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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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Version of 25 September 2018

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) 1107/2009, (EU) 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)[1], and in particular Article 18(8) thereof,

Whereas:

(1) Regulation (EU) 2017/625 lays down rules for the official controls and other official activities performed by the competent authorities of the Member States to verify compliance with Union legislation *inter alia* in the area of food safety at all stages of production, processing and distribution. In particular, it provides for official controls in relation to products of animal origin intended for human consumption. In addition, it repeals Regulation (EC) No 854/2004[2] with effect from 14 December 2019. That Regulation currently lays down specific rules for official controls on products of animal origin intended for human consumption, including requirements on uniform practical arrangements for the performance of the controls.

(2) The rules laid down in this Regulation should ensure a continuation of the requirements to ensure the verification of food business operators' compliance with the rules for the safe handling of products of animal origin, in particular as laid down in:

[1] OJ L 95, 7.4.2017, p. 1.

[2] Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

– Council Directive 96/23/EC[3] as regards measures to monitor certain substances and residues;

– Regulation (EC) No 999/2001 of the European Parliament and of the Council[4] as regards controls on transmissible spongiform encephalopathies;

– Council Directive 2002/99/EC[5] as regards animal health rules on products of animal origin;

– Regulation (EC) No 178/2002 of the European Parliament and of the Council[6] as regards the general principles and requirements of food law;

– Directive 2003/99/EC of the European Parliament and of the Council[7] as regards the monitoring of zoonoses and zoonotic agents;

– Commission Decision 2003/467/EC[8] as regards control of tuberculosis, brucellosis and enzootic-bovine-leukosis;

– Regulation (EC) No 2160/2003 of the European Parliament and of the Council[9] as regards Salmonella controls;

– Regulations (EC) No 852/2004 of the European Parliament and of the Council[10] as regards the hygiene of foodstuffs;

– Regulation (EC) No 853/2004 of the European Parliament and of the Council[11] as regards the specific hygiene rules for food of animal origin;

– Council Regulation (EC) No 1/2005[12] as regards the protection of animals during transport and related operations;

– Commission Regulation (EC) No 2073/2005[13] as regards microbiological criteria in foodstuffs;

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3 Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

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

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

6 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).

7 Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Directive 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 325, 12.12.2003, p. 31).

8 Commission Decision 2003/467/EC of 23 June 2003 establishing the official tuberculosis, brucellosis and enzootic-bovine-leukosis-free status of certain Member States and regions of Member States as regards bovine herds (OJ L 156, 25.6.2003, p. 74).

9 Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents (OJ L 325, 12.12.2003, p. 1).

10 Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

11 Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

12 Council Regulation (EC) No 1/2005 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (OJ L 3, 5.1.2005, p. 1).

– Commission Regulations (EC) No 1881/2006[14] and (EC) No 124/2009[15] as regards maximum levels for certain contaminants in foodstuffs;

– Council Directive 2007/43/EC[16] as regards the protection of chickens;

– Regulation (EC) No 1069/2009 of the European Parliament and of the Council[17] as regards health rules on animal by-products;

– Council Regulation (EC) No 1099/2009[18] as regards the protection of animals at the time of killing;

– Directive 2010/63/EU of the European Parliament and of the Council[19] as regards the protection of animals used for scientific purposes;

– Commission Implementing Regulation (EU) No 636/2014[20] as regards trade in unskinned large wild game;

– Commission Implementing Regulation (EU) 2015/1375[21] as regards official controls for *Trichinella*; and

– Regulation (EU) 2016/429 of the European Parliament and of the Council[22] as regards animal health rules.

(3) The practical arrangements for the performance of official controls on products of animal origin should be considered where a minimum level of official controls is necessary to respond to recognised uniform hazards and risks that might be posed by products of animal origin, covering all aspects that are important for protecting human health and, where appropriate, animal health and animal welfare. They should be based on the most recent relevant information available and scientific evidence from the EFSA opinions.

(4) On 31 August 2011, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat (swine)[23]. The recommendations of that opinion were taken into account in the requirements for pig meat inspections laid

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13 Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

14 Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

15 Regulation (EC) No 124/2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed (OJ L 40, 11.2.2009, p. 1).

16 Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production (OJ L 182, 12.7.2007, p. 19).

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

18 Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, p. 1).

19 Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

20 Commission Implementing Regulation (EU) No 636/2014 of 13 June 2014 on a model certificate for the trade of unskinned large wild game (OL L 175, 14.6.2014, p. 16).

21 Commission Implementing Regulation (EU) 2015/1375 of 10 August 2015 laying down specific rules on official controls for Trichinella in meat (OJ L 212, 11.8.2015, p. 7).

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

23 *EFSA Journal 2011*;9(10):2351

down in Regulation (EC) No 854/2004 and should be maintained in the requirements laid down in this Regulation.

(5) On 23 May 2012, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat (poultry)[24]. That opinion identifies *Campylobacter* spp. and *Salmonella* spp. as the main hazards to be covered in poultry meat inspections through an integrated food safety assurance system, achievable through improved food chain information (FCI) and risk-based interventions.

(6) On 6 June 2013, the European Food Safety Authority (EFSA) adopted a scientific opinion on the human health hazards to be covered by the inspection of meat (bovine animals)[25]. That opinion identifies *Salmonella* spp. and pathogenic verocytotoxin-producing *Escherichia coli* (*E. coli*) as the most relevant hazards for meat inspections in bovine animals. It recommends the omission of palpation and incision during the post-mortem inspection of animals subjected to routine slaughter, since it may reduce spreading and cross-contamination with the high-priority biological hazards. However, palpations and incisions during post-mortem inspection, necessary to survey the occurrence of tuberculosis and *Taenia saginata* (tapeworm) cysticercosis, should be maintained.

(7) Also on 6 June 2013, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat from sheep and goats[26]. That opinion identifies pathogenic verocytotoxin-producing *E. coli* as the most relevant hazard for meat inspections in sheep and goats. It also recommends omitting palpation and incisions to the extent possible from the post-mortem inspection of sheep and goats subject to routine slaughter. However, palpation and incisions for the surveillance of tuberculosis and fascioliasis should be maintained in older animals for reasons of animal and human health surveillance.

(8) Also on 6 June 2013, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat (solipeds)[27]. That opinion recommends the use of visual-only inspection in solipeds, which may have a significant favourable effect on the microbiological status of soliped carcase meat. Such inspection is considered unlikely to affect the overall surveillance of animal diseases.

(9) Also on 6 June 2013, EFSA adopted a scientific opinion on the meat inspection of farmed game. That opinion recommends omitting palpation and incision unless abnormalities are detected, while at the same time underlining that such omission might have consequences for the overall surveillance of tuberculosis.

(10) The recommendations set out in these EFSA opinions should be taken into account when laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption. The possible impact on trade with third countries should also be taken into account. At the same time, a smooth transition from the current requirements, as laid down in Regulation (EC) No 854/2004, should be ensured.

(11) The practical arrangements for the performance of official controls on products of animal origin should be established where a minimum level of official controls is

[24] *EFSA Journal 2012*;10(6):2741.
[25] *EFSA Journal* 2013;11(6):3266.
[26] *EFSA Journal* 2013;11(6):3265.
[27] *EFSA Journal* 2013;11(6):3263.

deemed necessary to respond to recognised uniform hazards and risks that might be posed by products of animal origin, covering all aspects that are important for protecting human health and, where appropriate, animal health and animal welfare. They should be based on the most recent relevant information available and scientific evidence from the EFSA opinions.

(12) These practical arrangements should apply to official controls on products of animal origin laid down in Article 18 of Regulation (EU) 2017/625 and in Commission Delegated Regulation (EU) [SANTE/10193/2017][28]. These practical arrangements for the application of official controls should be uniform and facilitate the application of the requirements for a minimum level of official controls, taking into account the size of small businesses as laid down in Art 16 of Regulation (EU) 2017/625 by the use of a threshold in a non-discriminatory way.

(13) Since the structure of slaughterhouses and game-handling establishments differs across Member States, a threshold should be based on the number of animals slaughtered or handled, or on the demonstration that it represents a limited and fixed percentage of the meat placed on the market. Article 17(6) of Regulation (EC) No 1099/2009 defines livestock units and lays down conversion rates to express the number of animals of a certain species in such livestock units. These provisions should be used to set thresholds and harmonize derogations from certain requirements based on the size of a slaughterhouse to the extent possible.

(14) Specific requirements for auditing by the competent authorities should also be maintained to ensure the uniform practical verification of compliance with Union requirements on products of animal origin. Auditing is of particular interest for the verification of general and specific hygiene requirements and the application of procedures based on hazard analysis and critical control points (HACCP).

(15) Verification of compliance with the requirements on identification marking in Section I of Annex II to Regulation (EC) No 853/2004, as currently laid down in Regulation (EC) No 854/2004, should be maintained to allow tracing back the animals.

(16) Ante-mortem and post-mortem inspections are essential to verify compliance with requirements on human and animal health and animal welfare. In order to ensure at least the same level of human and animal health and animal welfare protection as provided by Regulation (EC) No 854/2004 and fair trade in an open market, it is necessary to lay down uniform practical requirements for such inspections, including cases where official controls are performed under the responsibility of the official veterinarian. As regards official controls on fresh meat, these inspections should be supplemented by appropriate documentary checks, controls on the safe disposal of specified risk material, as defined in Article 3(g) of Regulation (EC) No 999/2001, and other animal by-products, and laboratory testing where appropriate.

(17) It is important to identify cases of suspected and established non-compliance where competent authorities must take measures with respect to certain products of animal origin. Non-compliance with good hygiene practices should also result in corrective action by competent authorities.

[28] Commission Delegated Regulation (EU) …/… of ../../…. concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L …., ../../…., p. …).

(18) The health mark defined in point 51 in Article 3 of Regulation (EU) 2017/625 covers meat of certain species and attests that the meat is fit for human consumption. Technical requirements of the health mark and practical arrangements for its application should be laid down in a specific and uniform way in order to indicate the fitness of the meat for human consumption and to prevent any trade disruption.

(19) Specific requirements for the performance of official controls and the uniform minimum frequency for such controls on raw milk, milk products and fishery products should be laid down to ensure a high level of consumer protection and fair competition between food business operators.

(20) Commission Regulation (EC) No 2074/2005[29] lays down *inter alia* implementing measures for the organisation of official controls under Regulation (EC) No 854/2004 as regards recognised methods for the detection of marine biotoxins in live bivalve molluscs, testing methods for raw milk and heat-treated milk, official controls in fishery products and the inspection of meat. It is appropriate to merge all implementing measures for the organisation of official controls and include the ones from Regulation (EC) No 2074/2005 in this Regulation in which they should be deleted.

(21) The current conditions for the classification and monitoring of classified production and relaying areas for live bivalve molluscs have proven to be effective and ensure a high level of consumer protection. They should therefore be maintained.

(22) A reference method for the analysis of *E. coli* in live bivalve molluscs, as currently laid down in Regulation (EC) No 854/2004, should be maintained.

(23) The limits for marine biotoxins are laid down in Regulation (EC) No 853/2004. In particular, point 2 in Chapter V of Section VIII of Annex IV to that Regulation provides that live bivalve molluscs must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the limits established in that Chapter.

(24) Specific requirements for the performance of official controls and the uniform minimum frequency for such controls on raw milk, milk products should be laid down to ensure a high level of consumer protection and fair competition between food business operators.

(25) Specific requirements for the performance of official controls and the uniform minimum frequency for such controls on fishery products should be laid down to ensure a high level of consumer protection and fair competition between food business operators. Those controls should include at least regular checks on the hygiene conditions of landing and first sale, regular inspections of vessels and establishments, including fish auctions and wholesale markets, and checks on storage and transport. Specific requirements for the control of vessels should also be envisaged.

[29] Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 (OJ L 338, 22.12.2005, p. 27).

(26) Those controls should also include practical arrangements as regards organoleptic examinations, freshness indicators, controls on histamine, residues and contaminants, microbiological checks. Special attention should be paid to the controls of parasites and on poisonous fishery products. Fishery products not meeting those hygiene requirements should be declared as unfit for human consumption;

(27) Special requirements concerning the official controls on fishery products caught by vessels flying the flag of member States entering the Union after being transferred in a third country with or without storage shall also be established;

(28) There is an increasing interest in the production and placing of the market of reptile meat. In order to ensure the safety of reptile meat, it is relevant to introduce specific official controls at slaughter in addition to the existing general hygiene rules laid down in Regulation (EC) No 852/2004 and the *Trichinella* controls laid down in Implementing Regulation (EU) 2015/1375.

(29) Regulation (EC) No 2074/2005 should be amended accordingly.

(30) As Regulation (EU) 2017/625 repeals Regulation (EC) No 854/2004 with effect from 14 December 2019, this Regulation should also apply from that date.

(31) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

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 action 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) …/…[SANTE/10193/2017].

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.

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 points 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(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[30].

(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) 'specific risk material' means specific risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001;

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

[30] 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).

(16) 'holding of provenance' means the holding where the animals were last reared. In the case of semi-domesticated cervids as defined in point 2(q) of Annex I to Regulation (EC) No 999/2001 of the European Parliament and of the Council[31], it includes round-ups intended to select animals for slaughter;

(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) 'poultry flock' means a poultry 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) [SANTE/10193/2017];

(26) 'low-capacity game-handling establishment' means a game-handling establishment as defined in Article 2(18) of Delegated Regulation (EU) [SANTE/10193/2017];

(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;

(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;

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

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

(35) 'small wild game' means small wild game as defined in point 1.7 of Annex I to Regulation (EC) No 853/2004;

(36) 'milk production holding' means a milk production holding as defined in point 4.2 of Annex I of Regulation (EC) No 853/2004.

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

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

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

(40) '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;

(41) 'dispatch centre' means a dispatch centre as defined in point 2.7 of Annex I of Regulation (EC) No 853/2004

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

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

(44) 'freezer vessel' means freezing vessel as defined in point 3.3 of Annex I to Regulation (EC) No 853/2004;

(45) 'reptiles' means reptiles as defined in Article 2(n) of Commission Delegated Regulation [SANTE/10279/2018][32];

(46) 'reptile meat' means reptile meat as defined in Article 2(o) of Delegated Regulation (EU) [SANTE/10279/2018];

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

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

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

[32] Commission Delegated Regulation (EU) …/…. of ../../…. supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to conditions to be respected by consignments of certain animals and goods intended for human consumption entering the Union (OJ L …., ../../…., p. …).

TITLE II
SPECIFIC REQUIREMENTS FOR THE PERFORMANCE OF OFFICIAL CONTROLS AND THE UNIFORM MINIMUM FREQUENCY 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.
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[33];
      – maximum residue limits for pharmacologically active substances, in accordance with Commission Regulation (EU) No 37/2010[34] and Commission Implementing Regulation (EU) 2018/470[35];

[33] 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).

[34] 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).

– prohibited and non-authorised substances, in accordance with Commission Regulation (EU) No 37/2010, Council Directive 96/22/EC[36], Commission Decision 2005/34/EC[37];

– 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[38];

(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.

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.

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35 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).

36 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 ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ L 125, 23.5.1996, p. 3).

37 Commission Decision 2005/34 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, 20.1.2055, p 16).

38 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).

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.

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 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 faecal or 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;

(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.

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) [SANTE/10281/2018][39], 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 30 of Implementing Regulation (EU) [SANTE/10281/2018] 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 each poultry flock, as defined in Article 2(3)(b) of Regulation (EC) No 2160/2003, and a representative sample of 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.

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.

[39] Commission Implementing Regulation (EU) …. of ../../…. . laying down model official certificates for the entry into the Union of certain animals and goods and amending Regulation (EU) 2016/759 (OJ L …, ../../…., p. …)

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) [SANTE/10193/2017], 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 and 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:

   (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) The competent authority may increase the thresholds laid down in point (a) (i) and (ii) ensuring that the derogation is applied in the smallest slaughterhouses and game-handling establishments complying with the definition of low-capacity slaughterhouse or 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

(i) for the species concerned;

(ii) or for all ungulates together;

(iii) of all poultry together; or,

(iv) 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[40];

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

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

(2) 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

(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 not authorised 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;

[40] 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).

(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.

4. In low-capacity slaughterhouses or 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 [SANTE/10193/2017], 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;

   (b) the lungs, trachea and oesophagus; palpation of the lungs; palpation and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifucationes, 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. The official veterinarian shall proceed with the following post-mortem inspection procedures using incision and palpation of the carcase and offal, depending on the possible risk to human health, animal health or animal welfare 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. bifucationes, 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 others than those referred to in Article 18(1) shall undergo the following post-mortem inspection procedures:

(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 examination and palpation of the lungs; incision and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifucationes, 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. The official veterinarian shall proceed with the following post-mortem inspection procedures 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) an incision of the bronchial and mediastinal lymph nodes (Lnn. bifucationes, 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) 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 authority is 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. bifucationes*, *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.

2. The official veterinarian shall proceed with the following post-mortem inspection procedures 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 provided otherwise, these examinations are not necessary if the competent authority is 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 authority is 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. bifucationes, 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*);

(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. The official veterinarian shall proceed with the following post-mortem inspection procedures 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 provided otherwise, these examinations are not necessary if the competent authority is 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. bifucationes, 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*);

(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. supramammarii*);

(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. The official veterinarian shall proceed with the following post-mortem inspection procedures 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;

(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. The official veterinarian shall proceed with the following post-mortem inspection procedures 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;

(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

The official veterinarian shall proceed with the additional post-mortem inspection procedures referred to in Articles 18(3), 19(2), 20(2), 21(2), 22(2) and 23(2) using incision and palpation of the carcase and offal, where, in his/her opinion, one of the following indicates a possible risk to human health, animal health or animal welfare:

(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 of this Regulation;

(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:

   (a) daily inspection of the viscera and body cavities of a representative sample of each poultry 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 poultry 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 have been found during ante-mortem inspection and verification of food chain information that may indicate the need for measures laid down in Articles 40 to 44.

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.

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 Articles 21, however in the case of reindeer the post-mortem procedures for ovine animals laid down in Articles 20 shall be used and the tongue may be used for human consumption without inspection of the head;

   (b) in the case of large game of the family *Cervidae* and other large game, not covered by paragraph (a), the post-mortem procedures for bovine animals laid down in Article 19;

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

   (d) in the case of birds, including 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 examination 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;

(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 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 should be declared unfit for human consumption or whether each carcase should be inspected individually.

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 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 authority may decide that incision of the masseters at post-mortem inspection is not compulsory where:

   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) if 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.

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 equidae 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 countries and regions 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.

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 infection with 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 authority 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[41] 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, pork and poultry production.

2. Where the food business operator fails on several occasions to comply with the process hygiene criterion, the competent authority 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.

Article 36

Practical arrangements for official controls for *Campylobacter*

1. The competent authority 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 2073/2005by 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 authority 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

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

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 not authorised, 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;

   (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 and during transport in accordance with Regulation (EC) No 1/2005 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);

(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 authority 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[42] 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 diseases 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).

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

[42] 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).

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 show 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 non-authorised 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.

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 to avoid contamination of other meat.

5. The official veterinarian shall ensure that animals that might contain residues of prohibited or non-authorised 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.

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

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, 19 and 22 of Council Regulation (EC) No 1099/2009, the official veterinarian shall

verify that the food business operator immediately takes the necessary corrective measures and prevents recurrence.

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 points 1 to 4 pending the arrival of the official veterinarian.

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;

(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 to 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 of 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 not authorised under Regulation (EU) No 37/2010 or Directive 96/22/EC;

(k) 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;

(l) has been treated illegally with decontaminating substances;

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

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

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

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

(q) derives from emaciated animals;

(r) 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 remains under the control of the competent authority;

(s) shows soiling, faecal or other contamination;

(t) 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;

(u) 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;

(v) 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

   (b) if the competent authority considers 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:

   (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, provided that the competent authorities introduced a system in place in the slaughterhouse or game-handling establishment ensuring that all parts of the animal can be traced, and no parts of the examined animals bearing the mark leave the slaughterhouse or game-handling establishment until a negative result has been obtained except when provided for in accordance with Article 2(3) of Regulation (EU) 2015/1375;

   (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.

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 unless, 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:

   (c) the health status of the animals;

   (d) the absence of the use of prohibited or non-authorised pharmacologically active substances; and

   (e) that the possible presence of residues of authorised pharmacologically active substances, pesticides or contaminants does not exceed the levels laid down in accordance with 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.

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 *Holothuridea* that are not filter feeders.

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.

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.

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

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 on the protection of animals used for scientific purposes, elements of replacement, refinement and reduction must be taken into account when biological methods are used

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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 or monitoring 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 monitoring 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;

   (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 are exceeded, 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 ;

   (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 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 monitor classified production and relaying areas from which they have prohibited the harvesting of live bivalve molluscs or subjected harvesting to special conditions, to ensure that products of animal origin harmful to human health are not placed on the market.~~

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.

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) 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 60(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;

(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 non-EU 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 non-EU 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 non-EU 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 non-EU country, such country appears on a list of non-EU 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 non-EU country.

3. Where the competent authorities of a Member State authorise the competent authorities of another Member State or of a non EU 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 must include at least the practical arrangements laid down in Annex V 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 checks or checks for parasites as established in Section VII of Annex III of Regulation (EC) N°853/2004 and/or Regulation (EC) N°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 not authorised 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;

(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 authority of that third country and completed in accordance with the model health certificate set out in Annex I Part II Chapter B to Implementing Regulation (EU) [SANTE/10281/2018]

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) [SANTE/10279/2018].

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 must be listed as provided for in Article 3 of Delegated Regulation (EU) [SANTE/10279/2018].and the vessel must appear in a list as provided for in Article 5 of Delegated Regulation (EU) [SANTE/10279/2018].

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 ON REPTILE MEAT

Article 73

Ante-mortem and post-mortem inspection of reptiles

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

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. Annexes 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.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER