTER III: SLAUGHTER HYGIENE

Food business operators operating slaughterhouses in which domestic ungulates are slaughtered must ensure compliance with the following requirements.

1. After arrival in the slaughterhouse, the slaughter of the animals must not be unduly delayed. However, where required for welfare reasons, animals must be given a resting period before slaughter.

2. (a) Meat from animals other than those referred to in subparagraphs (b) and (c) must not be used for human consumption if they die other than by being slaughtered in the slaughterhouse.

   (b) Only live animals intended for slaughter may be brought into the slaughter premises, with the exception of:

      (i) animals that have undergone emergency slaughter outside the slaughterhouse in accordance with Chapter V,

      (ii) farmed game slaughtered at the place of production in accordance with Section V, and

      (iii) wild game, in compliance with Section VI, Chapter II.

   (c) Meat from animals that undergo slaughter following an accident in a slaughterhouse may be used for human consumption if, on inspection, no serious lesions other than those due to the accident are found.

3. The animals or, where appropriate, each batch of animals sent for slaughter must be identified so that their origin can be traced.

4. The state of cleanliness of the animals must be such as to minimise the risk of contaminating the meat during slaughter operations.

5. Slaughterhouse operators must follow the instructions of the competent authority to ensure that ante-mortem inspection is carried out under suitable conditions.

6. Animals brought into the slaughter hall must be slaughtered without undue delay.

7. Stunning, bleeding, skinning, dressing and evisceration must be carried out without undue delay and in a manner that avoids contaminating the meat. In particular:

(a) [the trachea and oesophagus must remain intact during bleeding, except in the case of slaughter according to a religious custom;] [1]

(b) during the removal of hides and fleece:

(i) contact between the outside of the skin and the carcase must be prevented, and

(ii) operators and equipment coming into contact with the outer surface of hides and fleece must not touch the meat;

(c) measures must be taken to prevent the spillage of digestive tract content during and after evisceration and to ensure that evisceration is completed as soon as possible after stunning; and

(d) removal of the udder must not result in contamination of the carcase with milk or colostrum.

8. Complete skinning must be carried out, except for porcine animals and the heads of ovine and caprine animals. Heads must be handled so as to avoid contamination of other meat. [2]

9. When not skinned, porcine animals must have their bristles removed immediately. The risk of contamination of the meat with scalding water must be minimised. Only approved additives may be used for this operation. Porcine animals must be thoroughly rinsed afterwards with potable water.

10. The carcases must not contain visible faecal contamination. Any limited visible contamination must be removed without delay.

11. Carcases and offal must not come into contact with floors, walls or work stands.

12. Slaughterhouse operators must follow the instructions of the competent authority to ensure that post-mortem inspection is carried out under suitable conditions.

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[1] Some delegations advocated the deletion of this subparagraph. Others believed that it was necessary to emphasise the need to avoid contaminating the meat. The change to the chapeau seeks to address this concern, perhaps permitting the deletion of subparagraph (a).

[2] The revised wording of this paragraph clarifies that heads must always be handled so as to avoid contamination. It would provide for the use of unskinned sheep and goats' heads for human consumption. However, were it to reinstate the current rules, the Regulation on official controls would require the skinning of all such heads for inspection purposes.

13. Until post-mortem inspection is completed, parts of a slaughtered animal subject to such inspection must:

(a) remain identifiable as belonging to a given carcase; and

(b) come into contact with no other carcase, offal or viscera, including those that have already undergone post-mortem inspection.

However, provided that it shows no pathological lesion, the penis may be discarded immediately.

14. Both kidneys must be removed from their fatty covering. In the case of bovine and porcine animals, and solipeds, the peri-renal capsule must also be removed.

15. If the blood or offal of several animals is collected in the same container before completion of post-mortem inspection, the entire contents must be declared unfit for human consumption if the carcase of one or more of the animals concerned has been declared unfit for human consumption.

16. After post-mortem inspection:

(a) the tonsils of bovine animals under six weeks, porcine animals and solipeds must be removed hygienically;

(b) parts unfit for human consumption must be removed as soon as possible from the clean sector of the establishment;

(c) meat detained or declared unfit for human consumption and inedible by-products must not come into contact with meat declared fit for human consumption; and

(d) viscera or parts of viscera remaining in the carcase, except for the kidneys, must be removed entirely and as soon as possible, unless the competent authority authorises otherwise.

17. After completion of slaughter and post-mortem inspection, the meat must be stored in accordance with the requirements laid down in Chapter VI.

18. Where establishments are approved for the slaughter of different animal species or for the handling of carcases of farmed game and wild game, precautions must be taken to prevent cross-contamination by separation either in time or in space of operations carried out on the different species. Separate facilities for the reception and storage of unskinned carcases of farmed game slaughtered at the farm and for wild game must be available.

19. If the slaughterhouse does not have lockable facilities reserved for the slaughter of sick or suspect animals, the facilities used to slaughter such animals must be cleaned, washed and disinfected under official supervision before the slaughter of other animals is resumed.

CHAPTER IV: HYGIENE DURING CUTTING AND BONING

Food business operators must ensure that cutting and boning of meat of domestic ungulates takes place in accordance with the following requirements.

1. Carcases of domestic ungulates may be cut into half-carcases, and half-carcases into quarters or a maximum of three wholesale cuts, in slaughterhouses. Further cutting and boning must be carried out in a cutting plant.

2. The work on meat must be organised in such a way as to prevent or minimise contamination. To this end, food business operators must ensure in particular that:

   (a) meat intended for cutting is brought into the workrooms progressively as needed;

   (b) during cutting, boning, trimming, slicing, dicing, wrapping and packaging, the meat is maintained at not more than 3 ºC for offal and 7 ºC for other meat (by means of an ambient temperature of 12 ºC or an alternative system having an equivalent effect); and

   (c) where the premises are approved for the cutting of meat of different animal species, precautions are taken to avoid cross-contamination, where necessary by separation of the operations on the different species in either space or time.

3. However, meat may be boned and cut prior to reaching the temperature referred to in point 2(b):

   (a) in accordance with Chapter VI, point 3; or

   (b) when the cutting room is on the same site as the slaughter premises, provided that the meat is transferred either:

      (i) directly from the slaughter premises to the cutting room; or

      (ii) after a waiting period in a chilling or refrigerating room.

      As soon as it is cut and, where appropriate, packaged, the meat must be chilled to the temperature referred to in point 2(b). [1]

[1] One delegation suggested the addition of the following sentence: "The surface temperature of meat must be recorded regularly at the end of the cutting process.". The representative of the Commission replied that any food business that properly implemented HACCP principles would record the temperature of meat.

CHAPTER V: EMERGENCY SLAUGHTER OUTSIDE THE SLAUGHTERHOUSE [1]

1. Food business operators must ensure that meat from domestic ungulates that:

   (a) have undergone emergency slaughter outside the slaughterhouse because an accident or welfare considerations prevented transport to the slaughterhouse; but

   (b) did not suffer from a generalised physiological or functional problem,

   is placed on the market for human consumption only if all the requirements of paragraph 2 are fulfilled.

2. (a) A veterinarian must examine the animal before slaughter.

   (b) Animal welfare requirements must be complied with.

   (c) The slaughtered and bled animal must be transported as quickly as possible after slaughter under satisfactory hygiene conditions to a slaughterhouse approved for that purpose. [Where the slaughtered animal cannot be brought to such a slaughterhouse within an hour, it must be transported in a container or means of transport in which the ambient temperature is maintained at not more than 4 ºC.] [2] Evisceration must be carried out as soon as possible, if necessary on the spot. If an excessively long period elapses between slaughter and evisceration, the official veterinarian may require special checks to be carried out at post-mortem inspection. If evisceration is carried out on the spot, the viscera must accompany the carcase to the slaughterhouse.

   (d) During transport to the slaughterhouse, the slaughtered animal and, where appropriate, the viscera must be transported hygienically and accompanied by a certificate issued by the veterinary surgeon who ordered slaughter attesting to the outcome of ante-mortem inspection, the nature of any treatment administered to the animal and, if appropriate, the result of the inspection of the viscera.

   (e) The slaughtered animal must be declared wholly or partly fit for human consumption after having been submitted to a detailed post-mortem examination, where necessary supplemented by a bacteriological and residue examination.

   [(f) The meat must not be provided with the health mark but with an identification mark approved by the competent authority]. [3]

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[1] Several delegations suggested that the limited application of this Chapter and its complexity might argue in favour of its deletion.

[2] Within the informal Drafting Group there were doubts about the necessity for, and practicability of, this provision and the equivalent provision in Section IV.

[3] Some delegations supported the deletion of this subparagraph. Others opposed its deletion, arguing that a meat resulted from emergency slaughter needed to be treated differently from other meat. One delegation suggested a compromise: to modify the subparagraph to provide for a supplementary identification mark in addition to the health mark.

CHAPTER VI: STORAGE, TRANSPORT AND MATURATION

Food business operators must ensure that the storage, transport and maturation of meat of domestic ungulates takes place in accordance with the following requirements.

1. (a) Post-mortem inspection must be followed immediately by chilling in the slaughterhouse to ensure a temperature throughout the meat of not more than 3 ºC for offal and 7 ºC for other meat along a chilling curve that ensures a continuous decrease of the temperature. However, meat may be cut and boned during chilling in accordance with Chapter IV, point 3(b).

   (b) During the chilling operations, there must be adequate ventilation to prevent condensation on the surface of the meat.

2. Meat must attain the temperature specified in point 1 and remain at that temperature during storage.

3. Meat must attain the temperature specified in point 1 before transport, and remain at that temperature during transport. However, transport may also take place:

   (a) under conditions laid down in accordance with the procedure referred to in Article 19(2); and

   (b) [1] if the competent authority so authorises to enable the production of specific products, provided that:

      (i) such transport takes place in accordance with the requirements that the competent authority specifies in respect of transport from one given establishment to another; and

      (ii) the meat leaves the slaughterhouse immediately and transport takes no more than two hours.

4. Meat intended for freezing must be frozen without undue delay, taking into account where necessary a stabilisation period before freezing. [2]

5. Exposed meat must be stored in a separate room from packaged meat, unless stored at different times.

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[1] Warm transport is currently possible to permit the production of specific products and from small slaughterhouses without chilling facilities. The draft Regulation on general hygiene would not generally allow slaughterhouses to operate without chilling facilities.
The informal Drafting Group suggested this rule for consideration.

[2] The Working Party has agreed that a recital in the final Regulation should explain that the stabilisation period refers to *rigor mortis*.

6. Unpackaged meat must not be transported with:

   (a) packaged meat, unless adequate physical separation is provided;

   (b) with stomachs, unless they are scalded and cleaned; and

   (c) with heads and feet unless they are skinned or scalded and depilated.

7. When destined for further processing, stomachs must be scalded or cleaned before transport and heads and feet must be skinned or scalded and depilated.

SECTION III: MEAT FROM POULTRY AND LAGOMORPHS

The requirements of this Section apply, by analogy, to meat from farmed lagomorphs.

CHAPTER I: TRANSPORT OF BIRDS TO THE SLAUGHTERHOUSE [1]

Food business operators transporting birds to slaughterhouses must ensure compliance with the following requirements.

1. During collection and transport, birds must be handled carefully without causing unnecessary distress.

2. Birds showing symptoms of disease or originating in flocks known to be contaminated with agents of public health importance may only be transported to the slaughterhouse when permitted by the competent authority.

3. Crates for delivering poultry to the slaughterhouse and modules, where used, must be made of non-corrodible material and be easy to clean and disinfect. Immediately after emptying and, if necessary, before re-use, all equipment used for collecting and delivering live birds must be cleaned, washed and disinfected.

[1] Some delegations queried the appropriateness of having detailed rules on animal welfare in a regulation on food hygiene. The representative of the Commission explained that welfare and hygiene are linked (for example, salmonella spreads more rapidly when animals suffer from stress).

CHAPTER II: REQUIREMENTS FOR SLAUGHTERHOUSES

Food business operators must ensure that the construction, layout and equipment of slaughterhouses in which poultry are slaughtered meet the following requirements.

1. Slaughterhouses must be constructed, laid out and equipped in accordance with the following conditions.

2. They must have a room or covered space for the reception of the animals and for their inspection before slaughter. [1]

3. To avoid contaminating meat, they must:

   (a) have a sufficient number of rooms, appropriate to the operations being carried out;

   (b) have a separate room for evisceration and further dressing, including the addition of seasonings to whole poultry carcases, unless the competent authority authorises separation in time of these operations within a specific slaughterhouse on a case-by-case basis;

   (c) ensure separation in space or time of the following operations, if carried out in the slaughterhouse:

      (i) stunning and bleeding,

      (ii) plucking and any scalding, and

      (iii) dispatching meat;

   (d) have installations that prevent contact between the meat and the floors, walls and fixtures; and

   (e) have slaughter lines (where operated) that are designed to allow a constant progress of the slaughter process and to avoid cross-contamination between the different parts of the slaughter line. Where more than one slaughter line is operated in the same premises, there must be adequate separation of the lines to prevent cross-contamination.

4. They must have facilities for disinfecting tools with hot water supplied at not less than 82 ºC, or an alternative system having an equivalent effect.

5. The equipment for washing hands used by the staff engaged in handling exposed meat must have taps designed to prevent the spread of contamination.

[1] One delegation requested the addition of the option, weather permitting, of having a waiting pen, as provided for in Section I, Chapter I, paragraph 1.

6. There must be lockable facilities for the refrigerated storage of detained meat and separate lockable facilities for the storage of meat declared unfit for human consumption.

7. There must be a separate place with appropriate facilities for the cleaning, washing and disinfection of:

   (a) transport equipment such as crates; and

   (b) means of transport.

   These places and facilities are not compulsory for (b) if officially authorised places and facilities exist nearby.

8. They must have an adequately equipped lockable facility or, where needed, room for the exclusive use of the veterinary service.

CHAPTER III: REQUIREMENTS FOR CUTTING PLANTS

1. Food business operators must ensure that cutting plants handling poultry meat:

   (a) are constructed so as to allow constant progress of the operations and to ensure separation between the different batches;

   (b) have rooms for the separate storage of packaged and exposed meat, unless stored at different times;

   (c) have cutting rooms equipped to ensure with the requirement laid down in Chapter V;

   (d) have equipment for washing hands used by staff handling exposed meat with taps designed to prevent the spread of contamination; and

   (e) have facilities for disinfecting tools with hot water supplied at not less than 82 ºC, or an alternative system having an equivalent effect.

2. If the following operations are undertaken in a cutting plant:

   (a) the evisceration of geese and ducks reared for the production of "foie gras", which have been stunned, bled and plucked on the fattening farm; or

   (b) the evisceration of delayed eviscerated poultry,

   food business operators must ensure that separate rooms are available for that purpose.

CHAPTER IV: SLAUGHTER HYGIENE

Food business operators operating slaughterhouses in which poultry are slaughtered must ensure compliance with the following requirements.

1. (a) Meat from animals other than those referred to in subparagraph (b) must not be used for human consumption if they die other than by being slaughtered in the slaughterhouse.

   (b) Only live animals intended for slaughter may be brought into the slaughter premises, with the exception of:

      (i) delayed eviscerated poultry, and geese and ducks reared for the production of "foie gras", that are slaughtered at the farm in accordance with Chapter VI,

      (ii) farmed game slaughtered at the place of production in accordance with Section IV, and

      (iii) small wild game in accordance with Section V, Chapter III. [1]

2. Slaughterhouse operators must follow the instructions of the competent authority to ensure that ante-mortem inspection is carried out under suitable conditions.

3. Where establishments are approved for the slaughter of different animal species or for the handling of farmed ratites and small wild game, precautions must be taken to prevent cross contamination by separation either in time or in space of the operations carried out on the different species. Separate facilities for the reception and storage of carcases of farmed ratites slaughtered at the farm and for small wild game must be available.

4. Animals brought into the slaughter room must be slaughtered without undue delay.

5. Stunning, bleeding, skinning or plucking, dressing and evisceration must be carried out without undue delay in such a way that contamination of the meat is avoided. In particular, measures must be taken to prevent the spillage of digestive tract contents during evisceration.

6. Slaughterhouse operators must follow the instructions of the competent authority to ensure that the post-mortem inspection is carried out under suitable conditions, and in particular that slaughtered poultry can be inspected properly.

[1] Some delegations oppose the delivery of dead birds to the slaughterhouse, except for the production of foie gras.

7. After post-mortem inspection:

(a) parts unfit for human consumption must be removed as soon as possible from the clean sector of the establishment;

(b) meat detained or declared unfit for human consumption and inedible by-products must not come into contact with meat declared fit for human consumption; and

(c) viscera or parts of viscera remaining in the carcase, except for the kidneys, must be removed entirely, if possible, and as soon as possible, unless otherwise authorised by the competent authority.

8. After inspection and evisceration, slaughtered birds must be cleaned [1] and chilled to not more than 4 ºC as soon as possible, unless the meat is cut while warm.

9. When poultry carcases are subjected to an immersion chilling process, account must be taken of the following. [2]

(a) Every precaution must be taken to avoid cross-contamination of carcases, taking into account parameters such as carcase weight, water temperature, volume and direction of water flow and chilling time.

(b) Equipment must be entirely emptied, cleaned and disinfected whenever this is necessary. [3]

10. Sick or suspect birds or birds slaughtered in application of disease eradication or control programmes must not be slaughtered in the establishment except when permitted by the competent authority. In that event, slaughter must be performed under official supervision and steps taken to prevent contamination; the premises must be cleaned and disinfected before being used again.

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[1] Some delegations suggest expanding the requirement to clean slaughtered birds (either by stating that the cleaning process must not make the meat unfit for human consumption or by requiring the removal of contaminants).

[2] Some delegations want the Regulation to prohibit the use of the immersion chilling process. Other delegations believe that the process should remain an option, since it would not present a health risk were the HACCP system properly applied or warned that a ban on the use of the immersion chilling process might be problematic for companies that use the process only to prepare frozen poultry for export to third countries. One delegation advocates stricter criteria, to make clear that the process must not render carcasses unfit for human consumption.

[3] Some delegations suggest that subparagraph (b) require emptying, cleaning and disinfection to take place daily.

CHAPTER V: HYGIENE DURING CUTTING AND BONING

Food business operators must ensure that cutting and boning of poultry meat takes place in accordance with the following requirements.

1. The work on meat must be organised in such a way as to prevent or minimise contamination. To this end, food business operators must ensure in particular that:

   (a) meat intended for cutting is brought into the workrooms progressively as needed; [1]

   (b) during cutting, boning, trimming, slicing, dicing, wrapping and packaging, the temperature of the meat is maintained at not more than 4 ºC (by means of an ambient temperature of 12 ºC or an alternative system having an equivalent effect); and

   (c) where the premises are approved for the cutting of meat of different animal species, precautions are taken to avoid cross-contamination, where necessary by separation of the operations on the different species in either space or time.

2. However, meat may be boned and cut prior to reaching the temperature referred to in point 1(b) when the cutting room is on the same site as the slaughter premises, provided that it is transferred either:

   (a) directly from the slaughter premises to the cutting room; or

   (b) after a waiting period in a chilling or refrigerating room.

   As soon as it is cut and, where appropriate, packaged, the meat must be chilled to the temperature referred to in point 1(b).

[1] One delegation suggests that paragraph 1(a) refer to the need to avoid the possibility of congestion or undue delay in the cutting process (a problem specific to poultry).

CHAPTER VI: SLAUGHTER ON THE FARM

Food business operators may slaughter poultry referred to in Chapter IV, point 1(b), on the farm only with the authorisation of the competent authority and in compliance with the following requirements.

1. The farm must undergo regular veterinary inspection and must not be placed under any animal or public health restriction.

2. The food business operator must inform the competent authority in advance of the date of slaughter.

3. The holding must have facilities for concentrating the birds to allow an ante-mortem inspection of the group to be made.

4. The holding must have premises suitable for the hygienic slaughter and further handling of the birds.

5. Animal welfare requirements must be complied with.

6. Records or documentation required under Annex I to Regulation (EC) No …/… [*on the hygiene of foodstuffs*][a certificate signed by the competent authority and stating that it examined the birds before slaughter on the farm of origin and found them to be healthy] must accompany the birds. [1]

7. In the case of poultry reared for the production of "foie gras", the uneviscerated birds must be transported immediately, under respect of cold chain principles [2], to a slaughterhouse or cutting plant. They must be eviscerated within 24 hours of slaughter under the supervision of the competent authority.

3. Delayed eviscerated poultry obtained at the farm of production may be kept for up to 15 days at a temperature of not more than 4 ºC. It must then be eviscerated in a slaughterhouse or in a cutting plant.

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[1] The Working Party needs to choose between the alternative formulations between square brackets; that is, it must decide whether to rely on the records required under the general hygiene Regulation or to provide for a specific certificate.

[2] It is not clear what "under respect of cold chain principles" means.

SECTION IV: MEAT OF FARMED GAME

1. The provisions of Section II apply to the production and placing on the market of meat from even-toed farmed game mammals (Cervidae and Suidae), unless the competent authority considers them inappropriate. [1]

2. The provisions of Section III apply to the production and placing on the market of meat from ratites. Appropriate facilities must be provided, adapted to the size of the animals.

3. Notwithstanding paragraphs 1 and 2, food business operators slaughter farmed game at the place of origin with the authorisation of the competent authority if:

   (a) the animals cannot be transported, to avoid any risk for the handler or to protect the welfare of the animals; [2]

   (b) the herd undergoes regular veterinary inspection and is not under any animal or public-health restriction;

   (c) the owner of the animals submits a request;

   (d) the competent authority is informed in advance of the date of slaughter of the animals;

   (e) the holding has procedures [3] for concentrating the animals to allow an ante-mortem inspection of the group to be made;

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[1] The wording of this paragraph reflects the view of some delegations that flexibility is necessary since the rules for domestic ungulates might not always be appropriate for farmed game.

[2] Some delegations have concerns about allowing slaughter to take place on the farm. However, several delegations argue that, for many species of farmed game, transport to a slaughterhouse would unduly stress the animals, impairing the quality of their meat.

[3] Some delegations propose the use of the word "procedures" rather than "facilities" to provide greater flexibility

(f) the holding has facilities suitable for the slaughter, bleeding and, where ratites are to be plucked, plucking of the animals; [1]

(g) animal welfare requirements are complied with;

(h) slaughtered and bled animals are transported suspended, under satisfactory conditions of hygiene, to an approved establishment as soon as possible after slaughter. [Where animals slaughtered at the place of rearing cannot be brought within one hour to an approved establishment, they must be transported in a container or means of transport in which the ambient temperature is maintained at not more than 4 ºC.] [2] Evisceration must be carried out as soon as possible after in the slaughterhouse; [3] and

(i) during transport to the approved establishment, slaughtered animals are accompanied by a certificate issued and signed by the official veterinarian attesting to a favourable result of the ante-mortem inspection, correct slaughter and bleeding and the time of slaughter.

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[1] The representative of the Commission prefers maintaining a requirement for "premises", rather than "facilities". Several delegations believe such a strict requirement to be inappropriate.

[2] Within the informal Drafting Group there were doubts about the necessity for, and practicability of, this provision and the equivalent provision in Section II, Chapter V.

[3] Several delegations request the addition of clarification regarding when, where and how evisceration must take place.

SECTION V: WILD GAME MEAT

CHAPTER I: TRAINING OF HUNTERS IN HEALTH AND HYGIENE [1]

1. Persons who hunt wild game and place it on the market for human consumption must have sufficient knowledge of wild game hygiene and pathology to undertake an initial examination of wild game on the spot.

2. In a hunting team, at least one person must have the knowledge referred to in paragraph 1. That person may be the gamekeeper or the game manager. References in this Section to a "trained person" are references to that person.

3. Training must be provided to the satisfaction of the competent authority to enable hunters to become trained persons. It should cover at least the following subjects:

   (a) the normal anatomy, physiology and behaviour of wild game;

   (b) abnormal behaviour and pathological changes in wild game due to diseases, environmental contamination or other factors which may affect human health after consumption;

   (c) the hygiene rules and proper techniques for the handling, transportation, evisceration etc. of wild game animals after killing; and

   (d) legislation and administrative provisions on the animal and public health and hygiene conditions governing the placing on the market of wild game.

4. The competent authority should encourage hunters' organisations to provide such training.

CHAPTER II: HANDLING OF LARGE WILD GAME

1. After killing, large wild game must have their stomachs and intestines removed as soon as possible. Stomachs and intestines may be left at the place of killing.

2. An examination to identify any characteristics that may indicate that the meat presents a health risk must take place as soon as possible after killing. The trained person or, where appropriate, a veterinarian must carry out the examination.

[1] The amendments to this Section seek essentially to make its requirements clearer. Its new structure reflects the view of several delegations that it should lay down different rules for small wild game and large wild game.

3. If no abnormal characteristics are found during the examination, no abnormal behaviour were observed before killing, and there is no suspicion of environmental contamination, the trained person may either:

   (a) attach a declaration stating this and indicating the date and time of killing to the animal body, in which case the game may be transported to a game handling establishment,[with all the remaining viscera, which must remain identifiable as belonging to a given animal][with the possible exception of the head and any offal removed for private consumption], where all further handling must take place; or

   (b) [in circumstances specified by the competent authority] [1] deliver the game directly to the final consumer or to the retail trade.

4. If abnormal characteristics are found during the examination, abnormal behaviour were observed before killing, or there is suspicion of environmental contamination, the wild game must be:

   (a) transported together with the viscera (except for the stomach and intestines), which must remain identifiable as belonging to a given animal, to a game handling establishment and presented for inspection to the competent authority; or

   (b) disposed of in accordance with Community law or, where none applies, any applicable national law.

5. Chilling must begin as soon as possible after killing, depending on climatic conditions, and achieve a temperature of not more than 7 °C. Unless the competent authority permits a longer period and climatic conditions so permit, chilling must begin at least [12/24] hours after killing.

6. During transport to the game handling establishment, heaping must be avoided.

7. Game delivered to a game handling establishment must be presented to the competent authority for inspection.

8. In addition, unskinned large game may be placed on the market only if:

   (a) [the requirements of Regulation (EC) No …/… [*on official controls*] are complied with;][the declaration referred to in paragraph 3(a) accompanies the game;]

[1] Some delegations believe that the competent authority should be able to regulate the circumstances in which hunters can place wild game on the market without it passing through a game handling establishment.

(b) it is chilled to not more than:

(i) 7 °C and kept below this temperature for no more than 7 days following post-mortem inspection [1], or

(ii) 1 ºC and kept below this temperature for no more than 15 days following post-mortem inspection; and

(c) it is stored and handled separately from other food.

9. Meat from large wild game that, by virtue of its species and the region that it inhabited, may be infested by *Trichinella spiralis* may be placed on the market only if a sample undergoes an examination in an officially recognised laboratory with a negative result.

10. The rules laid down in Section II, Chapter IV, apply to the cutting and boning of large wild game.

CHAPTER III: HANDLING OF SMALL WILD GAME [2]

1. An examination to identify any characteristics that may indicate that the meat presents a health risk must take place as soon as possible after killing. The trained person or, where appropriate, a veterinarian must carry out the examination.

2. If no abnormal characteristics are found during the examination, no abnormal behaviour were observed before killing, and there is no suspicion of environmental contamination, the game may be released directly for private consumption or, in circumstances specified by the competent authority, to the retail trade.

3. When small wild game is transported to a game handling establishment, it must be chilled within 24 hours of killing to a temperature of not more than 4 °C. Evisceration must be carried out, or completed, without undue delay upon arrival at the game handling establishment.

4. The rules laid down in Section III, Chapter V, apply to the cutting and boning of small wild game.

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[1] One delegation questioned the use of the post-mortem inspection to set a limit on the length of time that unskinned large game can be stored. The time that lapses between the killing of an animal and the post-mortem inspection may vary considerably.

[2] One delegation wishes to retain the current derogation for traditional hunting methods. This relates to paragraphs 3 and 4.

SECTION VI: MINCED MEAT, MEAT PREPARATIONS AND MECHANICALLY SEPARATED MEAT (MSM) [1]

CHAPTER I: REQUIREMENTS FOR PRODUCTION ESTABLISHMENTS

Food business operators operating establishments producing minced meat, meat preparations or MSM must ensure that they:

1. are constructed so as to allow constant progress of the operations and to ensure separation between the different batches;

2. have rooms for the separate storage of packaged and exposed meat, unless stored at different times;

3. have rooms equipped to ensure compliance with the temperature conditions laid down in Chapter III;

4. have equipment for washing hands used by staff handling exposed meat with taps designed to prevent the spread of contamination; and

5. have facilities for disinfecting tools with hot water supplied at not less than 82 ºC, or an alternative system having an equivalent effect. [2]

[1] The Working Party may wish to consider whether any of the requirements of this Section should apply to retail outlets supplying the final consumer.

[2] At the suggestion of the informal Drafting Group, the structural requirements for establishments preparing minced meat, meat preparations and MSM now mirror those for cutting plants.

CHAPTER II: REQUIREMENTS FOR RAW MATERIAL

Food business operators producing minced meat, meat preparations or MSM must ensure that the raw materials used satisfy the following requirements.

1. The raw material used to prepare minced meat must meet the following requirements.

   (a) It must not include meat with organoleptic deficiencies.

   (b) It must derive from skeletal muscle, including adherent fatty tissues.

   (c) It must not derive from:

      (i) scrap cuttings and scrap trimmings (other than whole muscle cuttings), MSM or meat containing bone fragments or skin, [1]

      (ii) [meat from the following parts of bovine, porcine, ovine and caprine animals:] [2] meat of the head with the exception of the masseters, the non-muscular part of the linea alba, the region of the carpus and the tarsus, bone scrapings and the muscles of the diaphragm (unless the serosa has been removed).

   (d) [It must meet any additional national requirements agreed in accordance with the procedure referred to in Article 19(2).] [3]

2. Minced meat used to prepare meat preparations must fulfil the requirements of point 1.

3. The raw material used to produce MSM must meet the following requirements.

   (a) It must comply with the requirements for fresh meat.

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[1] One delegation wonders whether it is reasonable to exclude meat containing skin in the case of mince prepared from pigs or poultry.

[2] One delegation queried the omission of solipeds from this list. The Working Party needs to review this list once it has decided whether the rules for minced meat should apply to meat from all animals or only to meat from particular species.

[3] Some delegations wish to maintain the current ban on intra-Community trade in minced poultry and horsemeat. Several delegations support the Commission proposal to allow trade in any type of minced meat that complies with the hygiene rules. One delegation wishes to prohibit the use of meat from animals that have undergone emergency slaughter and meat from low capacity establishments supplying the local market only. The Commission's proposal (Chapter II, paragraph 6) would have allowed Member States to relax the rules on the production of minced meat. This new paragraph reflects the fact that the demand is for tighter rules.

(b) [Only bones and poultry carcases may be used to produce MSM.] [1]

(b) The following material must not be used to produce MSM:

(i) for poultry, the feet, neckskin, neckbones and head; and

(ii) for other animals, the bones of the head, feet, tails, femur, tibia, fibula, humerus, radius and ulna. [2]

CHAPTER III: HYGIENE DURING AND AFTER PRODUCTION

Food business operators producing minced meat, meat preparations or MSM must ensure compliance with the following requirements.

1. The work on meat must be organised in such a way as to prevent or minimise contamination. To this end, food business operators must ensure in particular that the meat used is:

(a) at a temperature of not more than 4 ºC for poultry, 3 ºC for offal and 7 ºC for other meat; and

(b) brought into the preparation room progressively as needed. [3]

[2. The following requirements apply to the production of minced meat and meat preparations.

(a) Unless the competent authority authorises boning immediately before mincing, frozen or deep-frozen meat used for the preparation of minced meat or meat preparations must be boned before freezing. It may only be stored for a limited period.

(b) When prepared from chilled meat, minced meat must be prepared:

(i) within no more than 6 days from the slaughter of the animals, or

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[1] This rule currently appears in the definition of "mechanically separated meat". Moving the rule to this Section would comply with the guidelines on the quality of the drafting of Community legislation and would enable the updating of the rule in the light of technological developments or scientific advice.

[2] It is not necessary to repeat ban on the use of ruminant material to produce MSM provided for in Regulation (EC) No 999/2001, which lays down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. It is clear from Article 1(3) that this prohibition takes precedence over the rules of the hygiene Regulation.

[3] At the suggestion of the informal Drafting Group, this new requirement mirror one for cutting plants.

(ii) within no more than 15 days from the slaughter of the animals in the case of boned, vacuum-packed beef and veal.] [1]

(c) Immediately after production, minced meat and meat preparations must be wrapped or packaged and be:

(i) chilled to an internal temperature of not more than 2 ºC for minced meat and 4 °C for meat preparations; or

(ii) frozen to an internal temperature of not more than -18 °C.

These temperature conditions must be maintained during storage and transport

3. The following requirements apply to the production of MSM. [2]

(a) Raw material for deboning from an on-site slaughterhouse must be no more than 7 days old. Otherwise, raw material for deboning must be no more than 5 days old.

(b) If mechanical separation does not take place immediately after deboning the flesh-bearing bones must be stored and transported at a temperature not exceeding 2 °C or, if frozen, at a temperature not exceeding -18 °C.

(c) Flesh-bearing bones obtained from frozen carcases must not be refrozen.

(d) If not used within one hour of being obtained, MSM must be chilled immediately to a temperature of not more than 2 °C.

(e) If, after chilling, MSM is not processed within 24 hours, it must be frozen within 12 hours of production. The freezing layers must reach an internal temperature not exceeding -18 °C within six hours.

(f) Frozen MSM must be wrapped or packaged before storage or transport, must not be stored for more than three months and must be maintained at a temperature of not more than -18 ºC during storage and transport.

(g) MSM may only be used in heat-treated meat products in which the temperature increases to not less than 70 °C during 30 minutes or any other time/temperature combination providing the same security.

4. Minced meat, meat preparations and MSM must not be re-frozen after thawing.

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[1] The informal Drafting Group queried the need for these provisions, which relate to considerations of quality rather than hygiene.

[2] These requirements derive from the report of the Scientific Veterinary Committee of 16 September 1997.

SECTION VII: MEAT PRODUCTS

1. Food business operators must ensure that the following items are not used in the preparation of processed meat products: [1]

   (a) genital organs of both female and male animals, except testicles;

   (b) urinary organs, except the kidneys and the bladder;

   (c) the cartilage of the larynx, the trachea and the extra-lobular bronchi;

   (d) eyes and eyelids;

   (e) the external auditory meatus;

   (f) horn tissue; and

   (g) in poultry, the head - except the comb and the ears, the wattles and caruncles - the oesophagus, the crop, the intestines and the genital organs.

2. Minced meat and meat preparations used to product meat products need not satisfy the requirements of Section VI.

[1] One delegation suggests that the same prohibition apply to meat preparations. Another wants to add meat from animals that have undergone emergency slaughter to the list (and, if low capacity establishments generally supplying the local market are not subject to approval, meat from such establishments).

SECTION VIII: 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.

3. Chapters V, VI, VIII and IX, and paragraph 3 of Chapter VII, apply to retail outlets delivering live bivalve molluscs directly to the final consumer.

[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.] [2]

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.

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[1] Some delegations believe that the rules for bivalve molluscs, particularly the requirement for classified production areas, are not appropriate for echinoderms and marine gastropods. The representative of the Commission has undertaken to consider whether it would be possible to address these concerns by clarifying the meaning of "by analogy".

[2] Several delegations do not favour maintaining a general exemption for coastal fishermen. One delegation prefers to retain it.

B DOCUMENTARY REQUIREMENTS

1. 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 19(2). Food business operators may use electronic documents in compliance with rules laid down in accordance with the same procedure.

2. The registration document must be in at least one official language of the Member State in which the receiving establishment is located.

3. Food business operators sending batches of live bivalve molluscs must complete the relevant sections of the registration document so that they are easy to read and cannot be altered. Food business operators receiving batches must date-stamp the document on receipt of the batch or record the date of receipt in another manner.

4. 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).

5. However, registration documents are not necessary if:

   (a) the staff gathering live bivalve molluscs also operate the dispatch centre, purification centre, relaying area or processing establishment receiving the live bivalve molluscs; and

   (b) the competent authority:

      (i) supervises all the establishments concerned; and

      (ii) 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]

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 (where appropriate, after removal of sand, mud or slime in the same or another establishment). The permitted treatment methods are:

   (a) sterilisation in hermetically sealed containers;

   (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/cm^2, 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 19(2).

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

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,

   (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.

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. [1]

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;

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

(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; and

(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.

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.

CHAPTER III: STRUCTURAL REQUIREMENTS FOR DISPATCH AND PURIFICATION CENTRES

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

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

(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.

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

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 water.

2. Operation of the purification system must allow live bivalve molluscs rapidly to resume and to maintain 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.

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.

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

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.

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 water.

3. Live bivalve molluscs must come from:

   (a) a class A production area;

   (b) a relaying area;

   (c) a purification centre; or

   (d) another dispatch centre.

4. The requirements laid down in points 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.

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 normal amounts of intravalvular liquid.

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

3. Limits for marine biotoxins: [1]

   (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 19(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 testing method used must be recognised in accordance with the procedure referred to in Article 19(2) and 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).

4. Additional requirements may be laid down in accordance with the procedure referred to in Article 19(2) in co-operation with the relevant Community Reference Laboratory, including:

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

   (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; and

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

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[1] It may be necessary to update these requirements in the light of recent Commission decisions.

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

CHAPTER VI: PACKAGING OF LIVE BIVALVE MOLLUSCS

1. Oysters must be packaged with the concave shell downwards.

2. Individual consumer-size packages of live bivalve molluscs must be closed and remain closed after leaving the dispatch centre and until presented for sale to the final consumer.

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 I, 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 that are not in individual consumer-size packages 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.

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 and, as regards dispatch centres, comply with the relevant requirements of Chapters III and IV.

4. Food business operators handling pectinidae must comply:

   (a) as regards unpackaged pectinidae, with the documentary requirements of Chapter I, Part B; or

   (b) as regards packaged pectinidae, with the requirements of Chapter VII concerning identification marking and labelling.

5. This Chapter may be extended to live bivalve molluscs other than pectinidae in accordance with the procedure referred to in Article 19(2).

SECTION IX: FISHERY PRODUCTS

1. This Section applies to both wild and farmed fishery products. It does not apply to mammals, reptiles and frogs.

2. This Section does not apply to bivalve molluscs, echinoderms, tunicates and marine gastropods when placed on the market live. With the exception of Chapters I and II, it applies to such animals after processing, in which case they must have been obtained in accordance with Section VIII.

3. Chapter III, Parts A, C, D and E, and Chapter IV apply to retail outlets delivering fishery products directly to the final consumer. [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 vessels take place in accordance with the rules laid down in Part II.

I. STRUCTURAL AND EQUIPMENT REQUIREMENTS

A. Requirements for all vessels [2]

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.

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[1] One delegation argued that Chapters V, VI and VII ought also to apply to retail trade. If, however, only retail outlets delivering products of animal origin to the final consumer are excluded from the scope of the Regulation, as envisaged in Article 1, this is perhaps not necessary.

[2] One delegation argues that more detailed requirements are required for fishing vessels (particularly those engaged in primary production, for which the Regulation on the hygiene of foodstuffs would only lay down very general requirements).

3. Equipment and material used for working on fishery products must be made of corrosion-resistant material that is easy to clean and disinfect.

B. Requirements for vessels designed and equipped to preserve fresh fishery products for more than twenty-four hours

1. 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 fishery products at the temperatures laid down in Chapter VI.

2. 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. Holds and containers used for the storage of fishery products must ensure their preservation under satisfactory conditions of hygiene and, where necessary, ensure that melt water does not remain in contact with the products.

3. 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 not more than 3 ºC 6 hours after loading and not more than 0 °C after 16 hours.

C. Requirements for freezer vessels

Freezer vessels must:

1. have freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of not more than -18 ºC;

2. have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than -18 ºC 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; and

3. meet the requirements for vessels designed and equipped to preserve fishery vessels for more than 24 hours laid down in Part B, paragraph 2.

D. Requirements for 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) 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. Factory vessels that freeze fishery products must have equipment meeting the requirements for freezer vessels laid down in Part C, points 1 and 2.

II. HYGIENE REQUIREMENTS

1. When in use, the parts of 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. [1]

5. Ice used to chill fishery products must meet the requirements of Annex II, Chapter VII, of Regulation (EC) …/… [*on the hygiene of foodstuffs*].

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 not more than -9 °C must be achieved for the product. The brine must not be a source of contamination for the fish.

[1] Since the requirement to put in place a system based on the HACCP principles would not apply to primary production, one delegation suggests that "as soon as possible" is too vague.

CHAPTER II: REQUIREMENTS DURING AND AFTER LANDING

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

   (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.

3. After landing, fishery products, other than those kept alive, must undergo chilling as soon as possible and be stored at a temperature approaching that of melting ice.

CHAPTER III: REQUIREMENTS FOR ESTABLISHMENTS, INCLUDING VESSELS, HANDLING FISHERY PRODUCTS

A REQUIREMENTS FOR FRESH FISHERY 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 appropriate facilities. Re-icing must be carried out as often as necessary. Packaged fresh fishery 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 prepared fresh fishery products must ensure that melt water does not remain in contact with the products.

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. [1]

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] Some delegations advocate tighter rules on the raw material that can be used to produce mechanically separated fish flesh. There would be more scope to do this if the definition of "mechanically recovered fish flesh" contained in Annex I were deleted.

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.

3. After shelling or shucking, cooked products must be frozen immediately, or be chilled as soon as possible to the temperature laid down in Chapter VI.

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 19(2).

B HISTAMINE

1. If there is any doubt as to the freshness of fishery products, whether due to the organoleptic examination required under Part A or on other grounds, food business operators must check the level of histamine in fishery products before placing them on the market.

2. The histamine level must not exceed [100][200] ppm in any sample.

3. 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 19(2) have been exceeded.

D 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.

2. Frozen blocks prepared on board vessels must be adequately wrapped before landing.

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 not more than -18 ºC 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 not more than -9 ºC.

3. Fishery products kept alive must be kept at a temperature that does not adversely affect their safety and viability.

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 not more than -18 ºC in all parts of the product, possibly with 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.

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.

SECTION X: RAW MILK AND PROCESSED DAIRY PRODUCTS

CHAPTER I: RAW MILK - PRIMARY PRODUCTION

Food business operators producing or, as appropriate, collecting raw milk must ensure compliance with the requirements laid down in this Chapter.

I. HEALTH REQUIREMENTS FOR RAW MILK PRODUCTION

1. Raw milk must come from animals:

   (a) that do not show any symptoms of infectious diseases communicable to humans through milk;

   (b) that are in a good general state of health, present no sign of disease that might result in the contamination of milk and, in particular, are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder;

   (c) that do not have any udder wound likely to affect the milk;

   (d) to which no unauthorised substances or products have been administered and that have not undergone illegal treatment within the meaning of Directive 96/23/EC;

   (e) in respect of which, where authorised products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed. [1]

2. (a) In particular, as regards brucellosis, raw milk must come from:

      (i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC, is free or officially free of brucellosis;

      (ii) sheep or goats belonging to a holding officially free or free of brucellosis within the meaning of Directive 91/68/EEC; or

      (iii) females of other species belonging, for species susceptible to brucellosis, to herds regularly checked for that disease under a control plan that the competent authority has approved.

[1] At the suggestion of some delegations, subparagraphs (d) and (e) now mirror Article 9(A)(3) of Directive 91/68/EC.

(b) As regards tuberculosis, raw milk must come from:

(i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC, is officially free of tuberculosis; or

(ii) females of other species belonging, for species susceptible to tuberculosis, to herds regularly checked for this disease under a control plan that the competent authority has approved.

(c) If goats are kept together with cows, they must be inspected and tested for tuberculosis.

3. However, raw milk from animals that do not meet the requirements of paragraph 2 may be used with the authorisation of the competent authority:

(a) in the case of cows or buffaloes that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, after having undergone a heat treatment such as to show a negative reaction to the phosphatase test;

(b) [1] in the case of sheep or goats that do not show a positive reaction to tests for brucellosis, nor any symptom of that disease either:

(i) for the manufacture of cheese with a maturation period of at least two months, or

(ii) after having undergone heat treatment such as to show a negative reaction to the phosphatase test; [2] and

(c) in the case of females of other species that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, but belong to a herd where brucellosis or tuberculosis has been detected after the checks referred to in paragraph 2(a)(iii) or 2(b)(ii), if treated to ensure its safety.

4. Raw milk from any animal not complying with the requirements of paragraphs 1 to 3 - in particular, any animal showing individually a positive reaction to the prophylactic tests vis-à-vis tuberculosis or brucellosis as laid down in Directive 64/432/EEC and Directive 91/68/EEC - must not be used for human consumption.

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[1] One delegation has a reservation on this provision, requesting a modification to enable the continued use of milk from vaccinated animals (which would show a positive reaction to tests). That delegation accepts that such milk should have to undergo heat treatment or other form of processing. The representative of the Commission is considering this issue with a view to finding a technical solution to the problem of vaccinated animals.

[2] Some delegations wish to amend this provision, arguing that a negative reaction to the phosphatase test does not always provide sufficient guarantees.

5. The isolation of animals that are infected, or suspected of being infected, with any of the diseases referred to in paragraph 1 or 2 must be effective to avoid any adverse effect on other animals' milk.

II. HYGIENE ON MILK PRODUCTION HOLDINGS

A. Requirements for premises and equipment [1]

1. Milking equipment, and premises where milk is stored, handled or cooled must be located and constructed so as to limit the risk of contamination of milk.

2. Premises for the storage of milk must be protected against vermin, have adequate separation from premises where animals are housed and, where necessary to meet the requirements laid down in Part B, have suitable refrigeration equipment.

3. Surfaces of equipment that are intended to come into contact with milk (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials.

4. After use, such surfaces must be cleaned and, where necessary, disinfected. After each journey, or after each series of journeys when the period of time between unloading and the following loading is very short, but in all cases at least once a day, containers and tanks used for the transport of raw milk must be cleaned and disinfected before re-use.

B. Hygiene during milking, collection and transport

1. Milking must be carried out hygienically, ensuring in particular:

   (a) that, before milking starts, the teats, udder and adjacent parts are clean;

   (b) that milk from each animal is checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk presenting such abnormalities is not used for human consumption;

   (c) [2] that milk from animals showing clinical signs of udder disease is not used for human consumption other than in accordance with a veterinary prescription;

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[1] Some delegations believe that further requirements are necessary to supplement the basic requirements laid down for primary production in Annex I to the Regulation on the hygiene of foodstuffs. One delegation wishes to be able to maintain stricter national requirements.

[2] One delegation argues that subparagraphs (c) and (d) duplicate requirements laid down in paragraph 1 of Part I of Chapter I and should therefore be deleted.

(d) the identification of animals undergoing medical treatment likely to transfer residues to the milk, and that the milk of such animals is not used for human consumption before the end of the prescribed withdrawal period; and

(e) that teat dips or sprays are used only if the competent authority has approved them and in a manner that does not produce unacceptable residue levels in the milk. [1]

2. Immediately after milking, milk must be held in a clean place designed and equipped to avoid contamination. It must be cooled immediately to not more than 8 °C in the case of daily collection, or not more than 6 °C if collection is not daily.

3. During transport the cold chain must be maintained and, on arrival at the establishment of destination, the temperature of the milk must not be more than 10 ºC.

4. Food business operators need not comply with the temperature requirements laid down in paragraphs 2 and 3 if the milk meets the standards provided for in Part III and either:

(a) the milk is processed within 2 hours of milking; or

(b) a higher temperature is necessary for technological reasons related to the manufacture of certain processed dairy products and the competent authority so authorises.

C. Staff hygiene

1. Persons performing milking and/or handling raw milk must wear suitable clean clothes.

2. Persons performing milking must wash their hands immediately before milking and keep them as clean as possible throughout milking. For this purpose, suitable facilities must be available near the place of milking to enable persons performing milking and handling raw milk to wash their hands and arms.

III. STANDARDS FOR RAW MILK ON COLLECTION [2]

1. The following standards for raw milk apply pending the establishment of standards in the context of more specific legislation on the quality of milk and processed dairy products.

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[1] It will be necessary to ensure consistency between this requirement and those of Directive 98/8/EEC on biocidal products.

[2] A recital should state that the standards laid down in this Section are reference figures for food business operators' own-checks, not maximum figures beyond which raw milk cannot be placed on the market.
One delegation would like an exemption permitting the placing on the market of colostrum. If retained, the procedures provided for in Article 18 would enable this.

2. A representative number of samples of raw milk collected from milk production holdings taken by random sampling must be checked. The checks may be carried out by, or on behalf of:

(a) the food business operator producing the milk,

(b) the food business operator collecting the milk,

(c) a group of food business operators, or

(d) in the context of a national or regional control scheme. [1]

3. (a) Food business operators must take steps to ensure that raw milk meets the following standards:

(i) for raw cows' milk:

Plate count at 30 °C (per ml)	≤ 100 000 (*)
Somatic cell count (per ml)	≤ 400 000 (**)

(ii) for raw milk from other species:

Plate count at 30 °C (per ml)	≤ 1 500 000 (*)

(b) However, if raw milk from species other than cows is intended for the manufacture of products made with raw milk by a process that does not involve any heat treatment, food business operators must take steps to ensure that the raw milk used meets the following standard.

Plate count at 30 °C (per ml)	≤ 500 000 (*)

(*) Rolling geometric average over a two-month period, with at least two samples per month. [2]

(**) Rolling geometric average over a three-month period, with at least one sample per month, unless the competent authority specifies another methodology to take account of seasonal variations in production levels.

[1] One delegation requested the inclusion of provisions on the laboratories used to carry out checks. However, horizontal provision may appear in the forthcoming proposal on official controls.

[2] One delegation considers that more flexible sampling rules would be appropriate for species other than cows and that the proposed standard is too high.

4. When raw milk fails to meet the standards laid down in paragraph 3, the food business operator must take measures to correct the situation. Food business operators must inform the competent authority of repeated or excessive overshooting of the standards, to enable it to ensure that appropriate measures are taken. [1]

5. Food business operators must take steps to ensure that raw milk is not placed on the market if either:

   (a) it contains antibiotic residues in a quantity that, in respect of any one of the substances referred to in Annexes I and III to Regulation (EEC) No 2377/90, exceeds the levels authorised under that Regulation; or

   (b) the combined total of residues of antibiotic substances exceeds a value fixed in accordance with the procedure referred to in Article 19(2).

CHAPTER II: REQUIREMENTS FOR MILK USED IN PROCESSED DAIRY PRODUCTS

I. TEMPERATURE REQUIREMENTS

1. Food business operators must ensure that, upon acceptance at a processing establishment, milk is quickly cooled to not more than 6 °C and kept at that temperature until processed.

2. However, food business operators may keep milk at a higher temperature if:

   (a) processing begins immediately after milking, or within 4 hours of acceptance at the processing establishment; or

   (b) the competent authority authorises a higher temperature for technological reasons concerning the manufacture of certain milk products.

II. REQUIREMENTS FOR HEAT TREATMENT [2]

1. When raw milk or processed dairy products undergo heat treatment, food business operators must ensure that this satisfies the requirements of Regulation (EC) …/… [*on the hygiene of foodstuffs*], Annex II, Chapter XI.

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[1] Some delegations want the text to clarify "repeated or excessive overshooting".
The Regulation on official controls would specify the steps for competent authorities to take.
Some delegations believe that it should, like the current legislation, provide for a ban on the delivery of milk from holdings that repeatedly fail to meet the standards.

[2] Since food other than milk undergoes heat treatment (e.g., fruit juice), the Regulation on the hygiene of foodstuffs should contain general rules on heat treatment.

2. When considering whether to subject raw milk to heat treatment, food business operators must have regard to:

   (a) the procedures developed in accordance with the HACCP principles pursuant to Regulation (EC) …/… [*on the hygiene of foodstuffs*]; and

   (b) any directions that the competent authority may give in this regard.

III. STANDARDS FOR RAW COWS' MILK [1]

1. Food business operators manufacturing processed dairy products must take steps to ensure that, when processed:

   (a) raw cows' milk used to prepare processed dairy products has a plate count at 30 ºC of less than 300 000 per ml; and

   (b) processed cows' milk used to prepare processed dairy product has a plate count at 30 ºC of less than 100 000 per ml.

2. When milk fails to meet the standards laid down in paragraph 1, the food business operator must take measures to correct the situation. Food business operators must inform the competent authority of repeated or excessive overshooting of the standards, to enable it to ensure that appropriate measures are taken.

CHAPTER III: WRAPPING AND PACKAGING

Sealing must be carried out immediately after filling in the establishment where the last heat treatment of liquid processed dairy products takes place, by means of sealing devices which ensure the protection of milk against contamination. The sealing system must be designed in such a way that, after opening, the evidence of its opening remains clear and easy to check. [2]

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[1] One delegation wonders why there should only be standards for cows' milk.
It might be helpful for a recital in the Regulation to explain why the standard for raw milk used to manufacture processed dairy products is three times higher than the standard for raw milk collected from the farm. There are two reasons. First, the standard for milk used to manufacture processed diary products is an absolute value, whereas for raw milk collected from the farm it is an average. Second, compliance with the temperature requirements laid down in this Section does not halt all bacterial growth during transport and storage.

[2] One delegation questions the need for sealing to take place in the establishment applying the last heat treatment. The requirement for food business operators to have in place systems based on the HACCP principles should enable heat-treated milk to be transported in bulk and packaged elsewhere.

CHAPTER IV: LABELLING [1]

1. In addition to the requirements of Directive 2000/13/EC, except in the cases envisaged in Article 13(4) and (5) of that Directive, labelling must clearly show:

   (a) in the case of raw milk intended for direct human consumption, the words "raw milk";

   (b) in the case of products manufactured from raw milk, the manufacturing process for which does not include any heat treatment or any physical or chemical treatment, the words "made with raw milk".

2. The requirements of paragraph 1 apply to products destined for retail trade. The term "labelling" includes any packaging, document, notice, label, ring or collar accompanying or referring to such products.

CHAPTER V: IDENTIFICATION MARKING

Notwithstanding the identification marking requirements laid down in Section I, the identification mark may include a reference to where the approval number of the establishment is shown in the place of the approval number itself.

[1] Several delegations wish to maintain national requirements for labels on raw milk to instruct consumers to boil it. Directive 2000/13/EC permits this.

SECTION XI: EGGS AND PROCESSED EGG PRODUCTS

CHAPTER I: EGGS [1]

1. At the producer's premises, and until sale to the consumer, eggs must be kept clean, dry, free of extraneous odour, effectively protected from shocks and out of direct sunshine. [2]

2. Eggs must be stored and transported at a temperature, preferably constant, that is best suited to assure optimal conservation of their hygiene properties.

3. Eggs must be delivered to the consumer within a maximum time limit of 21 days of laying. [3]

CHAPTER II: PROCESSED EGG PRODUCTS

I. REQUIREMENTS FOR ESTABLISHMENTS

Food business operators must ensure that establishments for the manufacture of processed egg products are constructed, laid out and equipped so as to ensure separation of the following operations:

1. washing, drying and disinfecting dirty eggs, where carried out;

2. breaking eggs, collecting their contents and removing parts of shells and membranes; and

3. operations other than those referred to in points 1 and 2.

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[1] A recital should clarify that the rules of this Chapter would replace those of Council Decision 94/371/EC, which the repeal of Annex II to Directive 92/118/EEC would render spent.

[2] One delegation believes that the Regulation should lay down rules for the washing of eggs. Other delegations consider that washing should be allowed only just before breaking for the manufacture of processed egg products.

[3] One delegation believes that it is not appropriate for the Regulation to lay down a time limit. There is no similar requirement for any other food of animal origin.

II. RAW MATERIALS FOR THE MANUFACTURE OF PROCESSED EGG PRODUCTS

Food business operators must ensure that raw materials used to manufacture processed egg products comply with the following requirements.

1. The shells of eggs used in the manufacture of processed egg products must be fully developed and contain no breaks. However, cracked eggs may be used for the manufacture of processed egg products if the establishment of production or a packing centre delivers them directly to a processing establishment, where they must be broken as soon as possible.

2. Liquid egg obtained in an establishment approved for that purpose may be used as raw material. Liquid egg must be obtained in accordance with the requirements of points 1, 2, 3, 4 and 7 of Part III.

III. SPECIAL HYGIENE REQUIREMENTS FOR THE MANUFACTURE OF PROCESSED EGG PRODUCTS

Food business operators must ensure that all operations are carried out in such a way as to avoid any contamination during production, handling and storage of processed egg products, in particular by ensuring compliance with the following requirements.

1. Eggs must not be broken unless they are clean and dry.

2. Eggs must be broken in a manner that minimises contamination, in particular by ensuring adequate separation from other operations. Cracked eggs must be processed as soon as possible.

3. Eggs other than those of hens, turkeys or guinea fowl must be handled and processed separately. All equipment must be cleaned and disinfected when processing of hens', turkeys' and guinea fowls' eggs is resumed.

4. Egg contents may not be obtained by the centrifuging or crushing of eggs, nor may centrifuging be used to obtain the remains of egg whites from empty shells for human consumption.

5. After breaking, each particle of processed egg product must undergo a treatment as quickly as possible to eliminate microbiological hazards or to reduce them to an acceptable level. A batch that has been insufficiently treated may immediately undergo treatment again in the same establishment, if this treatment renders it fit for human consumption. Where a batch is found to be unfit for human consumption, it must be denatured so as to ensure that it is not used for human consumption.

6. A treatment is not required for egg white intended for the manufacture of dried or crystallised albumin destined subsequently to undergo heat treatment.

7. If treatment is not carried out immediately after breaking, liquid egg must be stored either frozen or at a temperature of not more than 4 °C. The storage period before processing at 4 °C must not exceed 48 hours. However, these requirements do not apply to products to be de-sugared, if de-sugaring process is performed as soon as possible.

8. Products that have not been stabilised so as to be kept at room temperature must be cooled to not more than 4 °C. Products for freezing must be frozen immediately after treatment.

IV. ANALYTICAL SPECIFICATIONS

1. The concentration of 3-OH-butyric acid must not exceed 10 mg/kg in the dry matter of the unmodified processed egg product.

2. The lactic acid content must not exceed 1 g/kg of processed egg product dry matter (applicable only to unprocessed products). However, for fermented products, this value must be the one recorded before the fermentation process. [1]

3. The quantity of eggshell remains, egg membranes and any other particles in the processed egg product must not exceed 100 mg/kg of processed egg product.

V. LABELLING AND IDENTIFICATION MARKING

1. In addition to the general requirements for identification marking laid down in Section I, consignments of processed egg products, destined not for retail but for use as an ingredient in the manufacture of another product, must have a label giving the temperature at which the processed egg products must be maintained and the period during which conservation may thus be assured.

2. In the case of liquid eggs, the label referred to in paragraph 1 must also bear the words: "non-pasteurised egg products - to be treated at place of destination" and indicate the date and hour of breaking.

[1] Several delegations question whether it is appropriate to drop the current standard for succinic acid.

SECTION XII: FROGS' LEGS AND SNAILS

Food business operators preparing frogs' legs or snails for human consumption must ensure compliance with the following requirements.

1. Frogs and snails must be killed in an establishment constructed, laid out and equipped for that purpose.

2. Establishment in which frogs' legs are prepared must have a room reserved for the storage and washing of live frogs, and for their slaughter and bleeding. This room must be physically separate from the preparation room.

3. Frogs and snails that die before being killed must not be prepared for human consumption.

4. Frogs and snails must be subjected to an organoleptic examination carried out by sampling. If that examination indicates that they might present a hazard,[1] they must not be used for human consumption.

5. Immediately following preparation, frogs' legs must be washed fully with running potable water and immediately chilled to the temperature of melting ice, frozen to a temperature of not more than -18 °C or processed.

6. After killing, snails' hepato-pancreas must, if it might present a hazard, be removed and not be used for human consumption.

[1] Some delegations had doubts about the use of the term "hazard" in points 4 and 6, believing that the suggested requirements duplicated food business operators' general obligation to implement procedures based on the HACCP principles. The Presidency and the representative of the Commission consider that it is appropriate - and consistent with the approach taken for other products of animal origin - to have explicit rules for the most essential operational and structural requirements.
One delegation wondered whether it would be appropriate for these requirements to apply to retail trade.

SECTION XIII: RENDERED ANIMAL FATS AND GREAVES

CHAPTER I: REQUIREMENTS APPLICABLE TO ESTABLISHMENTS COLLECTING OR PROCESSING RAW MATERIALS

Food business operators must ensure that establishments collecting or processing raw materials for the production of rendered animal fats and greaves comply with the following requirements.

1. Centres for the collection of raw materials and further transport to processing establishments must be equipped with facilities for the storage of raw materials at a temperature of not more than 7 °C.

2. Each processing establishment must have:

   (a) refrigeration facilities;

   (b) a dispatch room, unless the establishment dispatches rendered animal fat only in tankers; and

   (c) if appropriate, suitable equipment for the preparation of products consisting of rendered animal fats mixed with other foodstuffs and/or seasonings.

3. However, the refrigeration facilities required under points 1 and 2(a) are not necessary if the arrangements for the supply of raw materials ensure that they are never stored or transported without active refrigeration for more than 12 hours before rendering.

CHAPTER II: HYGIENE REQUIREMENTS FOR THE PREPARATION OF RENDERED ANIMAL FAT AND GREAVES

Food business operators preparing rendered animal fats and greaves must ensure compliance with the following requirements.

1. Raw materials must:

   (a) come from animals that are slaughtered in a slaughterhouse, after undergoing ante-mortem and post-mortem inspection, and are fit for human consumption;

   (b) consist of adipose tissues or bones, which are reasonably free from blood and impurities;

   (c) come from establishments approved or registered under this Regulation or Regulation (EC) No …/… [*on the hygiene of foodstuffs*]; and

   (d) be transported, and stored until rendering, in hygienic conditions and at an internal temperature of not more than 7 °C. However, raw materials may be stored and transported without active refrigeration for up to 12 hours before rendering.

2. During rendering the use of solvents is prohibited.

3. When the fat for refining meets the standards laid down in point 4, rendered animal fat prepared in accordance with points 1 and 2 may be refined in the same establishment or in another establishment with a view to improving its physico-chemical quality.

4. Rendered animal fat, depending on type, must meet the following standards:

	Ruminants			Porcine animals			Other animal fat	
	Edible tallow		Tallow for refining	Edible fat		Lard and other fat for refining	Edible	For refining
	Premier jus(1)	Other		Lard(2)	Other			
FFA (m/m% oleic acid) maximum	0.75	1.25	3.0	0.75	1.25	2.0	1.25	3.0
Peroxide maximum	4 meq/kg	4 meq/kg	6 meq/kg	4 meq/kg	4 meq/kg	6 meq/kg	4 meq/kg	10 meq/kg
Total insoluble impurities	Maximum 0.15%			Maximum 0.5%				
Odour, taste, colour	Normal							

(1) Rendered animal fat obtained by low-temperature rendering of fresh fat from the heart, caul, kidneys and mesentery of bovine animals, and fat from cutting rooms.

(2) Rendered animal fat obtained from the adipose tissues of porcine animals.

5. Greaves intended for human consumption must be stored in accordance with the following temperature requirements.

(a) When greaves are rendered at a temperature of not more than 70 °C, they must be stored:

(i) at a temperature of not more than 7 °C for a period not exceeding 24 hours, or

(ii) at a temperature of not more than -18° C.

(b) When greaves are rendered at a temperature of more than 70 °C and have a moisture content of 10% (m/m) or more, they must be stored:

(i) at a temperature of not more than 7 °C for a period not exceeding 48 hours or a time/temperature ratio giving an equivalent guarantee, or

(ii) at a temperature of -18 °C or below.

(c) When greaves are rendered at a temperature of more than 70 °C and have a moisture content of less than 10% (m/m), there are no specific requirements.

SECTION XIV: TREATED STOMACHS, BLADDERS AND INTESTINES

Food business operators treating stomachs, bladders and intestines must ensure compliance with the following requirements.

1. Animal intestines, bladders and stomachs may be placed on the market only if:

   (a) they come from animals that are slaughtered in a slaughterhouse, after undergoing ante-mortem and post-mortem inspection, and are fit for human consumption;

   (b) they are salted, heated or dried; and

   (c) after the treatment referred to in subparagraph (b), effective measures are taken to prevent re-contamination.

2. Treated stomachs, bladders and intestines that cannot be kept at ambient temperature must be stored chilled using facilities intended for that purpose until their dispatch. In particular, products that are not salted or dried must be kept at a temperature of not more than 3 °C.

SECTION XV: GELATINE

Food business operators manufacturing gelatine must ensure compliance with the following requirements.

CHAPTER I: REQUIREMENTS FOR RAW MATERIALS

1. For the production of gelatine intended for use in food, the following raw materials may be used:

   (a) bones;

   (b) hides and skins of farmed ruminant animals;

   (c) pig skins;

   (d) poultry skin;

   (e) tendons and sinews;

   (f) wild game hides and skins; and

   (g) fish skin and bones.

2. The use of hides and skins is prohibited if they have undergone any tanning process, regardless of whether this process was completed.

3. Raw materials listed in paragraph 1(a) to (e) must derive from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante-and post-mortem inspection, or in the case of wild game hides and skins from wild game found fit for human consumption.

4. Raw materials must come from establishments approved or registered under this Regulation or Regulation (EC) No …/… [*on the hygiene of foodstuffs*].

5. Collection centres and tanneries may also supply raw material for the production of gelatine intended for human consumption if the competent authority specifically authorises them for this purpose and they fulfil the following requirements.

   (a) They must have storage rooms with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities.

   (b) The storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials.

   (c) If raw material not in conformity with this Chapter is stored and/or processed in these premises, it must be segregated from raw material in conformity with this Chapter throughout the period of receipt, storage, processing and dispatch.

CHAPTER II: TRANSPORT AND STORAGE OF RAW MATERIALS

1. In place of the identification mark provided for in Section I, a document indicating the establishment of origin and conforming to the model laid down in the Appendix to this Annex must accompany raw materials during transport, when delivered to a collection centre or tannery and when delivered to the gelatine-processing establishment. [1]

2. Raw materials must be transported and stored chilled or frozen unless they are processed within 24 hours after their departure. However, degreased and dried bones or ossein, salted, dried and limed hides, and hides and skins treated with alkali or acid may be transported and stored at ambient temperature.

[1] Some delegations believed that the requirement for a document was unnecessary in view of the general obligation to ensure traceablility. However, a majority of delegations wished to retain it. A majority of delegations also wanted the Regulation to lay down a model for the document, at least pending the agreement of satisfactory rules on traceability and identification for all products of animal origin.

CHAPTER III: REQUIREMENTS FOR THE MANUFACTURE OF GELATINE

1. The production process for gelatine must ensure that:

   (a) all ruminant bone material derived from animals born, reared or slaughtered in countries or regions classified as having a low incidence of BSE in accordance with Community legislation is subjected to a process which ensures that all bone material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at minimum concentration of 4% and pH < 1.5) over a period of at least two days, followed by an alkaline treatment of saturated lime solution (pH > 12.5) for a period of at least 20 days with a sterilisation step of 138-140 °C during four seconds or by an equivalent process approved by in accordance with the procedure referred to in Article 19(2); and

   (b) other raw material is subjected to a treatment with acid or alkali, followed by one or more rinses. The pH must be adjusted subsequently. Gelatine must be extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation. [1]

2. The use of preservatives, other than sulphur dioxide and hydrogen peroxide, is prohibited. [2]

3. If a food business operator manufacturing gelatine complies with the requirements applying to gelatine intended for human consumption in respect of all the gelatine that it produces, it may produce and store gelatine not intended for human consumption in the same establishment.

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[1] The Working Party noted that it would be necessary to amend this paragraph since new rules on gelatine should shortly be adopted under the TSE Regulation in the light of the recent opinion of the SSC.

[2] Some delegations suggested that this provision be deleted, as it was not consistent with Community legislation on food additives. The representative of the Commission undertook to consider this suggestion.

CHAPTER IV: REQUIREMENTS FOR FINISHED PRODUCTS [1]

Food business operators must ensure that gelatine complies with the residue limits set out in the following table.

Residue	**Limit**
As	1 ppm
Pb	5 ppm
Cd	0.5 ppm
Hg	0.15 ppm
Cr	10 ppm
Cu	30 ppm
Zn	50 ppm
Moisture (105 °C)	15%
Ash (550 °C)	2%
SO_2 (Reith Williams)	50 ppm
H_2O_2 (European Pharmacopoeia 1986 (V_2O_2))	10 ppm

[1] Some delegations believe that these requirements should appear in the Community legislation on contaminants.

APPENDIX

DOCUMENT TO ACCOMPANY RAW MATERIAL DESTINED FOR THE PRODUCTION OF GELATINE

I. Identification of raw material

Type of products: .....

Date of manufacture: .....

Type of packaging: .....

Number of packages: .....

Guaranteed storage period: .....

Net weight (kg): .....

II. Origin of raw material

Address(es) and registration number(s) of the approved production establishment(s): .....

.....

III. Destination of raw material

The raw material will be sent:

from: .....

(place of loading)

to: .....

(country and place of destination)

by the following means of transport: .....

Name and address of consignor: .....

Name and address of consignee: .....

ANNEX III

REQUIREMENTS FOR CERTIFICATES ACCOMPANYING IMPORTS

1. The representative of the competent authority of the third country of dispatch issuing a certificate to accompany a consignment of products of animal origin destined for the Community must sign the certificate and ensure that it bears an official stamp.
This requirement applies to each sheet of the certificate if it consists of more than one.

2. Certificates must be drawn up in the official language or languages of the Member State of destination and those of the Member State in which the border inspection takes place, or be accompanied by a certified translation into that language or languages. However, a Member State may consent to the use of an official Community language other than its own.

3. The original version of the certificate must accompany consignments on entry into the Community.

4. Certificates must consist of:

   (a) a single sheet of paper; or

   (b) two or more pages that are part of an integrated and indivisible sheet of paper; or

   (c) a sequence of pages numbered so as to indicate that it is a particular page in a finite sequence (for example, "page 2 of 4 pages").

5. Certificates must bear a unique identifying number. Where the certificate consists of a sequence of pages, each page must indicate this number.

6. The certificate must be issued before the consignment to which it relates leaves the control of the competent authority of the third country of dispatch. Certificates may be issued while consignments are in transit only if the competent authority of the third country of dispatch has been determined, in accordance with the procedure referred to in Article X(2), to have in place appropriate control systems. [1]

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[1] Several delegations have a reservation on the second sentence of this paragraph, in particular because of the possibility of fraud. Other delegations believe that the proposed procedure is acceptable and provides for appropriate safeguards.

Possible consequential modifications to the draft Regulation on the hygiene of foodstuffs

1. ARTICLE 2 - DEFINITIONS

A. The definitions of "potable water" and "clean seawater" could read as follows; there could also be new definitions of "clean water", "to disinfect" and "food business operator at the level of primary production":

- "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;

- "to disinfect" means to use a disinfectant and then to rinse with potable water or, where appropriate, clean water;

- "food business operator at the level of primary production" means a food business operator carrying out primary production and those associated operations referred to in Annex I.

B. If, as suggested in Part 3, Annex I is amended in such a manner that it uses the terms "live bivalve molluscs" and "fisheries products", the definitions of these terms should be moved from the specific to the general Regulation.

2. ARTICLE 4 - FOOD BUSINESS OPERATORS' DUTIES

A. Article 4(8) could read as follows:

"8. Pending the setting of the criteria referred to in paragraph 6(a), the relevant requirements and standards laid down in the Directives referred to in Articles 1 and 2 of Directive …/…/EC [*repealing certain Directives on the hygiene of foodstuffs and on the health conditions for the production and placing on the market of certain products of animal origin intended for human consumption, and amending Directives 89/662/EEC and 91/67/EEC*] or their implementing rules, shall continue to apply, as shall national rules adopted in accordance with those Directives or their implementing rules.". [1]

B. Article 4 could also contain new general provisions on contaminants and methodology:

"9. In respect of contaminants, food business operators shall ensure that food does not contain:

(a) higher levels than specified in Community legislation [2]; or

(b) such quantities that the calculated dietary intake exceeds the permissible daily intake.

10. When this Regulation, Regulation (EC) …/… [*laying down specific hygiene rules for food of animal origin*] or their implementing rules do not specify sampling or analysis methods, food business operators may use methods that offer equivalent results to those obtained using the reference method, if they are scientifically validated in accordance with internationally recognised rules or protocols."

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[1] The revised drafting of this paragraph makes clear that only national rules permitted under existing Community legislation may continue to apply pending the setting of harmonised microbiological and temperature criteria. It would enable the continuation of national temperature requirements with respect to eggs, as agreed within the Working Party (doc. 12951/01).

[2] A recital could refer to Regulation (EC) No 315/93, Article 2(3) of which provides for the establishment, through comitology, of limits for contaminants in food.

3. ANNEX I - PRIMARY PRODUCTION AND ASSOCIATED OPERATIONS

A. The title of Annex I could become "Primary production and associated operations".

B. To clarify which associated operations are subject to the same rules as primary production, Part A of Annex I could read as follows:

"1. This Annex applies to primary production and the following associated operations:

(a) the storage and handling of primary products at the place of production, provided that this does not substantially alter their nature (including, as regards fishery products, bleeding, heading, gutting, removing fins, refrigeration and wrapping operations carried out on board fishing vessels, but no other form of preparation and no form of processing) [1];

(b) transport operations within the place of production; and

(c) in the case of products of plant origin, live bivalve molluscs, live echinoderms, live tunicates, live marine gastropods and fishery products, transport operations to deliver unprocessed primary products from the place of production to another establishment." [2]

C. In Part B, paragraphs 4 and 5 could include a new subparagraphs requiring food business operators:

– to use potable water, or clean water, whenever necessary to prevent the contamination of foodstuffs;

– to ensure that staff involved in the preparation of foodstuffs are in good health and undergo training on health risks.

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[1] One delegation believes that freezing should also be part of primary production, if no processing takes place before freezing. Another delegation believes 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] The Working Party may wish to consider whether to include wild game in this list.

4. ANNEX II, CHAPTER V - EQUIPMENT REQUIREMENTS

To clarify its requirements, the Chapter could 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.".

5. ANNEX II, CHAPTER VII - WATER SUPPLY

Paragraphs 1 and 4 could read as follows:

"1. (a) There must be an adequate supply of potable water, which must be used whenever necessary to ensure that foodstuffs are not contaminated.

(b) Clean water may be used with whole fishery products. Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing. 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 whole fishery products, clean water. It must be made, handled and stored under conditions that protect it from contamination.".

6. ANNEX II, CHAPTER IX - REQUIREMENTS FOR ALL FOODSTUFFS

The last sentence of paragraph 3 could read as follows:

"Adequate procedures must be in place control pests and to prevent domestic animals from having access to places where food is prepared, handled or stored.".

In the Commission's proposal, the rule concerning domestic animals would have applied only to live bivalve molluscs. The Working Party agreed that it should be a general requirement.

7. ANNEX II, CHAPTER XI – REQUIREMENTS FOR HEAT TREATMENT

There was agreement during the discussions on milk that general requirements for heat treatment could be re-inserted as Chapter XI. These could read as follows:

"1. Any heat treatment process used to process raw milk or to process further a processed dairy product must:

(a) raise every party of the product treated to a given temperature for a given period of time; and

(b) prevent the product from becoming contaminated during the process.

2. To ensure that the process employed achieves the desired objectives, food business operators must regularly check the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including by the use of automatic devices.

3. The process used should conform to an internationally recognised standard (for example, pasteurisation, ultra high temperature or sterilisation).".

TABLE OF DERIVATIONS

Annex A: Regulation laying down specific hygiene rules for food of animal origin

In the following table, the acronym "CP" stands for the Commission's proposal (document 10427/00 – COM(2000) 438 final).

Provision	**Derivation**
Article 1	doc. 7959/01, Annex A, Article A
Article 2	CP, Article 2
Article 3	doc. 7959/01, Annex A, Article F
Article 4	doc. 7959/01, Annex A, Article B [(a)]
Article 5	doc. 7959/01, Annex A, Article C
Article 6	doc. 13911/01, Annex A [(b)]
Articles 7 – 14	doc. 13911/01, Annex B [(b)]
Article 15	doc. 7959/01, Annex A, Article E [(c)]
Article 16	doc. 13255/01, Annex B
Article 17	CP, Article 6 & doc. 10880/1/01 REV 1
Article 18	new [(d)]
Article 19	doc. 11017/01, Article 15
Article 20	CP, Article 7
Annex I, Part 1	doc. 6343/01
Annex I, Parts 2 & 3	doc. 12259/01, Annex A
Annex I, Part 4	doc. 12590/01
Annex I, Part 5	doc. 12951/01
Annex I, Part 6	CP

Provision	Derivation
Annex I, Part 7	docs 6343/01 (7.1 – 7.4), 12590/01 (7.5), 12951/01 (7.6) & CP (7.7 – 7.10)
Annex I, Part 8	doc. 6343/01
Annex II, Sections I - VII	doc. 7959/01, Annex B, Annex II, Sections 0 – VI
Annex II, Sections VIII & IX	doc. 12259/01, Annex A [(e)]
Annex II, Section X	doc. 12590/01 [(f)]
Annex II, Section XI	doc. 12951/01
Annex II, Sections XII – XV	doc. 13256/01
Annex III	doc. 13911/01, Annex C [(b)]

Annex B: Regulation on the hygiene of foodstuffs

Suggested modification to	Derivation
Article 2	doc. 12259/01, Annex B, Part 1 & doc. 12590/01, page 8, footnote 3
Article 4	A: doc. 12951/01, page 4, footnote 3 B: docs 12259/01 [(g)]; 12590/01, page 13, footnote 3 & 13256/01, page 6, footnote 1
Annex I	A & B: doc. 12259/01, Annex B, Part 2 C: doc. 12590/01, page 8, footnote 3 & page 10, footnote 1
Annex II, Chapter V	doc. 12259/01, Annex B, Part 3
Annex II, Chapter VII	doc. 12259/01, Annex B, Part 4
Annex II, Chapter IX	doc. 12259/01, page 18, footnote 2
Annex II, Chapter XI	doc. 12590/01, page 13

NOTES

[a] The drafting of this Article has been considerably modified to reflect the outcome of the discussions on approval and registration within the Working Party on 15 and 16 November 2001 (document 14510/01).

[b] These provisions have been modified to reflect the discussion within the Working Party on 27 November 2001 (document 5046/02).

[c] This Article has been expanded to cover eggs, as agreed within the Working Party on 26 September 2001 (document 12951/01).

[d] Article 25 of Regulation (EC) No 999/2001 contains a similar provision.

[e] These Sections have been slightly modified to reflect the discussion within the Working Party on 11 October 2001 (document 13347/01).

[f] This Section has been slightly modified to reflect the discussion within the Working Party on 28 November 2001.

[g] Provisions similar to the suggested paragraph on contaminants appeared in Annex A to document 12259/01 (on pages 19 and 30). However, they would have applied only to live bivalve molluscs and fisheries products. The Working Party agreed on 11 October that the requirements should apply to all food (doc. 13347/01).