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►B ►C1 REGULATION (EC) No 853/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 29 April 2004

laying down specific hygiene rules for food of animal origin ◄

(OJ L 139, 30.4.2004, p. 55)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Regulation (EC) No 2074/2005 of 5 December 2005	L 338	27	22.12.2005
►M2	Commission Regulation (EC) No 2076/2005 of 5 December 2005	L 338	83	22.12.2005
►M3	Commission Regulation (EC) No 1662/2006 of 6 November 2006	L 320	1	18.11.2006
►M4	Council Regulation (EC) No 1791/2006 of 20 November 2006	L 363	1	20.12.2006
►M5	Commission Regulation (EC) No 1243/2007 of 24 October 2007	L 281	8	25.10.2007
►M6	Commission Regulation (EC) No 1020/2008 of 17 October 2008	L 277	8	18.10.2008
►M7	Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009	L 87	109	31.3.2009
►M8	Commission Regulation (EC) No 1161/2009 of 30 November 2009	L 314	8	1.12.2009
►M9	Commission Regulation (EU) No 558/2010 of 24 June 2010	L 159	18	25.6.2010
►M10	Commission Regulation (EU) No 150/2011 of 18 February 2011	L 46	14	19.2.2011
►M11	Commission Regulation (EU) No 1276/2011 of 8 December 2011	L 327	39	9.12.2011
►M12	Commission Regulation (EU) No 16/2012 of 11 January 2012	L 8	29	12.1.2012
►M13	Council Regulation (EU) No 517/2013 of 13 May 2013	L 158	1	10.6.2013
►M14	Commission Regulation (EU) No 786/2013 of 16 August 2013	L 220	14	17.8.2013
►M15	Commission Regulation (EU) No 218/2014 of 7 March 2014	L 69	95	8.3.2014
►M16	Commission Regulation (EU) No 633/2014 of 13 June 2014	L 175	6	14.6.2014
►M17	Commission Regulation (EU) No 1137/2014 of 27 October 2014	L 307	28	28.10.2014
►M18	Commission Regulation (EU) 2016/355 of 11 March 2016	L 67	22	12.3.2016
►M19	Commission Regulation (EU) 2017/1978 of 31 October 2017	L 285	3	1.11.2017
►M20	Commission Regulation (EU) 2017/1981 of 31 October 2017	L 285	10	1.11.2017
►M21	Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019	L 198	241	25.7.2019

►**M22**	Commission Delegated Regulation (EU) 2020/2192 of 7 December 2020	L 434	10	23.12.2020
►**M23**	Commission Delegated Regulation (EU) 2021/1374 of 12 April 2021	L 297	1	20.8.2021
►**M24**	Regulation (EU) 2021/1756 of the European Parliament and of the Council of 6 October 2021	L 357	27	8.10.2021
►**M25**	Commission Delegated Regulation (EU) 2022/2258 of 9 September 2022	L 299	5	18.11.2022
►**M26**	Commission Delegated Regulation (EU) 2023/166 of 26 October 2022	L 24	1	26.1.2023
►**M27**	Commission Delegated Regulation (EU) 2024/1141 of 14 December 2023	L 1141	1	19.4.2024
►**M28**	Commission Delegated Regulation (EU) 2025/1449 of 18 July 2025	L 1449	1	29.10.2025

Corrected by:

►**C1**	Corrigendum, OJ L 226, 25.6.2004, p. 22 (853/2004)			

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REGULATION (EC) No 853/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 29 April 2004

laying down specific hygiene rules for food of animal origin

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No 852/2004. They shall apply to unprocessed and processed products of animal origin.

2. Unless expressly indicated to the contrary, this Regulation shall not apply to food containing both products of plant origin and processed products of animal origin. However, processed products of animal origin used to prepare such food shall be obtained and handled in accordance with the requirements of this Regulation.

3. This Regulation shall not apply in relation to:

(a) primary production for private domestic use;

(b) the domestic preparation, handling or storage of food for private domestic consumption;

(c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;

▼M24

(d) the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer;

▼C1

(e) hunters who supply small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer.

4. Member States shall establish, according to national law, rules governing the activities and persons referred to in paragraph 3(c), (d) and (e). Such national rules shall ensure the achievement of the objectives of this Regulation.

5. (a) Unless expressly indicated to the contrary, this Regulation shall not apply to retail.

▼C1

(b) However, this Regulation shall apply to retail when operations are carried out with a view to the supply of food of animal origin to another establishment, unless:

(i) the operations consist only of storage or transport, in which case the specific temperature requirements laid down in Annex III shall nevertheless apply;

or

(ii) the supply of food of animal origin from the retail establishment is to other retail establishments only and, in accordance with national law, is a marginal, localised and restricted activity.

(c) Member States may adopt national measures to apply the requirements of this Regulation to retail establishments situated on their territory to which it would not apply pursuant to subparagraphs (a) or (b).

6. This Regulation shall apply without prejudice to:

(a) relevant animal and public health rules, including more stringent rules laid down for the prevention, control and eradication of certain transmissible spongiform encephalopathies;

(b) animal welfare requirements;

and

(c) requirements concerning the identification of animals and the traceability of products of animal origin.

Article 2

Definitions

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

1. the definitions laid down in Regulation (EC) No 178/2002;

2. the definitions laid down in Regulation (EC) No 852/2004;

3. the definitions laid down in Annex I;

and

4. any technical definitions contained in Annexes II and III.

CHAPTER II

FOOD BUSINESS OPERATORS' OBLIGATIONS

Article 3

General obligations

1. Food business operators shall comply with the relevant provisions of Annexes II and III.

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2. Food business operators shall not use any substance other than potable water or, when Regulation (EC) No 852/2004 or this Regulation permits its use, clean water, to remove surface contamination from products of animal origin, unless use of the substance has been approved by the Commission. For that purpose the Commission is empowered to adopt delegated acts in accordance with Article 11a supplementing this Regulation. 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 this Regulation.

▼C1

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 relevant requirements of Regulation (EC) No 852/2004, those of Annexes II and III of this Regulation and other relevant requirements of food law;

and

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

2. Without prejudice to Article 6(3) of Regulation (EC) No 852/2004, establishments handling those products of animal origin for which Annex III to this Regulation lays down requirements shall not operate unless the competent authority has approved them in accordance with paragraph 3 of this Article, with the exception of establishments carrying out only:

(a) primary production;

(b) transport operations;

(c) the storage of products not requiring temperature-controlled storage conditions;

or

(d) retail operations other than those to which this Regulation applies pursuant to Article 1(5)(b).

3. An establishment subject to approval in accordance with paragraph 2 shall not operate unless the competent authority has, in accordance with Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption ([1]):

(a) granted the establishment approval to operate following an on-site visit;

or

(b) provided the establishment with conditional approval.

([1]) See page 83 of this Official Journal.

▼C1

4. Food business operators shall cooperate with the competent authorities in accordance with Regulation (EC) No 854/2004. In particular, food business operators shall ensure that an establishment ceases to operate if the competent authority withdraws its approval or, in the case of conditional approval, fails to prolong it or to grant full approval.

5. This Article shall not prevent an establishment from placing food on the market between the date of application of this Regulation and the first subsequent inspection by the competent authority, if the establishment:

(a) is subject to approval in accordance with paragraph 2 and placed products of animal origin on the market in accordance with Community legislation immediately prior to the application of this Regulation;

or

(b) is of a type in respect of which there was no requirement for approval before the application of this Regulation.

Article 5

Health and identification marking

1. Food business operators shall not place on the market a product of animal origin handled in an establishment subject to approval in accordance with Article 4(2) unless it has either:

(a) a health mark applied in accordance with Regulation (EC) No 854/2004;

or

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

2. Food business operators may apply an identification mark to a product of animal origin only if the product has been manufactured in accordance with this Regulation in establishments meeting the requirements of Article 4.

3. Food business operators may not remove a health mark applied in accordance with Regulation (EC) No 854/2004 from meat unless they cut or process it or work upon it in another manner.

Article 6

Products of animal origin from outside the Community

1. Food business operators importing products of animal origin from third countries shall ensure that importation takes place only if:

(a) the third country of dispatch appears on a list, drawn up in accordance with Article 11 of Regulation (EC) No 854/2004, of third countries from which imports of that product are permitted;

▼C1

(b) (i) the establishment from which that product was dispatched, and in which it was obtained or prepared, appears on a list, drawn up in accordance with Article 12 of Regulation (EC) No 854/2004, of establishments from which imports of that product are permitted, when applicable,

(ii) in the case of fresh meat, minced meat, meat preparations, meat products and MSM, the product was manufactured from meat obtained in slaughterhouses and cutting plants appearing on lists drawn up and updated in accordance with Article 12 of Regulation (EC) No 854/2004 or in approved Community establishments,

and

(iii) in the case of live bivalve molluscs, echinoderms, tunicates and marine gastropods, the production area appears on a list drawn up in accordance with Article 13 of that Regulation, when applicable;

(c) the product satisfies:

(i) the requirements of this Regulation, including the requirements of Article 5 on health and identification marking;

(ii) the requirements of Regulation (EC) No 852/2004;

and

(iii) any import conditions laid down in accordance with Community legislation governing import controls for products of animal origin,

and

(d) the requirements of Article 14 of Regulation (EC) No 854/2004 concerning certificates and documents are satisfied, when applicable.

2. By way of derogation from paragraph 1, the importation of fishery products may also take place in accordance with the special provisions laid down in Article 15 of Regulation (EC) No 854/2004.

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

(a) products are made available for control upon importation in accordance with Directive 97/78/EC ([1]);

(b) importation complies with the requirements of Directive 2002/99/EC ([2]);

and

(c) operations under their control that take place after importation are carried out in accordance with the requirements of Annex III.

([1]) Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9). Directive amended by the 2003 Act of Accession.

([2]) Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (OJ L 18, 23.1.2003, p. 11).

▼C1

4. Food business operators importing food containing both products of plant origin and processed products of animal origin shall ensure that the processed products of animal origin contained in such food satisfy the requirements of paragraphs 1 to 3. They must be able to demonstrate that they have done so (for example, through appropriate documentation or certification, which need not be in the format specified in paragraph 1(d)).

CHAPTER III

TRADE

Article 7

Documents

1. When required in accordance with Annex II or III, food business operators shall ensure that certificates or other documents accompany consignments of products of animal origin.

2. In accordance with the procedure referred to in Article 12(2):

(a) model documents may be established;

and

(b) provision may be made for the use of electronic documents.

Article 8

Special guarantees

1. Food business operators intending to place the following food of animal origin on the market in Sweden or Finland shall comply with the rules set out in paragraph 2 in respect of salmonella:

(a) meat from bovine and porcine animals, including minced meat but excluding meat preparations and MSM;

(b) meat from poultry of the following species: domestic fowl, turkeys, guinea-fowl, ducks and geese, including minced meat but excluding meat preparations and MSM;

and

(c) eggs.

2. (a) In the case of meat from bovine and porcine animals and meat from poultry, 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.

▼C1

(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 a control programme recognised, in respect of the food of animal origin concerned and in accordance with the procedure referred to in Article 12(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, 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).

(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.

▼M7

3. ►M21 (a) The Commission is empowered to adopt delegated acts in accordance with Article 11a amending paragraphs 1 and 2 of this Article in order to update the requirements set out in those paragraphs, taking into account changes in Member States' control programmes or the adoption of microbiological criteria in accordance with Regulation (EC) No 852/2004. ◄

(b) In accordance with the regulatory procedure referred to in Article 12(2), the rules laid down in paragraph 2 of this Article in respect of any of the foodstuffs referred to in paragraph 1 of this Article may be extended, in whole or in part, to any Member State, or any region of a Member State, that has a control programme recognised as equivalent to that approved for Sweden and Finland in respect of the food of animal origin concerned.

▼C1

4. For the purposes of this Article, ‘control programme’ means a control programme approved in accordance with Regulation (EC) No 2160/2003.

CHAPTER IV

FINAL PROVISIONS

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Article 10

Amendment and adaptation of Annexes II and III

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1. The Commission is empowered to adopt delegated acts in accordance with Article 11a amending Annexes II and III. The amendments shall have the aim of ensuring and facilitating the achievement of the objectives of this Regulation, taking into account the relevant risk factors, and shall be justified on the basis of:

(a) the experience gained by food business operators and/or competent authorities, in particular on the implementation of HACCP-based systems pursuant to Article 5;

(b) the experience gained by the Commission, in particular on the outcome of its audits;

(c) technological developments and their practical consequences, and consumer expectations with regard to food composition;

(d) scientific advice, particularly new risk assessments;

(e) microbiological and temperature criteria for foodstuffs;

(f) changes in patterns of consumption.

The amendments referred to in the first subparagraph shall concern:

(a) the requirements on the identification marking of products of animal origin;

(b) the objectives of HACCP-based procedures;

(c) the requirements on the food chain information;

(d) the specific hygiene requirements for the premises, including means of transport, where products of animal origin are produced, handled, processed, stored or distributed;

(e) the specific hygiene requirements for the operations involving the production, handling, processing, storage, transport or distribution of products of animal origin;

(f) the rules for the transport of meat while it is warm;

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(g) the health standards or checks, where there is scientific evidence indicating that they are necessary to protect public health;

(h) the extension of Annex III, Section VII, Chapter IX, to live bivalve molluscs other than pectinidae;

(i) the criteria for determining when epidemiological data indicate that a fishing ground does not present a health hazard with regard to the presence of parasites and, consequently, for determining when the competent authority may authorise food business operators not to freeze fishery products in accordance with Annex III, Section VIII, Chapter III, Part D;

(j) the additional health standards for live bivalve molluscs in cooperation with the relevant Union Reference Laboratory, including:

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

(ii) virus testing procedures and virological standards; and

(iii) sampling plans and the methods and analytical tolerances to be applied to check compliance with the health standards.

2. The Commission is empowered to adopt delegated acts in accordance with Article 11a in order to supplement this Regulation by granting derogations from Annex II and III, taking into account the relevant risk factors and provided that such derogations do not affect the achievement of the following objectives of this Regulation:

(a) to facilitate the fulfilment, by small businesses, of the requirements laid down in the Annexes;

(b) to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food;

(c) to accommodate the needs of food businesses situated in regions that are subject to special geographic constraints;

(d) to facilitate the work of establishments producing raw material which is intended for the production of highly refined food products and which has undergone a treatment ensuring its safety.

▼C1

3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 8, national measures adapting the requirements laid down in Annex III.

4. (a) The national measures referred to in paragraph 3 shall have the aim of:

▼C1

(i) enabling the continued use of traditional methods at any of the stages of production, processing or distribution of food;

or

(ii) accommodating the needs of food businesses situated in regions that are subject to special geographic constraints.

(b) In other cases, they shall apply only to the construction, layout and equipment of establishments.

5. Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. Each notification shall:

(a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought;

(b) describe the foodstuffs and establishments concerned;

(c) explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation;

and

(d) give any other relevant information.

6. The other Member States shall have three months from the receipt of a notification referred to in paragraph 5 to send written comments to the Commission. In the case of adaptations arising from paragraph 4(b), this period shall, at the request of any Member State, be extended to four months. The Commission may, and when it receives written comments from one or more Member States shall, consult Member States within the committee referred to in Article 12(1). The Commission may decide, in accordance with the procedure referred to in Article 12(2), whether the envisaged measures may be implemented, subject, if necessary, to appropriate amendments. Where appropriate, the Commission may propose general measures in accordance with paragraph 1 or 2 of this Article.

7. A Member State may adopt national measures adapting the requirements of Annex III only:

(a) in compliance with a decision adopted in accordance with paragraph 6;

(b) if, one month after the expiry of the period referred to in paragraph 6, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision in accordance with paragraph 6;

or

(c) in accordance with paragraph 8.

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8. A Member State may, of its own initiative and subject to the general provisions of the Treaty, maintain or establish national rules:

(a) prohibiting or restricting the placing on the market within its territory of raw milk or raw cream intended for direct human consumption;

or

(b) permitting the use, with the authorisation of the competent authority, of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards plate count and somatic cell count of the manufacture of cheeses with an ageing or ripening period of at least 60 days, and dairy products obtained in connection with the manufacture of such cheeses, provided that this does not prejudice the achievement of the objectives of this Regulation.

Article 11

Specific decisions

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Without prejudice to the general application of Article 9 and Article 10 (1), the Commission may lay down the following measures by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 12(2):

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2. to specify, in respect of MSM, which calcium content is not significantly higher than that of minced meat;

3. to lay down other treatments that may be applied in a processing establishment to live bivalve molluscs from class B or C production areas that have not been submitted to purification or relaying;

4. to specify recognised testing methods for marine biotoxins;

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9. to lay down freshness criteria and limits with regard to histamine and total volatile nitrogen for fisheries products;

10. to permit the use for the manufacture of certain dairy products of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards its plate count and somatic cell count;

11. without prejudice to Directive 96/23/EC [1], to fix a maximum permitted value for the combined total of residues of antibiotic substances in raw milk;

and

[1] Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products (OJ L 125, 23.5.1996, p. 10). Directive as amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

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12. to approve equivalent processes for the production of gelatine or collagen.

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Article 11a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 3(2), Article 8(3)(a) and Article 10(1) and (2) shall be conferred on the Commission for a period of five years from 26 July 2019. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of powers referred to in Article 3(2), Article 8(3)(a) and Article 10(1) and (2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ([1]).

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 3(2), Article 8(3)(a) and Article 10(1) and (2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

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Article 12

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period provided for in Article 5(6) of Decision 1999/468/EC shall be set at three months.

([1]) OJ L 123, 12.5.2016, p. 1.

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Article 13

Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on any matter falling within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing to extend Annex III, Section III, to other animal species.

Article 14

Report to the European Parliament and to the Council

1. The Commission shall, not later than 20 May 2009, submit a report to the European Parliament and the Council reviewing the experience gained from the implementation of this Regulation.

2. The Commission shall, if appropriate, accompany the report with relevant proposals.

Article 15

This Regulation shall enter into force on the 20th day after that of its publication in the *Official Journal of the European Union*.

It shall apply 18 months after the date on which all of the following acts have entered into force:

(a) Regulation (EC) No 852/2004;

(b) Regulation (EC) No 854/2004;

and

(c) Directive 2004/41/EC.

However, it shall apply no earlier than 1 January 2006.

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

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ANNEX I

DEFINITIONS

For the purpose of this Regulation:

1. MEAT

1.1. ‘Meat’ means edible parts of the animals referred to in points 1.2 to 1.8, including blood.

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 ungulates and lagomorphs, as well as other land mammals that are hunted for human consumption and are considered to be wild game under the applicable law in the Member State concerned, including mammals living in enclosed territory under conditions of freedom similar to those of wild game;

and

— wild birds that are hunted for human consumption.

1.6. ‘Farmed game’ means farmed ratites and farmed land mammals other than those referred to in point 1.2.

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

1.8. ‘Large wild game’ means wild land mammals living freely in the wild that do not fall within the definition of 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, including viscera and blood.

1.12. ‘Viscera’ means the organs of 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’ or ‘MSM’ means the product obtained by removing meat from flesh-bearing bones after boning or from poultry carcases, using mechanical means resulting in the loss or modification of the muscle fibre structure.

1.15. ‘Meat preparations’ means fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings or additives added to it or which has undergone processes insufficient to modify the internal muscle fibre 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.

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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 production areas, purification centres or dispatch centres in tanks or any other installation containing clean seawater, or in natural sites, to remove sand, mud or slime, to preserve or to improve organoleptic qualities and to ensure that they are in a good state of vitality before wrapping or packaging.

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 area with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live bivalve molluscs.

2.7. ‘Dispatch centre’ means any on-shore or off-shore 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 all seawater or freshwater animals (except for live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, and all mammals, reptiles and frogs) whether wild or farmed and including all edible forms, parts and products of such animals.

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, if necessary, chilling or freezing: filleting, slicing, skinning, shelling, shucking, mincing or processing.

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.

▼C1

3.4. ‘Mechanically separated fishery product’ means any product obtained by removing flesh from fishery products using mechanical means resulting in the loss or modification of the flesh structure.

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.

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 °C 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 — that are produced by farmed birds and are fit for direct human consumption or for the preparation of egg products.

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

5.3. ‘Cracked eggs’ means eggs with damaged 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 RNA (family Ranidae).

6.2. ‘Snails’ means terrestrial gastropods of the species *Helix pomatiaLinné*, *Helix aspersaMuller*, *Helix lucorum* and species of the family Achatinidae.

7. PROCESSED PRODUCTS

7.1. ‘Meat products’ means processed products resulting from the processing of meat or from the further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat.

7.2. ‘Dairy products’ means processed products resulting from the processing of raw milk or from the further processing of such processed products.

7.3. ‘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.

7.4. ‘Processed fishery products’ means processed products resulting from the processing of fishery products or from the further processing of such processed products.

▼C1

7.5. ‘Rendered animal fat’ means fat derived from rendering meat, including bones, and intended for human consumption.

7.6. ‘Greaves’ means the protein-containing residue of rendering, after partial separation of fat and water.

7.7. ‘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.

7.8. ‘Collagen’ means the protein-based product derived from animal bones, hides, skins and tendons manufactured in accordance with the relevant requirements of this Regulation.

7.9. ‘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:

— food of animal origin, including honey and blood;

— live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption;

and

— other animals destined to be prepared with a view to being supplied live to the final consumer.

8.2. ‘Wholesale market’ means a food business that includes several separate units which share common installations and sections where foodstuffs are sold to food business operators.

▼C1

ANNEX II

REQUIREMENTS CONCERNING SEVERAL PRODUCTS OF ANIMAL ORIGIN

SECTION I: IDENTIFICATION MARKING

When required in accordance with Article 5 or 6, and subject to the provisions of Annex III, food business operators must ensure that products of animal origin have an identification mark applied in compliance with the following provisions.

A. APPLICATION OF THE IDENTIFICATION MARK

▼M6

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

▼M3

2. However, when a product's packaging and/or wrapping is removed or it is further processed in another establishment, a new mark must be applied to the product. In such cases, the new mark must indicate the approval number of the establishment where these operations take place.

▼M6

3. An identification mark is not necessary on packs of eggs when a packing centre code is applied in accordance with Part A of Annex XIV to Council Regulation (EC) No 1234/2007 ([1]).

▼C1

4. Food business operators must, in accordance with Article 18 of Regulation (EC) No 178/2002, have in place systems and procedures to identify food business operators from whom they have received and to whom they have delivered products of animal origin.

B. FORM OF THE IDENTIFICATION MARK

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

6. 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.

▼M22

In the case of Member States ([2]), however, these codes are BE, BG, CZ, DK, DE, EE, GR, ES, FR, HR, IE, IT, CY, LV, LT, LU, HU, MT, NL, AT, PL, PT, SI, SK, FI, RO, SE and UK(NI)

▼M2

_____

▼C1

7. The mark must indicate the approval number of the establishment. If an establishment manufactures both food to which this Regulation applies and food to which it does not, the food business operator may apply the same identification mark to both types of food.

▼M27

8. When applied in an establishment located within the Union, the mark must be oval in shape and include the abbreviation of European Union ('EU') in one of the official languages of the Union as follows: EC, EU, EL, UE, EE, AE, ES, EÚ.;

([1]) OJ L 299, 16.11.2007, p. 1.

([2]) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex, references to Member States include the United Kingdom in respect of Northern Ireland.

▼M27

Those abbreviations must not be included in marks applied by establishments located outside the Union on products imported into the Union.

8a. The requirements on the form of the identification mark in this Part B may be replaced by the requirements for a special identification mark in accordance with Article 65(1), point (h), of Regulation (EU) 2016/429 of the European Parliament and of the Council [1], and the rules adopted in accordance with Article 67, point (a), Article 71(3) or (4), or Article 259(1) or (2) of that Regulation.

▼C1

C. METHOD OF MARKING

9. 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.

10. In the case of packaging containing cut meat or offal, the mark must be applied to a label fixed to the packaging, or printed on the packaging, in such a way that it is destroyed when the packaging is opened. This is not necessary, however, if the process of opening destroys the packaging. When wrapping provides the same protection as packaging, the label may be affixed to the wrapping.

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

12. In the case of liquid, granulate and powdered products of animal origin carried in bulk, and fishery products carried in bulk, an identification mark is not necessary if accompanying documentation contains the information specified in points 6, 7 and, where appropriate, 8.

13. When products of animal origin are placed in a package destined for direct supply to the final consumer, it is sufficient to apply the mark to the exterior of that package only.

14. 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.

SECTION II: OBJECTIVES OF HACCP-BASED PROCEDURES

1. Food business operators operating slaughterhouses must ensure that the procedures that they have put in place in accordance with the general requirements of Article 5 of Regulation (EC) No 852/2004 meet the requirements that the hazard analysis shows to be necessary and the specific requirements listed in point 2.

2. The procedures must guarantee that each animal or, where appropriate, each lot of animals accepted onto the slaughterhouse premises:

(a) is properly identified;

[1] Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (‘Animal Health Law’) (OJ L 84, 31.3.2016, p. 1).

▼C1

(b) is accompanied by the relevant information from the holding of provenance referred to in Section III;

(c) does not come from a holding or an area subject to a movement prohibition or other restriction for reasons of animal or public health, except when the competent authority so permits;

(d) is clean;

(e) is healthy, as far as the food business operator can judge;

and

(f) is in a satisfactory state as regards welfare on arrival at the slaughterhouse.

3. In the event of failure to comply with any of the requirements listed under point 2, the food business operator must notify the official veterinarian and take appropriate measures.

SECTION III: FOOD CHAIN INFORMATION

▼M27

Food business operators operating slaughterhouses or game-handling establishments must, as appropriate, request, receive, check and act upon food chain information as set out in this Section in respect of all animals, other than wild game, sent or intended to be sent to the slaughterhouse or game-handling establishment.

▼M6

1. ►M27 Slaughterhouse or game-handling establishment ◄ operators must not accept animals onto the ►M27 slaughterhouse or game-handling establishment ◄ premises unless they have requested, and been provided with, relevant food chain information contained in the records kept at the holding of provenance in accordance with Regulation (EC) No 852/2004.

▼C1

2. ►M27 Slaughterhouse or game-handling establishment ◄ operators must be provided with the information no less than 24 hours before the arrival of animals at the slaughterhouse, except in the circumstances mentioned in point 7.

▼M6

3. The relevant food chain information referred to in point 1 is to cover, in particular:

▼M15

(a) the status of the holding of provenance or the regional animal health status, and whether the holding is officially recognised to apply controlled housing conditions in relation to *Trichinella* in accordance with Point A of Chapter I of Annex IV to Commission Regulation (EC) No 2075/2005 ([1]);

▼C1

(b) the animals' health status;

(c) veterinary medicinal products or other treatments administered to the animals within a relevant period and with a withdrawal period greater than zero, together with their dates of administration and withdrawal periods;

(d) the occurrence of diseases that may affect the safety of meat;

(e) the results, if they are relevant to the protection of public health, of any analysis carried out on samples taken from the animals or other samples taken to diagnose diseases that may affect the safety of meat, including samples taken in the framework of the monitoring and control of zoonoses and residues;

(f) relevant reports about previous *ante*- and *post-mortem* inspections of animals from the same holding of provenance including, in particular, reports from the official veterinarian;

([1]) OJ L 338, 22.12.2005, p. 60.

▼C1

(g) production data, when this might indicate the presence of disease;

and

(h) the name and address of the private veterinarian normally attending the holding of provenance.

4. (a) However, it is not necessary for the ►M27 slaughterhouse or game-handling establishment ◄ operator to be provided with:

(i) the information referred to in point 3(a), (b), (f) and (h), if the operator is already aware of this information (for example, through a standing arrangement or a quality assurance scheme);

or

(ii) the information referred to in point 3(a), (b), (f) and (g), if the producer declares that there is no relevant information to report.

(b) The information need not be provided as a verbatim extract from the records of the holding of provenance. It may be provided through electronic data exchange or in the form of a standardised declaration signed by the producer.

5. Food business operators deciding to accept animals onto the ►M27 slaughterhouse or game-handling establishment ◄ premises after evaluating the relevant food chain information must make it available to the official veterinarian without delay and, except in the circumstances mentioned in point 7, no less than 24 hours before the arrival of the animal or lot. The food business operator must notify the official veterinarian of any information that gives rise to health concerns before *ante-mortem* inspection of the animal concerned.

6. If any animal arrives at the ►M27 slaughterhouse or game-handling establishment ◄ without food chain information, the operator must immediately notify the official veterinarian. Slaughter of the animal may not take place until the official veterinarian so permits.

▼M8

7. If the competent authority so permits and provided it does not jeopardise the objectives of this Regulation, food chain information may arrive less than 24 hours before the arrival of the animals of all species to which it relates at the ►M27 slaughterhouse or game-handling establishment ◄ or accompany these animals to the ►M27 slaughterhouse or game-handling establishment ◄.

However, any item of food chain information, knowledge of which may result in serious disruption of the ►M27 slaughterhouse or game-handling establishment ◄ activity, is to be made available to the food business operator operating the ►M27 slaughterhouse or game-handling establishment ◄ in sufficient time before the animals arrive at the ►M27 slaughterhouse or game-handling establishment ◄, in order for that food business operator to plan the ►M27 slaughterhouse or game-handling establishment ◄ activity accordingly.

The food business operator operating the ►M27 slaughterhouse or game-handling establishment ◄ must evaluate the relevant information and must submit the food chain information received to the official veterinarian. The slaughter or dressing of the animals may not take place until the official veterinarian so permits.

▼C1

8. Food business operators must check passports accompanying domestic solipeds to ensure that the animal is intended for slaughter for human consumption. If they accept the animal for slaughter, they must give the passport to the official veterinarian.

▼**M12**

SECTION IV: REQUIREMENTS APPLICABLE TO FROZEN FOOD OF ANIMAL ORIGIN

1. For the purposes of this Section, ‘date of production’ means:

   (a) the date of slaughter in the case of carcasses, half carcasses or quarter carcases;

   (b) the date of killing in the case of bodies of wild game;

   (c) the date of harvesting or catching, in the case of fishery products;

   (d) the date of processing, cutting, mincing or preparation, as appropriate, for any other food of animal origin.

2. Until the stage at which a food is labelled in accordance with Directive 2000/13/EC or used for further processing, food business operators must ensure that in the case of frozen food of animal origin intended for human consumption, the following information is made available to the food business operator to whom the food is supplied and, upon request, to the competent authority:

   (a) the date of production; and

   (b) the date of freezing, if different from the date of production.

   Where a food is made from a batch of raw materials with different dates of production and of freezing, the oldest dates of production and/or of freezing, as appropriate, must be made available.

3. The appropriate form in which the information must be made available is up to the choice of the supplier of the frozen food, as long as the information requested in paragraph 2 will be clearly and unequivocally available to and retrievable by the business operator to whom the food is supplied.

▼C1

ANNEX III

SPECIFIC REQUIREMENTS

SECTION I: MEAT OF DOMESTIC UNGULATES

CHAPTER I: TRANSPORT OF LIVE ANIMALS TO THE SLAUGHTERHOUSE

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

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

2. Animals showing symptoms of disease or originating in herds known to be contaminated with agents of public health importance may only be transported to the slaughterhouse when the competent authority so permits.

CHAPTER II: REQUIREMENTS FOR SLAUGHTERHOUSES

▼M27

Food business operators must ensure that the construction, layout and equipment of slaughterhouses in which domestic ungulates are slaughtered meet the requirements laid down in the following points 1 to 9. Mobile partial slaughterhouses must operate in cooperation with complementary permanent slaughtering facilities in order to constitute a complete slaughterhouse complying with the requirements laid down in the following points 1 to 9. Mobile partial slaughterhouses may operate with several complementary slaughtering facilities, thus constituting several slaughterhouses.

▼C1

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 that the welfare of the animals is respected. 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:

      (i) stunning and bleeding;

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

      (iii) evisceration and further dressing;

▼C1

(iv) handling clean guts and tripe;

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

(vi) packaging offal;

and

(vii) 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 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.

3. They must have facilities for disinfecting tools with hot water supplied at not less than 82 °C, 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 for livestock. However, slaughterhouses need not have these places and facilities if the competent authority so permits and official authorised places and facilities exist nearby.

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.

8. If manure or digestive tract 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.

CHAPTER III: REQUIREMENTS FOR CUTTING PLANTS

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

1. are constructed so as to avoid contamination of meat, in particular by:

(a) allowing constant progress of the operations;

or

(b) ensuring separation between the different production batches;

2. have rooms for the separate storage of packaged and exposed meat, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat;

3. have cutting rooms equipped to ensure compliance with the requirements laid down in Chapter V;

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

▼C1

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

CHAPTER IV: SLAUGHTER HYGIENE

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

▼M27 1. After arrival at 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. Animals that are presented at a slaughterhouse for slaughter shall be slaughtered there and direct movements to another slaughterhouse may be allowed only in exceptional cases in accordance with Article 43(6), second subparagraph of Implementing Regulation (EU) 2019/627.

▼C1

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 otherwise 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 VI;

▼M23

(ii) animals slaughtered at the holding of provenance in accordance with Chapter VIa of this Section or in accordance with point 3 of Section III;

▼C1

(iii) wild game, in compliance with Section IV, 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. Animals must be clean.

5. Slaughterhouse operators must follow the instructions of the veterinarian appointed by the competent authority in accordance with Regulation (EC) No 854/2004 to ensure that ante-mortem inspection of every animal to be slaughtered is carried out under suitable conditions.

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

7. Stunning, bleeding, skinning, evisceration and other dressing 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;

(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;

▼C1

(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.

▼M3

8. Carcases and other parts of the body intended for human consumption must be completely skinned, except in the case of porcine animals, the heads of ovine and caprine animals and calves, the muzzle and lips of bovine animals and the feet of bovine, ovine and caprine animals. Heads, including muzzle and lips, and feet must be handled in such a way as to avoid contamination.

▼C1

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 visible contamination must be removed without delay by trimming or alternative means having an equivalent effect.

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 of all slaughtered animals is carried out under suitable conditions in accordance with Regulation (EC) No 854/2004.

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 other 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:

▼M3

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

▼C1

(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;

▼C1

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 VII.

▼M23

18. Unless intended for use as animal by-product in accordance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council ([1]):

(a) stomachs must be scalded or cleaned; however, when intended for rennet production, the stomachs:

(i) are only required to be emptied in the case of young bovine animals

(ii) are not required to be emptied, scalded or cleaned in the case of young ovine and caprine animals;

(b) intestines must be emptied and cleaned;

(c) heads and feet must be skinned or scalded and depilated; however, when authorised by the competent authority, visibly clean heads, not containing specified risk materials in accordance with Article 8 of Regulation (EC) No 999/2001 of the European Parliament and of the Council ([2]), and visibly clean feet, intended for processing into food, may be transported to and skinned or scalded and depilated in an approved establishment.

▼C1

19. 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.

20. 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 V: 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 or quarters, and half carcases into no more than 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:

([1]) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

([2]) Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

▼C1

(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 °C for offal and 7 °C for other meat, by means of an ambient temperature of not more than 12 °C 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 before it reaches the temperature referred to in point 2(b) in accordance with Chapter VII, point 3.

4. Meat may also be boned and cut prior to reaching the temperature referred to in point 2(b) when the cutting room is on the same site as the slaughter premises. In this case, the meat must be transferred to the cutting room either directly from the slaughter premises or 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).

▼M20

5. Carcases, half carcases, quarters, or half carcases cut into no more than three wholesale cuts may be boned and cut prior to reaching the temperature referred to in point 2(b) when they have been transported under the derogation set out in point 3(b) of Chapter VII of Section I. In this case, throughout cutting or boning, the meat must be subjected to air temperatures that ensure a continuous decrease of the temperature of the meat. As soon as it is cut and, where appropriate, packaged, the meat must be chilled to the temperature referred to in point 2(b) if it is not already below this temperature.

▼C1

CHAPTER VI: EMERGENCY SLAUGHTER OUTSIDE THE SLAUGHTERHOUSE

Food business operators must ensure that meat from domestic ungulates that have undergone emergency slaughter outside the slaughterhouse may be used for human consumption only if it complies with all the following requirements.

1. An otherwise healthy animal must have suffered an accident that prevented its transport to the slaughterhouse for welfare reasons.

▼M23

2. The official veterinarian must carry out an ante-mortem inspection of the animal.

3. The slaughtered and bled animal must be transported to the slaughterhouse hygienically and without undue delay. Removal of the stomach and intestines, but no other dressing, may take place on the spot, under the supervision of the official veterinarian. Any viscera removed must accompany the slaughtered animal to the slaughterhouse and be identified as belonging to that animal.

▼C1

4. If more than two hours elapse between slaughter and arrival at the slaughterhouse, the animal must be refrigerated. Where climatic conditions so permit, active chilling is not necessary.

▼M28

5. The food chain information required in accordance with Section III of Annex II must accompany the slaughtered animal to the slaughterhouse.

▼C1

6. ►M23 The official certificate set out in Chapter 5 of Annex IV to Commission Implementing Regulation (EU) 2020/2235 ([1]) shall accompany the slaughtered animal to the slaughterhouse or be sent in advance in any format. ◄

7. The slaughtered animal must be fit for human consumption following post-mortem inspection carried out in the slaughterhouse in accordance with Regulation (EC) No 854/2004, including any additional tests required in the case of emergency slaughter.

8. Food business operators must follow any instructions that the official veterinarian may give after post-mortem inspection concerning the use of the meat.

▼M15

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▼M27

CHAPTER VIa: SLAUGHTER AT THE HOLDING OF PROVENANCE OF DOMESTIC BOVINE ANIMALS, OTHERS THAN BISONS, AND OVINE, CAPRINE AND PORCINE ANIMALS AND DOMESTIC SOLIPEDS OTHER THAN EMERGENCY SLAUGHTER

Up to three domestic bovine animals, other than bisons, up to three domestic solipeds, up to six domestic porcine animals or up to nine ovine or caprine animals may be slaughtered at the same occasion at the holding of provenance, when authorised by the competent authority in accordance with the following requirements:

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(b) there is an agreement between the slaughterhouse and the owner of the animal intended for slaughter; the owner must inform the competent authority in writing of such an agreement;

(c) the slaughterhouse or the owner of the animals intended for slaughter must inform the official veterinarian at least three days in advance of the date and time of intended slaughter of the animals;

(d) the official veterinarian who carries out the ante-mortem inspection of the animal intended for slaughter must be present at the time of slaughter;

(e) the mobile unit to be used for the bleeding and transport of the slaughtered animals to the slaughterhouse must allow their hygienic handling and bleeding, and the proper disposal of their blood and must be part of a slaughterhouse approved by the competent authority in accordance with Article 4(2); however the competent authority may allow bleeding outside the mobile unit if the blood is not intended for human consumption and the slaughter does not take place in restricted zones as defined in Article 4(41) of Regulation (EU) 2016/429 of the European Parliament and of the Council ([2]) or establishments in which animal health restrictions are applied in accordance with Regulation (EU) 2016/429 and any acts adopted on its basis;

([1]) Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).

([2]) Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (‘Animal Health Law’) (OJ L 84, 31.3.2016, p. 1).

▼M23

(f) the slaughtered and bled animals must be transported directly to the slaughterhouse hygienically and without undue delay; removal of the stomach and intestines, but no other dressing, may take place on the spot, under the supervision of the official veterinarian; any viscera removed must accompany the slaughtered animal to the slaughterhouse and be identified as belonging to each individual animal;

(g) if more than two hours elapse between the time of slaughter of the first animal and the time of arrival at the slaughterhouse of the slaughtered animals, the slaughtered animals must be refrigerated; where climatic conditions so permit, active chilling is not necessary;

(h) the owner of the animal must inform the slaughterhouse in advance of the intended time of arrival of the slaughtered animals, which must be handled without undue delay after arrival at the slaughterhouse;

(i) in addition to the food chain information to be submitted in accordance with Section III of Annex II to this Regulation, the official certificate set out in Chapter 3 of Annex IV to Implementing Regulation (EU) 2020/2235 must accompany the slaughtered animals to the slaughterhouse or be sent in advance in any format.

▼C1

CHAPTER VII: STORAGE AND TRANSPORT

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

1. (a) Unless other specific provisions provide otherwise, post-mortem inspection must be followed immediately by chilling in the slaughterhouse to ensure a temperature throughout the meat of not more than 3 ° C for offal and 7 °C 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 V, point 4.

(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.

▼M27

2a. For the purposes of this point, ‘dry-ageing’ means the storage of fresh meat in aerobic conditions of hanging carcasses or cuts either unpacked or packed in bags permeable to water vapour in a refrigerated room or cabinet and left to age for several weeks at controlled environmental conditions of temperature, relative humidity and airflow.

▼M27

Before placing on the market or freezing, bovine meat subject to dry-ageing must be stored at a surface temperature of – 0,5 to 3,0 °C, with a relative humidity of a maximum of 85 % and an airflow of 0,2 to 0,5 m/s in a dedicated room or cabinet for a maximum of 35 days starting at the end of the stabilisation period upon slaughter. However, food business operators may apply other combinations of surface temperature, relative humidity, airflow and time, or do dry-ageing of meat of other species, if they demonstrate to the satisfaction of the competent authority that equivalent guarantees are provided on the safety of the meat.

In addition, the following specific measures shall be applied:

(i) the dry-ageing shall start immediately after the stabilisation period upon slaughter and unduly delayed cutting and/or transport to an establishment carrying out the dry-ageing;

(ii) the meat shall not be loaded into the room or the cabinet until the temperature and relative humidity referred to in the second subparagraph have been achieved;

(iii) the meat shall be hanged from the bone or, if using a shelf, sufficient perforation to facilitate air flow with regular turning using hygienic methods must be ensured;

(iv) a higher airflow may be applied at the start of the dry-ageing process to facilitate early crust development and reduce the surface water activity;

(v) thermometers, relative humidity probes and other equipment to accurately monitor and facilitate control of room or cabinet conditions must be used;

(vi) air leaving the evaporator, returning to the evaporator and coming in contact with the beef must be filtered or UV treated;

(vii) when the crust is trimmed, such trimming shall be carried out in a hygienic manner.

▼M20

3. Meat must attain the temperature specified in point 1 before transport, and remain at that temperature during transport.

However, following points (a) and (b) shall apply.

(a) Transport of meat for the production of specific products may take place before the temperature specified in point 1 is attained if the competent authority so authorises, provided that:

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

▼M20

(ii) the meat leaves the slaughterhouse, or a cutting room on the same site as the slaughter premises, immediately and transport takes no more than 2 hours;

and,

(iii) such transport is justified for technological reasons.

(b) Transport of carcases, half carcases, quarters, or half carcases cut into three wholesale cuts of ovine and caprine animals, bovine animals and porcine animals may commence before the temperature specified in point 1 is attained, provided that all of the following conditions are fulfilled:

(i) the temperature is monitored and recorded within the framework of procedures based on the HACCP principles;

(ii) food business operators dispatching and transporting the carcases, half carcases, quarters, or half carcases cut into three wholesale cuts have received documented authorisation from the competent authority at the place of departure to make use of this derogation;

(iii) the vehicle transporting the carcases, half carcases, quarters, or half carcases cut into three wholesale cuts are fitted with an instrument that monitors and records air temperatures to which the carcases, half carcases, quarters, or half carcases cut into three wholesale cuts are subjected in such a way that competent authorities are enabled to verify compliance with the time and temperature conditions set out in point (viii);

▼M27

(iv) per transport, the vehicle transporting the carcases, half carcases, quarters, or half carcases cut into three wholesale cuts collects meat from a maximum of three slaughterhouses or from one cold store collecting directly from slaughterhouses; all the requirements laid down in this point (b) shall apply to all loads of carcases, half carcases, quarters, or half carcases cut into three wholesale cuts dispatched from the slaughterhouse and cold store collecting from the above mentioned slaughterhouse;

(v) carcases, half carcases, quarters, or half carcases cut into three wholesale cuts must have a core temperature of 15 °C at the start of the transport if they are to be transported in the same compartment as meat which meets the temperature requirement set out in point 1 for offal and 7 °C for other meat;

(vi) a declaration by the food business operator accompanies the consignment; that declaration must state the duration of chilling before the first loading, the time at which the first loading of the carcases, half carcases, quarters, or half carcases cut into three wholesale cuts was started, the surface temperature at that time, the maximum transportation air temperature to which the carcases, half carcases, quarters, or half carcases cut into three wholesale cuts may be subjected, the maximum transport time permitted, the date of authorisation and the name of the competent authority authorising the transport in accordance with point (ii);

(vii) the food business operator of destination must notify the competent authority before receiving for the first time carcases, half carcases, quarters, or half carcases cut into three wholesale cuts, not attaining the temperature referred to in point 1 before the start of transport;

▼M27

(viii) the meat must be transported in accordance with the following parameters:

— For a maximum transport time ([1]) of six hours:

Species	Surface temperature ([1])	Maximum time to chill to surface temperature ([2])	Maximum transportation air temperature ([3])	Maximum daily mean carcase aerobic colony count ([4])
Ovine and caprine animals	7 °C	8 hours	6 °C	$\log_{10}$ 3,5 cfu/cm^2
Bovine animals		20 hours		$\log_{10}$ 3,5 cfu/cm^2
Porcine animals		16 hours		$\log_{10}$ 4 cfu/cm^2

([1]) Maximum surface temperature allowed at loading and thereafter measures at the thickest part of the carcase, half carcases, quarters, or half carcases cut into three wholesale cuts.
([2]) Maximum time allowed from the moment of killing until the reaching of the maximum surface temperature allowed at loading.
([3]) The maximum air temperature to which the meat is allowed to be subjected from the moment loading begins, and throughout the whole duration of the transport.
([4]) Slaughterhouse maximum daily mean carcase aerobic colony count using a rolling window of 10 weeks, allowed for carcases of the relevant species, as assessed by the operator to the satisfaction of the competent authority, according to the sampling and testing procedures laid out in points 2.1.1, 2.1.2 of Chapter 2, and point 3.2 of Chapter 3, of Annex I to Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

The maximum transport time may be extended to 30 hours if a core temperature below 15 °C is reached before the start of the transport.

— For a maximum transport time ([1]) of 60 hours:

Species	Surface temperature ([1])	Maximum time to chill to surface temperature ([2])	Core temperature ([3])	Maximum transportation air temperature ([4])	Maximum daily mean carcase aerobic colony count ([5])
Ovine and caprine animals	4 °C	12 hours	15 °C	3 °C	$\log_{10}$ 3 cfu/cm^2
Bovine animals		24 hours			

([1]) Maximum surface temperature allowed at loading and thereafter measures at the thickest part of the carcase, half carcases, quarters, or half carcases cut into three wholesale cuts.
([2]) Maximum time allowed from the moment of killing until the reaching of the maximum surface temperature allowed at loading.
([3]) The maximum core temperature of the meat allowed at the time of loading, and thereafter.
([4]) The maximum air temperature to which the meat is allowed to be subjected from the moment loading begins, and throughout the whole duration of the transport.
([5]) Slaughterhouse maximum daily mean carcase aerobic colony count using a rolling window of 10 weeks, allowed for carcases of the relevant species, as assessed by the operator to the satisfaction of the competent authority, according to the sampling and testing procedures laid out in points 2.1.1, 2.1.2 of Chapter 2, and point 3.2 of Chapter 3, of Annex I to Regulation (EC) No 2073/2005.

([1]) Maximum time allowed from the start of loading of meat into the vehicle until the completion of the final delivery. Loading of the meat into the vehicle may be postponed beyond the maximum time allowed for chilling of the meat to its specified surface temperature. If this happens, then the maximum transport time allowed must be shortened by the same length of time by which the loading was postponed. The competent authority of the Member State of destination may limit the number of delivery points.

▼M27

(ix) methods for measuring the surface temperature shall be validated and the following method shall be used as reference method:

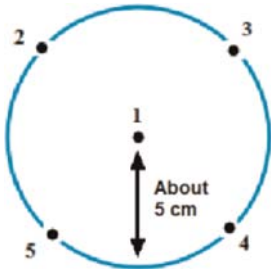
— a thermometer calibrated in accordance with the latest version of ISO 13485 shall be used;

— the sensor shall be penetrated perpendicularly in the thickest part at a depth of 0,5 to 1 cm of the external part of either:

(a) the shoulder; or

(b) the leg for bovine, ovine and caprine animals or of the ham, or the internal surface of the ham in the middle upper part for porcine animals;

— five temperature measurements shall be carried out as follows:



— at least one of the five measurements must be below the surface temperature requirements laid down in point (viii).

▼M23

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

However, food business operators carrying out a retail activity may freeze meat in view of its redistribution for the purpose of food donations in accordance with the following conditions:

(i) in the case of meat for which a 'use by' date is applied in accordance with Article 24 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council ([1]), before the expiry of that date;

(ii) without undue delay to a temperature of – 18 °C or lower;

(iii) ensuring that the date of freezing is documented and provided either on the label or by other means;

(iv) excluding meat that has been frozen before (defrosted meat); and,

(v) in accordance with any condition laid down by the competent authorities for freezing and further use as food.

▼C1

5. Exposed meat must be stored and transported separately from packaged meat, unless stored or transported at different times or in such a way that the packaging material and the manner of storage or transport cannot be a source of contamination for the meat.

([1]) Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

▼C1

SECTION II: MEAT FROM POULTRY AND LAGOMORPHS

CHAPTER I: TRANSPORT OF LIVE ANIMALS TO THE SLAUGHTERHOUSE

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

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

2. Animals 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 animals 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 animals must be cleaned, washed and disinfected.

CHAPTER II: REQUIREMENTS FOR SLAUGHTERHOUSES

▼M27

Food business operators must ensure that the construction, layout and equipment of slaughterhouses in which poultry or lagomorphs are slaughtered meet the requirements laid down in the following points 1 to 7. Mobile partial slaughterhouses must operate in cooperation with complementary permanent slaughtering facilities in order to constitute a complete slaughterhouse complying with the requirements laid down in the following points 1 to 7. Mobile partial slaughterhouses may operate with several complementary slaughtering facilities, thus constituting several slaughterhouses.

▼C1

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

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 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:

      (i) stunning and bleeding;

      (ii) plucking or skinning, and any scalding;

      and

      (iii) dispatching meat;

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

   and

▼C1

(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.

3. They must have facilities for disinfecting tools with hot water supplied at not less than 82 °C, 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:

(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.

7. 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 meat from poultry or lagomorphs:

(a) are constructed so as to avoid contamination of meat, in particular by:

(i) allowing constant progress of the operations;

or

(ii) ensuring separation between the different production batches;

(b) have rooms for the separate storage of packaged and exposed meat, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat;

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

▼C1

(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 °C, 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 or lagomorphs are slaughtered must ensure compliance with the following requirements.

1. (a) Meat from animals other than those referred to in (b) must not be used for human consumption if they die otherwise 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, geese and ducks reared for the production of 'foie gras' and birds that are not considered as domestic but which are farmed as domestic animals, if slaughtered at the farm in accordance with Chapter VI;

(ii) farmed game slaughtered at the place of production in accordance with Section III;

and

(iii) small wild game in accordance with Section IV, Chapter III.

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, evisceration and other dressing 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 animals can be inspected properly.

▼C1

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 animals must be cleaned and chilled to not more than 4 °C as soon as possible, unless the meat is cut while warm.

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

   (a) Every precaution must be taken to avoid 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 and at least once a day.

10. Sick or suspect animals, and animals 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.

CHAPTER V: HYGIENE DURING AND AFTER CUTTING AND BONING

Food business operators must ensure that cutting and boning of meat of poultry and lagomorphs 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;

   (b) during cutting, boning, trimming, slicing, dicing, wrapping and packaging, the temperature of the meat is maintained at not more than 4 °C by means of an ambient temperature of 12 °C 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 to the cutting room either:

   (a) directly from the slaughter premises;

   or

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

▼M9

3. As soon as the meat is cut and, where appropriate, packaged, it must be chilled to a temperature of not more than 4 °C.

4. Meat must attain a temperature of not more than 4 °C before transport, and be maintained at that temperature during transport. However, if the competent authority so authorises, livers for the production of *foie gras* may be transported at a temperature of more than 4 °C, provided that:

   (a) 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

   (b) the meat leaves the slaughterhouse, or a cutting room immediately and transport takes no more than two hours.

▼M23

5. Meat intended for freezing must be frozen without undue delay.

   However, food business operators carrying out a retail activity may freeze meat in view of its redistribution for the purpose of food donations in accordance with the following conditions:

   (i) in the case of meat for which a ‘use by’ date is applied in accordance with Article 24 of Regulation (EU) No 1169/2011, before the expiry of that date;

   (ii) without undue delay to a temperature of – 18 °C or lower;

   (iii) ensuring that the date of freezing is documented and provided either on the label or by other means;

   (iv) excluding meat that has been frozen before (defrosted meat); and,

   (v) in accordance with any condition laid down by the competent authorities for freezing and further use as food.

▼M9

6. Exposed meat must be stored and transported separately from packaged meat, unless stored or transported at different times or in such a way that the packaging material and the manner of storage or transport cannot be a source of contamination for the meat.

▼C1

CHAPTER VI: SLAUGHTER ON THE FARM

Food business operators may slaughter poultry referred to in Chapter IV, point 1 (b)(i), 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.

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

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▼M25

7. In addition to the food chain information to be submitted in accordance with Section III of Annex II to this Regulation, the animal health certificate set out in Chapter 2 of Annex IV to Implementing Regulation (EU) 2020/2235 must accompany the slaughtered animal to the slaughterhouse or cutting plant, or be sent in advance in any format.

▼C1

8. In the case of poultry reared for the production of ‘foie gras’, the unevisceratedbirds must be transported immediately and, if necessary, refrigerated to a slaughterhouse or cutting plant. They must be eviscerated within 24 hours of slaughter under the supervision of the competent authority.

9. 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 °C. It must then be eviscerated in a slaughterhouse or in a cutting plant located in the same Member State as the farm of production.

▼M1

CHAPTER VII: WATER RETENTION AGENTS

Food business operators shall ensure that poultrymeat that has been treated specifically to promote water retention is not placed on the market as fresh meat but as meat preparations or used for the production of processed products.

▼C1

SECTION III: MEAT OF FARMED GAME

▼M23

1. The provisions of Section I apply to the production and placing on the market of meat from even-toed farmed game mammals, unless the competent authority considers them inappropriate.

▼C1

2. The provisions of Section II apply to the production and placing on the market of meat from ratites. However, those of Section I apply where the competent authority considers them appropriate. Appropriate facilities must be provided, adapted to the size of the animals.

3. Notwithstanding points 1 and 2, food business operators may slaughter farmed ratites and farmed ungulates referred to in point 1 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;

(b) the herd undergoes regular veterinary inspection;

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

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

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

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

(g) animal welfare requirements are complied with;

▼M27

(h) slaughtered and bled animals are transported to the slaughterhouse or to a game-handling establishment, as appropriate, hygienically and without undue delay. If transport takes more than two hours, the animals must be refrigerated; where climatic conditions so permit, active chilling shall not be required. Evisceration may take place on the spot, under the supervision of the official veterinarian;

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(j) the health certificate set out in Chapter 3 of Annex IV to Implementing Regulation (EU) 2020/2235, issued and signed by the official veterinarian, attesting to a favourable result of the ante-mortem inspection, correct slaughter and bleeding and the date and time of slaughter, must accompany the slaughtered animal to the slaughterhouse or to a game-handling establishment, as appropriate, or must be sent in advance in any format.

3a By way of derogation from point 3(j), the competent authority may authorise that the attestation of the correct slaughter and bleeding and of the date and time of slaughter be included only in the food chain information in accordance with Section III to Annex II of this Regulation provided that:

(a) the holding is not situated in a restricted zone defined in Article 4(41) of Regulation (EU) 2016/429;

(b) the food business operator has demonstrated the appropriate level of competence to slaughter animals without causing the animals any avoidable pain, distress or suffering in accordance with Article 7(2) of Regulation (EC) No 1099/2009 and without prejudice to Article 12 of that Regulation.

▼C1

4. Food business operators may also slaughter bison on the farm in accordance with point 3 in exceptional circumstances.

SECTION IV: WILD GAME MEAT

▼M23

For the purpose of this Section, ‘collection centre’ means an establishment used to store the bodies and viscera of wild game before their transport to a game handling establishment.

▼C1

CHAPTER I: TRAINING OF HUNTERS IN HEALTH AND HYGIENE

1. Persons who hunt wild game with a view to placing it on the market for human consumption must have sufficient knowledge of the pathology of wild game, and of the production and handling of wild game and wild game meat after hunting, to undertake an initial examination of wild game on the spot.

2. It is however enough if at least one person of a hunting team has the knowledge referred to in point 1. References in this Section to a ‘trained person’ are references to that person.

3. The trained person could also be the gamekeeper or the game manager if he or she is part of the hunting team or located in the immediate vicinity of where hunting is taking place. In the latter case, the hunter must present the wild game to the gamekeeper or game manager and inform them of any abnormal behaviour observed before killing.

▼C1

4. 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.

5. 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 and, if necessary, be bled.

2. The trained person must carry out an examination of the body, and of any viscera removed, to identify any characteristics that may indicate that the meat presents a health risk. The examination must take place as soon as possible after killing.

3. Meat of large wild game may be placed on the market only if the body is transported to a game-handling establishment as soon as possible after the examination referred to in point 2. The viscera must accompany the body as specified in point 4. The viscera must be identifiable as belonging to a given animal.

▼M10

4. (a) If no abnormal characteristics are found during the examination referred to in point 2, no abnormal behaviour was observed before killing, and there is no suspicion of environmental contamination, the trained person must attach to the animal body a numbered declaration stating this. This declaration must also indicate the date, time and place of killing.

   The declaration need not be attached to the animal body and may cover more than one animal body, provided that each animal body is appropriately identified and the declaration bears an indication of the identification number of each animal body covered by it, with the corresponding date, time and place of killing. All animal bodies covered by a single declaration may only be sent to a single game-handling establishment.

   The head and the viscera need not accompany the body to the game-handling establishment, except in the case of species susceptible to trichinosis (porcine animals, solipeds and others), whose heads (except for tusks) and diaphragm must accompany the body.

   However, the competent authority may authorise that heads of animals susceptible to *Trichinella* infestation be sent to a technical plant for the production of game trophies, which has been approved in accordance with Article 18 of Regulation (EC) No 1774/2002. The technical plant shall be indicated in the declaration of the trained person. A copy of that declaration shall be sent to the technical plant. Where the results of the *Trichinella* examination of the carcase are positive, the competent authority shall carry out an official check to verify the proper handling of the head in the technical plant.

▼M10

However, hunters must comply with any additional requirements imposed in the Member State where hunting takes place, in particular to permit the monitoring of certain residues and substances in accordance with Directive 96/23/EC.

▼C1

(b) In other circumstances, the head (except for tusks, antlers and horns) and all the viscera except for the stomach and intestines must accompany the body. The trained person who carried out the examination must inform the competent authority of the abnormal characteristics, abnormal behaviour or suspicion of environmental contamination that prevented him or her from making a declaration in accordance with (a);

▼M23

(c) If no trained person is available to carry out the examination referred to in point 2 in a particular case, the head, except for tusks, antlers and horns, and all the viscera, except for the stomach and the intestines, must accompany the body which must be transported to a game handling-establishment as soon as possible after killing.

▼C1

5. Chilling must begin within a reasonable period of time after killing and achieve a temperature throughout the meat of not more than 7 °C. Where climatic conditions so permit, active chilling is not necessary.

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

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

▼M16

8. In addition, unskinned large wild game:

(a) may be skinned and placed on the market only if:

(i) before skinning, it is stored and handled separately from other food and it is not frozen;

(ii) after skinning, it undergoes a final inspection in a game-handling establishment in accordance with Regulation (EC) No 854/2004;

▼M23

(b) may be sent to a game handling establishment in another Member State only if, during transport to that game-handling establishment, it is accompanied by an official certificate set out in Chapter 2 of Annex II to Implementing Regulation (EU) 2020/2235 issued and signed by an official veterinarian, attesting that the requirements set out in point 4 of this Chapter as regards the availability of a declaration, when relevant, and the accompaniment of relevant parts of the body, have been complied with.

▼M16

In case the game handling establishment, close to the hunting area, is in another Member State, transport to this game handling establishment need not be accompanied by the certificate but by the declaration of the trained person referred to in point 2 to comply with Article 3(1) of Directive 89/662/EEC, taking into account the animal health status of the Member State of origin.

▼C1

9. The rules laid down in Section I, Chapter V, apply to the cutting and boning of large wild game.

▼M23

10. The bodies and viscera of large wild game may be transported to and stored in a collection centre before being sent to a game handling establishment provided that:

▼M23

(a) the collection centre is either:

(1) registered with the competent authority as a food business carrying out primary production as referred to in Article 4(2)(a) when only receiving bodies as first collection centre, or

(2) approved by the competent authority as a food business in accordance with Article 4(2) when receiving bodies from other collection centres;

(b) if the animals are eviscerated, their heaping is prohibited during transport to and storage in the collection centre;

(c) killed animals are transported to the collection centre hygienically and without delay;

(d) the temperature conditions laid down in point 5 are complied with;

(e) storage time is kept to the minimum possible;

(f) no other handling takes place on the bodies and viscera of the large wild game; however the examination by a trained person and the removal of viscera may take place under the conditions laid down in points 2, 3 and 4.

▼C1

CHAPTER III: HANDLING OF SMALL WILD GAME

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

2. If abnormal characteristics are found during the examination, abnormal behaviour was observed before killing, or environmental contamination is suspected, the trained person must inform the competent authority.

▼M23

3. Meat of small wild game may be placed on the market only if the body is transported to a game-handling establishment as soon as possible after the examination referred to in point 1 or, if no trained person is available to carry out that examination in a particular case, as soon as possible after killing

▼C1

4. Chilling must begin within a reasonable period of time of killing and achieve a temperature throughout the meat of not more than 4 °C. Where climatic conditions so permit, active chilling is not necessary.

5. Evisceration must be carried out, or completed, without undue delay upon arrival at the game -handling establishment, unless the competent authority permits otherwise.

6. Small wild game delivered to a game-handling establishment must be presented to the competent authority for inspection.

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

▼M23

8. The bodies, including viscera, of small wild game may be transported to and stored in a collection centre before being sent to a game handling establishment provided that:

(a) the collection centre is either:

(1) registered with the competent authority as a food business carrying out primary production as referred to in Article 4(2)(a) when only receiving bodies as first collection centre, or

(2) approved by the competent authority as a food business in accordance with Article 4(2) when receiving bodies from other collection centres;

(b) if the animals are eviscerated, their heaping is prohibited during transport to and storage in the collection centre;

(c) killed animals are transported to the collection centre hygienically and without delay;

(d) the temperature conditions laid down in point 4 are complied with;

(e) storage time is kept to the minimum possible;

(f) no other handling takes place on the bodies, including viscera, of the small wild game; however the examination by a trained person and the removal of viscera may take place under the conditions laid down in points 1 and 2.

▼C1

SECTION V: MINCED MEAT, MEAT PREPARATIONS AND MECHANICALLY SEPARATED MEAT (MSM)

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 avoid contamination of meat and products, in particular by:

(a) allowing constant progress of the operations;

or

(b) ensuring separation between the different production batches;

2. have rooms for the separate storage of packaged and exposed meat and products, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat or products;

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

4. have equipment for washing hands used by staff handling exposed meat and products 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 °C, or an alternative system having an equivalent effect.

▼C1

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 comply with the requirements for fresh meat;

   (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);

      (ii) MSM;

      (iii) meat containing bone fragments or skin;

         or

      (iv) 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).

2. The following raw material may be used to prepare meat preparations:

   (a) fresh meat;

   (b) meat meeting the requirements of point 1;

      and

   (c) if the meat preparation is clearly not intended to be consumed without first undergoing heat treatment:

      (i) meat derived from the mincing or fragmentation of meat meeting the requirements of point 1 other than point 1(c)(i);

         and

      (ii) MSM meeting the requirements of Chapter III, point 3(d).

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

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

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

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

         and

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

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 °C for poultry, 3 °C for offal and 7 °C for other meat;

      and

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

▼C1

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 be stored only for a limited period.

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

(i) in the case of poultry, within no more than three days of their slaughter;

(ii) in the case of animal other than poultry, within no more than six days of their slaughter;

or

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

(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 °C 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 and use of MSM produced using techniques that do not alter the structure of the bones used in the production of MSM and the calcium content of which is not significantly higher than that of minced meat.

(a) Raw material for deboning from an on-site slaughterhouse must be no more than seven days old; otherwise, raw material for deboning must be no more than five days old. However, poultry carcases must be no more than three days old.

(b) Mechanical separation must take place immediately after deboning.

(c) If not used immediately after being obtained, MSM must be wrapped or packaged and then chilled to a temperature of not more than 2 °C or frozen to an internal temperature of not more than –18 °C. These temperature requirements must be maintained during storage and transport.

(d) If the food business operator has carried out analyses demonstrating that MSM complies with the microbiological criteria for minced meat adopted in accordance with Regulation (EC) No 852/2004 it may be used in meat preparations that are clearly not intended to be consumed without first undergoing heat treatment and in meat products.

(e) MSM not shown to comply with the criteria referred to in (d) may be used only to manufacture heat-treated meat products in establishments approved in accordance with this Regulation.

▼C1

4. The following requirements apply to the production and use of MSM produced using techniques other than those mentioned in point 3.

(a) Raw material for deboning from an on-site slaughterhouse must be no more than seven days old; otherwise, raw material for deboning must be no more than five days old. However, poultry carcases must be no more than three 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 of not more than 2 °C or, if frozen, at a temperature of not more than -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 and reach an internal temperature of not more than –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 °C during storage and transport.

(g) MSM may be used only to manufacture heat-treated meat products in establishments approved in accordance with this Regulation.

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

▼M27

6. Meat preparations subjected to dry-ageing, shall comply with the requirements laid down in Section I, Chapter VII, point 2a of this Annex III.

▼C1

CHAPTER IV: LABELLING

1. In addition to the requirements of Directive 2000/13/EC ([1]), food business operators must ensure compliance with the requirement of point 2 if, and to the extent that, national rules in the Member State in the territory of which the product is placed on the market so require.

2. Packages intended for supply to the final consumer containing minced meat from poultry or solipeds or meat preparations containing MSM must bear a notice indicating that such products should be cooked before consumption.

SECTION VI: MEAT PRODUCTS

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

(a) genital organs of either female or 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;

([1]) Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29). Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

▼C1

(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. All meat, including minced meat and meat preparations, used to produce meat product must meet the requirements for fresh meat. However, minced meat and meat preparations used to produce meat products need not satisfy other specific requirements of Section V.

SECTION VII: LIVE BIVALVE MOLLUSCS

▼M19

1. This Section applies to live bivalve molluscs. With the exception of the provisions on purification, it also applies to live echinoderms, live tunicates and live marine gastropods. The provisions on the classification of production areas set out in Chapter II, Part A, of that Section do not apply to marine gastropods and to echinoderms which are not filter feeders.

▼M23

1a. For the purpose of this Section, ‘intermediary operator’ means a food business operator, including traders, other than the first supplier, with or without premises, who carries out its activities between production areas, relaying areas or any establishments.

▼C1

2. Chapters I to VIII apply to animals harvested from production areas that the competent authority has classified in accordance with Regulation (EC) No 854/2004. Chapter IX applies to pectinidae harvested outside those areas.

3. Chapters V, VI, VIII and IX, and point 3 of Chapter VII, apply to retail.

4. The requirements of this Section supplement those laid down in Regulation (EC) No 852/2004:

(a) In the case of operations that take place before live bivalve molluscs arrive at a dispatch or purification centre, they supplement the requirements of Annex I to that Regulation.

(b) In the case of other operations, they supplement the requirements of Annex II to that Regulation.

CHAPTER I: GENERAL 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 otherwise 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 set out in points 3 to 7 have been complied with.

▼M23

3. Whenever a food business operator moves a batch of live bivalve molluscs between production areas, relaying areas or any establishments, a registration document must accompany the batch.

▼C1

4. The registration document must be in at least one official language of the Member State in which the receiving establishment is located and contain at least the information specified below.

▼C1

(a) In the case of a batch of live bivalve molluscs sent from a production area, the registration document must contain at least the following information:

(i) the gatherer's identity and address;

(ii) the date of harvesting;

(iii) the location of the production area described in as precise detail as is practicable or by a code number;

(iv) the health status of the production area;

(v) the shellfish species and quantity;

and

(vi) the destination of the batch.

(b) In the case of a batch of live bivalve molluscs sent from a relaying area, the registration document must contain at least the information referred to in (a) and the following information:

(i) the location of the relaying area;

and

(ii) the duration of relaying.

(c) In the case of a batch of live bivalve molluscs sent from a purification centre, the registration document must contain at least the information referred to in (a) and the following information:

(i) the address of the purification centre;

(ii) the duration of purification;

and

(iii) the dates on which the batch entered and left the purification centre.

▼M23

(d) Where a batch of live bivalve molluscs is sent by an intermediary operator, a new registration document, filled-in by the intermediary operator, must accompany the batch. The registration document must contain at least the information referred to in points (a), (b) and (c) and the following information:

(i) the name and address of the intermediary operator;

(ii) in the case of conditioning or in the case of re-immersion for storing purpose, the date of starting, the date of end and the place of the conditioning or the re-immersion;

(iii) if a conditioning in a natural site was carried out, the intermediary operator must confirm that the natural site where the conditioning took place was classified at the time of conditioning as an class A production area open for harvest;

(iv) if a re-immersion in natural site was carried out, the intermediary operator must confirm that the natural site where the re-immersion took place was classified at the time of re-immersion with the same classification of the production area where the live bivalve molluscs were harvested.

(v) if a re-immersion was carried out in an establishment, the intermediary operator must confirm that the establishment was approved at the time of the re-immersion. The re-immersion shall not cause additional contamination to the live bivalve molluscs.

(vi) in the case of grouping, the species, the date when the grouping started, the date of the end of the grouping, the status of the area where the live bivalve molluscs were harvested, and the batch of the grouping, that always consists of the same species, captured on the same date, and in the same production area.

▼C1

5. 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.

6. 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).

7. However, 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) a single competent authority supervises all the establishments concerned,

registration documents are not necessary if that competent authority so permits.

▼M23

8. Intermediary operators must be:

(a) registered with the competent authority as a food business carrying out primary production as referred to in Article 4(2)(a) if they do not have premises or if they have premises where they only handle, wash and store at ambient temperature live bivalve molluscs, without grouping nor conditioning, or

(b) approved by the competent authority as a food business operator in accordance with Article 4(2) if, in addition to carrying out the activities referred to in point (a), they have a cold store or they group or split batches of live bivalve molluscs or they carry out conditioning or re-immersion.

9. Intermediary operators may receive live bivalve molluscs from production areas classified as A, B or C, from relaying areas or from other intermediary operators. Intermediary operators can send live bivalve molluscs:

(a) from class A production areas to dispatch centres or another intermediary operator;

(b) from class B production areas only to purification centres, processing establishments or to another intermediary operator;

(c) from class C production areas to processing establishments or to another intermediary operator with premises.

▼C1

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 cooperation with food business operators — as being of class A, B or C in accordance with Regulation (EC) No 854/2004.

2. Food business operators may place live bivalve molluscs collected from class A production areas on the market for direct human consumption only 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.

▼C1

4. Food business operators may place live bivalve molluscs collected from class C production areas on the market for human consumption only after relaying over a long period in accordance with Part C of this Chapter.

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 for purification or relaying may be sent to a processing establishment, where they must undergo treatment to eliminate pathogenic micro-organisms (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;

   and

   (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). A validated methodology must be used. Procedures based on the HACCP principles must be in place to verify the uniform distribution of heat.

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.

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;

▼C1

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

and

(d) if carrying out conditioning in natural sites, use only areas that the competent authority has classified as being of class A.

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.

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

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

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

(c) immerse live bivalve molluscs in seawater at the relaying area for an appropriate period, fixed depending on the water temperature, which period must be of at least two months' duration unless the competent authority agrees to a shorter period on the basis of the food business operator's risk analysis;

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.

▼C1

(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.

▼M23

1. Before purification commences, live bivalve molluscs must be free of mud and accumulated debris and washed if necessary, using clean water.

▼C1

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 achieve compliance with allow the health standards of Chapter V and microbiological criteria adopted in accordance with Regulation (EC) No 852/2004.

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 clean 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, wrapping 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.

▼C1

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

In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, 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. They must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits:

▼M23

(a) for paralytic shellfish poison (PSP), 800 micrograms of saxitoxin equivalents diHCl per kilogram;

▼C1

(b) for amnesic shellfish poison (ASP), 20 milligrams of domoic acid per kilogram;

▼M23

(c) for okadaic acid and dinophysistoxins together 160 micrograms of okadaic acid equivalents per kilogram;

▼M14

(d) for yessotoxins, 3,75 milligrams of yessotoxin equivalent per kilogram;

▼C1

and

(e) for azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram.

CHAPTER VI: WRAPPING AND PACKAGING OF LIVE BIVALVE MOLLUSCS

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

▼M9

2. All packages of live bivalve molluscs leaving dispatch centres or destined for another dispatch centre, must be closed. Packages of live bivalve molluscs, intended for direct retail sale, must remain closed until they are presented for sale to the final consumer.

▼C1

CHAPTER VII: IDENTIFICATION MARKING AND LABELLING

1. The label, including the identification mark, must be waterproof.

▼C1

2. In addition to the general requirements for identification marks contained in Annex II, 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 food safety or their 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.

▼M25

CHAPTER IX: SPECIFIC REQUIREMENTS FOR PECTINIDAE, MARINE GASTROPODS AND ECHINODERMS WHICH ARE NOT FILTER FEEDERS HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS

Food business operators harvesting pectinidae, marine gastropods and echinoderms which are not filter feeders, outside classified production areas or handling such pectinidae, and/or such marine gastropods and/or echinoderms must comply with the following requirements:

1. Pectinidae, marine gastropods and echinoderms which are not filter feeders, must not be placed on the market unless they are harvested and handled in accordance with Part B of Chapter II and meet the standards laid down in Chapter V, as demonstrated by a system of own checks by the food business operators operating a fish auction, a dispatch centre or a processing establishment;

2. In addition to point 1, where data from official monitoring programmes enable the competent authority to classify fishing grounds – where appropriate, in cooperation with food business operators – the provisions of Part A of Chapter II apply by analogy to pectinidae;

3. Pectinidae, marine gastropods and echinoderms which are not filter feeders, must not be placed on the market for human consumption otherwise than via a fish auction, a dispatch centre or a processing establishment. When they handle pectinidae and/or such marine gastropods, and/or echinoderms 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, marine gastropods and echinoderms which are not filter feeders, must comply with the following requirements:

▼M25

(a) with the documentary requirements of Chapter I, points 3 to 7, where applicable. In this case, the registration document must clearly indicate the location of the area, indicating the system used to describe the coordinates, where the live pectinidae and/or live marine gastropods and/or live echinoderms were harvested; or

(b) with the requirements of Chapter VI, point 2, concerning the closing of all packages of live pectinidae, live marine gastropods and live echinoderms dispatched for retail sale and Chapter VII concerning identification marking and labelling.

▼M23

CHAPTER X: MODEL OF REGISTRATION DOCUMENT OF LIVE BIVALVE MOLLUSCS, LIVE ECHINODERMS, LIVE TUNICATES AND LIVE MARINE GASTROPODS

REGISTRATION DOCUMENT OF LIVE BIVALVE MOLLUSCS, LIVE ECHINODERMS, LIVE TUNICATES AND LIVE MARINE GASTROPODS

Part I – Supplier

I.1 IMSOC Reference number	**I.2 Internal reference number**
I.3 Supplier Name Address Registration or Approval No Country ISO Country code Activity	**I.4 Receiving food business operator** Name Address Registration or Approval No Country ISO Country code Activity
I.5 Description of goods **Aquaculture** □ Natural Banks □ • CN code or FAO 3-Alpha code | species | quantity | package | batch | date of harvesting| date of starting of conditioning | date of end of conditioning | place of conditioning| date of starting of re-immersion | date of end of re-immersion |place of re-immersion| date of starting of grouping | date of end of grouping | production area | health status including, if applicable, harvested in accordance with Article 62(2) of Implementing Regulation (EU) 2019/627	
I.6 From relaying area Yes □ No □ Relaying area Duration of relaying Date of starting Date of end	**I.7 From purification/dispatch centre** **Auction hall Yes □ No □** **Purification/dispatch centre/auction hall approval number** **Date of entry** **Date of exit** **Duration of purification**
I.8 From Intermediary operator **Yes □ No □** **Name** **Address** **Registration or Approval No** **Country** **ISO Country code** **Activity** **Date of arrival** **Date of exit**	
I.9 Declaration of the supplier I, the undersigned food business operator responsible for dispatching the consignment declare that, to the best of my knowledge and belief, the information provided in Part I of this document is true and complete.	

▼M23

REGISTRATION DOCUMENT OF LIVE BIVALVE MOLLUSCS, LIVE ECHINODERMS, LIVE TUNICATES AND LIVE MARINE GASTROPODS

	Date	Name of signatory	Signature
Part II – Receiving operator	**II.1 Internal reference number (receiving)**		
	II.2 Declaration of the receiving food business operator I, the undersigned food business operator responsible for receiving the consignment declare that the consignment has arrived on [DATE] in my premises.		
	Name of signatory	Signature	

Explanatory notes

Box	Description
	Part I – Supplier
	This part of the document shall be filled by the food business operator dispatching a batch of live bivalve molluscs.
I.1	**IMSOC reference number** This is the unique alpha-numeric code assigned by the IMSOC
I.2	**Internal reference number** This box may be used by the **dispatching** food business operator to indicate an internal reference number.
I.3	**►M25 Supplier** Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the establishment of origin. In the case of production areas, please indicate the area as authorised by the competent authorities (CAs). In the case of live pectinidae, marine gastropods or echinoderms, indicate the location of the harvesting area. Where applicable, indicate the registration or approval number of the establishment. Indicate the activity (gatherer, purification centre, dispatch centre, auction hall or intermediary activities). Where the batch of live bivalve molluscs is sent from a purification centre/dispatch centre, or, in case of pectinidae, marine gastropods and echinoderms which are not filter feeders harvested outside classified production areas, from a fish auction, indicate the approval number and the address of the purification centre/dispatch centre or fish auction. ◄
I.4	**Receiving food business operator** Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the establishment of destination. In the case of production or relaying areas please indicate the area as authorised by the CAs. Where applicable, indicate the registration or approval number of the establishment Indicate the activity (gatherer, purification centre, dispatch centre, processing establishment or intermediary activities).
I.5	**Description of goods** Indicate as required, the Combined Nomenclature code or FAO 3-Alpha code, species, quantity, type of packaging (bags, bulk, etc.), batch, date of harvesting, date of starting and end of conditioning (when applicable), place of conditioning (indicate the classification of the production area and its location or the approval number of the establishment, when applicable), date of starting and end of re-immersion (when applicable), place of re-immersion (indicate the classification of the production area and its location or the approval number of the establishment when applicable), date of starting and end of grouping (when applicable), production area and its health status (classification of the production area when applicable). When LBMs have been harvested in accordance with Article 62(2) of the Implementing Regulation 2019/627 then this should be explicitly stated.

▼M23

Box	Description
	When grouping of live bivalve molluscs is performed, the batch must refer to bivalves of the same species, harvested on the same day and coming from the same production area. Delete as appropriate
I.6	**From relaying area** Where the batch of live bivalve molluscs is sent from a relaying area, indicate the relaying area, as authorised by the CAs, and the duration of the relaying (date of starting and end).
I.7	►M25 **From purification centre/dispatch centre or fish auction** Where the batch of live bivalve molluscs is sent from a purification centre/dispatch centre, or, in case of pectinidae, marine gastropods and echinoderms which are not filter feeders harvested outside classified production areas, from an auction hall, indicate the approval number and the address of the purification centre/dispatch centre or auction hall. If sent from a purification centre, the duration of the purification and the dates on which the batch entered and left the purification centre. Delete as appropriate. ◄
I.8	**From intermediary operator** Indicate the name and address (street, city and region/province/state, as appropriate), country and ISO country code of the intermediary operator. Where applicable, indicate the registration or approval number and the activity.
I.9	**Declaration of the supplier** Include the date, name of the signatory and the signature.

Part II – Receiving food business operator

This part of the document shall be filled by the food business operator receiving a batch of live bivalve molluscs.

II.1	**Internal reference number (receiving)** This box may be used by the food business operator receiving the batch to indicate an internal reference number.
II.2	**Declaration of the receiving food business operator** Indicate the date of arrival of the batch of live bivalve molluscs at the premises of the receiving food business operator. In the case of an intermediary operator without premises indicate the date of purchase of the batch. Include the name of the signatory and the signature.

▼C1

SECTION VIII: FISHERY PRODUCTS

▼M25

1. This Section shall not apply to bivalve molluscs, echinoderms, tunicates and marine gastropods if they are still alive when placed on the market. With the exception of Chapters I and II, it shall apply to such animals when they are not placed on the market live, in which case they must have been obtained in accordance with Section VII.

   For the purpose of this Section, 'superchilling' means a process by which the temperature of fresh fishery product is lowered to between the initial freezing point of the fish and about 1 to 2 °C lower.

   This Section shall apply to thawed unprocessed fishery products and fresh fishery products to which food additives have been added in accordance with the appropriate Union legislation.

▼M6

2. Chapter III, Parts A, C and D, Chapter IV, Part A and Chapter V apply to retail.

▼C1

3. The requirements of this Section supplement those laid down in Regulation (EC) No 852/2004:

   (a) In the case of establishments, including vessels, engaged in primary production and associated operations they supplement the requirements of Annex I to that Regulation.

▼C1

(b) In the case of other establishments, including vessels, they supplement the requirements of Annex II to that Regulation.

▼M6

(c) In the case of water supply, they supplement the requirements of Annex II, Chapter VII to that Regulation; clean seawater may be used for the handling and washing of fishery products, the production of ice used to chill fishery products and the rapid cooling of crustaceans and molluscs after their cooking.

▼M5

By way of derogation from point (a), point 7 of Part A of Annex I to Regulation (EC) No 852/2004 may not apply to operators engaged in small-scale coastal fishing within the meaning of Article 26(1) of Council Regulation (EC) No 1198/2006 ([1]), and carrying out their activities only for short periods of less than 24 hours.

▼C1

4. In relation to fishery products:

(a) primary production covers the farming, fishing and collection of live fishery products with a view to their being placed on the market;

and

(b) associated operations cover any of the following operations, if carried out on board fishing vessels: slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping; they also include:

1. the transport and storage of fishery products the nature of which has not been substantially altered, including live fishery products, within fish farms on land;

and

2. the transport of fishery products the nature of which has not been substantially altered, including live fishery products, from the place of production to the first establishment of destination.

CHAPTER I: REQUIREMENTS FOR VESSELS

Food business operators must ensure that:

▼M23

1. vessels used to harvest fishery products from their natural environment, or to handle or process them after harvesting, and reefer vessels comply with the structural and equipment requirements laid down in Part I; and

▼C1

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**

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.

([1]) OJ L 223, 15.8.2006, p. 1.

▼C1

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

4. When vessels have a water intake for water used with fishery products, it must be situated in a position that avoids contamination of the water supply.

▼M23

5. Vessels must be designed and constructed so as not to cause contamination of the fishery products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances. Holds, tanks, or containers used for storing, cooling or freezing unprotected fishery products including those destined for the production of feed, shall not be used for other purposes than the storing, cooling or freezing those products, as well as ice or brine used for such purposes. In the case of reefer vessels, the provisions applicable to unprotected fishery products apply to all the products transported.

▼C1

B. **Requirements for vessels designed and equipped to preserve fresh fishery products for more than 24 hours**

1. Vessels designed and equipped to preserve fishery products for more than 24 hours must be equipped with holds, tanks or containers for the storage of fishery products at the temperatures laid down in Chapter VII.

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 seawater, 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 seawater reaches not more than 3 °C six hours after loading and not more than 0 °C after 16 hours and allow the monitoring and, where necessary, recording of temperatures.

▼M28

C. **Requirements for freezer vessels**

1. Freezer vessels must:

(a) have freezing equipment with sufficient capacity to freeze as quickly as possible in a continuous process and with a thermal arrest period as short as possible, so as to achieve a core temperature of not more than – 18 °C;

(b) have refrigeration equipment with a sufficient capacity to maintain fishery products in the storage holds at not more than – 18 °C. Storage holds must not be used for freezing

▼M28

unless they fulfil the conditions laid down in (a) of this point and 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;

(c) meet the requirements for vessels designed and equipped to preserve fishery products for more than 24 hours laid down in Part I.B, point 2.

2. In addition to the requirements laid down in point 1 of this Part, freezer vessels that freeze tuna in brine as referred to in Part II, point 8, must be equipped with a system that:

(a) continuously monitors in real-time and records the temperature of the brine on board using electronic means of temperature measurement;

(b) allows real-time onshore monitoring of the temperature of the brine by the food business operator.

3. The food business operators of freezer vessels that freeze tuna in brine as referred to in Part II, point 8, must give access, upon request, to the competent authorities to the data on the temperature of the brine collected through the system referred to in point 2(a) and (b) of this Part.

4. The food business operators of freezer vessels that freeze tuna in brine as referred to in Part II, point 8, must set up a validation plan regarding the freezing capacity of the freezer vessels freezing tuna in brine, that must include the following:

(a) coherent kinetic studies and a correlation curve between brine and core temperature, on the one hand, and the time and cooling periods as referred to in Part II, points 8(a) and (b), on the other hand; these studies and correlation curve must be based on the tuna temperature recorded by the instruments placed in sampled tunas as well as other criteria that the competent authorities may establish;

(b) evidence that the temperature probes or sensors are certified in accordance with the relevant international temperature measurements standards.

5. The competent authority must check the validation plan, and identify the freezing capacity, of freezer vessels that freeze tuna in brine as referred to in Part II, point 8, during the approval process of those freezer vessels in accordance with Article 4(3) of this Regulation or, in the case of freezer vessels flying the flag of a third country, when placing the freezer vessels on the list drawn up in accordance with Article 127(3), points (e)(ii) and (iii), of Regulation (EU) 2017/625.

▼C1

D. **Requirements for factory vessels**

1. Factory vessels must have at least:

▼C1

(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 disposing 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. However, factory vessels on board which crustaceans and molluscs are cooked, chilled and wrapped, need not meet the requirements of point 1 if no other form of handling or processing takes place on board such vessels.

3. ►M28 Factory vessels that freeze fishery products must have equipment meeting the requirements for freezer vessels laid down in Part I.C, points 1(a) and 1(b). ◄

▼M23

E. **Requirements for reefer vessels**

▼M28

Reefer vessels transporting and/or storing frozen fishery products in bulk must have equipment meeting the requirements for freezer vessels laid down in point 1(b) of Part C concerning their capacity to maintain the temperature.

▼C1

II. HYGIENE REQUIREMENTS

1. When in use, the parts of vessels or containers set aside for the storage of fishery products must be kept clean and maintained in good repair and condition. In particular, they must not be contaminated by fuel or bilge water.

▼C1

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. ►M6 ——————— ◄

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.

▼M6

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▼M23

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 fishery products must be washed immediately. The viscera and parts that may constitute a danger to public health must be removed as soon as possible and kept apart from fishery products intended for human consumption. Livers and roes intended for human consumption must be refrigerated or preserved under ice, at a temperature approaching that of melting ice, or be frozen.

7. Where freezing in brine of the whole fish intended for canning is practiced, a temperature of not more than – 9 °C must be achieved for the fishery product. Even if it is subsequently frozen at a temperature of – 18 °C, the whole fish initially frozen in brine at a temperature of not more than – 9 °C must be destined for canning. The brine must not be a source of contamination for the fish.

▼M28

8. Whole tuna (genus *Thunnus and Katsuwonus)* may be frozen in brine at – 18 °C at core in freezer vessels referred to in Section VIII, Chapter I, Part I.C, point 2 provided that the decrease in temperature is carried out in a continuous process, and subject to compliance with the following requirements:

(a) where a direct freezing process in brine is carried out, its total duration to reach – 18 °C at core must not exceed 96 hours after the first capture of tuna has been placed in brine, and the tuna must reach a core temperature below 0 °C in less than 24 hours;

(b) where a cooling process in cooled clean seawater is carried out before placing the tuna in brine, the temperature of the mixture of tuna and cooled clean seawater must reach 3 °C in less than 6 hours, and 0 °C in less than 16 hours; the total cooling process in cooled clean seawater must not exceed 72 hours after the first capture of tuna has been placed in the cooled clean seawater tank; once tuna is placed in brine, the total duration of the freezing process, from 0 °C to – 18 °C at core, must not exceed 72 hours;

▼**M28**

(c) food business operators must monitor the salt concentration of the brine and take appropriate action to maintain the salt concentration set out in their validation plan;

(d) for verification purposes, the food business operators must continuously record the temperature of a sample of tuna through a temperature-measuring instrument inserted in the temperature-sensitive part of the fish that will freeze last.

▼**C1**

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 specified in Chapter VII;

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 compliance with the following requirements.

(a) (i) There must be lockable facilities for the refrigerated storage of detained fishery products and separate lockable facilities for the storage of fishery products declared unfit for human consumption.

(ii) If the competent authority so requires, there must be an adequately equipped lockable facility or, where needed, room for the exclusive use of the competent authority.

(b) At the time of display or storage of fishery products:

(i) the premises must not be used for other purposes;

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

(iii) persons having access to the premises must not introduce other animals;

▼C1

and

(iv) the premises must be well lit to facilitate official controls.

3. When chilling was not possible on board the vessel, fresh fishery products, other than those kept alive, must undergo chilling as soon as possible after landing and be stored at a temperature approaching that of melting ice.

4. Food business operators must cooperate with relevant competent authorities so as to permit them to carry out official controls in accordance with Regulation (EC) No 854/2004, in particular as regards any notification procedures for the landing of fishery products that the competent authority of the Member State the flag of which the vessel is flying or the competent authority of the Member State where the fishery products are landed might consider necessary.

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

Food business operators must ensure compliance with the following requirements, where relevant, in establishments handling fishery products.

▼M25

A. REQUIREMENTS FOR FRESH FISHERY PRODUCTS

1. Whole and gutted fresh fishery products may be transported and stored in cooled water on board vessels. They may also continue to be transported in cooled water after landing, and be transported from aquaculture establishments, until they arrive at the establishment on land carrying out any activity other than transport or sorting. When three-layered polyethylene containers filled with water and ice are used, the whole and gutted fresh fishery products may be transported after arriving at the establishment on land carrying out other activity than transport provided that the requirements of Chapter VIII, point 1(a) are met.

2. 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 or in case of whole or gutted fresh fishery products, in three-layered polyethylene containers made of insulating material filled with ice and water.

3. Re-icing must be carried out as often as necessary. When three-layered polyethylene containers filled with water and ice are used, they must be clean and undamaged. The water must have a temperature as close to 0 ° C as possible and cover all the fish. Ice shall cover the whole surface of the water within containers, making sure that all fish is below the ice layer.

4. Packaged fresh fishery products must be chilled to a temperature approaching that of melting ice.

5. Operations such as heading and gutting must be carried out hygienically. Where gutting is possible from a technical and commercial viewpoint, it must be carried out as quickly as possible after the products have been caught or landed. The products must be washed thoroughly immediately after these operations.

▼M25

6. 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 work tables beyond the time necessary for their preparation. Fillets and slices must be wrapped and, where necessary, packaged and must be chilled as quickly as possible after their preparation.

7. Containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice must ensure that melt water is drained away and does not remain in contact with any fishery products.

▼M23

B. REQUIREMENTS FOR FROZEN PRODUCTS

▼M28

Establishments on land that freeze or store frozen fishery products must have equipment, adapted to the activity carried out, that satisfies the requirements for freezer vessels laid down in Section VIII, Chapter I, Part I.C, points 1(a) and 1(b).

▼C1

C. REQUIREMENTS FOR MECHANICALLY SEPARATED FISHERY PRODUCTS

Food business operators manufacturing mechanically separated fishery products must ensure compliance with the following requirements.

1. The raw materials used must satisfy the following requirements.

(a) Only whole fish and bones after filleting may be used to produce mechanically separated fishery products;

(b) All raw materials must be free from guts.

2. The manufacturing process must satisfy the following requirements:

(a) Mechanical separation must take place without undue delay after filleting.

(b) If whole fish are used, they must be gutted and washed beforehand.

(c) After production, mechanically separated fishery products must be frozen as quickly as possible or incorporated in a product intended for freezing or a stabilising treatment.

▼M11

D. REQUIREMENTS CONCERNING PARASITES

1. Food business operators placing on the market the following fishery products derived from finfish or cephalopod molluscs:

(a) fishery products intended to be consumed raw; or

(b) marinated, salted and any other treated fishery products, if the treatment is insufficient to kill the viable parasite;

must ensure that the raw material or finished product undergo a freezing treatment in order to kill viable parasites that may be a risk to the health of the consumer.

▼M11

2. For parasites other than trematodes the freezing treatment must consist of lowering the temperature in all parts of the product to at least:

(a) – 20 °C for not less than 24 hours; or

(b) – 35 °C for not less than 15 hours.

3. Food business operators need not carry out the freezing treatment set out in point 1 for fishery products:

(a) that have undergone, or are intended to undergo before consumption a heat treatment that kills the viable parasite. In the case of parasites other than trematodes the product is heated to a core temperature of 60 °C or more for at least one minute;

(b) that have been preserved as frozen fishery products for a sufficiently long period to kill the viable parasites;

(c) from wild catches, provided that:

(i) there are epidemiological data available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites; and

(ii) the competent authority so authorises;

(d) derived from fish farming, cultured from embryos and have been fed exclusively on a diet that cannot contain viable parasites that present a health hazard, and one of the following requirements is complied with:

(i) have been exclusively reared in an environment that is free from viable parasites; or

(ii) the food business operator verifies through procedures, approved by the competent authority, that the fishery products do not represent a health hazard with regard to the presence of viable parasites.

4. (a) When placing on the market, except when supplied to the final consumer, fishery products referred to in point 1 must be accompanied by a document issued by the food business operator performing the freezing treatment, stating the type of freezing treatment that the products have undergone.

(b) Before placing on the market fishery products referred to in points 3 (c) and (d) which have not undergone the freezing treatment or which are not intended to undergo before consumption a treatment that kills viable parasites that present a health hazard, a food business operator must ensure that the fishery products originate from a fishing ground or fish farming which complies with the specific conditions referred to in one of those points. This provision may be met by information in the commercial document or by any other information accompanying the fishery products.

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CHAPTER IV: REQUIREMENTS FOR CERTAIN PROCESSED FISHERY PRODUCTS

Food business operators must ensure compliance with the following requirements in establishments handling certain processed fishery products.

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A. REQUIREMENTS FOR COOKING OF CRUSTACEANS AND MOLLUSCS

1. Rapid cooling must follow cooking. 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 set out in Chapter VII.

B. REQUIREMENTS FOR FISH OIL INTENDED FOR HUMAN CONSUMPTION

1. Raw materials used in the preparation of fish oil for human consumption must:

(a) come from establishments, including vessels, registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation;

(b) derive from fishery products which are fit for human consumption and which comply with the provisions set out in this Section;

(c) be transported and stored in hygienic conditions;

(d) be chilled as soon as possible and remain at the temperatures set out in Chapter VII.

By way of derogation from point 1(d), the food business operator may refrain from chilling the fishery products when whole fishery products are used directly in the preparation of fish oil for human consumption, and the raw material is processed within 36 hours after loading, provided that the freshness criteria are met and the total volatile basic nitrogen (TVB-N) value of the unprocessed fishery products do not exceed the limits set out in point 1 of Chapter I of Section II of Annex II to Commission Regulation (EC) No 2074/2005 ([1]).

2. The production process for fish oil must ensure that all raw material intended for the production of crude fish oil is subject to a treatment including, where relevant, heating, pressing, separation, centrifugation, processing, refining and purification steps before being placed on the market for the final consumer.

3. Provided that the raw materials and the production process comply with the requirements applying to fish oil intended for human consumption a food business operator may produce and store both fish oil for human consumption and fish oil and fish meal not intended for human consumption in the same establishment.

4. Pending the establishment of specific Community legislation food business operators must ensure compliance with national rules for fish oil being placed on the market for the final consumer.

([1]) OJ L 338, 22.12.2005, p. 27.

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CHAPTER V: HEALTH STANDARDS FOR FISHERY PRODUCTS

In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure, depending on the nature of the product or the species, that fishery products placed on the market for human consumption meet the standards laid down in this Chapter. ►M6 The requirements of Parts B and D shall not apply to whole fishery products that are used directly for the preparation of fish oil intended for human consumption. ◄

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.

B. HISTAMINE

Food business operators must ensure that the limits with regard to histamine are not exceeded.

C. TOTAL VOLATILE NITROGEN

Unprocessed fishery products must not be placed on the market if chemical tests reveal that the limits with regard to TVB-N or TMA-N have been exceeded.

D. PARASITES

Food business operators must ensure that fishery products have been subjected to a visual examination for the purpose of detecting visible parasites before being placed on the market. They must not place fishery products that are obviously contaminated with parasites on the market for human consumption.

E. TOXINS HARMFUL TO HUMAN HEALTH

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1. Fishery products derived from poisonous fish of the following families must not be placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae.

Fresh, prepared, frozen and processed fishery products belonging to the family *Gempylidae*, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may only be placed on the market in wrapped/packaged form and must be appropriately labelled to provide information to the consumer on preparation/cooking methods and on the risk related to the presence of substances with adverse gastrointestinal effects.

The scientific name of the fishery products must accompany the common name on the label.

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2. Fishery products containing biotoxins such as ciguatoxin or muscle-paralysing toxins must not be placed on the market. However, fishery products derived from bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII and comply with the standards laid down in Chapter V, point 2, of that section.

CHAPTER VI: 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.

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

3. When fishery products are wrapped on board fishing vessels, food business operators must ensure that wrapping material:

(a) is not a source of contamination;

(b) is stored in such a manner that it is not exposed to a risk of contamination;

(c) intended for re-use is easy to clean and, where necessary, to disinfect.

CHAPTER VII: STORAGE OF FISHERY PRODUCTS

Food business operators storing fishery products must ensure compliance with the following requirements.

1. Fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice.

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2. Frozen fishery products must be kept at a temperature of not more than – 18 °C in all parts of the product; however, whole fish initially frozen in brine intended for the manufacture of canned food may be kept at a temperature of not more than – 9 °C.

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

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4. Where fresh fishery products, thawed unprocessed fishery products, or processed fishery products need to be at a temperature lower than that of melting ice to permit the use of machines that slice or cut fishery products, they may be maintained at such technologically required temperature for a period of time as short as possible and in any case not exceeding 96 hours. Storage and transport at that temperature shall not be allowed.

Where frozen fishery products need to be at a temperature higher than – 18 °C to permit the use of machines that slice or cut fishery products, they may be maintained at such technologically required temperature for a period of time as short as possible and in any case not exceeding 96 hours. Storage and transport at that temperature shall not be allowed.

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CHAPTER VIII: TRANSPORT OF FISHERY PRODUCTS

Food business operators transporting fishery products must ensure compliance with the following requirements.

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1. During transport, fishery products must be maintained at the required temperature. In particular:

(a) fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice. When three-layered polyethylene containers filled with water and ice are used for transporting whole and gutted fresh fishery products, ice must be present during the whole storage/transport, which must be carried out at controlled temperature. The transport and storage of whole and gutted fresh fishery products in three-layered polyethylene containers filled with water and ice must not exceed 3 days;

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(b) frozen fishery products, with the exception of whole fish initially frozen in brine intended for the manufacture of canned food, must be maintained during transport at an even temperature of not more than – 18 °C in all parts of the product, possibly with short upward fluctuations of not more than 3 °C;

(c) if the superchilling process is used for transporting fresh fishery products, the transport in boxes without ice shall be permitted under the condition that those boxes clearly indicate that they contain superchilled fishery products. During transport, superchilled fishery products must respect temperature requirements included in a range between – 0.5 and – 2 °C temperature in the core of the product. The transport and storage of superchilled fishery products must not exceed 5 days.

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2. Food business operators need not comply with point 1(b) 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, if the journey is short and the competent authority so permits.

3. If fishery products are kept under ice, 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 as not adversely to affect food safety or their viability.

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SECTION IX: RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS

For the purpose of this Section,

1. ‘Colostrum’ means the fluid secreted by the mammary glands of milk-producing animals up to three to five days post parturition that is rich in antibodies and minerals, and precedes the production of raw milk.

2. ‘Colostrum-based products’ means processed products resulting from the processing of colostrum or from the further processing of such processed products.

CHAPTER I: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION

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

I. HEALTH REQUIREMENTS FOR RAW MILK AND COLOSTRUM PRODUCTION

1. Raw milk and colostrum must come from animals:

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

(b) that are in a good general state of health, present no sign of disease that might result in the contamination of milk and colostrum 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 and colostrum;

(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;

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(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.

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

(i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC ([1]), 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 ([2]); 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.

(b) As regards tuberculosis, raw milk and colostrum 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, such goats must be inspected and tested for tuberculosis.

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3. However, raw milk or colostrum from animals that does not meet the requirements set out in point 2 may be used with the authorisation of the competent authority:

(a) in the case of cows, buffaloes, sheep or goats or females from other species that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, and in the case of sheep or goats which have been vaccinated against brucellosis as part of an approved eradication programme and do not show any symptom of that disease, after having undergone a heat treatment such as to show, where applicable, a negative reaction to the alkaline phosphatase test. When the alkaline phosphatase test is not suitable to demonstrate the effectiveness of the heat treatment applied, such as situations where raw milk is produced from non-bovine species or separated in different fractions before being heat-treated, food business operators shall be permitted to provide the competent authority with the necessary assurances and keep associated records as part of their procedures based on hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004;

(b) in the case of sheep or goats that do not show a positive reaction to tests for brucellosis, or which have been vaccinated against brucellosis as part of an approved eradication programme, and which do not show any symptom of that disease, for the manufacture of cheese with a maturation period of at least two months.

([1]) Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ 121, 29.7.1964, p. 1977/64). Directive as last amended by Regulation (EC) No 21/2004 (OJ L 5, 9.1.2004, p. 8).

([2]) Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19). Directive as last amended by Commission Decision 2005/932/EC.

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4. Raw milk and colostrum from any animal not complying with the appropriate requirements of points 1 to 3, and 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.

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

II. HYGIENE ON MILK AND COLOSTRUM PRODUCTION HOLDINGS

A. **Requirements for premises and equipment**

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

2. Premises for the storage of milk and colostrum 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 and colostrum (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and must 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 milk and colostrum must be cleaned and disinfected in an appropriate manner 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 and colostrum from each animal is checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk and colostrum presenting such abnormalities is not used for human consumption;

(c) that milk and colostrum from animals showing clinical signs of udder disease are not used for human consumption otherwise than in accordance with the instructions of a veterinarian;

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

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(e) that teat dips or sprays are used only after authorisation or registration in accordance with the procedures laid down in Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ([1]):

(f) that colostrum is milked separately and not mixed together with raw milk.

2. Immediately after milking, milk and colostrum must be held in a clean place designed and equipped to avoid contamination.

(a) Milk 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;

(b) Colostrum must be stored separately and immediately cooled to not more than 8 °C in the case of daily collection, or not more than 6 °C if collection is not daily, or frozen.

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

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

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

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

C. **Staff hygiene**

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

2. Persons performing milking must maintain a high degree of personal cleanliness. Suitable facilities must be available near the place of milking to enable persons performing milking and handling raw milk and colostrum to wash their hands and arms.

III. CRITERIA FOR RAW MILK AND COLOSTRUM

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

(b) National criteria for colostrum, as regards plate count, somatic cell count or antibiotic residues, apply pending the establishment of specific Community legislation.

2. A representative number of samples of raw milk and colostrum collected from milk production holdings taken by random sampling must be checked for compliance with points 3 and 4 in case of raw milk and with the existing national criteria referred to in point 1(b) in case of colostrum. The checks may be carried out by, or on behalf of:

(a) the food business operator producing the milk;

([1]) OJ L 123, 24.4.1998, p. 1. Directive as last amended by Commission Directive 2006/50/EC (OJ L 142, 30.5.2006, p. 6).

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(b) the food business operator collecting or processing the milk;

(c) a group of food business operators; or

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

3. (a) Food business operators must initiate procedures to ensure that raw milk meets the following criteria:

(i) for raw cows' milk:

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

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

(ii) for raw milk from other species:

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

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

(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 criterion:

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

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

4. Without prejudice to Directive 96/23/EC, food business operators must initiate procedures 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 ([1]), exceeds the levels authorised under that Regulation; or

(b) the combined total of residues of antibiotic substances exceeds any maximum permitted value.

5. When raw milk fails to comply with point 3 or 4, the food business operator must inform the competent authority and take measures to correct the situation.

([1]) Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ L 224, 18.8.1990, p. 1). Regulation as last amended by Commission Regulation (EC) No 1231/2006 (OJ L 225, 17.8.2006, p. 3).

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CHAPTER II: REQUIREMENTS CONCERNING DAIRY AND COLOSTRUM-BASED PRODUCTS

I. TEMPERATURE REQUIREMENTS

1. Food business operators must ensure that, upon acceptance at a processing establishment,

(a) milk is quickly cooled to not more than 6 °C;

(b) colostrum is quickly cooled to not more than 6 °C or maintained frozen,

and kept at that temperature until processed.

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

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

(b) the competent authority authorises a higher temperature for technological reasons concerning the manufacture of certain dairy or colostrum-based products.

II. REQUIREMENTS FOR HEAT TREATMENT

1. When raw milk, colostrum, dairy or colostrum-based products undergo heat treatment, food business operators must ensure that this satisfies the requirements laid down in Chapter XI of Annex II to Regulation (EC) No 852/2004. In particular, they shall ensure, when using the following processes, that they comply with the specifications mentioned:

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(a) Pasteurisation is achieved by a treatment involving:

(i) a high temperature for a short time: at least 72 °C for 15 seconds;

(ii) a low temperature for a long time: at least 63 °C for 30 minutes; or

(iii) any other combination of time-temperature conditions to obtain an equivalent effect.

The treatment referred to in (i), (ii) and (iii) shall ensure that the products show, where applicable, a negative reaction to an alkaline phosphatase test immediately after such treatment. When the alkaline phosphatase test is not suitable to demonstrate the effectiveness of the pasteurisation, such as situations where products are derived from non-bovine species or separated in different fractions before being pasteurised, food business operators shall be permitted to provide the competent authority with the necessary assurances and keep associated records as part of their procedures based on hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004.

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(b) Ultra high temperature (UHT) treatment is achieved by a treatment:

(i) involving a continuous flow of heat at a high temperature for a short time (not less than 135 °C in combination with a suitable holding time) such that there are no viable microorganisms or

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spores capable of growing in the treated product when kept in an aseptic closed container at ambient temperature, and

(ii) sufficient to ensure that the products remain microbiologically stable after incubating for 15 days at 30 °C in closed containers or for seven days at 55 °C in closed containers or after any other method demonstrating that the appropriate heat treatment has been applied.

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

(a) have regard to the procedures developed in accordance with the HACCP principles pursuant to Regulation (EC) No 852/2004; and

(b) comply with any requirements that the competent authority may impose in this regard when approving establishments or carrying out checks in accordance with Regulation (EC) No 854/2004.

III. CRITERIA FOR RAW COWS' MILK

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1. Food business operators manufacturing dairy products must initiate procedures to ensure that, immediately before being heat treated and if its period of acceptance specified in the HACCP-based procedures is exceeded:

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

(b) heat treated cows' milk used to prepare dairy products has a plate count at 30 °C of less than 100 000 per ml.

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2. When milk fails to meet the criteria laid down in paragraph 1, the food business operator must inform the competent authority and take measures to correct the situation.

CHAPTER III: WRAPPING AND PACKAGING

Sealing of consumer packages must be carried out immediately after filling in the establishment where the last heat treatment of liquid dairy products and colostrum-based products, takes place by means of sealing devices that prevent 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.

CHAPTER IV: LABELLING

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 made with 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';

(c) in case of colostrum, the word 'colostrum';

(d) in case of products made with colostrum, the words 'made with colostrum'.

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.

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CHAPTER V: IDENTIFICATION MARKING

By way of derogation from the requirements of Annex II, Section I:

1. rather than indicating the approval number of the establishment, the identification mark may include a reference to where on the wrapping or packaging the approval number of the establishment is indicated;

2. in the case of the reusable bottles, the identification mark may indicate only the initials of the consigning country and the approval number of the establishment.

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SECTION X: EGGS AND EGG PRODUCTS

CHAPTER I: EGGS

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1. At the producer's premises, and until sale to the consumer, eggs must be kept clean, dry, free of unintended extraneous odour, effectively protected from shocks and out of direct sunshine. Any intentional application of extraneous odour to eggs must not be aimed at hiding a pre-existing odour.

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2. Eggs must be stored and transported until sale to the final consumer at a temperature, preferably constant, that is best suited to assure optimal conservation of their hygiene properties, unless the competent authority imposes national temperature requirements for egg storage facilities and for vehicles transporting eggs between such storage facilities.

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3. Eggs must be delivered to the consumer within a maximum time limit of 28 days of laying.

4. For eggs produced by hens of the species *Gallus gallus*, the 'date of minimum durability' as defined in Article 2(2), point (r), of Regulation (EU) No 1169/2011 shall be fixed at not more than 28 days after the laying. Where the period of laying is indicated, this date shall be determined from the first day of that period.

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CHAPTER II: EGG PRODUCTS

I. REQUIREMENTS FOR ESTABLISHMENTS

Food business operators must ensure that establishments for the manufacture of 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.

II. RAW MATERIALS FOR THE MANUFACTURE OF EGG PRODUCTS

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

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

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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 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 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 before 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.

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

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

7. If processing 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 processing.

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IV. ANALYTICAL SPECIFICATIONS

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

2. The lactic acid content of raw material used to manufacture egg products must not exceed 1 g/kg of dry matter. However, for fermented products, this value must be the one recorded before the fermentation process.

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

V. LABELLING AND IDENTIFICATION MARKING

1. In addition to the general requirements for identification marking laid down in Annex II, Section I, consignments of 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 egg products must be maintained and the period during which conservation may thus be assured.

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

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SECTION XI: 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 otherwise than by being killed in the establishment 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, 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 a temperature approaching that of melting ice, frozen or processed.

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

▼M23

7. The requirements laid down in points 1, 3, 4 and 6, also apply to any other snails of the Family of *Helicidae, Hygromiidae* or *Sphincterochilidae*, when intended for human consumption.

8. The requirements laid down in points 1 to 5 also apply to frogs’ legs of the genus *Pelophylax* from the Family of *Ranidae*, and the genus *Fejervarya, Limnonectes* and *Hoplobatrachus* from the Family of *Dicroglossidae*, when intended for human consumption.

▼C1

SECTION XII: 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 otherwise than as provided for in Chapter II, point 1(d).

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) derive from animals which have been slaughtered in a slaughterhouse, and which have been found fit for human consumption following ante-mortem and post-mortem inspection;

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

   (c) come from establishments registered or approved pursuant to Regulation (EC) No 852/2003 or in accordance with this Regulation;

   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 if rendered within 12 hours after the day on which they were obtained.

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.

▼C1

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.

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SECTION XIII: 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 derive from animals which have been slaughtered in a slaughter-house, and which have been found fit for human consumption following ante-mortem and post-mortem inspection;

   (b) they are salted, heated or dried;

   and

   (c) after the treatment referred to in (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 XIV: GELATINE

1. Food business operators manufacturing gelatine must ensure compliance with the requirements of this section.

2. For the purpose of this section, ‘tanning’ means the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents.

▼C1

CHAPTER I: REQUIREMENTS FOR RAW MATERIALS

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

▼M9

(a) bones, other than specified risk materials as defined in Article 3(1)(g) of Regulation (EC) No 999/2001 of the European Parliament and of the Council ([1]);

▼C1

(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 point 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-mortem and post-mortem inspection or, in the case of hides and skins from wild game, found fit for human consumption.

▼M18

4. (a) Raw materials that have not undergone any preserving treatment other than chilling, freezing or quick-freezing must come from establishments registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation,

(b) The following treated raw materials may be used:

(i) bones other than specified risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001 coming from establishments under the control of and listed by the competent authority, and that have been subjected to one of the following treatments:

— crushed to pieces of approximately 15 mm and degreased with hot water at a temperature of minimum 70 °C for at least 30 minutes, minimum 80 C for at least 15 minutes, or minimum 90 °C for at least 10 minutes, and then separated and subsequently washed and dried for at least 20 minutes in a stream of hot air with an initial temperature of minimum 350 °C, or for 15 minutes in a stream of hot air with an initial temperature of more than 700 °C,

— sun-dried for a minimum of 42 days at an average temperature of at least 20 °C,

— acid treatment such that the pH is maintained at less than 6 to the core for at least 1 hour before drying;

(ii) hides and skins of farmed ruminant animals, pig skins, poultry skins and wild game hides and skins coming from establishments under the control of and listed by the competent authority, and that have been subjected to one of the following treatments:

([1]) OJ L 147, 31.5.2001, p 1.

▼M18

— treatment with alkali to establish a pH > 12 to the core followed by salting for at least 7 days,

— drying for at least 42 days at a temperature of at least 20 °C,

— acid treatment such that the pH is maintained at less than 5 to the core for a minimum of 1 hour,

— alkali treatment throughout at a pH > 12 for at least 8 hours;

(iii) bones other than specified risk material defined in Article 3(1)(g) of Regulation (EC) No 999/2001, hides and skins of farmed ruminant animals, pig skins, poultry skins, fish hides and wild game hides and skins that have undergone any other treatment than those specified in point (i) or (ii) and that come from establishments registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation.

For the purposes of the first 2 indents of point (b)(ii), the duration of the treatments may include the time of transportation.

The treated raw materials referred to in points (b)(i) and (b)(ii) must be derived from:

— domestic and farmed ruminant animals, pigs and poultry which have been slaughtered in a slaughterhouse and the carcasses of which have been found fit for human consumption following ante- and post-mortem inspection, or

— from killed wild game whose carcasses have been found fit for human consumption following post-mortem inspection.

▼C1

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 Annex II, Section I, a document indicating the establishment of origin and containing the information set out 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.

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.

▼M18

3. After the veterinary checks provided for in Directive 97/78/EC, and without prejudice to the conditions laid down in Article 8(4) of that Directive, raw materials for the production of gelatine for human consumption, for which animal health certification is required, must be transported directly to the establishment at the place of destination.

   All precautions, including safe disposal of animal by-products, waste, unused or surplus material, shall be taken to avoid risks of spreading diseases to animals.

▼M5

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 with a controlled or undetermined BSE risk 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. This treatment is followed either by:

      — an alkaline treatment of saturated lime solution (pH > 12,5) for a period of at least 20 days with a heat treatment step of 138 °C minimum during at least four seconds, or

      — an acid treatment (pH < 3,5) during 10 hours minimum with a heat treatment step of 138 °C minimum during at least four seconds, or

      — a heat-and-pressure process for at least 20 minutes with saturated steam of 133 °C at more than 3 bars, or

      — any approved equivalent process;

   (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 more times in succession, followed by purification by means of filtration and heat treatment.

2. A food business operator may produce and store both gelatine intended for human consumption and gelatine not intended for human consumption in the same establishment provided that the raw materials and the production process comply with the requirements applying to gelatine intended for human consumption.

▼M18

CHAPTER IV: REQUIREMENTS FOR FINISHED PRODUCTS

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
SO_2 (European Pharmacopoeia, latest edition)	50 ppm
H_2O_2 (European Pharmacopoeia, latest edition)	10 ppm

▼M5

CHAPTER V: LABELLING

Wrapping and packaging containing gelatine must bear the words ‘gelatine fit for human consumption’ and must indicate the date of minimum durability.

▼C1

SECTION XV: COLLAGEN

▼M18

1. Food business operators manufacturing collagen must ensure compliance with the requirements of this section. Without prejudice to other provisions, products derived from collagen must be made from collagen which complies with the requirements of this section.

▼C1

2. For the purpose of this section, ‘tanning’ means the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents.

CHAPTER I: REQUIREMENTS FOR RAW MATERIALS

▼M9

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

   (a) bones, other than specified risk materials as defined in Article 3(1)(g) of Regulation (EC) No 999/2001;

   (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.

▼C1

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 point 1(a) to (d) 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 hides and skins from wild game, found fit for human consumption.

▼M18

4. (a) Raw materials that have not undergone any preserving treatment other than chilling, freezing or quick-freezing must come from establishments registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation.

   (b) The following treated raw materials may be used:

      (i) bones other than specified risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001 coming from establishments under the control of and listed by the competent authority, and that have been subjected to one of the following treatments:

▼M18

— crushed to pieces of approximately 15 mm and degreased with hot water at a temperature of minimum 70 °C for at least 30 minutes, minimum 80 °C for at least 15 minutes, or minimum 90 °C for at least 10 minutes, and then separated and subsequently washed and dried for at least 20 minutes in a stream of hot air with an initial temperature of minimum 350 °C, or for 15 minutes in a stream of hot air with an initial temperature of more than 700 °C,

— sun-dried for a minimum of 42 days at an average temperature of at least 20 °C,

— acid treatment such that the pH is maintained at less than 6 to the core for at least 1 hour before drying;

(ii) hides and skins of farmed ruminant animals, pig skins, poultry skins and wild game hides and skins coming from establishments under the control of and listed by the competent authority, and that have been subjected to one of the following treatments:

— treatment with alkali to establish a pH > 12 to the core followed by salting for at least 7 days,

— drying for at least 42 days at a temperature of at least 20 °C,

— acid treatment such that the pH is maintained at less than 5 to the core for a minimum of 1 hour,

— alkali treatment throughout at a pH > 12 for at least 8 hours;

(iii) bones other than specified risk material defined in Article 3(1)(g) of Regulation (EC) No 999/2001, hides and skins of farmed ruminant animals, pig skins, poultry skins, fish hides and wild game hides and skins that have undergone any other treatment than those specified in point (i) or (ii) and that come from establishments registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation.

For the purposes of the first 2 indents of point (b)(ii), the duration of the treatments may include the time of transportation.

The treated raw materials referred to in point (b) must be derived from:

— domestic and farmed ruminant animals, pigs and poultry which have been slaughtered in a slaughterhouse and the carcasses of which have been found fit for human consumption following ante- and post-mortem inspection, or

— from killed wild game whose carcasses have been found fit for human consumption following post-mortem inspection.

▼C1

5. Collection centres and tanneries may also supply raw material for the production of collagen 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.

▼C1

(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 Annex II, Section I, a document indicating the establishment of origin and containing the information set out 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 collagen-processing establishment.

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.

▼M18

3. After the veterinary checks provided for in Directive 97/78/EC, and without prejudice to the conditions laid down in Article 8(4) of that Directive, raw materials for the production of collagen for human consumption, for which animal health certification is required, must be transported directly to the establishment at the place of destination.

All precautions, including safe disposal of animal by-products, waste, unused or surplus material, shall be taken to avoid risks of spreading diseases to animals.

▼C1

CHAPTER III: REQUIREMENTS FOR THE MANUFACTURE OF COLLAGEN

▼M18

1. The production process for collagen must ensure that:

(a) all ruminant bone material derived from animals born, reared or slaughtered in countries or regions with a controlled or undetermined BSE risk as determined in accordance with Article 5 of Regulation (EC) No 999/2001 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 a minimum concentration of 4 % and pH < 1,5) over a period of at least 2 days; this treatment must be followed by pH adjustment using acid or alkali followed by:

(i) either one or more rinses and at least one of the following processes:

— filtration,

— milling,

— extrusion,

(ii) or any approved equivalent process;

(b) raw materials other than that referred to in point (a) must be subjected to a treatment involving washing, pH adjustment using acid or alkali followed by:

▼M18

(i) either one or more rinses and at least one of the following processes:

— filtration,

— milling,

— extrusion,

(ii) or any approved equivalent process.

▼C1

2. After having been subjected to the process referred to in point 1, collagen may undergo a drying process.

▼M5

3. A food business operator may produce and store both collagen intended for human consumption and collagen not intended for human consumption in the same establishment provided that the raw materials and the production process comply with the requirements applying to collagen intended for human consumption.

▼M18

CHAPTER IV: REQUIREMENTS FOR FINISHED PRODUCTS

Food business operators must ensure that collagen 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
SO_2 (European Pharmacopoeia, latest edition)	50 ppm
H_2O_2 (European Pharmacopoeia, latest edition)	10 ppm

▼C1

CHAPTER V: LABELLING

Wrapping and packaging containing collagen must bear the words ‘collagen fit for human consumption’ and indicate the date of preparation.

▼M25

SECTION XVI: HIGHLY REFINED PRODUCTS

(1) Food business operators manufacturing the following highly refined products of animal origin must ensure that the treatment of the raw materials used eliminates any animal or public health risk:

(a) chondroitin sulphate;

(b) hyaluronic acid;

(c) other hydrolysed cartilage products;

(d) chitosan;

(e) glucosamine;

(f) rennet;

(g) isinglass;

▼M28

(h) food additives of animal origin authorised in accordance with Article 4 of Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([1]) 4 straipsnį;

▼M25

(i) food flavourings that are authorised in accordance with Regulation (EC) No 1334/2008 of the European Parliament and of the Council ([2]);

(j) fat derivatives.

(2) The raw materials used for the manufacturing of the highly refined products referred to in point 1 must be derived from:

(a) animals, including feathers thereof, which have been slaughtered in a slaughterhouse and the meat of which have been found fit for human consumption following ante-mortem and post-mortem inspection, or

(b) fishery products complying with Section VIII, or

(c) rendered fats and greaves complying with Section XII, or wool, if these products are submitted to one of the following processes:

(1) transesterification or hydrolysis at a temperature of at least 200 °C, under corresponding appropriate pressure, for at least 20 minutes (glycerol, fatty acids and esters);

(2) saponification with NaOH 12M:

— in a batch process at 95 °C for three hours; or

— in a continuous process at 140 °C 2 bars (2 000 hPa) for eight minutes; or

(3) hydrogenation at 160 °C at 12 bars (12 000 hPa) for 20 minutes;

▼M28

(4) when derived from wool grease, a heat treatment at least at 135 °C for at least 90 minutes;

▼M25

Human hair may not be used as a source for the manufacture of amino acids, or

▼M28

(d) insects.

([1]) 2008 m. gruodžio 16 d. Europos Parlamento ir Tarybos reglamentas (EB) Nr. 1333/2008 dėl maisto priedų (OL L 354, 2008 12 31, p. 16, ELI: http://data.europa.eu/eli/reg/2008/1333/oj).

([2]) Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavorings and certain food ingredients with flavoring properties for use in and on foods (OJ L 354, 31.12.2008, p. 34).

▼**M5**

Appendix to ANNEX III

MODEL DOCUMENT TO ACCOMPANY RAW MATERIAL DESTINED FOR THE PRODUCTION OF GELATINE OR COLLAGEN INTENDED FOR HUMAN CONSUMPTION

Number of the commercial document: .....

I. Identification of raw material

Nature of the raw material: .....

Animal species: .....

Type of packaging: .....

Number of packages: .....

Net weight (kg): .....

II. Origin of raw material

Type, name, address and approval/registration/special authorisation number of the establishment of origin:

.....

Name and address of the consignor ([1]): .....

III. Destination of raw material

Type, name, address and approval/registration/special authorisation number of the production establishment of destination:

.....

Name and address of the consignee ([2]): .....

IV. Means of transport: .....

Done at ....., on .....

.....

(Signature of the operator of the establishment of origin or its representatives)

([1]) Only if different from the establishment of origin.
([2]) Only if different from the establishment of destination.