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COMMISSION IMPLEMENTING REGULATION (EU) 2019/627

of 15 March 2019

laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls

(Text with EEA relevance)

(OJ L 131, 17.5.2019, p. 51)

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TITLE I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

This Regulation lays down uniform practical arrangements for the performance of official controls and actions in relation to the production of products of animal origin intended for human consumption. These official controls and actions shall be performed by the competent authorities taking into account the requirements of Article 18(2), (3) and (5) of Regulation (EU) 2017/625 and Delegated Regulation (EU) 2019/624.

The specific rules cover:

(a) specific requirements and uniform minimum frequency of official controls on any product of animal origin, as regards audits and identification marking;

(b) specific requirements and uniform minimum frequency of official controls on fresh meat, including specific requirements for audits and specific tasks as regards controls on fresh meat;

(c) measures to be taken in cases of non-compliance of fresh meat with Union requirements for the protection of human health and animal health and welfare;

(d) technical requirements and practical arrangements as regards the health mark referred to in Article 5 of Regulation (EC) No 853/2004;

(e) specific requirements and uniform minimum frequency of official controls on milk, colostrum, dairy products and colostrum-based products;

(f) conditions for the classification and monitoring of classified production and relaying areas for live bivalve molluscs, including decisions to be taken after monitoring classified production and relaying areas;

(g) specific requirements and uniform minimum frequency of official controls on fishery products.

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Article 2

Definitions

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

(1) ‘fresh meat’ means fresh meat as defined in point 1.10 of Annex I to Regulation (EC) No 853/2004;

(2) ‘colostrum’ means colostrum as defined in point 1 of Section IX of Annex III of Regulation (EC) No 853/2004;

(3) ‘dairy products’ means dairy products as defined in point 7.2. of Annex I to Regulation (EC) No 853/2004;

(4) ‘colostrum-based products’ means colostrum-based products as defined in point 2 of Section IX of Annex III of Regulation (EC) No 853/2004;

(5) ‘production area’ means a production area as defined in point 2.5 of Annex I of Regulation (EC) No 853/2004;

(6) ‘relaying area’ means relaying area as defined in point 2.6 of Annex I of Regulation (EC) No 853/2004;

(7) ‘bivalve molluscs’ means bivalve molluscs as defined in point 2.1 of Annex I of Regulation (EC) No 853/2004;

(8) ‘fishery products’ means fishery products as defined in point 3.1 of Annex I to Regulation (EC) No 853/2004;

(9) ‘establishment’ means an establishment as defined in Article 2(1)(c) of Regulation (EC) No 852/2004;

(10) ‘food business operator’ means a food business operator as defined in Article 3(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([1]);

(11) ‘microbiological criterion’ means microbiological criterion as defined in Article 2(b) of Regulation (EC) No 2073/2005;

(12) ‘slaughterhouse’ means slaughterhouse as defined in point 1.16 of Annex I of Regulation (EC) No 853/2004;

(13) ‘traceability’ means traceability as defined in Article 3(15) of Regulation (EC) No 178/2002;

(14) ‘specified risk material’ means specified risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001;

([1]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

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(15) ‘contamination’ means contamination as defined in Article 2(1)(f) of Regulation (EC) No 852/2004;

(16) ‘holding of provenance’ means a holding of provenance as defined in point 2 of Article 2 of Delegated Regulation (EU) 2019/624;

(17) ‘primary production’ means primary production as defined in Article 3(17) of Regulation (EC) No 178/2002;

(18) ‘domestic ungulates’ means domestic ungulates as defined in point 1.2 of Annex I of Regulation (EC) No 853/2004;

(19) ‘game-handling establishment’ means a game-handling establishment as defined in point 1.18 of Annex I of Regulation (EC) No 853/2004;

(20) ‘large wild game’ means large wild game as defined in point 1.8 of Annex I to Regulation (EC) No 853/2004;

(21) ‘flock’ means a flock as defined in Article 2(3)(b) of Regulation (EC) No 2160/2003;

(22) ‘lagomorphs’ means lagomorphs as defined in point 1.4 of Annex I of Regulation (EC) No 853/2004;

(23) ‘carcase’ means a carcase as defined in point 1.9 of Annex I to Regulation (EC) No 853/2004;

(24) ‘offal’ means offal as defined in point 1.11 of Annex I to Regulation (EC) No 853/2004;

(25) ‘low-capacity slaughterhouse’ means a low-capacity slaughterhouse as defined in Article 2(17) of Delegated Regulation (EU) 2019/624;

(26) ‘low-capacity game-handling establishment’ means a game-handling establishment as defined in Article 2(18) of Delegated Regulation (EU) 2019/624;

(27) ‘livestock unit’ means a livestock unit as defined in Article 17(6) of Regulation (EC) No 1099/2009;

(28) ‘small wild game’ means small wild game as defined in point 1.7 of Annex I of Regulation (EC) No 853/2004;

(29) ‘poultry’ means poultry as defined in point 1.3 of Annex I of Regulation (EC) No 853/2004;

(30) ‘cutting plant’ means a cutting plant as defined in point 1.17 of Annex I of Regulation (EC) No 853/2004;

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(31) ‘viscera’ means viscera as defined in point 1.12 of Annex I of Regulation (EC) No 853/2004;

(32) ‘meat’ means meat as defined in point 1.1 of Annex I of Regulation (EC) No 853/2004;

(33) ‘farmed game’ means farmed game as defined in point 1.6 of Annex I of Regulation (EC) No 853/2004;

(34) ‘wild game’ means wild game as defined in point 1.5 of Annex I to Regulation (EC) No 853/2004;

(35) ‘milk production holding’ means a milk production holding as defined in point 4.2 of Annex I of Regulation (EC) No 853/2004;

(36) ‘raw milk’ means raw milk as defined in point 4.1 of Annex I to Regulation (EC) No 853/2004;

(37) ‘purification centre’ means a purification centre as defined in point 2.8 of Annex I to Regulation (EC) No 853/2004;

(38) ‘marine biotoxins’ means marine biotoxins as defined in point 2.2 of Annex I to Regulation (EC) No 853/2004;

(39) ‘stages of production, processing and distribution’ means stages of production, processing and distribution as defined in Article 3(16) of Regulation (EC) No 178/2002;

(40) ‘dispatch centre’ means a dispatch centre as defined in point 2.7 of Annex I of Regulation (EC) No 853/2004;

(41) ‘placing on the market’ means placing on the market as defined in Article 3(8) of Regulation (EC) No 178/2002;

(42) ‘factory vessel’ means factory vessel as defined in point 3.2 of Annex I to Regulation (EC) No 853/2004;

(43) ‘freezer vessel’ means freezer vessel as defined in point 3.3 of Annex I to Regulation (EC) No 853/2004;

(44) ‘reptiles’ means reptiles as defined in point 15 of Article 2 of Commission Delegated Regulation (EU) 2019/625 ([2]);

(45) ‘reptile meat’ means reptile meat as defined in point 16 of Article 2 of Delegated Regulation (EU) 2019/625;

([2]) Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (see page 18 of this Official Journal).

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(46) ‘fresh fishery products’ means fresh fishery products as defined in point 3.5 of Annex I to Regulation (EC) No 853/2004;

(47) ‘prepared fishery products’ means prepared fishery products as defined in point 3.6 of Annex I to Regulation (EC) No 853/2004;

(48) ‘processed fishery products’ means processed fishery products as defined in point 7.4 of Annex I to Regulation (EC) No 853/2004.

TITLE II

SPECIFIC REQUIREMENTS FOR THE PERFORMANCE OF OFFICIAL CONTROLS AND THE UNIFORM MINIMUM FREQUENCY FOR OFFICIAL CONTROLS ON PRODUCTS OF ANIMAL ORIGIN

CHAPTER I

Specific requirements for audits by the competent authorities in establishments handling products of animal origin

Article 3

Requirements subject to auditing

1. When auditing good hygiene practices in establishments, the competent authorities shall verify that food business operators handling products of animal origin apply procedures continuously and properly concerning at least the following:

(a) the design and maintenance of premises and equipment;

(b) pre-operational, operational and post-operational hygiene;

(c) personal hygiene;

(d) training in hygiene and in work procedures;

(e) pest control;

(f) water quality;

(g) temperature control;

(h) controls on animals or food entering and leaving the establishment, and any accompanying documentation.

2. When auditing procedures based on hazard analysis and critical control points (HACCP), as laid down in Article 5 of Regulation (EC) No 852/2004, the competent authorities shall verify that food business operators handling products of animal origin apply such procedures continuously and properly.

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3. They shall, in particular, determine whether the procedures guarantee, to the extent possible, that products of animal origin:

(a) comply with Article 3 of Regulation (EC) No 2073/2005 as regards microbiological criteria;

(b) comply with Union legislation on:

— the monitoring of chemical residues, in accordance with Council Directive 96/23/EC and Commission Decision 97/747/EC ([3]);

— maximum residue limits for pharmacologically active substances, in accordance with Commission Regulation (EU) No 37/2010 ([4]) and Commission Implementing Regulation (EU) 2018/470 ([5]);

— prohibited and unauthorised substances, in accordance with Commission Regulation (EU) No 37/2010, Council Directive 96/22/EC ([6]), Commission Decision 2005/34/EC ([7]);

— contaminants, in accordance with Regulations (EC) No 1881/2006 and (EC) No 124/2009 setting maximum levels for certain contaminants in food;

— pesticide residues, in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council ([8]);

(c) do not contain physical hazards, such as foreign bodies.

4. Where a food business operator uses procedures set out in guides to the application of HACCP-based principles, in accordance with Article 5(5) of Regulation (EC) No 852/2004, the audit shall cover the correct use of those guides.

([3]) Commission Decision 97/747/EC of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products (OJ L 303, 6.11.1997, p. 12).

([4]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

([5]) Commission Implementing Regulation (EU) 2018/470 of 21 March 2018 on detailed rules on the maximum residue limit to be considered for control purposes for foodstuffs derived from animals which have been treated in the EU under Article 11 of Directive 2001/82/EC (OJ L 79, 22.3.2018, p. 16).

([6]) Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stock farming of certain substances having a hormonal or thyrostatic action and of β-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ L 125, 23.5.1996, p. 3).

([7]) Commission Decision 2005/34/EC of 11 January 2005 laying down harmonised standards for the testing for certain residues in products of animal origin imported from third countries (OJ L 16, 20.1.2005, p. 61).

([8]) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

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5. When carrying out auditing tasks, the competent authorities shall take special care:

(a) to determine whether staff and staff activities in the establishment at all stages of the production process comply with the requirements, as regards hygienic practices and HACCP laid down in Article 3 of Regulation (EC) No 2073/2005, Articles 4 and 5 of Regulation (EC) No 852/2004 and Article 3(1) of Regulation (EC) No 853/2004. To complement the audit, the competent authorities may carry out performance tests, in order to ascertain that staff are sufficiently skilled;

(b) to verify the food business operator's relevant records;

(c) to take samples for laboratory analysis where necessary;

(d) to document elements taken into account and the findings of the audit.

Article 4

Nature and frequency of auditing

1. The nature and frequency of auditing tasks in respect of individual establishments shall depend on the assessed risk. To this end, the competent authorities shall regularly assess:

(a) human and, where appropriate, animal health risks;

(b) in the case of slaughterhouses, animal welfare aspects;

(c) the type and throughput of the processes carried out;

(d) the food business operator's past record as regards compliance with food law.

2. Where food business operators in the food chain take additional measures to guarantee food safety by implementing integrated systems, private control systems or independent third-party certification, or by other means, and where these measures are documented and animals covered by such schemes are clearly identifiable, the competent authorities may take such measures into account when carrying out audits to review good hygiene practices and the HACCP-based procedures.

CHAPTER II

Specific requirements for identification marking

Article 5

Compliance with the requirements of Regulation (EC) No 853/2004 concerning the application of identification marks shall be verified in all establishments approved in accordance with that Regulation, in addition to verification of compliance with other traceability requirements in accordance with Article 18 of Regulation (EC) No 178/2002.

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CHAPTER III

Scientific and technological developments

Article 6

The Member States shall inform the Commission and other Member States on scientific and technological developments, as referred to in Article 16(2)(b) of Regulation (EU) 2017/625 for consideration and further action as appropriate.

TITLE III

SPECIFIC REQUIREMENTS FOR THE PERFORMANCE OF OFFICIAL CONTROLS AND THE UNIFORM MINIMUM FREQUENCY FOR OFFICIAL CONTROLS ON FRESH MEAT

CHAPTER I

Audits

Article 7

Additional requirements for audits in establishments handling fresh meat

1. In addition to the requirements for audits laid down in Articles 3 and 4, the competent authorities shall, when carrying out an audit in establishments handling fresh meat, verify continuous compliance with food business operators' own procedures concerning the collection, transport, storage and handling of fresh meat, and the use or disposal of animal by-products, including specified risk material, for which they are responsible.

2. In the course of audits in slaughterhouses, the competent authorities shall verify the evaluation of food chain information, as laid down in Section III of Annex II to Regulation (EC) No 853/2004.

3. When carrying out audits of HACCP-based procedures, the competent authorities shall check that due regard is given to the procedures set out in Section II of Annex II to Regulation (EC) No 853/2004 and that the food business operators' procedures guarantee, to the extent possible, that fresh meat:

(a) does not contain pathological abnormalities or changes;

(b) does not bear

(i) faecal contamination; or,

(ii) any other contamination considered to pose an unacceptable human health risk;

(c) complies with the microbiological criteria in Article 3 of Regulation (EC) No 2073/2005;

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(d) does not contain specified risk material, in accordance with the requirements in Regulation (EC) No 999/2001.

CHAPTER II

Official controls on fresh meat

Article 8

Relevance of audit results

When carrying out official controls in accordance with this Chapter, the official veterinarian shall take into account the results of the audits carried out in accordance with Chapter I. Where appropriate, the official veterinarian shall target official controls to deficiencies detected during previous audits.

Section 1

Checks of documents

Article 9

Obligations of the competent authorities as regards checks of documents

1. The competent authorities shall inform the food business operator of the holding of provenance of the minimum elements of food chain information to be supplied to the slaughterhouse operator in accordance with Section III of Annex II to Regulation (EC) No 853/2004.

2. The competent authorities shall perform the necessary checks of documents to verify that:

(a) the food chain information is consistently and effectively communicated between the food business operator who raised or kept the animals before dispatch and the slaughterhouse operator;

(b) the food chain information is valid and reliable;

(c) feedback of relevant information to the holding of provenance, if applicable, is provided in accordance with Article 39(5).

3. Where animals are dispatched for slaughter to another Member State, the competent authorities at the holding of provenance and the place of slaughter shall cooperate to ensure that the food chain information provided by the food business operator of the holding of provenance is easily accessible to the slaughterhouse operator receiving it.

Article 10

Obligations of the official veterinarian as regards checks of documents

1. The official veterinarian shall verify the results of the checks and evaluations of food chain information provided by the slaughterhouse operator in accordance with Section III of Annex II to Regulation (EC) No 853/2004. The official veterinarian shall take those checks and evaluations into account when carrying out ante-mortem and post-mortem inspections, together with any other relevant information from the records of the animals' holding of provenance.

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2. When carrying out ante-mortem and post-mortem inspections, the official veterinarian shall take into account official certificates provided for in accordance with Article 29 of Commission Implementing Regulation (EU) 2019/628 ([9]), and any declarations by veterinarians carrying out official controls or other checks at the level of primary production.

3. In the case of the emergency slaughter of domestic ungulates outside the slaughterhouse, the official veterinarian at the slaughterhouse shall examine the certification provided for in accordance with Article 29 of Implementing Regulation (EU) 2019/628 and issued by the official veterinarian who carried out the ante-mortem inspection in accordance with point 6 of Chapter VI of Section I of Annex III to Regulation (EC) No 853/2004 and any other relevant information provided by the food business operator.

4. In the case of large wild game, the official veterinarian at the game-handling establishment shall examine and take into account the declaration accompanying the body of the animal, as issued by a trained person in accordance with point 4(a) of Chapter II of Section IV of Annex III to Regulation (EC) No 853/2004.

Section 2

Ante-mortem inspection

Article 11

Requirements as regards ante-mortem inspection at the slaughterhouse

1. All animals shall be subjected to ante-mortem inspection before slaughter. However, inspection can be limited to a representative sample of birds from each flock and a representative sample of lagomorphs from each holding of provenance of lagomorphs.

2. Ante-mortem inspection shall take place within 24 hours of arrival of the animals at the slaughterhouse and less than 24 hours before slaughter. The official veterinarian may require an additional ante-mortem inspection at any other time.

3. Ante-mortem inspections shall determine whether, as regards the particular animal inspected, there is any sign:

(a) that the health and welfare of the animal has been compromised;

(b) of any condition, abnormalities or disease that make the fresh meat unfit for human consumption or that might adversely affect animal health, paying particular attention to the detection of zoonotic diseases and animal diseases for which animal health rules are laid down in Regulation (EU) 2016/429;

(c) of the use of prohibited or unauthorised substances, misuse of veterinary medicinal products or the presence of chemical residues or contaminants.

([9]) Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (see page 101 of this Official Journal).

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4. Ante-mortem inspection shall include verification of food business operators' compliance with their obligation to ensure that animals have a clean hide, skin or fleece, so as to avoid any unacceptable risk of contamination of the fresh meat during slaughter.

5. The official veterinarian shall carry out a clinical inspection of all animals that the food business operator or an official auxiliary may have put aside for a more thorough ante-mortem inspection.

6. Where the ante-mortem inspection is carried out at the holding of provenance in accordance with Article 5 of Delegated Regulation (EU) 2019/624, the official veterinarian at the slaughterhouse shall carry out ante-mortem inspection only when and to the extent specified.

Section 3

Post-mortem inspection

Article 12

Requirements for post-mortem inspection

1. Subject to the derogation stipulated in Point 4 of Chapter II of Section IV to Annex III of Regulation (EC) No 853/2004, carcases and accompanying offals, shall be subjected to post-mortem inspection:

(a) without delay after slaughter, or

(b) as soon as possible after arrival at the game-handling establishment.

2. The competent authorities may require the food business operator to provide special technical facilities and sufficient space to check offal.

3. The competent authorities shall:

(a) check all external surfaces, including those of body cavities of carcases, as well as offal;

(b) pay particular attention to the detection of zoonotic diseases and animal diseases for which animal health rules are laid down in Regulation (EU) 2016/429.

4. The speed of the slaughter line and the number of inspection staff present shall be such as to allow for proper inspection.

Article 13

Derogation on the timing of post-mortem inspection

1. By way of derogation from Article 12(1), the competent authorities may allow that, when neither the official veterinarian nor the official auxiliary are present in the game-handling establishment or slaughterhouse during slaughter and dressing, the post-mortem inspection is delayed by a maximum period of 24 hours from slaughter or arrival in the game-handling establishment, provided that:

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(a) the animals concerned are slaughtered in a low-capacity slaughterhouse or handled in a low-capacity game-handling establishment that slaughters or handles:

(i) fewer than 1 000 livestock units per year; or

(ii) fewer than 150 000 poultry, lagomorphs and small wild game per year;

(b) sufficient facilities exist within an establishment to store the fresh meat and offal so that they can be examined;

(c) the post-mortem inspection is carried out by the official veterinarian.

2. The competent authorities may increase the thresholds laid down in point (a) (i) and (ii) of paragraph 1 ensuring that the derogation is applied in the smallest slaughterhouses and game-handling establishments complying with the definition of low-capacity slaughterhouse or low-capacity game-handling establishment and provided that the combined annual production of these establishments does not exceed 5 % of the total amount of fresh meat produced in a Member State:

(a) for the species concerned;

(b) or for all ungulates together;

(c) of all poultry together; or,

(d) of all birds and lagomorphs together.

In such case, the competent authorities shall notify this derogation and the evidence to support it in accordance with the procedure laid down in Directive (EU) 2015/1535 of the European Parliament and of the Council ([10]);

3. For the purpose of point (a) (i) of paragraph 1, the conversion rates laid down in Article 17(6) of Regulation (EC) No 1099/2009 shall be used. However in case of ovine and caprine animals and small (< 100 kg life weight) *Cervidae* a conversion rate of 0,05 livestock units, and in case of other large game a conversion rate of 0,2 livestock units shall be used.

Article 14

Additional examination requirements for post-mortem inspection

1. Additional examinations, such as palpation and incision of parts of the carcase and offal, and laboratory tests, shall be carried out if needed to:

(a) reach a definitive diagnosis of a suspected hazard; or

([10]) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

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(b) detect the presence of:

(i) an animal disease for which animal health rules are laid down in Regulation (EU) 2016/429;

(ii) chemical residues or contaminants as referred to in Directive 96/23/EC and Decision 97/747/EC, especially:

— chemical residues in excess of the levels laid down in Regulations (EU) No 37/2010 and (EC) No 396/2005;

— contaminants exceeding the maximum levels laid down in Regulations (EC) No 1881/2006 and (EC) No 124/2009; or

— residues of substances that are prohibited or unauthorised in accordance with Regulation (EU) No 37/2010 or Directive 96/22/EC;

(iii) non-compliance with the microbiological criteria referred to in Article 3(1)(b) of Regulation (EC) No 2073/2005 or the possible presence of other microbiological hazards that would make the fresh meat unfit for human consumption;

(iv) other factors that might require the fresh meat to be declared unfit for human consumption or restrictions to be placed on its use.

2. During the post-mortem inspection, precautions shall be taken to ensure that contamination of fresh meat by actions such as palpation, cutting or incision is kept to a minimum.

Article 15

Requirements for post-mortem inspection of domestic solipeds, bovine animals over eight months old and domestic swine more than five weeks old, and large wild game

1. The requirements in this Article shall apply in addition to the requirements in Articles 12 and 14.

2. The official veterinarian shall require that carcases of domestic solipeds, bovine animals over eight months old and domestic swine more than five weeks old are submitted for post-mortem inspection split lengthways into half carcases down the spinal column.

3. If the post-mortem inspection so necessitates, the official veterinarian may require any head or any carcase to be split lengthways. However, to take account of particular eating habits, technological developments or specific sanitary situations, the official veterinarian may authorise the submission for post-mortem inspection of carcases of domestic solipeds, bovine animals more than eight months old and domestic swine more than five weeks old that are not split in half.

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4. In low-capacity slaughterhouses or low-capacity game-handling establishments handling fewer than 1 000 livestock units per year, the official veterinarian may, for sanitary reasons, authorise the cutting into quarter carcases of adult domestic solipeds, adult bovine animals and adult large wild game before post-mortem inspection.

Article 16

Additional requirements for post-mortem inspection in cases of emergency slaughter

In the event of emergency slaughter, the carcase shall be subjected to post-mortem inspection as soon as possible in accordance with Articles 12, 13, 14 and 15 before it is released for human consumption.

Article 17

Practical arrangements for post-mortem inspection of domestic bovine animals, domestic sheep and goats, domestic solipeds and domestic swine

Where the post-mortem inspection is performed by an official veterinarian, under the supervision of the official veterinarian or, where sufficient guarantees are in place, under the responsibility of the official veterinarian in accordance with Article 18(2)(c) of Regulation (EU) 2017/625 and Article 7 of Delegated Regulation (EU) 2019/624, the competent authorities shall ensure that the practical arrangements laid down in the following Articles 18 to 24 are complied with in the cases of domestic bovine animals, domestic sheep and goats, domestic solipeds and domestic swine in addition to the requirements laid down in Articles 12, 14 and 15.

Article 18

Young bovine animals

1. Carcases and offal of the following bovine animals shall undergo the post-mortem inspection procedures laid down in paragraph 2:

(a) animals under eight months old; and,

(b) animals under 20 months old if reared without access to pasture land during their whole life in an officially tuberculosis-free Member State or region of a Member State in accordance with Article 1 of Decision 2003/467/EC.

2. The post-mortem inspection procedures shall include at least a visual inspection of the following:

(a) the head and throat; together with palpation and examination of the retropharyngeal lymph nodes (*Lnn. retropharyngiales*), however, in order to ensure the surveillance of the officially tuberculosis free status, Member States may decide to carry out further investigations; inspection of the mouth and fauces;

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(b) the lungs, trachea and oesophagus; palpation of the lungs; palpation and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*);

(c) the pericardium and heart;

(d) the diaphragm;

(e) the liver and the hepatic and pancreatic lymph nodes, (*Lnn. portales*);

(f) the gastro-intestinal tract, the mesentery and gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*);

(g) the spleen;

(h) the kidneys;

(i) the pleura and peritoneum;

(j) the umbilical region and the joints of young animals.

3. ►M2 Post-mortem inspection procedures shall be carried out in accordance with Article 18(2)(c) of Regulation (EU) 2017/625 and Article 7 and 8 of Regulation (EU) 2019/624, using incision and palpation of the carcase and offal, when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24: ◄

(a) incision of the retropharyngeal lymph nodes (*Lnn. retropharyngiales*); palpation of the tongue;

(b) incision of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*); lengthwise opening of the trachea and the main branches of the bronchi; the lungs shall be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;

(c) lengthways incision of the heart so as to open the ventricles and cut through the interventricular septum;

(d) incision of the gastric and mesenteric lymph nodes;

(e) palpation of the spleen;

(f) incision of the kidneys and the renal lymph nodes (*Lnn. renales*);

(g) palpation of the umbilical region and the joints. The umbilical region shall be incised and the joints opened; the synovial fluid must be examined.

Article 19

Other bovine animals

1. Carcases and offal of bovine animals other than those referred to in Article 18(1) shall undergo the following post-mortem inspection procedures:

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(a) a visual inspection of the head and throat; incision and examination of the retropharyngeal lymph nodes (*Lnn. retropharyngiales*); examination of the external masseters, in which two incisions shall be made parallel to the mandible, and the internal masseters (internal pterygoid muscles), which shall be incised along one plane. The tongue shall be freed to permit a detailed visual inspection of the mouth and the fauces;

(b) an inspection of the trachea and oesophagus; visual inspection and palpation of the lungs; incision and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*);

(c) a visual inspection of the pericardium and heart, the latter being incised lengthways so as to open the ventricles and cut through the interventricular septum;

(d) a visual inspection of the diaphragm;

(e) a visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*);

(f) a visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*); palpation of the gastric and mesenteric lymph nodes;

(g) a visual inspection of the spleen;

(h) a visual inspection of the kidneys;

(i) a visual inspection of the pleura and the peritoneum;

(j) a visual inspection of the genital organs (except for the penis, if already discarded);

(k) a visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*).

2. ►M2 Post-mortem inspection procedures shall be carried out in accordance with Article 18(2)(c) of Regulation (EU) 2017/625 and Article 7 and 8 of Regulation (EU) 2019/624, using incision and palpation of the carcase and offal, when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24: ◄

(a) an incision and examination of the sub-maxillary and parotid lymph nodes (*Lnn. mandibulares* and *parotidei*); palpation of the tongue and the fauces;

(b) ►M2 ———— ◄ lengthwise opening of the trachea and the main branches of the bronchi; the lungs shall be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;

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(c) a palpation of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*); incision of the gastric surface of the liver and at the base of the caudate lobe to examine the bile ducts;

(d) an incision of the gastric and mesenteric lymph nodes;

(e) a palpation of the spleen;

(f) an incision of the kidneys and the renal lymph nodes (*Lnn. renales*);

(g) a palpation and incision of the udder and its lymph nodes (*Lnn. supramammarii*) in cows. Each half of the udder shall be opened by a long, deep incision as far as the lactiferous sinuses (*sinus lactiferes*) and the lymph nodes of the udder shall be incised, except where the udder is excluded from human consumption.

Article 20

Young domestic sheep and goats and sheep with no eruption of permanent incisors

1. Carcases and offal of sheep not having any permanent incisor erupted or less than 12 months of age, and goats less than six months of age, shall undergo the following post-mortem inspection procedures:

(a) a visual inspection of the head, including the throat, mouth, tongue and parotid and retropharyngeal lymph nodes. These examinations are not necessary if the competent authorities are able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;

(b) a visual inspection of the lungs, trachea and oesophagus and the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*);

(c) a visual inspection of the pericardium and heart;

(d) a visual inspection of the diaphragm;

(e) a visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*);

(f) a visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*);

(g) a visual inspection of the spleen;

(h) a visual inspection of the kidneys;

(i) a visual inspection of the pleura and peritoneum;

(j) a visual inspection of the umbilical region and joints.

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2. ►M2 Post-mortem inspection procedures shall be carried out in accordance with Article 18(2)(c) of Regulation (EU) 2017/625 and Article 7 and 8 of Regulation (EU) 2019/624, using incision and palpation of the carcase and offal, when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24: ◄

(a) a palpation of the throat, mouth, tongue and parotid lymph nodes. Unless animal-health rules provide otherwise, these examinations are not necessary if the competent authorities are able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;

(b) a palpation of the lungs; incision of the lungs, trachea, oesophagus, bronchial and mediastinal lymph nodes;

(c) an incision of the heart;

(d) a palpation of the liver and its lymph nodes; incision of the gastric surface of the liver to examine the bile ducts;

(e) a palpation of the spleen;

(f) an incision of the kidneys and the renal lymph nodes (*Lnn. renales*);

(g) a palpation of the umbilical region and joints; the umbilical region shall be incised and the joints opened; the synovial fluid shall be examined.

Article 21

Other domestic sheep and goats

1. Carcases and offal of sheep having a permanent incisor erupted or 12 months of age or more, and goats six months of age or more, shall undergo the following post-mortem inspection procedures:

(a) a visual inspection of the head, including the throat, mouth, tongue and parotid lymph nodes and palpation of the retropharyngeal lymph nodes. These examinations are not necessary if the competent authorities are able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;

(b) a visual inspection of the lungs, trachea and oesophagus; palpation of the lungs, the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*);

(c) a visual inspection of the pericardium and heart;

(d) a visual inspection of the diaphragm;

(e) a visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*); palpation of the liver and its lymph nodes; incision of the gastric surface of the liver to examine the bile ducts;

(f) a visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*);

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(g) a visual inspection of the spleen;

(h) a visual inspection of the kidneys;

(i) a visual inspection of the pleura and peritoneum;

(j) a visual inspection of the genital organs (except for the penis, if already discarded);

(k) a visual inspection of the udder and its lymph nodes.

2. ►M2 Post-mortem inspection procedures shall be carried out in accordance with Article 18(2)(c) of Regulation (EU) 2017/625 and Article 7 and 8 of Regulation (EU) 2019/624, using incision and palpation of the carcase and offal, when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24: ◄

(a) a palpation of the throat, mouth, tongue and parotid lymph nodes. Unless animal-health rules provide otherwise, these examinations are not necessary if the competent authorities are able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;

(b) an incision of the lungs, trachea, oesophagus and the bronchial and mediastinal lymph nodes;

(c) an incision of the heart;

(d) a palpation of the spleen;

(e) an incision of the kidneys and the renal lymph nodes (*Lnn. renales*).

Article 22

Domestic solipeds

1. Carcases and offal of domestic solipeds shall undergo the following post-mortem inspection procedures:

(a) a visual inspection of the head and, after freeing the tongue, the throat; the tongue shall be freed to permit a detailed visual inspection of the mouth and the fauces and must itself be visually examined;

(b) a visual inspection of the lungs, trachea, oesophagus and the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*);

(c) a visual inspection of the pericardium and the heart;

(d) a visual inspection of the diaphragm;

(e) a visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn portales*);

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(f) a visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*);

(g) a visual inspection of the spleen;

(h) a visual inspection of the kidneys;

(i) a visual inspection of the pleura and peritoneum;

(j) a visual inspection of the genital organs of stallions (except for the penis, if already discarded) and mares;

(k) a visual inspection of the udder and its lymph nodes (*Lnn. supram-ammarii*);

(l) a visual inspection of the umbilical region and joints of young animals;

(m) examination of the muscles and lymph nodes (*Lnn. subrhomboidei*) of the shoulders beneath the scapular cartilage after loosening the attachment of one shoulder, in the case grey horses, in order to inspect for melanosis and melanomata. The kidneys shall be exposed.

2. ►M2 Post-mortem inspection procedures shall be carried out in accordance with Article 18(2)(c) of Regulation (EU) 2017/625 and Article 7 and 8 of Regulation (EU) 2019/624, using incision and palpation of the carcase and offal, when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24: ◄

(a) a palpation and incision of the sub-maxillary, retropharyngeal and parotid lymph nodes (*Lnn. retropharyngiales, mandibulares* and *parotidei*); palpation of the tongue;

(b) a palpation of the lungs; palpation and incision of the bronchial and mediastinal lymph nodes. The trachea and the main branches of the bronchi shall be opened lengthwise and the lungs shall be incised in their posterior third, perpendicular to their main axes; however, these incisions are not necessary where the lungs are excluded from human consumption;

(c) an incision of the heart lengthwise, so as to open the ventricles and cut through the interventricular septum;

(d) a palpation and incision of the liver and the hepatic and pancreatic lymph nodes, (*Lnn. portales*);

(e) an incision of the gastric and mesenteric lymph nodes;

(f) a palpation of the spleen;

(g) a palpation of the kidneys and incision of the kidneys and the renal lymph nodes (*Lnn. renales*);

(h) an incision of the supramammary lymph nodes;

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(i) a palpation of the umbilical region and joints of young animals. In cases of doubt, the umbilical region shall be incised and the joints opened; the synovial fluid must be examined;

(j) an incision through the entire kidney in grey horses.

Article 23

Domestic swine

1. Carcases and offal of domestic swine shall undergo the following post-mortem inspection procedures:

(a) a visual inspection of the head and throat;

(b) a visual inspection of the mouth, fauces and tongue;

(c) a visual inspection of the lungs, trachea and oesophagus;

(d) a visual inspection of the pericardium and heart;

(e) a visual inspection of the diaphragm;

(f) a visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*); visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*);

(g) a visual inspection of the spleen; visual inspection of the kidneys; visual inspection of the pleura and peritoneum;

(h) a visual inspection of the genital organs (except for the penis, if already discarded);

(i) a visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*);

(j) a visual inspection of the umbilical region and joints of young animals.

2. ►M2 Post-mortem inspection procedures shall be carried out in accordance with Article 18(2)(c) of Regulation (EU) 2017/625 and Article 7 and 8 of Regulation (EU) 2019/624, using incision and palpation of the carcase and offal, when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24: ◄

(a) an incision and examination of the submaxillary lymph nodes (*Lnn. mandibulares*);

(b) a palpation of the lungs and the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*). The trachea and the main branches of the bronchi shall be opened lengthwise and the lungs shall be incised in their posterior third, perpendicular to their main axes; those incisions are not necessary where the lungs are excluded from human consumption;

▼B

(c) an incision of the heart lengthwise so as to open the ventricles and cut through the interventricular septum;

(d) a palpation of the liver and its lymph nodes;

(e) a palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;

(f) a palpation of the spleen;

(g) an incision of the kidneys and the renal lymph nodes (*Lnn. renales*);

(h) an incision of the supramammary lymph nodes;

(i) a palpation of the umbilical region and joints of young animals and, if necessary, incision of the umbilical region and opening of the joints.

Article 24

Indications of a possible risks to human health, animal health or animal welfare in domestic bovine animals, domestic sheep and goats, domestic solipeds and domestic swine

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The additional post-mortem inspection procedures referred to in Articles 18(3), 19(2), 20(2), 21(2), 22(2) and 23(2) shall be carried out using incision and palpation of the carcase and offal, where, in the opinion of the official veterinarian, a possible risk to human health, animal health or animal welfare is indicated by one of the following:

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(a) the checks and analysis of the checks of documents carried out in accordance with Articles 9 and 10;

(b) the findings of the ante-mortem inspection carried out in accordance with Article 11;

(c) the results of the verifications of compliance with animal welfare rules carried out in accordance with Article 38;

(d) the findings of post-mortem inspection carried out in accordance with Articles 12 to 24;

(e) additional epidemiological data or other data from the holding of provenance of the animals.

Article 25

Practical arrangements for post-mortem inspection of poultry

1. All poultry shall undergo post-mortem inspection which may include the assistance of slaughterhouse staff in accordance with Article 18(3) of Regulation (EU) 2017/625. The official veterinarian or official auxiliary, in accordance with Article 18(2)(c) of that Regulation shall personally carry out the following checks:

▼B

(a) daily inspection of the viscera and body cavities of a representative sample of each flock;

(b) a detailed inspection of a random sample of parts of birds or entire birds declared unfit for human consumption following post-mortem inspection from each flock;

(c) any further investigations necessary where there is reason to suspect that the meat from the birds concerned could be unfit for human consumption.

2. By way of derogation from paragraph 1, the competent authorities may decide that only a representative sample of poultry from each flock undergoes post-mortem inspection if:

(a) food business operators have a system in place to the satisfaction of the official veterinarian, that allows the detection and the separation of birds with abnormalities, contamination or defects;

(b) the slaughterhouse has a longstanding history of compliance with the requirements as regards:

(i) general and specific requirements in accordance with Article 4 of Regulation (EC) No 852/2004, including the microbiological criteria applicable to Point 1.28 and 2.1.5 of Annex I to Regulation (EC) No 2073/2005;

(ii) procedures based on the HACCP principles in accordance with Article 5 of Regulation (EC) No 852/2004; and

(iii) specific hygiene rules in accordance with Article 5 and Section II of Annex III to Regulation (EC) No 853/2004;

(c) no abnormalities that may indicate a serious problem for human or animal health that may indicate the need for measures laid down in Articles 40 to 44, have been found during ante-mortem inspection or verification of food chain information.

3. In case of poultry reared for the production of *foie gras* and delayed eviscerated poultry obtained at the holding of provenance in accordance with Points 8 and 9 of Chapter VI to Section II of Annex III to Regulation (EC) No 853/2004, post-mortem inspection shall take place at the cutting plant where such carcases are transported directly from the holding of provenance.

Article 26

Practical arrangements for post-mortem inspection of farmed lagomorphs

The practical arrangements for post-mortem inspection in poultry in accordance with Article 25, shall apply to farmed lagomorphs. The provisions applicable to a single poultry flock in Article 25 shall apply to farmed lagomorphs slaughtered the same day from a single holding of provenance.

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Article 27

Practical arrangements for post-mortem inspection of farmed game

1. The following post-mortem inspection procedures shall apply to farmed game:

(a) in the case of small (< 100 kg) *Cervidae*, the post-mortem procedures for ovine animals laid down in Article 21, however in the case of reindeer the post-mortem procedures for ovine animals laid down in Article 20 shall be used and the tongue may be used for human consumption without inspection of the head;

(b) in the case of game of the family *Suidae*, the post-mortem procedures for domestic swine laid down in Article 23;

▼M2

(c) in the case of other game ungulates, not covered by points (a) and (b) the post-mortem procedures for bovine animals laid down in Article 19;

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(d) in the case of ratites, the post-mortem procedures for poultry laid down in Article 25(1).

2. Where the animals have been slaughtered outside the slaughterhouse, the official veterinarian at the slaughterhouse shall verify the certificate.

Article 28

Practical arrangements for post-mortem inspection of wild game

1. The official veterinarian shall verify that a health certificate conforming to the specimen set out in the Annex to Regulation (EU) No 636/2014, or the declaration(s) in accordance with point 8(b) of Chapter II of Section IV of Annex III to Regulation (EC) No 853/2004, accompanies unskinned large wild game transported to the game-handling establishment from the territory of another Member State. The official veterinarian shall take into account the content of that certificate or declaration(s).

2. During post-mortem inspection, the official veterinarian shall carry out:

(a) a visual inspection of the carcase, its cavities and, where appropriate, organs with a view to:

(i) detecting any abnormalities not resulting from the hunting process. For this purpose, the diagnosis may be based on any information that the trained person has provided concerning the behaviour of the animal before killing;

(ii) checking that death was not due to reasons other than hunting;

(b) an investigation of organoleptic abnormalities;

(c) palpation and incisions of organs, where appropriate;

▼B

(d) where there are serious grounds for suspecting the presence of residues or contaminants, an analysis by sampling of residues not resulting from the hunting process, including environmental contaminants. Where a more extensive inspection is made on the basis of such suspicions, the veterinarian shall wait until that inspection has been concluded before assessing all the wild game killed during a specific hunt, or those parts suspected of showing the same abnormalities;

(e) examination for characteristics indicating that the meat presents a health risk, including:

(i) abnormal behaviour or disturbance of the general condition of the live animal, as reported by the hunter;

(ii) the generalised presence of tumours or abscesses affecting different internal organs or muscles;

(iii) arthritis, orchitis, pathological changes in the liver or the spleen, inflammation of the intestines or the umbilical region;

(iv) the presence of foreign bodies not resulting from the hunting process in the body cavities, stomach, intestines or urine, where the pleura or peritoneum are discoloured (when relevant viscera are present);

(v) the presence of parasites;

(vi) formation of a significant amount of gas in the gastro-intestinal tract with discolouring of the internal organs (when these viscera are present);

(vii) significant abnormalities of colour, consistency or odour of muscle tissue or organs;

(viii) aged open fractures;

(ix) emaciation and/or general or localised oedema;

(x) recent pleural or peritoneal adhesions;

(xi) other obvious extensive changes, such as putrefaction.

3. Where the official veterinarian so requires, the vertebral column and the head shall be split lengthwise.

4. In the case of small wild game not eviscerated immediately after killing, the official veterinarian shall carry out a post-mortem inspection on a representative sample of animals from the same source. Where inspection reveals a disease transmissible to humans or any of the characteristics listed in point (e) in paragraph 2, the official veterinarian shall carry out more checks on the entire batch to determine whether it shall be declared unfit for human consumption or whether each carcase shall be inspected individually.

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5. The official veterinarian may perform any further cuts and inspections of the relevant parts of the animals that are necessary to reach a final diagnosis. If an assessment cannot be made on the basis of the practical arrangements in paragraph 2, additional investigations shall be carried out in a laboratory.

6. In addition to the cases provided for in Article 45, meat presenting during post-mortem inspection any of the characteristics listed in point (e) in paragraph 2 shall be declared unfit for human consumption.

Section 4

Official controls on specific hazards and laboratory testing

Article 29

Practical arrangements for official controls for transmissible spongiform encephalopathies (TSEs)

1. In addition to the requirements of Regulation (EC) No 999/2001 concerning the official controls to be carried out in relation to TSEs, the official veterinarian shall check the removal, separation and, where appropriate, marking of specified risk material also in accordance with the rules laid down in Article 8(1) of that Regulation and in Article 12 of Regulation (EC) No 1069/2009 on animal by-products.

2. The official veterinarian shall ensure that the food business operator takes all necessary measures to avoid contaminating meat with specified risk material during slaughter, including stunning. This includes the removal of specified risk material.

Article 30

Practical arrangements for official controls for cysticercosis during post-mortem inspection in domestic bovine animals and *Suidae*

1. The post-mortem inspection procedures described in Articles 18, 19 and 23 shall be the minimum requirements for the examination for cysticercosis in bovine animals and *Suidae* (domestic swine, farmed game and wild game). In the case of bovine animals referred to in Article 19, the competent authorities may decide that incision of the masseters at post-mortem inspection is not compulsory if:

(a) a specific serological test is used;

(b) the animals have been raised on a holding of provenance officially certified to be free of cysticercosis; or,

(c) the prevalence of the source population or in a well-defined subpopulation is below one in a million, has been demonstrated with 95 % certainty or no cases have been detected in all slaughtered animals in the past five years (or two years where supported and justified by the competent authorities' risk analysis) based on data from reporting carried out in accordance with Article 9(1) of Directive 2003/99/EC.

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2. Meat infected with cysticerci shall be declared unfit for human consumption. However, where the animal is not generally infected with cysticercus, the parts not infected may be declared fit for human consumption after having undergone a cold treatment.

Article 31

Practical arrangements for official controls for *Trichinella* during post-mortem inspection

1. Carcases of *Suidae*, solipeds and other species susceptible to *Trichinella* shall be examined for *Trichinella* in accordance with Regulation (EU) 2015/1375 unless one of the derogations set out in Article 3 of that Regulation applies.

2. Meat from animals infected with trichinae shall be declared unfit for human consumption.

Article 32

Practical arrangements for official controls for glanders during post-mortem inspection of solipeds

1. Fresh meat of solipeds shall be placed on the market only if it was produced from solipeds kept for at least 90 days prior to the date of slaughter in a Member State or in a third country or region thereof from which it is authorised to bring solipeds into the Union.

2. In the case of solipeds originating from a Member State or third country or region thereof not meeting the World Organisation for Animal Health criteria for a glanders-free country, solipeds shall be inspected for glanders by a careful examination of the mucous membranes of the trachea, larynx, nasal cavities and sinuses and their ramifications, after splitting the head in the median plane and excising the nasal septum.

3. Meat produced from solipeds in which glanders has been diagnosed shall be declared unfit for human consumption.

Article 33

Practical arrangements for official controls for tuberculosis during post-mortem inspection

1. Where animals have reacted positively or inconclusively to tuberculin, or there are other grounds for suspecting infection, they shall be slaughtered separately from other animals, taking precautions to avoid the risk of contamination of other carcases, the slaughter line and staff present in the slaughterhouse.

2. All meat from animals in which post-mortem inspection has revealed localised lesions similar to tuberculoid lesions in a number of organs or a number of areas of the carcase shall be declared unfit for human consumption. However, where a tuberculoid lesion has been found in the lymph nodes of only one organ or part of the carcase, only the affected organ or part of the carcase and the associated lymph nodes shall be declared unfit for human consumption.

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Article 34

Practical arrangements for official controls for brucellosis during post-mortem inspection

1. Where animals have reacted positively or inconclusively to a brucellosis test, or there are other grounds for suspecting infection, they shall be slaughtered separately from other animals, taking precautions to avoid the risk of contamination of other carcases, the slaughter line and staff present in the slaughterhouse.

2. Meat from animals in which post-mortem inspection has revealed lesions indicating acute brucellosis shall be declared unfit for human consumption. In the case of animals reacting positively or inconclusively to a brucellosis test, the udder, genital tract and blood shall be declared unfit for human consumption even if no such lesion is found.

Article 35

Practical arrangements for official controls for *Salmonella*

1. The competent authorities shall verify the correct implementation by food business operators of points 2.1.3, 2.1.4 and 2.1.5 of Chapter 2 of Annex I of Regulation (EC) No 2073/2005 by applying one or more of the following measures:

(a) official sampling using the same method and sampling area as food business operators. At least 49 random samples ([11]) shall be taken in each slaughterhouse each year. This number of samples may be reduced in small slaughterhouses based on a risk evaluation;

(b) collecting all information on the total number and the number of *Salmonella*-positive samples taken by food business operators in accordance with Article 5 of Regulation (EC) No 2073/2005, in the framework of points 2.1.3, 2.1.4 and 2.1.5 of Chapter 2 of Annex I thereto;

(c) collecting all information on the total number and the number of *Salmonella*-positive samples taken in the framework of national control programmes in Member States or regions of Member States for which special guarantees have been approved in accordance with Article 8 of Regulation (EC) No 853/2004 as regards ruminant, equine, swine and poultry production.

2. Where the food business operator fails on several occasions to comply with the process hygiene criterion, the competent authorities shall require it to submit an action plan and shall strictly supervise its outcome.

3. The total number and the number of *Salmonella*-positive samples, differentiating between samples taken under points (a), (b) and (c) in paragraph 1, when applied, shall be reported in accordance with Article 9(1) of Directive 2003/99/EC.

([11]) If all are negative, 95 % statistical certainty is provided that the prevalence is below 6 %.

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Article 36

Practical arrangements for official controls for *Campylobacter*

1. The competent authorities shall verify the correct implementation by food business operators of point 2.1.9 (process hygiene criterion for *Campylobacter* on carcases of broilers) of Chapter 2 of Annex I of Regulation (EC) No 2073/2005 by applying the following measures:

(a) official sampling using the same method and sampling area as food business operators. At least 49 random samples shall be taken in each slaughterhouse each year. This number of samples may be reduced in small slaughterhouses based on a risk evaluation; or

(b) collecting all information on the total number and the number of *Campylobacter* samples with more than 1 000 cfu/g taken by food business operators in accordance with Article 5 of Regulation (EC) No 2073/2005, in the framework of point 2.1.9 of Chapter 2 of Annex I thereto.

2. Where the food business operator fails on several occasions to comply with the process hygiene criterion, the competent authorities shall require it to submit an action plan and shall strictly supervise its outcome.

3. The total number and the number of *Campylobacter* samples with more than 1 000 cfu/g, differentiating between samples taken under points (a) and (b) in paragraph 1, when applied, shall be reported in accordance with Article 9(1) of Directive 2003/99/EC.

Article 37

Specific requirements as regards laboratory tests

1. When performing laboratory tests in accordance with Article 18(2)(d)(ii) and (iv) of Regulation (EU) 2017/625, the official veterinarian shall ensure that, when sampling takes place, samples are appropriately identified and handled and sent to the appropriate laboratory in the framework of:

(a) the monitoring and control of zoonoses and zoonotic agents;

(b) the annual programme for the monitoring of TSEs in accordance with Article 6 of Regulation (EC) No 999/2001;

(c) the detection of pharmacologically active substances or products either prohibited or unauthorised, and controls for regulated pharmacologically active substances, pesticides, feed additives and contaminants exceeding applicable maximum Union limits, in particular in the framework of the national plans for the detection of residues or substances referred to in Article 110(2) of Regulation (EU) 2017/625 and in Article 5 of Directive 96/23/EC;

▼B

(d) the detection of animal diseases for which animal health rules are laid down in Regulation (EU) 2016/429.

2. The official veterinarian shall ensure that any additional laboratory testing deemed necessary for the fulfilment the obligations under Article 18(2) of Regulation (EU) 2017/625 takes place as required.

Section 5

Official controls on animal welfare

Article 38

Official controls on animal welfare at transport and slaughter

The official veterinarian shall verify compliance with the rules concerning the protection of animals during transport in accordance with Regulation (EC) No 1/2005 and at the time of slaughter in accordance with Regulation (EC) No 1099/2009 and national rules on animal welfare.

CHAPTER III

Communication of inspection results and measures to be taken by competent authorities in cases of specific non-compliance with requirements for fresh meat and for animal welfare

Article 39

Measures concerning the communication of the results of official controls

1. The official veterinarian shall record and evaluate the results of official controls carried out in accordance with Articles 7 to Article 38.

2. The following actions shall be taken by the official veterinarian where inspections reveal the presence of any disease or condition that might affect human or animal health, or compromise animal welfare:

(a) the official veterinarian shall inform the slaughterhouse operator;

(b) where the problem referred to in this paragraph arose during primary production and relates to human health, animal health, animal welfare or residues of veterinary medicinal products, unauthorised or prohibited substances, pesticide residues, feed additives or contaminants, the official veterinarian shall inform:

(i) the veterinarian attending the holding of provenance;

(ii) the official veterinarian who carried out any ante-mortem inspection at the holding of provenance, where different from (i);

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(iii) the food business operator responsible for the holding of provenance (provided that such information would not prejudice subsequent legal proceedings); and,

(iv) the competent authorities responsible for supervising the holding of provenance or the hunting area;

(c) where the animals concerned were raised in another country, the official veterinarian shall ensure that the country's competent authorities are informed.

3. The competent authorities shall enter the results of official controls in relevant databases, at least where the collection of such information is required under Article 4 of Directive 2003/99/EC, Article 8 of Council Directive 64/432/EEC ([12]) and Annex III to Directive 2007/43/EC.

4. Where the official veterinarian, while carrying out ante-mortem or post-mortem inspection or any other official control, suspects the presence of an animal disease for which animal health rules are laid down in Regulation (EU) 2016/429, he/she shall notify the competent authorities. The official veterinarian and competent authorities, within their respective areas of competence, shall take all necessary measures and precautions to prevent the possible spread of the disease agent.

5. The official veterinarian may use the model document in Annex I for the purpose of communicating the relevant results of ante-mortem and post-mortem inspections to the holding of provenance where the animals were kept before slaughter.

6. Where the animals were kept on a holding of provenance in another Member State, the competent authorities of the Member State in which they were slaughtered shall communicate the relevant results of ante-mortem and post-mortem inspections to the competent authorities in the Member State of provenance. They shall use the model document in Annex I in the official languages of both Member States involved or in a language agreed between both Member States.

Article 40

Measures in cases of non-compliance with requirements for food chain information

1. The official veterinarian shall ensure that animals are not slaughtered unless the slaughterhouse operator has been provided with, checked and evaluated relevant food chain information in accordance with Article 9(2)(a) and (b).

([12]) Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ L 121, 29.7.1964, p. 1977).

▼B

2. By way of derogation from paragraph 1, the official veterinarian may allow animals to undergo slaughter in the slaughterhouse if the relevant food chain information is not available. In such cases, the information shall be supplied before the meat is declared fit for human consumption and carcases and related offal shall be stored separately from other meat pending that declaration.

3. Where relevant food chain information is not available within 24 hours of an animal's arrival at the slaughterhouse, the official veterinarian shall declare all meat from the animal unfit for human consumption. If the animal has not yet been slaughtered, it shall be killed separately from other animals taking all necessary precautions to safeguard animal and human health.

Article 41

Measures in cases of non-compliance recorded in food chain information

1. The official veterinarian shall verify that the slaughterhouse operator does not accept animals for slaughter when the food chain information or any other accompanying records, documentation or information shows that:

(a) the animals come from a holding of provenance or an area subject to a movement prohibition or other restriction for reasons of animal or human health;

(b) rules on the use of veterinary medicinal products have not been complied with, animals have been treated with prohibited or unauthorised substances, or the legal limits for chemical residues or contaminants have not been complied with; or

(c) any other condition which might adversely affect human or animal health is present.

2. If the animals are already present at the slaughterhouse, they shall be killed separately and declared unfit for human consumption, taking precautions to safeguard animal and human health. Where the official veterinarian considers it necessary, official controls shall be carried out on the holding of provenance.

Article 42

Measures in cases of misleading food chain information

1. The competent authorities shall take appropriate action if they discover that the accompanying records, documentation or other information do not correspond to the true situation of the holding of provenance or the true condition of the animals, or aim deliberately to mislead the official veterinarian.

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2. They shall take action against the food business operator responsible for the holding of provenance of the animals, or any other person involved, including the slaughterhouse operator. In particular, this action may consist of extra controls. The food business operator responsible for the holding of provenance or any other person involved shall bear the costs of such extra controls.

Article 43

Measures in cases of non-compliance with requirements for live animals

1. The official veterinarian shall verify the food business operator's compliance with its duty under point 3 in Chapter IV of Section I of Annex III to Regulation (EC) No 853/2004 to ensure that animals accepted for slaughter for human consumption are properly identified. The official veterinarian shall ensure that animals whose identity is not ascertainable are killed separately and declared unfit for human consumption. Where the official veterinarian considers it necessary, official controls shall be carried out on the holding of provenance.

2. The official veterinarian shall ensure that animals subject to an unacceptable risk of contamination of the meat during slaughter, as laid down in Article 11(4), are not slaughtered for human consumption unless they are cleaned beforehand.

3. The official veterinarian shall ensure that animals with a disease or condition that may be transmitted to animals or humans handling or eating the meat and, in general, animals showing clinical signs of systemic disease or emaciation, or any other condition rendering meat unfit for human consumption, are not slaughtered for human consumption. Such animals shall be killed separately under such conditions that other animals or carcases cannot be contaminated, and declared unfit for human consumption.

4. The official veterinarian shall defer the slaughter of animals suspected of having a disease or condition that may adversely affect human or animal health. Such animals shall undergo detailed ante-mortem examination by the official veterinarian in order to make a diagnosis. In addition, the official veterinarian may decide that sampling and laboratory examinations must take place to supplement post-mortem inspection. If necessary to avoid contamination of other meat, the animals shall be slaughtered separately or at the end of normal slaughtering, taking all other necessary precautions.

5. The official veterinarian shall ensure that animals that might contain residues of prohibited or unauthorised pharmacologically active substances or residues of authorised pharmacologically active substances, pesticides or contaminants in excess of the levels laid down in accordance with Union legislation, are dealt with in accordance with Articles 16 to 19 of Directive 96/23/EC.

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6. The official veterinarian shall impose the conditions under which animals shall be dealt with under a specific scheme for the eradication or control of a specific disease, such as brucellosis or tuberculosis, or zoonotic agents such as salmonella, under his/her direct supervision. The competent authorities shall determine the conditions under which such animals may be slaughtered. These conditions shall be designed to minimise the contamination of other animals and the meat of other animals.

As a rule, animals that are presented to a slaughterhouse for slaughter shall be slaughtered there. However, in exceptional circumstances, such as a serious breakdown of the slaughter facilities, the official veterinarian may allow direct movements to another slaughterhouse.

Where non-compliance which results in a risk to animal or human health, or animal welfare, is detected during ante-mortem inspection at the holding of provenance, the official veterinarian shall not allow the animals to be transported to the slaughterhouse and the relevant measures regarding the communication of inspection results in accordance with Article 39(2)(b)(i) and (iii) shall apply.

Article 44

Measures in cases of non-compliance with requirements for animal welfare

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1. In cases of non-compliance with the rules concerning the protection of animals at the time of slaughter or killing laid down in Articles 3 to 9 and Articles 14 to 17 and 19 of Regulation (EC) No 1099/2009, the official veterinarian shall verify that the food business operator immediately takes the necessary corrective measures and prevents recurrence.

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2. The official veterinarian shall take a proportionate and stepped approach to enforcement action, ranging from issuing directions to slowing down and stopping production, depending on the nature and gravity of the problem.

3. Where appropriate, the official veterinarian shall inform other competent authorities of welfare problems.

4. Where the official veterinarian discovers non-compliance with the rules concerning the protection of animals during transport laid down in Regulation (EC) No 1/2005, he/she shall take the requisite measures in accordance with the relevant Union legislation.

5. Where an official auxiliary carries out checks on animal welfare and those checks identify non-compliance with the rules on the protection of animals, he/she shall immediately inform the official veterinarian. If necessary in urgent cases, he/she shall take the necessary measures referred to in paragraphs 1 to 4 pending the arrival of the official veterinarian.

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Article 45

Measures in cases of non-compliance with requirements for fresh meat

The official veterinarian shall declare fresh meat unfit for human consumption if it:

(a) derives from animals that have not undergone ante-mortem inspection in accordance with Article 18(2)(a) or (b) of Regulation (EU) 2017/625, except for wild game and stray reindeer referred to in Article 12(1)(b) of Delegated Regulation (EU) 2019/624;

(b) derives from animals whose offal has not undergone post-mortem inspection in accordance with Article 18(2)(c) of Regulation (EU) 2017/625, except in case of viscera of large wild game that do not need to accompany the body to a game-handling establishment in accordance with point 4 of Chapter II of Section IV in Annex III of Regulation (EC) No 853/2004;

(c) derives from animals that are dead before slaughter, stillborn, unborn or slaughtered under the age of seven days;

(d) results from the trimming of sticking points;

(e) derives from animals affected by animal diseases for which animal health rules are laid down in the Union legislation listed in Annex I to Directive 2002/99/EC, except if it is obtained in conformity with the specific requirements provided for in that Directive; this exception shall not apply if otherwise provided for in the requirements on the official controls of tuberculosis and brucellosis provided for in Articles 33 and 34 of this Regulation;

(f) derives from animals affected by a generalised disease, such as generalised septicaemia, pyaemia, toxaemia or viraemia;

(g) is not in conformity with the food safety criteria laid down in Chapter I of Annex I to Regulation (EC) No 2073/2005 for determining whether food may be placed on the market;

(h) exhibits parasitic infestation, unless otherwise provided for in the requirements on the official controls for cysticercosis provided for in Article 30;

(i) contains chemical residues or contaminants in excess of the levels laid down in Regulations (EU) No 37/2010, (EC) No 396/2005, (EC) No 1881/2006 and (EC) No 124/2009 or residues of substances that are prohibited or unauthorised under Regulation (EU) No 37/2010 or Directive 96/22/EC;

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(j) consists of the liver and kidneys of animals more than two years old from regions where implementation of plans approved in accordance with Article 5 of Directive 96/23/EC has revealed the generalised presence of heavy metals in the environment;

(k) has been treated illegally with decontaminating substances;

(l) has been treated illegally with ionising radiation, including UV-radiation;

(m) contains foreign bodies, except, in the case of wild game, material used to hunt the animal;

(n) exceeds maximum permitted radioactivity levels laid down under Union legislation or, in the absence of Union legislation, under national rules;

(o) indicates pathological or organoleptic changes, in particular a pronounced sexual odour or insufficient bleeding (except for wild game);

(p) derives from emaciated animals;

(q) contains specified risk material unless removal is allowed in another establishment in accordance with Point 4.3 of Annex V to Regulation (EC) No 999/2001 and the fresh meat remains under the control of the competent authorities;

(r) shows soiling, faecal or other contamination;

(s) consists of blood that may constitute a risk to human or animal health owing to the health status of any animal from which it derives or contamination arising during the slaughter process;

(t) in the opinion of the official veterinarian, after examination of all the relevant information, may constitute a risk to human or animal health or is for any other reason not suitable for human consumption;

(u) gives rise to specific hazards in accordance with Articles 29 to 36.

Article 46

Measures in cases of non-compliance with requirements on good hygiene practices

1. The competent authorities may instruct the food business operator to take immediate corrective action, including a reduction in the speed of slaughter, where this is considered necessary by the official present in the following cases:

(a) where contamination is detected on external surfaces of a carcase or its cavities and the food business operator does not take appropriate action to rectify the situation; or

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(b) if the competent authorities consider that good hygiene practices are jeopardised.

2. In such cases, the competent authorities shall increase the intensity of inspection until such time as they are satisfied that the food business operator has regained control of the process.

CHAPTER IV

Restrictions

Article 47

Restrictions for certain fresh meat

The official veterinarian may impose requirements concerning the use of fresh meat derived from animals:

(a) that have undergone emergency slaughter outside the slaughterhouse; or

(b) from flocks where a treatment of the meat is applied in accordance with Part E of Annex II to Regulation (EC) No 2160/2003 before the meat is placed on the market.

CHAPTER V

Health marking of meat fit for human consumption after ante-mortem and post-mortem inspection

Article 48

Technical requirements of the health mark and practical arrangements for its application

1. The official veterinarian shall supervise health marking and the marks used.

2. The official veterinarian shall ensure, in particular, that:

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(a) the health mark is applied only to domestic ungulates and farmed game mammals other than lagomorphs, having undergone ante-mortem and post-mortem inspection, and large wild game having undergone post mortem inspection, in accordance with Article 18(2)(a), (b) and (c) of Regulation (EU) 2017/625, where there are no grounds for declaring the meat unfit for human consumption. However, the mark may be applied before the results of any examination for *Trichinella* and/or TSE testing are available, in accordance with the provisions laid down respectively in Article 4(3) of Implementing Regulation (EU) 2015/1375 and in Chapter A of Annex III to Regulation (EC) No 999/2001, points 6.2 and 6.3 of point I and points 7.2 and 7.3 of point II;

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(b) the health mark is applied on the external surface of the carcase, by stamping in ink or hot branding, in such a manner that, if carcases are cut in the slaughterhouse into half carcases or quarters, or half carcases are cut into three pieces, each piece bears a health mark.

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3. The competent authorities shall ensure that the practical arrangements for the health mark are applied in accordance with Annex II.

4. The competent authorities shall ensure that meat from unskinned wild game does not bear a health mark until, after skinning in a game-handling establishment, it has undergone post-mortem inspection and been declared fit for human consumption.

TITLE IV

SPECIFIC REQUIREMENTS AND UNIFORM MINIMUM FREQUENCY OF OFFICIAL CONTROLS WITH RESPECT TO RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS, AS NECESSARY TO RESPOND TO RECOGNISED UNIFORM HAZARDS AND RISKS

Article 49

Control of milk and colostrum production holdings

1. The official veterinarian shall verify that the health requirements for raw milk and colostrum production as laid down in Part I of Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 are complied with. In particular, the official veterinarian shall verify:

(a) the health status of the animals;

(b) the absence of the use of prohibited or unauthorised pharmacologically active substances; and

(c) that the possible presence of residues of authorised pharmacologically active substances, pesticides or contaminants does not exceed the levels laid down in Regulations (EU) No 37/2010, (EC) No 396/2005 or (EC) No 1881/2006.

2. The official controls referred to in paragraph 1 may take place at the occasion of veterinary checks carried out pursuant to Union provisions on animal or human health or animal welfare.

3. If there are grounds for suspecting that the health requirements referred to in paragraph 1 are not being complied with, the official veterinarian shall check the general health status of the animals.

4. Milk and colostrum production holdings shall undergo official controls by the competent authorities to verify that hygiene requirements laid down in Part II of Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 are being complied with. These controls may involve inspections and the monitoring of controls carried out by professional organisations. If it is demonstrated that the hygiene is inadequate, the competent authorities shall verify that appropriate steps are taken to correct the situation.

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Article 50

Control of milk and colostrum

1. In the case of raw milk and colostrum, the competent authorities shall monitor the checks carried out in accordance with Part III of Chapter I, Section IX of Annex III to Regulation (EC) No 853/2004. When testing is used, the competent authorities shall use the analytical methods set out in Annex III to this Regulation to check compliance with the limits laid down for raw milk and colostrum in Part III of Chapter I, Section IX of Annex III to Regulation (EC) No 853/2004.

2. If the food business operator of the production holding has not corrected the situation within three months of the first notification to the competent authorities of non-compliance with the plate count and/or somatic cell count criteria for raw milk and colostrum, the competent authorities shall verify that:

(a) delivery of raw milk and colostrum from the production holding is suspended, or

(b) the raw milk and colostrum is subjected to requirements concerning its treatment and use necessary to protect human health in accordance with a specific authorisation of, or general instructions from the competent authorities.

This suspension or these requirements shall remain in place by the competent authorities until the food business operator has proved that the raw milk and colostrum again comply with the criteria.

3. The competent authorities shall use the analytical methods set out in Annex III of this Regulation to verify appropriate application of a pasteurisation process to dairy products as referred to in Part II of Chapter II, Section IX of Annex III to Regulation (EC) No 853/2004.

TITLE V

SPECIFIC REQUIREMENTS FOR OFFICIAL CONTROLS CONCERNING LIVE BIVALVE MOLLUSCS FROM CLASSIFIED PRODUCTION AND RELAYING AREAS

Article 51

Exclusion

This Title applies to live bivalve molluscs. It also applies to live echinoderms, live tunicates and live marine gastropods. This Title does not apply to live marine gastropods and live *Holothuroidea* that are not filter feeders.

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Article 52

Classification of production and relaying areas for live bivalve molluscs

1. The competent authorities shall fix the location and boundaries of the production and relaying areas that they classify in accordance with Article 18(6) of Regulation (EU) 2017/625. They may, where appropriate, do so in cooperation with the food business operator.

2. The competent authorities shall classify production and relaying areas from which they authorise the harvesting of live bivalve molluscs as Class A, Class B and Class C areas according to the level of faecal contamination. They may, where appropriate, do so in cooperation with the food business operator.

3. In order to classify production and relaying areas, the competent authorities shall fix a review period for sampling data from each production and relaying area in order to determine compliance with the standards referred to in Articles 53, 54 and 55.

CHAPTER I

Specific requirements for the classification of production and relaying areas for live bivalve molluscs

Article 53

Requirements for Class A areas

1. The competent authorities may classify as Class A areas those from which live bivalve molluscs may be collected for direct human consumption.

2. Live bivalve molluscs placed on the market from such areas shall meet the health standards for live bivalve molluscs set out in Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004.

3. Samples of live bivalve molluscs from Class A areas shall not exceed, in 80 % of samples collected during the review period, 230 *E. coli* per 100 g of flesh and intravalvular liquid.

4. The remaining 20 % of samples shall not exceed 700 *E. coli* per 100 g of flesh and intravalvular liquid.

5. When evaluating the results for the fixed review period for maintenance of a Class A area, the competent authorities may, on the basis of a risk assessment based on an investigation, decide to disregard an anomalous result exceeding the level of 700 *E. coli* per 100 g of flesh and intravalvular liquid.

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Article 54

Requirements for Class B areas

1. The competent authorities may classify as Class B areas those from which live bivalve molluscs may be collected and placed on the market for human consumption only after treatment in a purification centre or after relaying so as to meet the health standards referred to in Article 53.

2. Live bivalve molluscs from Class B areas shall not exceed, in 90 % of the samples, 4 600 *E. coli* per 100 g of flesh and intravalvular liquid.

3. The remaining 10 % of samples shall not exceed 46 000 *E. coli* per 100 g of flesh and intravalvular liquid.

Article 55

Requirements for Class C areas

1. The competent authorities may classify as Class C areas those from which live bivalve molluscs may be collected and placed on the market only after relaying over a long period so as to meet the health standards referred to in Article 53.

2. Live bivalve molluscs from Class C areas shall not exceed 46 000 *E. coli* per 100 g of flesh and intravalvular liquid.

Article 56

Sanitary survey requirements

1. Before classifying a production or relaying area, the competent authorities shall carry out a sanitary survey that includes:

(a) an inventory of the sources of pollution of human or animal origin likely to be a source of contamination for the production area;

(b) an examination of the quantities of organic pollutants released during the different periods of the year, according to the seasonal variations of human and animal populations in the catchment area, rainfall readings, waste-water treatment, etc.;

(c) determination of the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area.

2. The competent authorities shall carry out a sanitary survey fulfilling the requirements set out in paragraph 1 in all classified production and relaying areas, unless carried out previously.

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3. The competent authorities may be assisted by other official bodies or food business operators under conditions established by the competent authorities in relation to the performance of this survey.

Article 57

Monitoring programme

The competent authorities shall establish a monitoring programme for live bivalve mollusc production areas that is based on an examination of the sanitary survey referred to in Article 56. The number of samples, geographical distribution of sampling points and sampling frequency for the programme shall ensure that the results of the analysis are representative of the area in question.

Article 58

The competent authorities shall establish a procedure to ensure that the sanitary survey referred to in Article 56 and the monitoring programme referred to in Article 57 are representative of the area considered.

CHAPTER II

Conditions for the monitoring of classified production and relaying areas for live bivalve molluscs

Article 59

Monitoring of classified production and relaying areas

The competent authorities shall periodically monitor production and relaying areas classified in accordance with Article 18(6) of Regulation (EU) 2017/625 in order to check:

(a) that there is no malpractice with regard to the origin, provenance and destination of live bivalve molluscs;

(b) the microbiological quality of live bivalve molluscs in relation to the classified production and relaying areas;

(c) for the presence of toxin-producing plankton in production and relaying waters and marine biotoxins in live bivalve molluscs;

(d) for the presence of chemical contaminants in live bivalve molluscs.

Article 60

Recognised methods for the detection of marine biotoxins in live bivalve molluscs

1. The competent authorities shall use the analytical methods laid down in Annex V to check compliance with the limits laid down in point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 and, where appropriate, to verify compliance by food business operators. Food business operators shall use these methods where appropriate.

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2. In accordance with Article 4 of Directive 2010/63/EU, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used where possible, instead of a procedure as defined in Article 3(1) of that Directive.

3. In accordance with Article 4 of Directive 2010/63/EU, elements of replacement, refinement and reduction must be taken into account when biological methods are used.

Article 61

Sampling plans

1. For the purposes of the checks provided for in points (b), (c) and (d) of Article 59, the competent authorities shall draw up sampling plans providing for such checks to take place at regular intervals, or on a case-by-case basis if harvesting periods are irregular. The geographical distribution of the sampling points and the sampling frequency shall ensure that the results of the analysis are representative of the classified production and relaying area concerned.

2. Sampling plans to check the microbiological quality of live bivalve molluscs shall take particular account of:

(a) the likely variation in faecal contamination;

(b) the parameters referred to in Article 56(1).

3. Sampling plans to check for the presence of toxin-producing plankton in the water in classified production and relaying areas and for marine biotoxins in live bivalve molluscs shall take particular account of possible variations in the presence of plankton containing marine biotoxins. Sampling shall comprise:

(a) periodic sampling to detect changes in the composition of plankton containing toxins and their geographical distribution. Results suggesting an accumulation of toxins in live bivalve mollusc flesh shall be followed by intensive sampling;

(b) periodic toxicity tests using live bivalve molluscs from the affected area most susceptible to contamination.

4. The sampling frequency for toxin analysis in live bivalve molluscs shall be weekly during harvesting periods, except when:

(a) the sampling frequency may be reduced in specific classified relaying or production areas, or for specific types of live bivalve mollusc, if a risk assessment of toxins or phytoplankton occurrence suggests a very low risk of toxic episodes;

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(b) the sampling frequency shall be increased where such an assessment suggests that weekly sampling would not be sufficient.

5. The risk assessment referred to in paragraph 4 shall be reviewed periodically in order to assess the risk of toxins occurring in the live bivalve molluscs from these areas.

6. Where knowledge of toxin accumulation rates is available for a group of species growing in the same classified production or relaying area, the species with the highest rate may be used as an indicator species. This will allow the exploitation of all species in the group if toxin levels in the indicator species are below the regulatory limits. Where toxin levels in the indicator species are above the regulatory limits, the harvesting of the other species may be allowed only if further analysis of the other species shows toxin levels below the limits.

7. With regard to the monitoring of plankton, the samples shall be representative of the water column in the classified production or relaying area and provide information on the presence of toxic species and on population trends. If any changes in toxic populations that may lead to toxin accumulation are detected, the sampling frequency for live bivalve molluscs shall be increased or precautionary closures of the areas established until results of toxin analysis are obtained.

8. Sampling plans to check for the presence of chemical contaminants shall enable the detection of any overshooting of the levels laid down in Regulation (EC) No 1881/2006.

CHAPTER III

Management of classified production and relaying areas after monitoring

Article 62

Decisions following monitoring

1. Where the results of the monitoring provided for in Article 59 indicate that the health standards for live bivalve molluscs are not met or that there may otherwise be a risk to human health, the competent authorities shall close the classified production or relaying area concerned, preventing the harvesting of live bivalve molluscs. However, they may reclassify a production or relaying area as being of Class B or C if it meets the relevant criteria set out in Articles 54 and 55 and presents no other risk to human health.

2. Where the results of microbiological monitoring show that the health standards for live bivalve molluscs referred to in Article 53 not met, competent authorities may, on the basis of a risk assessment, and only on a temporary and non-recurring basis, permit continued harvesting without closure or reclassification subject to the following conditions:

(a) the classified production area concerned and all approved establishments receiving live bivalve molluscs from it are under the official control of the same competent authorities;

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(b) the live bivalve molluscs concerned are subjected to appropriate restrictive measures such as purification, relaying or processing.

3. The accompanying registration document, as referred to in Chapter I of Section VII of Annex III to Regulation (EC) No 853/2004, shall include all the information concerning the application of paragraph 2.

4. The competent authorities shall establish the conditions under which paragraph 2 can be availed of in order to ensure, for the production area concerned, maintenance of the compliance with the criteria established in Article 53.

Article 63

Re-opening of production areas

1. The competent authorities may re-open a closed production or relaying area only if the health standards for live bivalve molluscs comply once again with the relevant requirements of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 and present no other risk to human health.

2. Where the competent authorities have closed a production or relaying area because of the presence of plankton or levels of toxins in live bivalve molluscs that exceed the regulatory limit for marine biotoxins laid down in point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004, they may re-open it only if at least two consecutive analytical results separated by at least 48 hours are below the regulatory limit.

3. When deciding whether to re-open a production or relaying area, the competent authorities may take account of information on phytoplankton trends.

4. Where there are robust data on the dynamic of the toxicity for a given area, and provided that recent data on decreasing trends of toxicity are available, the competent authorities may decide to re-open an area with results below the regulatory limit in point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 obtained from a single sampling.

Article 64

Control system

1. The competent authorities shall set up a control system to ensure that products of animal origin harmful to human health are not placed on the market. The control system shall comprise laboratory tests to verify food business operators' compliance with the requirements for the end product, including live bivalve molluscs and any products derived from them, at all stages of production, processing and distribution.

2. This control system shall verify, where applicable, that the levels of marine biotoxins and contaminants do not exceed safety limits and that the microbiological quality of the molluscs does not constitute a hazard to human health.

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Article 65

Decision by the competent authorities

1. The competent authorities shall act promptly where a production area must be closed or reclassified, or may be re-opened, or where live bivalve molluscs are subject to the application of measures as referred to in Article 62(2).

2. When deciding on the classification, reclassification, opening or closure of production areas in accordance with Articles 52, 62 and 63, competent authorities may take into account the results of checks carried out by food business operators or organisations representing food business operators, only if the laboratory carrying out the analysis is designated by the competent authorities, and the sampling and analysis are performed in accordance with a protocol agreed upon jointly by the competent authorities and food business operators or organisation concerned.

CHAPTER IV

Other requirements

Article 66

Recording and exchange of information

The competent authorities shall:

(a) establish and keep up to date a list of classified production and relaying areas, with details of their location, and boundaries, as well as the Class in which the area is classified, from which live bivalve molluscs may be taken in accordance with the requirements of Article 52. This list shall be communicated to interested parties affected by this Regulation, such as producers, gatherers and operators of purification centres and dispatch centres;

(b) ►C1 immediately inform the interested parties such as producers, gatherers and operators of purification centres and dispatch centres, of any change to the location, boundaries or Class of a production area, of its temporary or final closure, or of the application of measures as referred to in Article 62(2). ◄

TITLE VI

SPECIFIC REQUIREMENTS AND UNIFORM MINIMUM FREQUENCY OF OFFICIAL CONTROLS WITH RESPECT TO FISHERY PRODUCTS

Article 67

Official controls on production and placing on the market

Official controls on the production and placing on the market of fishery products shall include verification of compliance with the requirements set out in Section VIII of Annex III to Regulation (EC) No 853/2004, in particular:

(a) a regular check on the hygiene conditions of landing and first sale;

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(b) regular inspections of vessels and establishments on land, including fish auctions and wholesale markets, in particular to check:

(i) whether the conditions for approval are still fulfilled;

(ii) whether the fishery products are handled correctly;

(iii) compliance with hygiene and temperature requirements;

(iv) the cleanliness of establishments, including vessels, and their facilities and equipment, and staff hygiene;

(c) checks on storage and transport conditions.

Article 68

Site of official controls

1. The competent authorities shall carry out official controls on vessels when these call at a port in a Member State. These controls shall concern all vessels landing fishery products at EU ports, irrespective of flag.

2. Flag state competent authorities may carry out official controls on vessels under their flag while the vessel is at sea or in a port in another Member State or a third country.

Article 69

Approval of factory, freezer or reefer vessels

1. Where a factory, freezer or reefer vessel flying the flag of a Member State is inspected with a view to granting approval of the vessel, the competent authorities of the flag Member State shall carry out official controls in accordance with Article 148 of Regulation (EU) 2017/625, particularly the time limits referred to in Article 148(4). If necessary, they may inspect the vessel while it is at sea or in a port in another Member State or a third country.

2. Where the competent authorities of the flag Member State have granted the vessel conditional approval in accordance with Article 148 of Regulation (EU) 2017/625, they may authorise the competent authorities of another Member State, or of a third country to carry out follow-up controls with a view to granting full approval, prolonging conditional approval or keeping approval under review, provided that, in the case of a third country, such country appears on a list of third countries from which imports of fishery products are permitted pursuant to Article 127 of Regulation (EU) 2017/625. If necessary, these competent authorities may inspect the vessel while it is at sea or in a port in another Member State or third country.

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3. Where the competent authorities of a Member State authorise the competent authorities of another Member State or of a third country to carry out controls on their behalf in accordance with this Article, the two competent authorities shall agree on the conditions governing such controls. These conditions shall ensure, in particular, that the competent authorities of the flag Member State receive reports on the results of the controls and on any suspected non-compliance without delay, so as to enable them to take the necessary measures.

Article 70

Official controls of fishery products

Official controls of fishery products shall include at least the practical arrangements laid down in Annex VI as regards:

(a) organoleptic examinations;

(b) freshness indicators;

(c) histamine;

(d) residues and contaminants;

(e) microbiological checks;

(f) parasites;

(g) poisonous fishery products.

Article 71

Decisions after controls

The competent authorities shall declare fishery products unfit for human consumption if:

(a) official controls carried out in accordance with Article 70 reveal they are not in compliance with organoleptic, chemical, physical or microbiological requirements or requirements for parasites as established in Section VII of Annex III of Regulation (EC) No 853/2004 and/or Regulation (EC) No 2073/2005;

(b) they contain in their edible parts chemical residues or contaminants in excess of the levels laid down in Regulations (EU) No 37/2010, (EC) No 396/2005, (EC) No 1881/2006, or residues of substances that are prohibited or unauthorised in accordance with Regulation (EU) No 37/2010 or Directive 96/22/EC, or are not in compliance with any other relevant Union legislation on pharmacologically active substances;

(c) they derive from:

(i) poisonous fish;

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(ii) fishery products not complying with the requirements on marine biotoxins;

(iii) live bivalve molluscs, echinoderms, tunicates or marine gastropods containing marine biotoxins in total quantities exceeding the limits referred to in Regulation (EC) No 853/2004; or

(d) the competent authorities consider that they may constitute a risk to human or animal health or are for any other reason not suitable for human consumption.

Article 72

Requirements concerning the official controls on fishery products caught by vessels flying the flag of Member States entering the Union after being transferred in third countries with or without storage

1. Fishery products intended for human consumption caught by vessels flying the flag of a Member State, unloaded, with or without storage, in third countries listed as provided for in Article 126(2)(a) of Regulation (EU) 2017/625 before entering the Union by a different means of transportation, shall be accompanied by a health certificate issued by the competent authorities of that third country and completed in accordance with the model health certificate set out in Chapter B of Part II to Annex III to Implementing Regulation (EU) 2019/628.

2. If the fishery products referred to in paragraph 1 are unloaded and transported to a storage facility located in the third country referred to in that paragraph, that storage facility shall appear in a list as provided for in Article 5 of Delegated Regulation (EU) 2019/625.

3. If the fishery products referred to in paragraph 1 are loaded in a vessel flying the flag of a third country, that third country shall be listed as provided for in Article 3 of Delegated Regulation (EU) 2019/625 and the vessel shall appear in a list as provided for in Article 5 of Delegated Regulation (EU) 2019/625.

4. Container vessels used to transport containerised fishery products are excluded from this requirement.

TITLE VII

SPECIFIC REQUIREMENTS FOR THE PERFORMANCE OF OFFICIAL CONTROLS AND UNIFORM MINIMUM FREQUENCY FOR OFFICIAL CONTROLS ON REPTILE MEAT

Article 73

Ante-mortem and post-mortem inspection of reptiles

Article 11 shall apply to the ante-mortem inspection of reptiles.

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Articles 12, 13 and 14 shall apply to the post-mortem inspection of reptiles. For the purpose of Article 13 (a)(i), a reptile will be considered as 0,5 livestock units.

TITLE VIII

FINAL PROVISIONS

Article 74

Amendments to Regulation (EC) No 2074/2005

Regulation (EC) No 2074/2005 is amended as follows:

1. Articles 5, 6b and 6c are deleted.

2. In Annex I, Section II and the Appendix are deleted.

3. In Annex II, Section II is deleted.

4. Annexes III and V are deleted.

5. Annex VIa is deleted.

6. Annex VIb and its Appendix are deleted.

Article 75

Entry in force and application

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

It shall apply from 14 December 2019.

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

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ANNEX I

MODEL DOCUMENT FOR COMMUNICATION WITH THE HOLDING OF PROVENANCE IN ACCORDANCE WITH ARTICLE 39(5)

1. **Identification details**

1.1. Holding of provenance (owner or manager)

Name/number

Full address

Telephone number

Electronic address if available

1.2. Identification numbers of … [please specify] or attach list

Total number of animals (by species)

Identification problems (if any)

1.3. Herd/flock/cage identification number (if applicable)

1.4. Animal species

1.5. Reference number of health certificate (if applicable)

2. **Ante-mortem findings**

2.1. Welfare

Number of animals affected

Type/class/age

Observations

2.2. Animals were delivered dirty

2.3. Clinical findings of disease

Number of animals affected

Type/class/age

Observations

Date of inspection

2.4. Laboratory results ([1])

([1]) Microbiological, chemical, serological, etc. (include results as attached).

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3. **Post-mortem findings**
3.1. Macroscopic findings Number of animals affected Type/class/age Organ or site of animal(s) affected Date of slaughter
3.2. Disease (codes may be used [2]) Number of animals affected Type/class/age Organ or site of the animal(s) affected Partially or totally condemned carcase (give reason) Date of slaughter
3.3. Laboratory results [3]
3.4. Other results
3.5. Welfare findings
4. **Additional information**
5. **Contact details of slaughterhouse (approval number)** Name Full address Telephone number Electronic address if available
6. **Official veterinarian (print name)** Signature and stamp
7. **Date**
8. **Number of pages attached to this form:**

[2] The competent authorities may introduce the following codes: code A for OIE-listed diseases; codes B100 and B200 for welfare issues and C100 to C290 for decisions concerning meat. The coding system can, if necessary, include further subdivisions (e.g. C141 for a mild generalised disease, C142 for a more severe disease, etc.). If codes are used, they must be readily available to the food business operator with a suitable explanation of their meaning.

[3] Microbiological, chemical, serological, etc. (include results as attached).

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ANNEX II

PRACTICAL ARRANGEMENTS FOR THE HEALTH MARK IN ACCORDANCE WITH ARTICLE 48

1. The health mark must be an oval mark at least 6,5 cm wide by 4,5 cm high bearing the following information in perfectly legible characters:

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(a) the name of the country in which the establishment is located, which may be written out in full in capitals or shown as a two-letter code in accordance with the relevant ISO code. In the case of Member States ([1]), however, these codes are BE, BG, CZ, DK, DE, EE, IE, GR, ES, FR, HR, IT, CY, LV, LT, LU, HU, MT, NL, AT, PL, PT, RO, SI, SK, FI, SE and UK(NI);

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(b) the approval number of the slaughterhouse; and

(c) (when the mark is applied in an establishment located in the Union) the abbreviation CE, EC, EF, EG, EK, EO, EY, ES, EÜ, EB, EZ, KE or WE. Those abbreviations must not appear on marks applied on meat imported into the Union from slaughterhouses located outside the Union.

2. Letters must be at least 0,8 cm high and figures at least 1 cm high. The dimensions of the characters and the mark may be reduced for the health marking of lamb, kids and piglets.

3. The ink used for health marking must be authorised in accordance with Union rules on the use of colouring substances in foodstuffs.

4. The health mark may also include an indication of the official veterinarian who carried out the health inspection of the meat.

([1]) 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.

▼B

ANNEX III

TESTING METHODS FOR RAW MILK AND HEAT-TREATED COW'S MILK IN ACCORDANCE WITH ARTICLE 50

CHAPTER I

DETERMINATION OF PLATE COUNT AND SOMATIC CELL COUNT

A. When verifying compliance with the criteria laid down in Part III of Section IX, Chapter I of Annex III to Regulation (EC) No 853/2004, the following standards must be applied as reference methods:

1. EN ISO 4833-1 for the plate count at 30 °C;

2. EN ISO 13366-1 for the somatic cell count.

B. The use of alternative analytical methods is acceptable:

1. for the plate count at 30 °C, where the methods are validated against the reference method mentioned in point 1 of Part A in accordance with the protocol set out in standard EN ISO 16140-2, supplemented by standard EN ISO 16297 for the specific case of plate count in raw milk.

   In particular, the conversion relationship between an alternative method and the reference method mentioned in point 1 of Part A is established according to standard EN ISO 21187.

2. for the somatic cell count, where the methods are validated against the reference method mentioned in point 2 of Part A in accordance with the protocol set out in standard ISO 8196-3 and operated in accordance with standard EN ISO 13366-2 or other similar internationally accepted protocols.

CHAPTER II

DETERMINATION OF ALKALINE PHOSPHATASE ACTIVITY IN COW'S MILK

A. To determine alkaline phosphatase activity in pasteurised cow's milk, standard EN ISO 11816-1 must be applied as the reference method.

B. The alkaline phosphatase activity in pasteurised cow's milk is expressed as milli units of enzyme activity per litre (mU/l). A unit of alkaline phosphatase activity is the amount of alkaline phosphatase enzyme that catalyses the transformation of 1 micromole of substrate per minute.

C. An alkaline phosphatase test is considered to give a negative result if the measured activity in cow's milk is not higher than 350 mU/l.

D. The use of alternative analytical methods is acceptable where they are validated against the reference methods mentioned in Part A in accordance with internationally accepted protocols and rules of good laboratory practices.

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ANNEX IV

REFERENCE TESTING METHOD FOR ANALYSIS OF E. COLI IN LIVE BIVALVE MOLLUSCS FOR CLASSIFICATION OF PRODUCTION AND RELAYING AREAS IN ACCORDANCE WITH ARTICLE 52(2)

The reference method for analysis of E. coli in live bivalve molluscs shall be the detection and 'most probable number' (MPN) technique specified in ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in ISO 16140.

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ANNEX V

RECOGNISED METHODS FOR THE DETECTION OF MARINE BIOTOXINS IN ACCORDANCE WITH ARTICLE 60

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CHAPTER I

PARALYTIC SHELLFISH POISON DETECTION METHOD

A. The paralytic shellfish poisoning (PSP) toxins content of the whole body or any part edible separately of bivalve molluscs shall be determined using the method described in the Standard EN 14526 ([1]) or any other internationally recognised validated method not entailing the use of a live animal.

B. The abovementioned methods shall determine at least the following compounds:

(a) Toxins Carbamate STX, NeoSTX, gonyautoxin 1 and 4 (GTX1 and GTX4 isomers determined together) and gonyautoxin 2 and 3 (GTX2 and GTX3 isomers determined together);

(b) Toxins N-sulfo-carbamoyl (B1), gonyautoxin-6 (B2), N-sulfocarbamoyl-gonyautoxin 1 and 2 (C1 and C2 isomers determined together), N-sulfocarbamoyl-gonyautoxin 3 and 4 (C3 and C4 isomers determined together);

(c) Toxins decarbamoyl dcSTX, dcNeoSTX, decarbamoylgonyautoxin-2 and -3 (isomers determined together).

B.1. If new analogues of the above toxins, for which a toxicity equivalent factor (TEF) has been established, appear, they shall be included in the analysis;

B.2. Total toxicity will be expressed in µg STX 2HCL equivalents/Kg and shall be calculated using TEFs as recommended in the most recent EFSA opinion or FAO OMS report, upon proposal of the European Reference Laboratory for marine biotoxins and its National Reference Laboratories network and acceptance by the European Commission. The TEFs used will be published in the European Reference Laboratory for marine biotoxins website ([2]);

C. If the results are challenged, the reference method shall be the method described in the Standard EN 14526 as referred in Part A.

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CHAPTER II

AMNESIC SHELLFISH POISON DETECTION METHOD

A. The amnesic shellfish poisoning (ASP) toxins content of the entire body or any part edible separately of bivalve molluscs shall be determined using the high-performance liquid chromatography with ultraviolet detection (HPLC/UV) method or any other internationally recognised validated method.

B. However, for screening purposes, AOAC official method 2006.02, as published in *AOAC International Journal* 90, 1011-1027 (ASP enzyme-linked immunosorbent assay (ELISA) method), or any other internationally recognised validated method may also be used.

C. If the results are challenged, the reference method shall be the HPLC/UV method.

([1]) Determination of saxitoxin-group toxins in shellfish – HPLC method using pre-column derivatization with peroxide or periodate oxidation.

([2]) http://www.aecosan.msssi.gob.es/en/CRLMB/web/home.html

▼B

CHAPTER III

LIPOPHILIC TOXIN DETECTION METHODS

A. The reference method for the detection of marine toxins as referred to in points (c), (d) and (e) in Chapter V(2) of Section VII of Annex III to Regulation (EC) No 853/2004 shall be the EU reference laboratory liquid chromatography-mass spectrometry/mass spectrometry (EURL LC-MS/MS) method. This method shall determine at least the following compounds:

(a) okadaic acid group toxins: OA, DTX1 and DTX2, including their esters (DTX3);

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(c) yessotoxins group toxins: YTX, 45 OH YTX, homo YTX and 45 OH homo YTX;

(d) azaspiracids group toxins: AZA 1, AZA 2 and AZA 3.

If new analogues of the above toxins appear, for which a toxicity equivalent factor (TEF) has been established, they shall be included in the analysis.

Total toxicity equivalence shall be calculated using TEFs as recommended by the European Food Safety Authority (EFSA) in Journal (2008) 589, 1-62 or any updated EFSA advice.

B. Methods other than those referred to in Part A, such as the LC-MS method, HPLC with appropriate detection, immunoassays and functional assays, such as the phosphatase inhibition assay, may be used as alternatives to, or as well as, the EURL LC-MS/MS method, provided that:

(a) either alone or combined they can detect at least the analogues identified in Part A; more appropriate criteria shall be defined where necessary;

(b) they meet the method performance criteria stipulated by the EURL LC-MS/MS method. Such methods must be intra-laboratory validated and successfully tested under a recognised proficiency test scheme. The European Reference Laboratory for marine biotoxins shall support activities toward inter-laboratory validation of the technique to allow for formal standardisation;

(c) their implementation provides an equivalent level of public health protection.

CHAPTER IV

DETECTION OF NEW OR EMERGING MARINE TOXINS

Chemical methods, alternative methods with appropriate detection, or the mouse bioassay can be used during the periodic monitoring of production areas and relaying areas for detecting new or emerging marine toxins on the basis of the national control programmes elaborated by the Member States.

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ANNEX VI

PRACTICAL ARRANGEMENTS FOR OFFICIAL CONTROLS ON FISHERY PRODUCTS IN ACCORDANCE WITH ARTICLE 70

CHAPTER I

GENERAL PROVISIONS

A. **Organoleptic examinations**

Random organoleptic controls shall be carried out at all stages of production, processing and distribution. One aim of the controls is to verify compliance with the freshness criteria established in accordance with this Regulation. In particular, this includes verifying, at all stages of production, processing and distribution, that fishery products at least meet the baselines of freshness criteria established in accordance with Council Regulation (EC) No 2406/96 ([1]).

B. **Freshness indicators**

When the organoleptic examination gives rise to any doubt as to the freshness of the fishery products, samples may be taken and subjected to laboratory tests to determine the levels of total volatile basic nitrogen (TVB-N) and trimethylamine nitrogen (TMA-N) in accordance with the technical arrangements in Chapter II.

The competent authorities shall use the criteria laid down in this Regulation.

When the organoleptic examination gives cause to suspect the presence of other conditions that may affect human health, appropriate samples shall be taken for verification purposes.

C. **Histamine**

Random testing for histamine shall be carried out to verify compliance with the permitted levels laid down in Regulation (EC) No 2073/2005.

D. **Residues and contaminants**

Monitoring arrangements shall be established in accordance with Directive 96/23/EC and Decision 97/747/EC to control compliance with the EU legislation on:

— maximum residue limits for pharmacologically active substances, in accordance with Regulations (EU) No 37/2010 and (EU) No 2018/470;

— prohibited and non-authorised substances, in accordance with Regulation (EU) No 37/2010, Directive 96/22/EC and Decision 2005/34/EC;

— contaminants, in accordance with Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in food; and

— pesticide residues, in accordance with Regulation (EC) No 396/2005.

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For wild caught fishery products monitoring arrangements shall be established to control compliance with the EU legislation on contaminants, in accordance with Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in food.

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E. **Microbiological checks**

Where necessary, microbiological controls shall be performed in accordance with the relevant rules and criteria laid down in Regulation (EC) No 2073/2005.

([1]) Council Regulation (EC) No 2406/96 of 26 November 1996 laying down common marketing standards for certain fishery products (OJ L 334, 23.12.1996, p. 1).

▼B

F. **Parasites**

Risk-based testing shall take place to verify compliance with Part D of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 and Section I of Annex II to Regulation (EC) No 2074/2005.

G. **Poisonous fishery products**

Controls shall take place to ensure that:

1. fishery products derived from poisonous fish of the following families are not placed on the market: *Tetraodontidae*, *Molidae*, *Diodontidae* and *Canthigasteridae*;

2. fresh, prepared, frozen and processed fishery products belonging to the family *Gempylidae*, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may be placed on the market only in wrapped/packaged form and are appropriately labelled to inform the consumer about preparation/cooking methods and the risk related to the presence of substances with adverse gastrointestinal effects. The scientific names of the fishery products and the common names shall appear on the label;

3. fishery products containing biotoxins such as ciguatera or other toxins dangerous to human health are not placed on the market. However, fishery products derived from live bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII of Annex III to Regulation (EC) No 853/2004 and comply with the standards laid down in point 2 of Chapter V of that Section.

CHAPTER II

CONTROLS ON TOTAL VOLATILE BASIC NITROGEN (TVB-N)

A. **TVB-N limit values for certain categories of fishery products and analysis methods to be used**

1. Unprocessed fishery products shall be regarded as unfit for human consumption where organoleptic assessment has raised doubts as to their freshness and chemical checks reveal that the following TVB-N limits are exceeded:

   (a) 25 mg of nitrogen/100 g of flesh for the species referred to in point 1 of Part B of this Chapter;

   (b) 30 mg of nitrogen/100 g of flesh for the species referred to in point 2 of Part B of this Chapter;

   (c) 35 mg of nitrogen/100 g of flesh for the species referred to in point 3 of Part B of this Chapter;

   (d) 60 mg of nitrogen/100 g of whole fishery product used directly for the preparation of fish oil for human consumption, as referred to in the second paragraph of point 1 of Chapter IV.B of Section VIII of Annex III to Regulation (EC) No 853/2004; however, where the raw material complies with points (a), (b) and (c) of the first paragraph of that point, Member States may set limits at a higher level for certain species pending the establishment of specific Union legislation.

   The reference method to be used for checking the TVB-N limits involves distilling an extract deproteinised by perchloric acid as set out in Part C below.

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2. Distillation as referred to in point 1 shall be performed using apparatus which complies with the diagram in Part D below.

3. The routine methods that may be used to check the TVB-N limit are as follows:

   (a) microdiffusion method described by Conway and Byrne (1933);

   (b) direct distillation method described by Antonacopoulos (1968);

   (c) distillation of an extract deproteinised by trichloracetic acid (Codex Alimentarius Committee on Fish and Fishery Products, 1968).

4. The sample shall consist of about 100 g of flesh, taken from at least three different points and mixed together by grinding.

Member States shall recommend that official laboratories use, as a matter of routine, the methods referred to above. Where the results are dubious or in the event of dispute regarding the results of analysis performed by one of the routine methods, only the reference method may be used to check the results.

B. **Species categories for which TVB-N limit values are fixed**

TVB-N limit values are fixed for the following species categories:

1. *Sebastes spp.*, *Helicolenus dactylopterus*, *Sebastichthys capensis*;

2. species belonging to the *Pleuronectidae* family (with the exception of halibut: *Hippoglossus spp.*);

3. *Salmo salar*, species belonging to the *Merlucciidae* family, species belonging to the *Gadidae* family.

C. **Reference procedure for determining the concentration of TVB-N in fish and fishery products**

1. Purpose and area of application

   This method describes a reference procedure for identifying the nitrogen concentration of TVB-N in fish and fishery products. The procedure is applicable at TVB-N concentrations of 5 mg/100 g to at least 100 mg/100 g.

2. Definitions

   ‘TVB-N concentration’ means the nitrogen content of volatile nitrogenous bases as determined by the reference procedure described.

   ‘Solution’ means an aqueous solution as follows:

   (a) perchloric acid solution = 6 g/100 ml;

   (b) sodium hydroxide solution = 20 g/100 ml;

   (c) hydrochloric acid standard solution 0,05 mol/l (0,05 N). When using an automatic distillation apparatus, titration must take place with a hydrochloric acid standard solution of 0,01 mol/l (0,01 N);

   (d) boric acid solution = 3 g/100 ml;

   (e) silicone anti-foaming agent;

   (f) phenolphtalein solution = 1 g/100 ml 95 % ethanol;

   (g) indicator solution (Tashiro mixed indicator) = 2 g methyl-red and 1 g methylene-blue dissolved in 1 000 ml 95 % ethanol.

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3. Brief description

The volatile nitrogenous bases are extracted from a sample using a solution of 0,6 mol/l perchloric acid. After alkalinisation, the extract undergoes steam distillation and the volatile base components are absorbed by an acid receiver. The TVB-N concentration is determined by titration of the absorbed bases. The concentration is expressed in mg/100 g.

4. Chemicals

Unless otherwise indicated, reagent-grade chemicals shall be used. The water used shall be either distilled or demineralised and of at least the same purity.

5. The following instruments and accessories shall be used:

(a) a meat grinder to produce a sufficiently homogenous fish mince;

(b) high-speed blender with a speed of 8 000 to 45 000 revolutions/min;

(c) fluted filter, diameter 150 mm, quick-filtering;

(d) burette, 5 ml, graduated to 0,01 ml;

(e) apparatus for steam distillation. The apparatus must be able to regulate various amounts of steam and produce a constant amount of steam over a given period of time. It must ensure that, during the addition of alkalising substances, the resulting free bases cannot escape.

6. Execution of the reference procedure

When working with perchloric acid, which is strongly corrosive, necessary caution and preventive measures shall be taken. The samples shall be prepared as soon as possible after their arrival, in accordance with the following instructions:

(a) Preparing the sample

The sample to be analysed is ground carefully using a meat grinder as described in point 5(a). An amount of 10 g ± 0,1 g of the ground sample is weighed out into a suitable container. This is mixed with 90,0 ml perchloric acid solution, homogenised for two minutes with a blender as described in point 5(b), and then filtered.

The extract thereby obtained can be kept for at least seven days at a temperature of between approximately 2 °C and 6 °C;

(b) Steam distillation

50,0 ml of the extract obtained in accordance with point (a) is put into an apparatus for steam distillation as described in point 5(e). For a later check on the extract's alkalinisation, several drops of phenolphtalein solution are added. After adding a few drops of silicone anti-foaming agent, 6,5 ml of sodium hydroxide solution is added to the extract and steam distillation begins immediately.

The steam distillation is regulated so that around 100 ml of distillate is produced in 10 minutes. The distillation outflow tube is submerged in a receiver with 100 ml boric acid solution, to which three to five drops of the indicator solution have been added. After exactly 10 minutes, distillation is ended. The distillation outflow tube is removed from the receiver and washed out with water. The volatile bases contained in the receiver solution are determined by titration with hydrochloric acid standard solution.

The pH of the end point must be 5,0 ± 0,1;

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(c) Titration

Duplicate analyses are required. The applied method is correct if the difference between the duplicates is not greater than 2 mg/100 g;

(d) Blank

A blind test is carried out as described in point (b). Instead of the extract, 50,0 ml perchloric acid solution is used.

7. Calculation of TVB-N concentration

By titration of the receiver solution with hydrochloric acid standard solution, the TVB-N concentration is calculated using the following equation:

$$\text{TVB-N (expressed inmg/100g sample)} = \frac{(V_1 - V_0) \times 0{,}14 \times 2 \times 100}{M}$$

where:

V1 = volume of 0,01 mol hydrochloric acid standard solution in ml for sample;

V0 = volume of 0,01 mol hydrochloric acid standard solution in ml for blank;

M = mass of sample in g.

In addition, the following is required:

(a) duplicate analyses. The applied method is correct if the difference between duplicates is not greater than 2 mg/100 g;

(b) equipment check. The equipment is checked by distilling solutions of NH_4Cl equivalent to 50 mg TVB-N/100 g;

(c) standard deviations. The standard deviation for repeatability Sr = 1,20 mg/100 g and the standard deviation for reproducibility SR = 2,50 mg/100 g are calculated.

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D. **TVB-N steam distillation apparatus**