# Non-paper in view of a possible implementing act based on Article 18(8) of Regulation (EU) 2017/625 (Official Control Regulation)

**Revision dated 20 September 2017**



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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**

(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 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 control activities by the competent authorities of the Member States performed in order to verify compliance with Union legislation in the area of, inter alia, food safety at all stages of the production, processing and distribution process. In particular, it provides that the official controls performed in relation to products of animal origin intended for human consumption are to verify compliance with the requirements laid down in Regulation (EC) No 852/2004 of the European Parliament and of the Council[2], Regulation (EC) No 853/2004 of the European Parliament and of the Council[3], Regulation (EC) No 1069/2009 of the European Parliament and of the Council[4] and Council Regulation (EC) No 1099/2009[5].

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1 OJ L 95, 7.4.2017, p. 1.

2 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 ).

3 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).

4 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).

5 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).

(2) In addition, Regulation (EU) 2017/625 repeals Regulation (EC) No 854/2004 of the European Parliament and of the Council[6] with effect from 14 December 2019. Regulation (EC) No 854/2004 currently lays down specific rules for controls on products of animal origin intended for human consumption, including requirements on uniform practical arrangements for the performance of the official controls.

(3) Such specific requirements should be maintained in particular to ensure verification of compliance by food business operators with the specific requirements for the safe handling of products of animal origin laid down in Regulation (EC) No 853/2004 of the European Parliament and of the Council[7], of Regulation (EC) No 999/2001 of the European Parliament and of the Council[8] and of Commission Regulation (EC) No 2073/2005[9].

(4) Specific rules for the performance of official controls on products of animal origin should cover all aspects that are important for protecting public health and, where appropriate, animal health and animal welfare. They should be based on the most recent relevant information available and should have a sound scientific basis.

(5) The European Food Safety Authority (EFSA) adopted on 31 August 2011 a Scientific Opinion on the public health hazards to be covered by inspection of meat (swine)[10]. The recommendations of that Opinion were already taken into account in the requirements for pig meat inspections laid down in Regulation (EC) No 854/2004, and should be maintained in the requirements laid down in this Regulation.

(6) The EFSA adopted on 23 May 2012 a Scientific Opinion on the public health hazards to be covered by inspection of meat (poultry)[11]. That Opinion identifies *Campylobacter* spp. and *Salmonella* spp. as the main hazards to be included in poultry meat inspections by establishing an integrated food safety assurance system, achievable through improved food chain information (FCI) and risk-based interventions.

(7) The EFSA adopted on 6 June 2013 a Scientific Opinion on the public health hazards to be covered by inspection of meat (bovine animals)[12]. That Opinion identifies *Salmonella* spp. and pathogenic verocytotoxin-producing *Escherichia coli* as the most relevant hazards for meat inspections in bovine animals. It recommends the omission of palpation and incision during post-mortem inspection for animals subjected to routine slaughter, since it may reduce the spreading and cross-contamination with the high-priority biological hazards. However, palpations and incisions during post-mortem infection, necessary to survey the occurrence of tuberculosis and *Taenia saginata* (tapeworm) cysticercosis, should be maintained.



6 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).

7 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).

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

9 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).

10 EFSA Journal 2011;9(10):2351.

11 EFSA Journal 2012;10(6):2741.

12 EFSA Journal 2013;11(6):3266.

(8) The EFSA adopted on 6 June 2013 a Scientific Opinion on the public health hazards to be covered by inspection of meat from sheep and goats[13]. That Opinion identifies pathogenic verocytotoxin-producing *Escherichia coli* as the most relevant hazard for meat inspections in sheep and goats. Similar to bovine animals, it also recommends omiting palpation and incisions from post-mortem inspections in animals subject to routine slaughter to the extent possible. Palpation and incisions for the surveillance of tuberculosis and fasciolosis should, however, be maintained in older animals for reasons of animal and public health surveillance.

(9) The EFSA adopted on 6 June 2013 a Scientific Opinion on the public health hazards to be covered by inspection of meat (solipeds)[14]. That Opinion recommends the use of a 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.

(10) The EFSA adopted on 6 June 2013 a Scientific Opinion on meat inspection of farmed game[15]. That Opinion recommends omitting palpation and incision unless abnormalities are detected, while at the same time underlining that such revision might have consequences for the overall surveillance of tuberculosis.

(11) The recommendations set out in the EFSA Opinions on meat inspections 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 laid down in Regulation (EC) No 854/2004 should be ensured.

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

(13) It is important to determine cases of suspected and established non-compliance where competent authorities need to take measures with respect to certain products of animal origin.

(14) Ante-mortem and post-mortem inspections are essential to verify compliance with requirements on public and animal health and animal welfare. In order to ensure at least the same level of public 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 inspection, including for cases when official controls are performed under the responsibility of the official veterinarian.

(15) Commission Regulation (EC) No 2074/2005[16] lays down certain requirements concerning post-mortem inspection which are to be repealed by [SANTE-2017-



13 EFSA Journal 2013;11(6):3265.
14 EFSA Journal 2013;11(6):3263.
15 EFSA Journal 2013;11(6):3264
16 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).

XXXX-00-00-TRA][17]. For reasons of simplification and consistency, equivalent provisions should be included in this Regulation.

(16) The health mark defined in point (51) of Article 3 of Regulation (EU) 2017/625 is applied to 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.

(17) Specific requirements for the performance of official controls and the uniform minimum frequency for such official 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.

(18) 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.

(19) 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 specific rules, pursuant to Article 18(8) of Regulation (EU) 2017/625, on uniform practical arrangements for the performance of official controls and actions taken by competent authorities in relation to the production of products of animal origin intended for human consumption.

Those specific rules cover:

(a) Specific requirements and uniform minimum frequency of official controls in products of animal origin;

(b) Conditions for the classification and monitoring of classified production and relaying areas for bivalve molluscs;

(c) Measures to be taken in case of specific non-compliance in fresh meat;

(d) Technical requirements and the practical arrangements of the health mark;

(e) Additional specific requirements and uniform minimum frequency of official controls with respect to milk, colostrum, dairy products and colostrum based products;

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(f) Additional specific requirements and uniform minimum frequency of official controls with respect to fishery products.

*Article 2*
*Definitions*

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

(a) The definitions laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council[18];

(b) The definitions laid down in Regulation (EC) No 852/2004;

(c) The definitions laid down in Regulation (EC) No 853/2004;

## TITLE II

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

### *CHAPTER I*

### *SPECIFIC REQUIREMENTS FOR AUDITS BY THE COMPETENT AUTHORITIES*

*Article 3*

*Audits in establishments handling any product of animal origin*

(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 elements:

(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), the competent authorities shall verify that food business operators

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handling products of animal origin, apply such procedures continuously and properly.

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

(a) comply with microbiological criteria laid down in accordance with Article 3 of Regulation (EC) No 2073/2005 within the context of a food safety management system;

(b) comply with Union legislation on chemical residues, contaminants and prohibited substances; acts

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

When, in accordance with Article 5 of Regulation (EC) No 852/2004, a food business operator uses procedures set out in guides to the application of HACCP-based principles rather than establishing its own specific procedures, the audit shall cover the correct use of these guides.

(3) When carrying out auditing tasks, the competent authority 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 relevant requirements of the Regulations (EC) No 2073/2005 and (EC) No 852/2004. To support the audit, the competent authority may carry out performance tests, in order to ascertain that staff performance is sufficiently skilled;

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

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

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

(4) The nature and frequency of auditing tasks in respect of individual establishments shall depend upon the assessed risk. To this end, the competent authority shall regularly assess:

(a) public 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.

## *CHAPTER II*

## *SPECIFIC TASKS OF THE OFFICIAL VETERINARIAN AS REGARDS OFFICIAL CONTROLS ON FRESH MEAT*

### SECTION 1: AUDITS

*Article 4*

*Additional requirements for audits in establishments handling fresh meat*

(1) When carrying out an audit, the official veterinarian shall verify continuous compliance with food business operators' own procedures concerning any collection, transport, storage, handling, processing of fresh meat, and use or disposal of animal by-products, including specified risk material, for which the food business operator is responsible. Checks on the evaluation of food-chain information should be included in slaughterhouses

(2) When carrying out audits of HACCP-based procedures, the official veterinarian shall check that the food business operators' procedures guarantee, to the extent possible, that fresh meat:

(a) does not contain patho-physiological abnormalities or changes;

(b) does not bear faecal or other contamination traces;

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

(d) regard is given in slaughterhouses to the procedures set out in Section II of Annex II to Regulation (EC) No 853/2004.

**SECTION 2: OTHER OFFICIAL CONTROLS**

*Article 5*

*General*

When carrying out official controls in accordance with this Section, the official veterinarian shall take into account the results of the audits carried out in accordance with Section I of this Chapter. Where appropriate, the official veterinarian shall target official controls accordingly.

*Article 6*

*Documentary checks*

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

(2) When carrying out inspection tasks, the official veterinarian shall take into account official certificates accompanying animals, and any declarations made by veterinarians carrying out controls at the level of primary production, including official veterinarians.

(3) When food business operators in the food chain take additional measures to guarantee food safety by implementing integrated systems, private control systems,

independent third party certification or by other means, and when these measures are documented and animals covered by these schemes are clearly identifiable, the official veterinarian may take this into account when carrying out inspection tasks and reviewing the HACCP-based procedures.

(4) In the case of emergency slaughter outside the slaughterhouse, the official veterinarian at the slaughterhouse shall examine the declaration accompanying the body of the animal issued by the veterinarian and the food business operator in accordance with points 5 and 6 of Chapter VI of Section I of Annex III to Regulation (EC) No 853/2004.

(5) In the case of hunted wild game, the official veterinarian at the game handling establishment shall examine and take into account the declaration accompanying the body of the animal issued by the trained person in accordance with point 1(a) of Chapter II of Section IV to Annex III to Regulation (EC) No 853/2004.

*Article 7*

*Ante-mortem inspection*

(1) The official veterinarian shall carry out an ante-mortem inspection of all animals before slaughter. For poultry and lagomorphs a representative sample can be inspected. Such inspection shall take place within 24 hours of the time of arrival at the slaughterhouse and less than 24 hours before the time of slaughter. The official veterinarian may require an additional ante-mortem inspection at any other time.

(2) Ante-mortem inspections shall in particular determine whether, as regards the particular animal inspected, there is any sign:

(a) that welfare has been compromised; or

(b) of any condition, abnormalities or disease which make the meat unfit for human consumption or 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 of the European Parliament and of the Council[19].

(c) Signs of misuse/illegal use of veterinary medicinal products.

(3) In addition, 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 ante-mortem inspection.

(4) Where provided for in Article 5 of Commission Delegated Regulation [SANTE-2017-10193-00-00-TRA][20], ante-mortem inspection may be carried out at the holding of provenance. In such cases, the official veterinarian at the slaughterhouse shall carry out ante-mortem inspection only when and to the extent specified.

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*Article 8*

*Official controls on animal welfare*

The official veterinarian shall verify compliance with relevant Union and national rules on animal welfare, such as rules concerning the protection of animals at the time of slaughter in accordance with Council Regulation (EC) No 1099/2009[21] and during transport in accordance with Council Regulation (EC) No 1/2005[22].

*Article 9*

*Post-mortem inspection*

(1) Carcases and accompanying offal's shall be subjected without delay after slaughter to post-mortem inspection. All external surfaces, including those of body cavities, shall be viewed. Minimal handling of the carcases and offals or special technical facilities may be required for that purpose. Particular attention shall be paid to the detection of zoonotic diseases and animal diseases for which animal health rules are laid down in Regulation (EU) 2016/429[23]. The speed of the slaughter line and the number of inspection staff present shall be such as to allow for proper inspection. The speed of the slaughter shall be reduced or other corrective action shall be taken immediately if faecal contamination is detected on external surfaces, including those of body cavities, to an extent not acceptable for the competent authority. The competent authority should increase the intensity of inspection until such time as it is satisfied that the FBO has regained control of the process.

(2) ~~Particularly in the case of animals having undergone emergency slaughter, a~~ Additional examinations shall take place, such as palpation and incision of parts of the carcase and offal and laboratory tests, if needed to:

(a) reach a definitive diagnosis; or

(b) detect the presence of:

(i) an animal disease,

(ii) chemical residues or contaminants in excess of the levels laid down in Union legislation,

(iii) non-compliance with microbiological criteria, or

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

(3) The official veterinarian shall require carcases of domestic solipeds, bovine animals over six months old, and domestic swine more than four weeks old to be submitted for post-mortem inspection split lengthways into half carcases down the spinal column. If the post-mortem inspection so necessitates, the official veterinarian may

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

[22] 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)

[23]

also 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 six months old, and domestic swine more than four weeks old, not split in half.

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

(5) In the event of an emergency slaughter, the carcase shall be subjected to post-mortem examination as soon as possible in accordance with paragraphs 1 to 4 of this Article before it is released for human consumption.

*Article 10*

*Practical arrangements for post-mortem inspection*

(1) Member States shall ensure that the practical arrangements of the post-mortem inspection referred to in Article 18(2)(c) of Regulation (EU) 2017/625 are applied in accordance with Chapters I to IX of Annex I to this Regulation for the following animals:

(a) domestic bovine animals;

(b) domestic sheep;

(c) domestic goats;

(d) domestic solipeds;

(e) domestic swine;

(f) poultry;

(g) farmed lagomorphs;

(h) farmed game;

(i) wild game.

(2) In addition to paragraph 1, Member States shall ensure that the practical arrangements of the post-mortem inspection referred to in Article 18(2) (c) of Regulation (EU) 2017/625 to address specific hazards, are applied out in accordance with Chapter X of Annex I to this Regulation.

*Article 11*

*Official controls on specified risk material and other animal by-products*

In accordance with rules on specified risk material laid down in Article 8 of Regulation (EC) No 999/2001 and on other animal by-products laid down in Regulation (EC) No 1069/2009, the official veterinarian shall check the removal, separation and, where appropriate, marking of such products.

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, and removal of specified risk material.

*Article 12*

*Laboratory testing*

(1) The official veterinarian shall ensure that when sampling takes place, samples are appropriately identified and handled and sent to the appropriate laboratory within the framework of:

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

(b) specific laboratory testing for the diagnosis of transmissible spongiform encephalopathies in accordance with Article 6 of Regulation (EC) No 999/2001;

(c) the detection of unauthorised substances or products and the control of regulated substances, in particular within the framework of the national plans for the detection of residues or substances referred to in Article 5 *of* Council Directive 96/23/EC[24]

(d) the detection of animal diseases for which animal health rules are laid down in Union legislation.

(2) The official veterinarian shall also ensure that any other necessary laboratory testing takes place.

## *CHAPTER III*

## SPECIFIC REQUIREMENTS FOR OFFICIAL TESTING METHODS FOR DETECTING MARINE BIOTOXINS

*Article 13*

*Testing methods*

The analytical methods laid down in Annex II of this Regulation shall be used by the competent authorities 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, by food business operators.

In accordance with Article 4 of Directive 2010/63/EU[25], wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of a procedure as defined in Article 3.1 of the Directive.



[24] 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).

[25] 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).

# TITLE III

## CONDITIONS FOR THE CLASSIFICATION AND MONITORING OF CLASSIFIED PRODUCTION AND RELAYING AREAS FOR LIVE BIVALVE MOLLUSCS

*Article 14*

*Reference method*

The reference method for analysis of *Escherichia coli* (*E. coli*) shall be the detection and Most Probable Number (MPN) technique specified in EN/ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in EN/ISO 16140.

*Article 15*

*Classification of production and relaying areas for live bivalve molluscs*

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

(2) The competent authority shall classify production areas from which it authorises the harvesting of live bivalve molluscs according to the level of faecal contamination. It may, where appropriate, do so in cooperation with the food business operator.

In order to classify production areas, the competent authority 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 this paragraph and in paragraphs 3, 4 and 5 of this Article.

(3) The competent authority may classify as being of Class A areas from which live bivalve molluscs may be collected for direct human consumption. Live bivalve molluscs placed on the market from these areas must 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.

Samples of live bivalve molluscs from Class A areas must not exceed, in 80 % of samples collected during the review period, 230 *E. coli* per 100 g of flesh and intravalvular liquid. The remaining 20 % of samples must not exceed 700 *E. coli* per 100 g of flesh and intravalvular liquid.

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

(4) The competent authority may classify as being of Class B areas from which live bivalve molluscs may be collected and only placed on the market for human

consumption after treatment in a purification centre or after relaying so as to meet the health standards referred to in paragraph 3.

Live bivalve molluscs from Class B areas must not exceed, in 90 % of the samples, 4 600 *E. coli* per 100 g of flesh and intravalvular liquid. In the remaining 10 % of samples, live bivalve molluscs must not exceed 46 000 *E. coli* per 100 g of flesh and intravalvular liquid.

(5) The competent authority may classify as being of Class C areas from which live bivalve molluscs may be collected and only placed on the market after relaying over a long period so as to meet the health standards referred to in paragraph 3.

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

(6) If the competent authority decides to classify a production or relaying area into one of three classifications set out in point 5, it shall:

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

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

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

(d) establish a sampling programme of live bivalve molluscs in the production area which is based on the examination of established data, and with a number of samples, a geographical distribution of the sampling points and a sampling frequency which must ensure that the results of the analysis are as representative as possible for the area considered.

*Article 16*

*Monitoring of classified relaying and production areas*

(1) Relaying and production areas classified in accordance with Article 18(6) of Regulation (EU) 2017/625 must be periodically monitored by the competent authority 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 biotoxins in live bivalve molluscs;

for the presence of chemical contaminants in live bivalve molluscs.

(2) For the purposes of the checks provided for in points 1(b), (c) and (d), sampling plans shall be drawn up by the competent authority 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 must ensure that the results of the analysis are as representative as possible for the classified production or monitoring area considered.

(3) Sampling plans to check the microbiological quality of live bivalve molluscs must take particular account of:

(a) the likely variation in faecal contamination;

(b) the parameters referred to in paragraph 6 of Article 15.

(4) Sampling plans to check for the presence of toxin-producing plankton in the water in classified production and relaying and for biotoxins in live bivalve molluscs must take particular account of possible variations in the presence of plankton containing marine biotoxins.

Sampling must comprise the following:

(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 must be followed by intensive sampling;

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

(5) The sampling frequency for toxin analysis in the live bivalve molluscs must, as a general rule, be weekly during the periods when harvesting is allowed. This sampling frequency may be reduced in specific classified monitoring or production areas, or for specific types of live bivalve molluscs, if a risk assessment on toxins or phytoplankton occurrence suggests a very low risk of toxic episodes. It must be increased where such an assessment suggests that weekly sampling would not be sufficient. The risk assessment must be periodically reviewed in order to assess the risk of toxins occurring in the live bivalve molluscs from these areas.

(6) When knowledge of toxin accumulation rates is available for a group of species [of live bivalve molluscs?] growing in the same classified production or relaying area, a 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. When toxin levels in the indicator species are above the regulatory limits, the harvesting of the other species may only be allowed if further analysis on the other species shows toxin levels below the limits.

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

(8) Sampling plans to check for the presence of chemical contaminants must enable the detection of any overshooting of the levels laid down in Commission Regulation (EC) No 1881/2006[26].

*Article 17*

*Decision after monitoring*

(1) Where the results of monitoring provided for in Article 16 show that the health standards for live bivalve molluscs are exceeded, or that there may be otherwise a risk to human health, the competent authority shall close the classified production area concerned, preventing the harvesting of live bivalve molluscs. However, the competent authority may reclassify a production area as being of Classes B or C if it meets the relevant criteria set out in Article 15 and presents no other risk to human health.

(2) The competent authority may re-open a closed production area only when the health standards for live bivalve molluscs once again comply with provisions of articles 15 and 16.

(3) If the competent authority closes a production because of the presence of plankton or excessive levels of toxins in live bivalve molluscs, at least two consecutive results below the regulatory limit separated by at least 48 hours are necessary to re-open it. The competent authority may take account of information on phytoplankton trends when taking this decision. When 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 authority may decide to re-open the area with results below the regulatory limit obtained from one single sampling.

*Article 18*

*Additional monitoring requirement*

(1) The competent authority shall monitor classified production areas from which it has 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.

(2) In addition to the monitoring of relaying and production areas, a control system shall be set up comprising laboratory tests to verify food business operators' compliance with the requirements for the end product of animal origin at all stages of production, processing and distribution. This control system must, in particular, verify that the levels of marine biotoxins and contaminants do not exceed safety limits and that the microbiological quality of the live bivalve molluscs does not constitute a hazard to human health.

[26] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L ……)

*Article 19*

*Recoding and exchange of information*

The competent authority 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 15. This list must be communicated to interested parties affected by Article 15, such as producers, gatherers and operators of purification centres and dispatch centres;

(b) Immediately inform the interested parties affected by this Regulation, such as producers, gatherers and operators of purification centres and dispatch centres, about any change of the location, boundaries or Class of a production area, or its closure, be it temporary or final;

(c) Act promptly where the controls set out in this Regulation indicate that a production area must be closed or reclassified or may be re-opened.

*Article 20*

*Food business operators' own checks*

To decide on the classification, opening or closure of production areas, the competent authority may take into account the results of controls that food business operators or organisations representing food business operators have carried out. In that event, the competent authority must have designated the laboratory carrying out the analysis and, if the competent Authority so authorises, sampling and analysis must have taken place in accordance with a protocol that the competent authority and the food business operators or organisation concerned have agreed.

## TITLE IV

## MEASURES TO BE TAKEN BY COMPETENT AUTHORITIES IN CASE OF SPECIFIC NON-COMPLIANCE WITH REQUIREMENTS FOR FRESH MEAT

*Article 21*

*Measures concerning the communication of inspection results*

(1) The official veterinarian shall record and evaluate the results of inspection activities and take appropriate action.

(2) Information requirements shall include the following:

(a) If inspections reveal the presence of any disease or condition that might affect public or animal health, or compromise animal welfare, the official veterinarian shall inform the slaughterhouse operator.

(b) When the problem identified arose during primary production, such as problems related to animal health, animal welfare or residues of veterinary medicinal products, the official veterinarian shall inform the veterinarian attending the holding of provenance, the food business operator responsible for the holding of provenance (provided that such information would not prejudice subsequent legal proceedings) and, where appropriate, the competent authority responsible for supervising the holding of provenance or the hunting area.

(c) If the animals concerned were raised in another Member State or in a third country, the official veterinarian shall inform the competent authority of the Member State where the establishment is located. That competent authority shall take appropriate measures in accordance with applicable Union legislation.

(3) The results of inspections and tests shall be included in relevant databases.

(4) When the official veterinarian, while carrying out ante-mortem or post-mortem inspection or any other inspection activity, suspects the presence of an infectious agent of animal diseases for which animal health rules are laid down in Union legislation, the official veterinarian shall notify, where appropriate, the competent authority, and both shall take all necessary measures and precautions to prevent the possible spread of the infectious agent in accordance with applicable Union legislation.

*Article 22*

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

(1) The official veterinarian shall verify that animals are not slaughtered unless the slaughterhouse operator has been provided with, checked and evaluated relevant food chain information.

(2) However, the official veterinarian may allow animals to undergo slaughter in the slaughterhouse even if the relevant food chain information is not available. In this case, all relevant food chain information must be supplied before the meat is approved for human consumption. Pending a final judgement, such carcases and related offal shall be stored separately from other meat.

(3) When relevant food chain information is not available within 24 hours of an animal's arrival at the slaughterhouse, all meat from the animal shall be declared unfit for human consumption. If the animal has not yet been slaughtered, it shall be killed separately from other animals.

(4) Animals may not be accepted for slaughter other than in accordance with procedures laid down under Union legislation to eliminate human or animal health risks nor when the accompanying records, documentation or other information show that:

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

(b) rules on the use of veterinary medicinal products have not been complied with; or

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

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 public health. Whenever the official veterinarian considers it necessary, official controls shall be carried out on the holding of provenance.

(5) The competent authority shall take appropriate action if it discovers that the accompanying records, documentation or other information do not correspond with the true situation on the holding of provenance or the true condition of the animals or aim deliberately to mislead the official veterinarian. The competent authority 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. This action may consist in particular 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 23*

*Measures in case of non-compliance with requirements for live animals*

(1) The official veterinarian shall verify compliance with the food business operator's duty pursuant 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 reasonably ascertainable are killed separately and declared unfit for human consumption. Whenever the official veterinarian considers it necessary, official controls shall be carried out on the holding of provenance.

(2) When there are overriding animal welfare considerations, horses may undergo slaughter at the slaughterhouse even if the legally required information concerning their identity has not been supplied. However, this information shall be supplied before the carcase may be declared fit for human consumption. These requirements also apply in the case of emergency slaughter of horses outside the slaughterhouse.

(3) The official veterinarian shall verify compliance with the food business operator's duty under Regulation (EC) No 853/2004 to ensure that animals that have such hide, skin or fleece conditions that there is an unacceptable risk of contamination of the meat during slaughter, are not slaughtered for human consumption unless they are cleaned beforehand.

(4) Animals with a disease or condition that may be transmitted to animals or humans through handling or eating meat and, in general, animals showing clinical signs of systemic disease or emaciation, must not be slaughtered for human consumption. Such animals shall be killed separately, under conditions such that other animals or carcases cannot be contaminated, and declared unfit for human consumption.

(5) The slaughter of animals suspected of having a disease or condition that may adversely affect human or animal health must be deferred. Such animals shall undergo detailed ante-mortem examination 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, the animals shall be slaughtered separately or at the end of normal slaughtering, taking all necessary precautions to avoid contamination of other meat.

(6) Animals that might contain residues of veterinary medicinal products in excess of the levels laid down in accordance with Union legislation, or residues of forbidden substances, shall be dealt with in accordance with Directive 96/23/EC.

(7) The official veterinarian must impose the conditions under which animals must 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 authority shall determine the conditions under which such animals may be slaughtered. These conditions shall have the aim of minimising contamination of other animals and the meat of other animals.

(8) Animals that are presented to a slaughterhouse for slaughter shall as a general rule 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.

*Article 24*

*Measures in case of non-compliance with requirements for animal welfare*

(1) When the rules concerning the protection of animals at the time of slaughter or killing are not respected, the official veterinarian shall verify that the food business operator immediately takes necessary corrective measures and prevents recurrence.

(2) The official veterinarian shall take a proportionate and progressive 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) When the official veterinarian discovers that rules concerning the protection of animals during transport are not being respected, he or she shall take necessary measures in accordance with the relevant Union legislation.

(5) When an official auxiliary carries out checks on animal welfare and those checks identify non-compliance with the rules on the protection of animals, the official auxiliary shall immediately inform the official veterinarian. If necessary in cases of urgency, the official auxiliary shall take the necessary measures referred to in points 1 to 4 of this Article pending the arrival of the official veterinarian.

*Article 25*

*Measures in case of non-compliance with requirements for fresh meat*

(1) Fresh meat shall be declared unfit for human consumption if it:

(a) derives from animals that have not undergone ante-mortem inspection, except for hunted wild game;

(b) derives from animals the offal of which has not undergone post-mortem inspection, unless otherwise provided for under this Regulation or Regulation (EC) No 853/2004;

(c) derives from animals which 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 Council Directive 2002/99/EC27, except if it is obtained in conformity with the specific requirements provided for in that legislation, unless otherwise provided for in Annex IV to 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 food safety criteria laid down in Regulation (EC) No 2073/2005 to determine whether food may be placed on the market;

(h) exhibits parasitic infestation, unless otherwise provided for in Annex IV to this Regulation;

(i) contains residues or contaminants in excess of the levels laid down in Union legislation. Any overshooting of the relevant level shall lead to additional analyses whenever appropriate;

(j) without prejudice to more specific Union legislation, derives from animals or carcases containing residues of forbidden substances or from animals that have been treated with forbidden substances;

(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 radiations or UV-radiation;

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

(o) exceeds the maximum permitted radioactivity levels laid down under Union legislation;

(p) indicates patho-physiological changes, anomalies in consistency, insufficient bleeding (except for wild game) or organoleptic anomalies except in case of a pronounced sexual odour;

(q) derives from emaciated animals;

(r) contains specified risk material, except as provided for in Regulation (EC) No 999/2001;

[27] 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).

(s) shows soiling, faecal or other contamination;

(t) consists of blood that may constitute a risk to public 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 public or animal health or is for any other reason not suitable for human consumption;

(v) gives rise to specific hazards in accordance with point 2 of, Chapter X.B to Annex IV, point 2 of Chapter X.C to Annex IV, point 3 of Chapter X.D to Annex IV, point 2 of Chapter X.E to Annex IV and point 2 of Chapter X.F to Annex IV.

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

(a) having 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 of the European Parliament and of the Council[28] before placing the meat on the market;

(c) with a pronounced sexual odour, in particular to avoid that the meat reaches the final consumer as fresh meat.

**Member States are requested to express their position on the pronounced sexual odour (preferred option + option(s) on which they are reluctant). Options may include:**

1. **keep provisions as in R 854/2004**
2. **Support the approach in this draft (as well rewording in 1(p), as in 2(c))**
3. **Support rewording of 1(p) but delete 2(c), leaving it to the FBO what to do with such meat.**

## TITLE V

## HEALTH MARKING

*Article 26*

*Technical requirements and the practical arrangements of the health mark*

(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 animals (domestic ungulates, farmed game mammals other than lagomorphs, and large wild game) having undergone ante-mortem and post-mortem inspection in accordance with this Regulation and when there are no grounds for declaring the meat unfit for human consumption. However, the health mark may be applied before the results of any examination for trichinosis is available, if the

[28] 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).

official veterinarian is satisfied that meat from the animal concerned will be placed on the market only if the results are satisfactory; and

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

(3) Member States shall ensure that the practical arrangements for its application are applied in accordance with Annex III

(4) Meat from unskinned wild game cannot 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.

(5) This Article applies without prejudice to animal health rules on health marking.

## TITLE VI

## SPECIFIC REQUIREMENTS AND UNIFORM MINIMUM FREQUENCY OF OFFICIAL CONTROLS WITH RESPECT TO RAW MILK, COLOSTRUM, MILK PRODUCTS, COLOSTRUM-BASED PRODUCTS

*Article 27*

*Control of milk and colostrum production holdings*

(1) Animals in production holdings and producing raw milk, colostrum, milk products and colostrum based products shall be subject to official controls by the official veterinarian to verify that the health requirements for raw milk and colostrum production, and in particular the health status of the animals and the use of veterinary medicinal products, are being complied with.

(2) These controls may take place at the occasion of veterinary checks carried out pursuant to Union provisions on animal or public health or animal welfare.

(3) If there are grounds for suspecting that the animal health requirements are not being complied with, the general health status of the animals shall be checked.

(4) Milk and colostrum production holdings shall undergo official controls to verify that hygiene requirements are being complied with. These official controls may involve inspections and/or the monitoring of controls that professional organisations carry out. If it is demonstrated that the hygiene is inadequate, the competent authority shall verify that appropriate steps are taken to correct the situation.

*Article 28*

*Control of milk and colostrum upon collection*

(1) In the case of raw milk and colostrum, the competent authority 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.

(2) The analytical methods set out in Annex IV to this Regulation shall be used by the competent authorities, to check compliance with the limits laid down in Annex III,

Section IX, Chapter I, Part III to Regulation (EC) No 853/2004 and to ensure appropriate application of a pasteurisation process to dairy products as referred to in Annex III, Section IX, Chapter II, Part II to that Regulation.

(3) If the food business operator has not corrected the situation within three months of the first notification by the competent authority of non-compliance with the criteria with regard to plate count and/or somatic cell count, delivery of raw milk and colostrum from the production holding must be suspended or — in accordance with a specific authorisation of, or general instructions from, the competent authority — subjected to requirements concerning its treatment and use necessary to protect public health. This suspension or these requirements shall remain in place until the food business operator has proved that the raw milk and colostrum again complies with these criteria.

## TITLE VII

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

*Article 29*

*Official controls of production and placing on the market*

(1) Official controls on the production and placing on the market of fishery products shall include, in particular:

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

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

i. where appropriate, whether the conditions for approval are still fulfilled,

ii. whether the fishery products are handled correctly,

iii. for compliance with hygiene and temperature requirements,

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

(c) checks on storage and transport conditions.

(2) Subject to paragraph 3, official controls of vessels:

(a) may be carried out when vessels call at a port in a Member State;

(b) concern all vessels landing fishery products at ports in the Union, irrespective of flag; and

(c) may, if necessary, when the competent authority of the Member State the flag of which the vessel is flying carries out the official control, be carried out while the vessel is at sea or when it is in a port in another Member State or in a third country.

(3) In the case of an inspection of a factory or freezer vessel flying the flag of a Member State carried out with a view to granting approval of the vessel, the competent authority of the Member State the flag of which the vessel is flying shall carry out inspections in such a manner as to comply with the requirements of Article 148 of Regulation (EU) 2017/625, particularly the time limits of Article 148(4). If necessary, that competent authority may inspect the vessel while it is at sea or when it is in a port in another Member State or in a third country.

When the competent authority of the Member State the flag of which the vessel is flying has granted the vessel conditional approval in accordance with Article 148 of Regulation (EU) 2017/625, that competent authority may authorise a competent authority of:

i. another Member State, or

ii. a third country that appears on a list of third countries from which imports of fishery products are permitted drawn up in accordance with Article 127 of Regulation (EU) 2017/625 to carry out a follow-up inspection with a view to granting full approval or prolonging conditional approval or to keeping approval under review. If necessary, that competent authority may inspect the vessel while it is at sea or when it is in a port in another Member State or in a third country.

(4) When the competent authority of a Member State authorises the competent authority of another Member State or of a third country to carry out inspections on its behalf in accordance with point 3, the two competent authorities shall agree on the conditions governing such inspections. These conditions shall ensure, in particular, that the competent authority of the Member State the flag of which the vessel is flying receives reports on the results of inspections and on any suspected non-compliance without delay, so as to enable it to take the necessary measures.

*Article 30*

*Official controls of fishery products*

Official controls of fishery products must include at least the practical arrangements lay down in Annex V as regards the following elements:

(a) organoleptic examinations;

(b) freshness indicators;

(c) histamine;

(d) residues and contaminants;

(e) microbiological checks;

(f) parasites

(g) poisonous fishery products

*Article 31*

*Decisions after controls*

Fishery products shall be declared unfit for human consumption if:

(1) organoleptic, chemical, physical or microbiological checks or checks for parasites have shown that they are not in compliance with Article 29;

(2) they contain in their edible parts contaminants or residues in excess of the limits laid down in Union legislation or at levels where the calculated dietary intake would exceed the acceptable daily or weekly intake for humans;

(3) they derive from:

(a) poisonous fish,

(b) fishery products not complying with the requirements concerning biotoxins,

(c) 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

(4) the competent authority considers that they may constitute a risk to public or animal health or are for any other reason not suitable for human consumption.

## TITLE VIII

## FINAL PROVISIONS

*Article 32*

This Regulation shall enter into force on the twentieth 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*
*[…]*