

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) No 1107/2009, (EU) No 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) (Text with EEA relevance)

TITLE II

OFFICIAL CONTROLS AND OTHER OFFICIAL ACTIVITIES IN MEMBER STATES

CHAPTER I

Competent authorities

Article 4

Designation of competent authorities

1 For each of the areas governed by the rules referred to in Article 1(2), Member States shall designate the competent authority or authorities on which they confer the responsibility to organise or perform official controls and other official activities.

2 Where, for the same area, a Member State confers the responsibility to organise or perform official controls or other official activities on more than one competent authority, at national, regional or local level, or where the competent authorities designated in accordance with paragraph 1 are allowed by that designation to transfer specific responsibilities for official controls or other official activities to other public authorities, the Member State shall:

- a ensure efficient and effective coordination between all authorities involved, and the consistency and effectiveness of official controls or other official activities across its territory; and
- b designate a single authority, in conformity with Member States' constitutional requirements, responsible for coordinating the cooperation and the contacts with the Commission and with other Member States in relation to the official controls and other official activities performed in each of the areas governed by the rules referred to in Article 1(2).

3 Competent authorities responsible for the verification of compliance with the rules referred to in point (i) of Article 1(2) may confer certain responsibilities related to official controls or other official activities to one or more organic control authorities. In such cases, they shall attribute a code number to each of them.

4 Member States shall ensure that the Commission is informed of the contact details and of any changes regarding:

- a the competent authorities designated in accordance with paragraph 1;
- b the single authorities designated in accordance with point (b) of paragraph 2;
- c the organic control authorities referred to in paragraph 3;
- d the delegated bodies referred to in Article 28(1).

The information referred to in the first subparagraph shall also be made available by Member States to the public, including on the internet.

Article 5

General obligations concerning the competent authorities and the organic control authorities

1 The competent authorities and the organic control authorities shall:

- a have procedures and/or arrangements in place to ensure the effectiveness and appropriateness of official controls and other official activities;
- b have procedures and/or arrangements in place to ensure the impartiality, quality and consistency of official controls and other official activities at all levels;
- c have procedures and/or arrangements in place to ensure that staff performing official controls and other official activities are free from any conflict of interest;
- d have, or have access to, an adequate laboratory capacity for analysis, testing and diagnosis;
- e have, or have access to, a sufficient number of suitably qualified and experienced staff so that official controls and other official activities can be performed efficiently and effectively;
- f have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls and other official activities efficiently and effectively;
- g have the legal powers to perform official controls and other official activities and to take the action provided for in this Regulation and in the rules referred to in Article 1(2);
- h have legal procedures in place in order to ensure that staff have access to the premises of, and documents kept by, operators so as to be able to accomplish their tasks properly;
- i have contingency plans in place, and be prepared to operate such plans in the event of an emergency, where appropriate, in accordance with the rules referred to in Article 1(2).

2 Any appointment of an official veterinarian shall be in writing and shall set out the official controls and the other official activities and related tasks for which the appointment has been made. Requirements imposed on staff of competent authorities that are provided for in this Regulation, including the requirement on freedom from any conflict of interest, shall apply to all official veterinarians.

3 Any appointment of an official plant health officer shall be in writing and shall set out the official controls and the other official activities and related tasks for which the appointment has been made. Requirements imposed on staff of competent authorities that are provided for in this Regulation, including the requirement on freedom from any conflict of interest, shall apply to all official plant health officers.

4 Staff performing official controls and other official activities shall:

- a receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to perform official controls and other official activities in a consistent manner;
- b keep up-to-date in their area of competence and receive regular additional training as necessary; and
- c receive training in the subject matters set out in Chapter I of Annex II and on the obligations of the competent authorities resulting from this Regulation, as appropriate.

Competent authorities, organic control authorities and delegated bodies shall develop and implement training programmes for the purpose of ensuring that staff performing official controls and other official activities receive the training referred to in points (a), (b) and (c).

5 When, within the services of a competent authority, more than one unit is competent to perform official controls or other official activities, efficient and effective coordination and cooperation shall be ensured between the different units.

Article 6

Audits of the competent authorities

1 To ensure their compliance with this Regulation, the competent authorities shall carry out internal audits or have audits carried out on themselves and shall take appropriate measures in the light of the results of those audits.

2 The audits referred to in paragraph 1 shall be subject to independent scrutiny and carried out in a transparent manner.

Article 7

Right of appeal

The decisions taken by the competent authorities in accordance with Article 55, Article 66(3) and (6), Article 67, point (b) of Article 137(3), and Article 138(1) and (2), concerning natural or legal persons shall be subject to such persons' right of appeal in accordance with national law.

The right of appeal shall not affect the obligation of competent authorities to take prompt action to eliminate or contain the risks to human, animal or plant health, to animal welfare or, as regards GMOs and plant protection products, also to the environment, in accordance with this Regulation and with the rules referred to in Article 1(2).

Article 8

Confidentiality obligations of the competent authorities

1 Competent authorities shall ensure that, subject to paragraph 3, information acquired when performing their duties in the context of official controls and other official activities is not disclosed to third parties where, under national or Union legislation, that information is, by its nature, covered by professional secrecy.

For that purpose, Member States shall ensure that appropriate confidentiality obligations are established for staff and other individuals employed during official controls and other official activities.

2 Paragraph 1 shall also apply to organic control authorities, delegated bodies and natural persons to which specific official control tasks have been delegated and to official laboratories.

3 Unless there is an overriding public interest in the disclosure of information covered by professional secrecy as referred to in paragraph 1, and without prejudice to situations where disclosure is required by Union or national legislation, such information shall include information whose disclosure would undermine:

- a the purpose of inspections, investigations or audits;
- b the protection of commercial interests of an operator or any other natural or legal person; or
- c the protection of court proceedings and legal advice.

4 The competent authorities, when determining whether there is an overriding public interest in the disclosure of information covered by professional secrecy as referred to in paragraph 1, shall take into account inter alia the possible risks to human, animal or plant health, or to the environment, and the nature, severity and extent of such risks.

5 The confidentiality obligations provided for in this Article shall not prevent the competent authorities from publishing or making otherwise available to the public information about the outcome of official controls regarding individual operators, provided, without prejudice to situations where disclosure is required by Union or national legislation, that the following conditions are met:

- a the operator concerned is given the opportunity to comment on the information that the competent authority intends to publish or make otherwise available to the public, prior to its publication or release, taking into account the urgency of the situation; and
- b the information which is published or made otherwise available to the public takes into account the comments expressed by the operator concerned or is published or released together with such comments.

CHAPTER II

Official controls

Section I

General requirements

Article 9

General rules on official controls

1 Competent authorities shall perform official controls on all operators regularly, on a risk basis and with appropriate frequency, taking account of:

- a identified risks associated with:
 - (i) animals and goods;

- (ii) the activities under the control of operators;
 - (iii) the location of the activities or operations of operators;
 - (iv) the use of products, processes, materials or substances that may influence food safety, integrity and wholesomeness, or feed safety, animal health or animal welfare, plant health or, in the case of GMOs and plant protection products, that may also have an adverse impact on the environment;
- b any information indicating the likelihood that consumers might be misled, in particular as to the nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production of food;
 - c operators' past record as regards the outcome of official controls performed on them and their compliance with the rules referred to in Article 1(2);
 - d the reliability and results of own controls that have been performed by the operators, or by a third party at their request, including, where appropriate, private quality assurance schemes, for the purpose of ascertaining compliance with the rules referred to in Article 1(2); and
 - e any information that might indicate non-compliance with the rules referred to in Article 1(2).

2 Competent authorities shall perform official controls regularly, with appropriate frequencies determined on a risk basis, to identify possible intentional violations of the rules referred to in Article 1(2), perpetrated through fraudulent or deceptive practices, and taking into account information regarding such violations shared through the mechanisms of administrative assistance provided for in Articles 102 to 108 and any other information pointing to the possibility of such violations.

3 Official controls that are performed prior to the placing on the market, or the movement of certain animals and goods in view of the issuance of the official certificates or official attestations required by the rules referred to in Article 1(2), as a condition for the placing on the market or the movement of the animals or goods shall be performed in accordance with both of the following:

- a the rules referred to in Article 1(2);
- b the applicable delegated and implementing acts adopted by the Commission in accordance with Articles 18 to 27.

4 Official controls shall be performed without prior notice, except where such notice is necessary and duly justified for the official control to be carried out. As regards official controls upon request from the operator, the competent authority may decide whether the official controls are to be performed with or without prior notice. Official controls with prior notice shall not preclude official controls without prior notice.

5 Official controls shall be performed as much as possible in such a manner that the administrative burden and operational disruption for operators are kept to the minimum necessary, but without this negatively affecting the effectiveness of those controls.

6 Competent authorities shall perform official controls in the same manner, while taking account of the need to adapt the controls to the specific situations, irrespective of whether the animals and goods concerned are:

- a available on the Union market, whether originating in the Member State where the official controls are performed or in another Member State;
- b to be exported from the Union; or
- c entering the Union.

7 To the extent strictly necessary for the organisation of the official controls, Member States of destination may require operators that have animals or goods delivered to them from another Member State to report the arrival of such animals or goods.

Article 10

Operators, processes and activities subject to official controls

1 To the extent necessary to ascertain compliance with the rules referred to in Article 1(2), competent authorities shall perform official controls on:

- a animals and goods at any stage of production, processing, distribution and use;
- b substances, materials or other objects which may influence the characteristics or health of animals and goods and their compliance with applicable requirements, at any stage of production, processing, distribution and use;
- c operators as regards activities, including the keeping of animals, equipment, means of transport, premises and other places under their control and their surroundings and on related documentation.

2 Without prejudice to the rules concerning existing lists or registers established on the basis of the rules referred to in Article 1(2), the competent authorities shall draw up and keep up-to-date a list of operators. Where such a list or register already exists for other purposes, it may also be used for the purposes of this Regulation.

3 The Commission shall adopt delegated acts in accordance with Article 144 to amend this Regulation concerning the setting out of categories of operators to be exempted from the list of operators referred to in paragraph 2 of this Article where their inclusion in such a list would constitute a disproportionate administrative burden for them compared to the risk related to their activities.

Article 11

Transparency of official controls

1 Competent authorities shall perform official controls with a high level of transparency and shall, at least once a year, make available to the public, including through publication on the internet, relevant information concerning the organisation and the performance of official controls.

They shall also ensure the regular and timely publication of information on the following:

- a the type, number and outcome of official controls;
- b the type and number of cases of non-compliance detected;
- c the type and number of cases where measures were taken by the competent authorities in accordance with Article 138; and
- d the type and number of cases where the penalties referred to in Article 139 were imposed.

The information referred to in points (a) to (d) of the second subparagraph of this paragraph may be provided, where appropriate, through the publication of the annual report referred to in Article 113(1).

2 Competent authorities shall establish procedures to ensure that any inaccuracies in the information made available to the public are appropriately rectified.

3 Competent authorities may publish, or make otherwise available to the public, information about the rating of individual operators based on the outcome of one or more official controls, provided that the following conditions are met:

- a the rating criteria are objective, transparent and publicly available; and
- b appropriate arrangements are in place to ensure the fairness, consistency and transparency of the rating process.

Article 12

Documented control procedures

1 Competent authorities shall perform official controls in accordance with documented procedures.

Those procedures shall cover the subject areas for control procedures set out in Chapter II of Annex II and shall contain instructions for staff performing official controls.

2 Competent authorities shall have control verification procedures in place.

3 Competent authorities shall:

- a take corrective actions in all cases where the procedures provided for in paragraph 2 identify shortcomings; and
- b update the documented procedures provided for in paragraph 1 as appropriate.

4 Paragraphs 1, 2 and 3 shall also apply to delegated bodies and organic control authorities.

Article 13

Written records of official controls

1 Competent authorities shall draw up written records of every official control that they perform. Those records may be on paper or in electronic form.

Those records shall contain:

- a a description of the purpose of the official controls;
- b the control methods applied;
- c the outcome of the official controls; and
- d where appropriate, action that the competent authorities require the operator concerned to take as a result of their official controls.

2 Unless the purposes of judicial investigations or the protection of court proceedings require otherwise, the operators subject to an official control shall be provided upon request with a copy of the records provided for in paragraph 1, except where an official certificate or official attestation has been issued. The operator shall be promptly informed in writing by the competent authorities of any case of non-compliance identified through the official controls.

3 Where official controls require the continuous or regular presence of staff or representatives of the competent authorities on the operator's premises, the records provided

for in paragraph 1 shall be produced with a frequency that enables the competent authorities and the operator to be:

- a regularly informed of the level of compliance; and
- b promptly informed of any case of non-compliance identified through the official controls.

4 Paragraphs 1, 2 and 3 shall also apply to delegated bodies, organic control authorities and natural persons to which certain official control tasks have been delegated.

Article 14

Methods and techniques for official controls

Official control methods and techniques shall include the following as appropriate:

- (a) an examination of the controls that operators have put in place and of the results obtained;
- (b) an inspection of:
 - (i) equipment, means of transport, premises and other places under their control and their surroundings;
 - (ii) animals and goods, including semi-finished goods, raw materials, ingredients, processing aids and other products used for the preparation and production of goods or for feeding or treating animals;
 - (iii) cleaning and maintenance products and processes;
 - (iv) traceability, labelling, presentation, advertising and relevant packaging materials including materials intended to come into contact with food;
- (c) controls on the hygiene conditions in the operators' premises;
- (d) an assessment of procedures on good manufacturing practices, good hygiene practices, good farming practices, and of procedures based on the principles of hazard analysis critical control points (HACCP);
- (e) an examination of documents, traceability records and other records which may be relevant to the assessment of compliance with the rules referred to in Article 1(2), including, where appropriate, documents accompanying food, feed and any substance or material entering or leaving an establishment;
- (f) interviews with operators and with their staff;
- (g) the verification of measurements taken by the operator and other test results;
- (h) sampling, analysis, diagnosis and tests;
- (i) audits of operators;
- (j) any other activity required to identify cases of non-compliance.

Article 15

Obligations of operators

1 To the extent that this is necessary for the performance of official controls or of other official activities, operators shall, where required by the competent authorities, give staff of the competent authorities access to:

- a the equipment, means of transport, premises and other places under their control and their surroundings;
- b their computerised information management systems;
- c the animals and goods under their control;
- d their documents and any other relevant information.

2 During official controls and other official activities, operators shall assist and cooperate with the staff of the competent authorities and organic control authorities in the accomplishment of their tasks.

3 The operator responsible for a consignment entering the Union shall, in addition to the obligations set out in paragraphs 1 and 2, make available, on paper or in electronic form, and without delay, all information concerning the animals and goods.

4 The Commission may, by means of implementing acts, lay down rules on the cooperation and exchange of information between operators and competent authorities related to the arrival and unloading of the animals and goods referred to in Article 47(1) where it is necessary to ensure their complete identification and the efficient performance of official controls on such animals and goods. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

5 For the purpose of Article 10(2) and subject to Article 10(3), operators shall provide the competent authorities with at least the following updated details:

- a their name and legal form; and
- b the specific activities they carry out, including activities undertaken by means of distance communication, and the places under their control.

6 The obligations of operators set out in this Article shall also apply in cases where official controls and other official activities are performed by official veterinarians, official plant health officers, delegated bodies, control authorities and natural persons to which certain official control tasks or certain tasks related to other official activities have been delegated.

Section II

Additional requirements for official controls and other official activities in certain areas

Article 16

Additional requirements

1 In the areas governed by the rules provided for in this Section, those rules shall apply in addition to the other rules set out in this Regulation.

2 When adopting delegated acts and implementing acts provided for in this Section, the Commission shall take into account the following:

- a the experience gained by competent authorities and food and feed business operators when applying the procedures referred to in Article 5 of Regulation (EC) No 852/2004 of the European Parliament and of the Council⁽¹⁾ and Article 6 of Regulation (EC) No 183/2005 of the European Parliament and of the Council⁽²⁾;
- b scientific and technological developments;
- c consumer expectations with regard to food composition and changes in patterns of consumption of food;
- d risks to human and animal health and plant health associated with animals and goods; and
- e information on possible intentional violations perpetrated through fraudulent or deceptive practices.

3 When adopting delegated acts and implementing acts provided for in this Section, and insofar as this does not prevent the achievement of the objectives pursued by the rules referred to in Article 1(2), the Commission shall also take into account the following:

- a the need to facilitate the application of the delegated acts and implementing acts, taking into account the nature and the size of small businesses;
- b the need to enable the continued use of traditional methods at any stage of production, processing or distribution of food, and the production of traditional foods; and
- c the needs of operators situated in regions that are subject to specific geographical constraints.

Article 17

Specific definitions

For the purpose of Article 18:

- (a) ‘under the responsibility of the official veterinarian’ means that the official veterinarian assigns the performance of an action to an official auxiliary;
- (b) ‘under the supervision of the official veterinarian’ means that an action is performed by an official auxiliary under the responsibility of the official veterinarian and the official veterinarian is present on the premises during the time necessary to perform that action;
- (c) ‘ante-mortem inspection’ means the verification, prior to slaughtering activities, of human and animal health and animal welfare requirements, including, where appropriate, the clinical examination of each individual animal, and the verification of the food chain information as referred to in Section III of Annex II to Regulation (EC) No 853/2004;
- (d) ‘post-mortem inspection’ means the verification in the slaughterhouse or game-handling establishment of compliance with requirements applicable to:
 - (i) carcasses as defined in point 1.9 of Annex I to Regulation (EC) No 853/2004 and offal as defined in point 1.11 of that Annex, for the purpose of deciding if the meat is fit for human consumption,
 - (ii) safe removal of specified risk material, and
 - (iii) the health and welfare of the animals.

Article 18

Specific rules on official controls and for action taken by the competent authorities in relation to the production of products of animal origin intended for human consumption

1 Official controls performed to verify compliance with the rules referred to in Article 1(2) of this Regulation in relation to products of animal origin intended for human consumption shall include the verification of compliance with the requirements laid down in Regulations (EC) No 852/2004, (EC) No 853/2004, (EC) No 1069/2009 and (EC) No 1099/2009 as applicable.

2 The official controls referred to in paragraph 1 performed in relation to the production of meat shall include:

- a the ante-mortem inspection performed in the slaughterhouse by an official veterinarian who may, as regards pre-selection of animals, be assisted by official auxiliaries trained for that purpose;
- b by way of derogation from point (a), as regards poultry and lagomorphs, the ante-mortem inspection 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;
- c the post-mortem inspection 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;
- d the other official controls performed in slaughterhouses, cutting plants and game-handling establishments, 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, to verify compliance with the requirements applicable to:
 - (i) the hygiene of meat production;
 - (ii) the presence of residues of veterinary medicinal products and contaminants in products of animal origin intended for human consumption;
 - (iii) audits of good hygiene practices and procedures based on HACCP principles;
 - (iv) laboratory tests to detect the presence of zoonotic agents and animal diseases and to verify compliance with the microbiological criterion as defined in point (b) of Article 2 of Commission Regulation (EC) No 2073/2005⁽³⁾;
 - (v) the handling and disposal of animal by-products and of specified risk material;
 - (vi) the health and welfare of the animals.

3 The competent authority may, on the basis of a risk analysis, allow slaughterhouse staff to assist in the performance of tasks relating to the official controls referred to in paragraph 2 in establishments slaughtering poultry or lagomorphs, or, in establishments slaughtering animals of other species, to carry out specific sampling and testing tasks relating to such controls, on condition that staff:

- a act independently from the production staff of the slaughterhouse;
- b have undergone appropriate training to carry out these tasks; and
- c carry out these tasks in the presence and following the instructions of the official veterinarian or of the official auxiliary.

4 Where the official controls referred to in points (a) and (c) of paragraph 2 have not identified any shortcoming that would make the meat unfit for human consumption, the health mark shall be applied to domestic ungulates, farmed game mammals other than lagomorphs, and large wild game, by the official veterinarian, under the supervision of the official veterinarian, under the responsibility of the official veterinarian, or, in compliance with the conditions laid down in paragraph 3, by the slaughterhouse staff.

5 The official veterinarian shall remain responsible for the decisions taken following official controls provided for in paragraphs 2 and 4, even if the performance of an action is assigned by him or her to the official auxiliary.

6 For the purpose of the official controls referred to in paragraph 1 performed in relation to live bivalve molluscs, the competent authorities shall classify production and relaying areas.

7 The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning specific rules for the performance of the official controls referred to in paragraphs 2 to 6 of this Article on:

- a criteria and conditions to determine, by way of derogation from point (a) of paragraph 2, when the ante-mortem inspection in certain slaughterhouses may be performed under the supervision or under the responsibility of an official veterinarian, provided that the derogations do not affect the achievement of the objectives of this Regulation;
- b criteria and conditions to determine, as regards poultry and lagomorphs, when sufficient guarantees are met for the official controls to be performed under the responsibility of an official veterinarian in regard to the ante-mortem inspections referred to in point (b) of paragraph 2;
- c criteria and conditions to determine, by way of derogation from point (a) of paragraph 2, when the ante-mortem inspection may be performed outside the slaughterhouse in case of emergency slaughter;
- d criteria and conditions to determine, by way of derogation from points (a) and (b) of paragraph 2, when the ante-mortem inspection may be performed at the holding of provenance;
- e criteria and conditions to determine when sufficient guarantees are met for the official controls to be performed under the responsibility of an official veterinarian with regard to the post-mortem inspection and auditing activities referred to in points (c) and (d) of paragraph 2;
- f criteria and conditions to determine, by way of derogation from point (c) of paragraph 2, when, in case of emergency slaughter, the post-mortem inspection is to be performed by the official veterinarian;
- g criteria and conditions to determine, in relation to *Pectinidae*, marine gastropods and *Holothuroidea*, by way of derogation from paragraph 6, when production and relaying areas are not to be classified;
- h specific derogations in respect to *Rangifer tarandus tarandus*, *Lagopus lagopus* and *Lagopus mutus*, in order to allow the continuation of longstanding local and traditional customs and practices, provided that the derogations do not affect the achievement of the objectives of this Regulation;
- i criteria and conditions to determine, by way of derogation from point (d) of paragraph 2, when the official controls in cutting plants may be performed by staff designated by the competent authorities for that purpose and appropriately trained;
- j specific minimum requirements for the staff of the competent authorities and for official veterinarian and official auxiliary in order to ensure an adequate performance of their tasks provided for in this Article, including specific minimum training requirements;

Status: This is the original version (as it was originally adopted).

- k appropriate minimum training requirements for the slaughterhouse staff assisting in the performance of tasks relating to official controls and other official activities in accordance with paragraph 3.

8 The Commission shall, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of the official controls referred to in this Article regarding:

- a specific requirements for the performance of official controls and the uniform minimum frequency of those official controls, having regard to the specific hazards and risks which exist in relation to each product of animal origin and the different processes it undergoes, where a minimum level of official controls is necessary to respond to recognised uniform hazards and risks which might be posed by products of animal origin;
- b the conditions for the classification and monitoring of classified production and relaying areas for live bivalve molluscs;
- c the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Articles 137(2) and 138(2);
- d the practical arrangements of the ante-mortem and post-mortem inspections referred to in points (a), (b) and (c) of paragraph 2, including the uniform requirements necessary to ensure that sufficient guarantees are met when the official controls are performed under the responsibility of the official veterinarian;
- e the technical requirements of the health mark and the practical arrangements for its application;
- f specific requirements for the performance of official controls and the uniform minimum frequency for those official controls on raw milk, milk products and fishery products, where a minimum level of official controls is necessary to respond to recognised uniform hazards and risks they might pose.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

9 While complying with the objectives of this Regulation and in particular as regards food safety requirements, the Member States may adopt national measures implementing pilot projects limited in time and extent, to evaluate alternative practical arrangements for the performance of official controls on the production of meat. Those national measures shall be notified in accordance with the procedure laid down in Articles 5 and 6 of Directive (EU) 2015/1535. The outcome of the evaluation conducted through the pilot projects shall be communicated to the Commission as soon as available.

10 For the purpose of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.

Article 19

Specific rules on official controls and for action taken by the competent authorities in relation to the residues of relevant substances in food and feed

1 Official controls to verify compliance with the rules referred to in points (a) and (c) of Article 1(2) shall include official controls, to be performed at any stage of production, processing and distribution, on relevant substances including substances to be used in food contact materials, contaminants, non-authorised, prohibited and undesirable substances whose use or presence on crops or animals or to produce or process food or feed may result in residues of those substances in food or feed.

2 The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of the official controls referred to in paragraph 1 of this Article and for action to be taken by the competent authorities following those official controls. Those delegated acts shall lay down rules on:

- a specific requirements for the performance of official controls, including, where appropriate, the range of samples and the stage of production, processing and distribution where the samples are to be taken in compliance with the methods to be used for sampling and laboratory analyses established in accordance with points (a) and (b) of Article 34(6), having regard to the specific hazards and risks related to substances referred to in paragraph 1 of this Article;
- b the cases where the competent authorities in relation to non-compliance or suspicion thereof are to take one or more of the measures referred to in Articles 137(2) and 138(2);
- c the cases where the competent authorities in relation to non-compliance or suspicion thereof of animals and goods from third countries are to take one or more of the measures referred to Articles 65 to 72.

3 The Commission may, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of the official controls referred to in paragraph 1 and for action to be taken by the competent authorities following those official controls, regarding:

- a uniform minimum frequency of such official controls, having regard to the hazards and risks related to substances referred to in paragraph 1;
- b specific additional arrangements and specific additional content to those provided for in Article 110, for the preparation of the relevant parts of the multi-annual national control plan (MANCP) provided for in Article 109(1);
- c specific practical arrangements for the activation of the mechanism of administrative assistance provided for in Articles 102 to 108.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

4 For the purpose of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.

Article 20

Specific rules on official controls and for action taken by the competent authorities in relation to animals, products of animal origin, germinal products, animal by-products and derived products

1 Official controls to verify compliance with the rules referred to in points (a), (c), (d), and (e) of Article 1(2) shall include official controls, to be performed at any stage of production, processing and distribution, on animals, on products of animal origin, on germinal products, on animal by-products and on derived products.

2 The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of official controls on animals, on products of animal origin, on germinal products, on animal by-products and on derived products to verify compliance with the Union rules referred to in points (d) and (e) of Article 1(2) and for action taken by the competent authorities following official controls. Those delegated acts shall lay down rules on:

- a specific requirements for the performance of official controls on animals, products of animal origin and germinal products to respond to recognised hazards and risks to

- human and animal health by means of official controls performed to verify compliance with disease prevention and control measures laid down in accordance with the rules referred to in point (d) of Article 1(2);
- b specific requirements for the performance of official controls on animal by-products and derived products to respond to specific hazards and risks to human and animal health by means of official controls performed to verify compliance with the rules referred to in point (e) of Article 1(2);
 - c the cases where the competent authorities in relation to non-compliance or suspicion thereof are to take one or more of the measures referred to in Articles 137(2) and 138(2).
- 3 The Commission may, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of official controls referred to in paragraph 1 regarding:
- a uniform minimum frequency of such official controls on animals, products of animal origin and germinal products where a minimum level of official controls is necessary to respond to recognised uniform hazards and risks to human and animal health by means of official controls performed to verify compliance with disease prevention and control measures laid down in accordance with the rules referred to in point (d) of Article 1(2); and
 - b uniform minimum frequency of such official controls on animal-by-products and derived products where a minimum level of official controls is necessary to respond to specific hazards and risks to human and animal health by means of official controls performed to verify compliance with the rules referred to in point (e) of Article 1(2).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

- 4 For the purpose of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.

Article 21

Specific rules on official controls and for action to be taken by the competent authorities in relation to the welfare requirements for animals

- 1 Official controls to verify compliance with the rules referred to in point (f) of Article 1(2) shall be performed at all relevant stages of production, processing and distribution along the agri-food chain.
- 2 Official controls to verify compliance with the rules laying down welfare requirements for animals in the event of their transport, in particular with Regulation (EC) No 1/2005, shall include:
- a in the case of long journeys between Member States and with third countries, official controls performed prior to the loading to check the fitness of the animals for transport;
 - b in the case of long journeys between Member States and with third countries, of domestic equidae other than registered equidae and domestic animals of the bovine, ovine, caprine and porcine species, and prior to those journeys:
 - (i) official controls on journey logs to verify that the journey log is realistic and indicates compliance with Regulation (EC) No 1/2005; and
 - (ii) official controls to verify that the transporter indicated in the journey log has a valid transporter authorisation, certificate of approval for the means

of transport for long journeys and certificates of competence for drivers and attendants;

- c at border control posts provided for in Article 59(1) and at exit points:
- (i) official controls on the fitness of the animals being transported and on the means of transport to verify compliance with Chapter II of Annex I to Regulation (EC) No 1/2005 and where applicable Chapter VI thereof;
 - (ii) official controls to verify that transporters comply with applicable international agreements and have valid transporter authorisations and certificates of competence for drivers and attendants; and
 - (iii) official controls to verify whether domestic equidae and domestic animals of bovine, ovine, caprine and porcine species have been or are to be transported over long journeys.

3 During the performance of official controls and other official activities, the competent authorities shall take the necessary measures to prevent or reduce to a minimum any delay between the loading of the animals and their departure, or during the transport.

The competent authorities shall not detain animals during the transport unless it is strictly necessary for animal welfare or animal or human health reasons. If animals have to be detained during transport for more than two hours, the competent authorities shall ensure that appropriate arrangements are taken for their care and, where necessary, their feeding, watering, unloading and accommodation.

4 Where a non-compliance is established following the official controls referred to in point (b) of paragraph 2 and is not corrected by the organiser prior to the long journey, by making appropriate changes to the transport arrangements, the competent authorities shall prohibit that long journey.

5 Where, following the official controls referred to in point (c) of paragraph 2, the competent authorities establish that animals are not fit to complete the journey, they shall give the order that animals be unloaded, watered, fed and rested until fit to continue their journey.

6 A notification of non-compliance with the rules referred to in paragraph 1 of this Article for the purposes of Articles 105 and 106 shall be made:

- a to the Member States that granted the authorisation to the transporter;
- b where non-compliance with any such rule applicable to the means of transport is identified, to the Member State that granted the certificate of approval of the means of transport;
- c where non-compliance with any such rule applicable to drivers is identified, to the Member State that issued the driver's certificate of competence.

7 For the purpose of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.

8 The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of official controls to verify compliance with Union rules referred to in point (f) of Article 1(2). Those delegated acts shall take into account the animal welfare risk related to the farming activities and to the transport, slaughter and killing of animals, and shall lay down rules on:

- a specific requirements for the performance of such official controls to respond to the risk associated with different animal species and means of transport, and the need to prevent non-compliant practices and to limit the suffering of animals;

- b the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Articles 137(2) and 138(2);
- c the verification of animal welfare requirements at border control posts and at exit points and the minimum requirements applicable to those exit points;
- d specific criteria and conditions for the activation of the mechanisms of administrative assistance provided for in Articles 102 to 108;
- e the cases and conditions where official controls to verify compliance with animal welfare requirements may include the use of specific animal welfare indicators based on measurable performance criteria, and the design of such indicators on the basis of scientific and technical evidence.

9 The Commission shall, by means of implementing acts, lay down rules on uniform practical arrangements on official controls performed to verify compliance with the Union rules referred to in point (f) of Article 1(2) laying down animal welfare requirements and on action taken by the competent authorities following such official controls, regarding:

- a uniform minimum frequency of such official controls, where a minimum level of official control is necessary to respond to the risk associated with different animal species and means of transport, and the need to prevent non-compliant practices and to limit the suffering of animals; and
- b the practical arrangements for keeping written records of official controls performed and their retention period.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 22

Specific rules on official controls and for action taken by the competent authorities in relation to plant health

1 Official controls to verify compliance with the rules referred to in point (g) of Article 1(2) shall include official controls on pests, plants, plant products and other objects, and on professional operators and other persons subject to those rules.

2 The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of official controls on plants, plant products and other objects in order to verify compliance with Union rules referred to in point (g) of Article 1(2) applicable to those goods and for action taken by the competent authorities following the performance of those official controls. Those delegated acts shall lay down rules on:

- a specific requirements for the performance of such official controls on the introduction into and movement in the Union of particular plants, plant products, and other objects subject to the rules referred to in point (g) of Article 1(2), to respond to recognised hazards and risks to plant health in relation to specific plants, plant products and other objects of a particular origin or provenance; and
- b the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Articles 137(2) and 138(2).

3 The Commission shall, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of official controls on plants, plant products and other objects in order to verify compliance with Union rules referred to in point (g) of

Article 1(2) applicable to those goods and for action taken by the competent authorities following such official controls on:

- a uniform minimum frequency of such official controls, where a minimum level of official control is necessary to respond to recognised uniform hazards and risks to plant health in relation to specific plants, plant products and other objects of a particular origin or provenance;
- b uniform frequency of official controls performed by competent authorities on operators authorised to issue plant passports in accordance with Article 84(1) of Regulation (EU) 2016/2031 having regard to whether those operators have implemented a pest risk management plan as referred to in Article 91 of that Regulation for the plants, plant products and other objects they produce;
- c uniform frequency of official controls performed by competent authorities on operators authorised to apply the mark referred to in Article 96(1) of Regulation (EU) 2016/2031 or to issue the official attestation referred to in point (a) of Article 99(2) of that Regulation.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

4 For the purpose of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.

Article 23

Specific rules on official controls and for action taken by the competent authorities in relation to GMOs for the purpose of food and feed production and genetically modified food and feed

1 Official controls to verify compliance with the rules referred to in points (a), (b) and (c) of Article 1(2) shall include official controls on GMOs for the purpose of food and feed production and on genetically modified food and feed performed at all relevant stages of production, processing and distribution along the agri-food chain.

2 The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of the official controls referred to in paragraph 1 of this Article and for action to be taken by the competent authorities following such official controls. Those delegated acts shall take into account the need to ensure a minimum level of official controls to prevent practices that infringe the rules referred to in point (b) of Article 1(2), and lay down:

- a specific requirements for the performance of official controls to respond to recognised uniform hazards and risks of:
 - (i) the presence in the agri-food chain of GMOs for food and feed production and of genetically modified food and feed which have not been authorised in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003;
 - (ii) the cultivation of GMOs for food and feed production and the correct application of the plan for monitoring referred to in point (e) of Article 13(2) of Directive 2001/18/EC and in point (b) of Article 5(5) and point (b) of Article 17(5) of Regulation (EC) No 1829/2003;
- b the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Articles 137(2) and 138(2).

3 The Commission may, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of the official controls referred to in paragraph 1, taking into account the need to ensure a minimum level of official controls to prevent practices that infringe those rules regarding uniform minimum frequency of such official controls where a minimum level of official control is necessary to respond to recognised uniform hazards and risks of:

- a the presence in the agri-food chain of GMOs for food and feed production and of genetically modified food and feed which have not been authorised in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003;
- b the cultivation of GMOs for food and feed production and the correct application of the plan for monitoring referred to in point (e) of Article 13(2) of Directive 2001/18/EC and in point (b) of Article 5(5) and point (b) of Article 17(5) of Regulation (EC) No 1829/2003.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

4 For the purpose of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.

Article 24

Specific rules on official controls and for action taken by the competent authorities in relation to plant protection products

1 Official controls to verify compliance with the rules referred to in point (h) of Article 1(2) of this Regulation shall include official controls on active substances and safeners, synergists, co-formulants and adjuvants as referred to in Article 2(2) and (3) of Regulation (EC) No 1107/2009.

2 For the purpose of establishing the frequency of risk based official controls referred to in paragraph 1, competent authorities shall take into account also the following:

- a results of relevant monitoring activities including those on pesticides residues carried out for the purpose of Article 32(2) of Regulation (EC) No 396/2005 and of Article 8 of Directive 2000/60/EC of the European Parliament and of the Council⁽⁴⁾;
- b information on non-authorised plant protection products, including illegal trade of plant protection product, and results of relevant controls by the authorities referred to in Article 8 of Regulation (EU) No 649/2012 of the European Parliament and of the Council⁽⁵⁾; and
- c information on poisoning related to plant protection products, including information available in accordance to Article 56 of Regulation (EC) No 1107/2009, and information on emergency health responses made available by the centres referred to in Article 45(1) of Regulation (EC) No 1272/2008 of the European Parliament and of the Council⁽⁶⁾.

3 The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of official controls referred to in paragraph 1 of this Article. Those delegated acts shall lay down rules on:

- a specific requirements for the performance of such official controls to respond to recognised uniform hazards and risks which might be posed by plant protection products, concerning the manufacture, placing on the market, entry into the Union, labelling, packaging, transport, storage and use of plant protection products to ensure their safe and sustainable use and to combat their illegal trade; and

- b the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Articles 137(2) and 138(2).

4 The Commission may, by means of implementing acts, lay down detailed rules on uniform practical arrangements for the performance of official controls on the products referred to in paragraph 1 regarding:

- a uniform minimum frequency of such official controls, where a minimum level of official control is necessary to respond to recognised uniform hazards and risks which might be posed by plant protection products, concerning the manufacture, placing on the market, entry into the Union, labelling, packaging, transport, storage and use of plant protection products to ensure their safe and sustainable use and to combat their illegal trade;
- b the collection of information, monitoring and reporting on suspected poisonings from plant protection products;
- c the collection of information, and the monitoring of and reporting on non-authorised plant protection products including illegal trade of plant protection products.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

5 For the purpose of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.

Article 25

Specific rules on official controls and other official activities for organic production and labelling of organic products

The Commission may, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of official controls to verify compliance with the rules referred to in point (i) of Article 1(2), regarding:

- (a) specific requirements and additional content to that provided for in Article 110 to prepare the relevant parts of the MANCP provided for in Article 109(1), and specific additional content to the report provided for in Article 113;
- (b) specific responsibilities and tasks for the European Union reference centres in addition to those provided for in Article 98;
- (c) practical arrangements for activating the mechanisms of administrative assistance provided for in Articles 102 to 108, including the exchange of information concerning instances of non-compliance or the likelihood of non-compliance between competent authorities and delegated bodies;
- (d) the methods to be used for sampling and for laboratory analyses and tests, excluding any rules involving the setting of thresholds.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 26

Specific rules on official controls and other official activities performed by the competent authorities in relation to protected designations of origin, protected geographical indications and traditional specialities guaranteed

1 By way of derogation from Article 31(3), in relation to the rules referred in point (j) of Article 1(2), where competent authorities have delegated the decisions concerning the authorisation to use the registered name of a product, they may also delegate the application of the following measures:

- a ordering that certain activities of the operator be subject to systematic or increased official controls;
- b ordering the operator to increase the frequency of own controls;
- c ordering the alteration of label in order to comply with the product specifications and the rules referred in point (j) of Article 1(2).

2 The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of official controls to verify compliance with the rules referred to in point (j) of Article 1(2). Those delegated acts shall lay down rules on:

- a requirements, methods and techniques referred to in Articles 12 and 14 for official controls performed to verify compliance with product specifications and labelling requirements;
- b specific methods and techniques referred to in Article 14 for the performance of official controls aimed at ensuring the traceability of goods and animals falling within the scope of the rules referred to in point (j) of Article 1(2) at all stages of production, preparation and distribution, and at providing assurances as to compliance with those rules;
- c the cases where the competent authorities, in relation to specific non-compliances, are to take one or more of the actions and measures referred to in Article 138(1) and (2).

3 The Commission may, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of the official controls to verify compliance with the rules referred to in point (j) of Article 1(2) regarding:

- a specific practical arrangements for activating the mechanisms of administrative assistance provided for in Articles 102 to 108, including the exchange of information concerning instances of non-compliance or the likelihood of non-compliance between competent authorities and delegated bodies; and
- b specific reporting obligations of the delegated bodies.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

4 For the purpose of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.

Article 27

Specific rules on official controls and for action taken by the competent authorities in cases of newly identified risks in relation to food and feed

1 The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of official controls on certain categories of food or feed to verify compliance with the rules referred to in points (a) to (e) of Article 1(2) and for action to be taken by the competent authorities following such official controls. Those delegated acts shall address newly identified risks which may arise through food or feed to human or animal health or, in relation to GMOs and plant protection products, also to the environment, or any such risks emerging from new patterns of production or consumption of food or feed, and which cannot be effectively addressed in the absence of such common rules. Those delegated acts shall lay down rules on:

- a uniform specific requirements for the performance of official controls to respond to the specific hazards and risks which exist in relation to each category of food and feed and the different processes it undergoes; and
- b the cases where the competent authorities, in relation to specific non-compliances, are to take one or more of the measures referred to in Articles 137(2) and 138(2).

2 The Commission may, by means of implementing acts, lay down rules on uniform practical arrangements on official controls performed on certain categories of food or feed to verify compliance with the rules referred to in points (a) to (e) of Article 1(2) to address newly identified risks which may arise through food or feed to human or animal health or, in relation to GMOs and plant protection products, also to the environment, or any such risks emerging from new patterns of production or consumption of food or feed, and which cannot be effectively addressed in the absence of such common rules regarding uniform minimum frequency of such official controls, where a minimum level of official control is necessary to respond to the specific hazards and risks which exist in relation to each category of food and feed and the different processes it undergoes. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

3 On duly justified imperative grounds of urgency relating to cases of serious risks to human or animal health or to the environment, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 145(3).

CHAPTER III

Delegation of certain tasks of the competent authorities

Article 28

Delegation by the competent authorities of certain official control tasks

1 Competent authorities may delegate certain official control tasks to one or more delegated bodies or natural persons in accordance with the conditions provided for in Articles 29 and 30 respectively. The competent authority shall ensure that the delegated body or natural person, to which such tasks have been delegated, have the powers needed to effectively perform these tasks.

2 Where a competent authority or a Member State decides to delegate certain official control tasks for the verification of compliance with the rules referred to in point (i) of Article 1(2) to one or more delegated bodies, it shall attribute a code number to each delegated body, and shall designate relevant authorities responsible for their approval and supervision.

Article 29

Conditions for delegating certain official control tasks to delegated bodies

The delegation of certain official control tasks to a delegated body referred to in Article 28(1) shall be in writing and shall comply with the following conditions:

- (a) the delegation contains a precise description of those official control tasks that the delegated body may perform, and the conditions under which it may perform those tasks;
- (b) the delegated body:
 - (i) has the expertise, equipment and infrastructure required to perform those official control tasks delegated to it;
 - (ii) has a sufficient number of suitably qualified and experienced staff;
 - (iii) is impartial and free from any conflict of interest and in particular is not in a situation which may, directly or indirectly, affect the impartiality of its professional conduct as regards the performance of those official control tasks delegated to it;
 - (iv) works and is accredited in accordance with standards relevant to the delegated tasks in question, including standard EN ISO/IEC 17020 'Requirements for the operation of various types of bodies performing inspection';
 - (v) has sufficient powers to perform the official control tasks delegated to it; and
- (c) there are arrangements in place ensuring efficient and effective coordination between the delegating competent authorities and the delegated body.

Article 30

Conditions for delegating certain official control tasks to natural persons

Competent authorities may delegate certain official control tasks to one or more natural persons, where the rules provided for in Articles 18 to 27 so allow. Such delegation shall be in writing and shall comply with the following conditions:

- (a) the delegation contains a precise description of those official control tasks that the natural persons may perform and the conditions under which the natural persons may perform those tasks;
- (b) the natural persons:
 - (i) have the expertise, equipment and infrastructure required to perform those official control tasks delegated to them;
 - (ii) are suitably qualified and experienced;

- (iii) act impartially and are free from any conflict of interest as regards the exercise of those official control tasks delegated to them; and
- (c) there are arrangements in place ensuring efficient and effective coordination between the delegating competent authorities and the natural persons.

Article 31

Conditions for delegating certain tasks related to other official activities

1 The competent authorities may delegate certain tasks related to other official activities to one or more delegated bodies subject to compliance with the following conditions:

- a the rules referred to in Article 1(2) do not prohibit such delegation; and
- b the conditions laid down in Article 29 are fulfilled with the exception of that laid down in point (b)(iv).

2 The competent authorities may delegate certain tasks related to other official activities to one or more natural persons subject to compliance with the following conditions:

- a the rules referred to in Article 1(2) allow such delegation; and
- b the conditions laid down in Article 30, applied *mutatis mutandis*, are fulfilled.

3 Competent authorities shall not delegate to a delegated body or to a natural person the decision concerning the tasks provided for in point (b) of Article 138(1) and in Article 138(2) and (3).

Article 32

Obligations of the delegated bodies and natural persons

Delegated bodies or natural persons to which certain official control tasks have been delegated in accordance with Article 28(1), or certain tasks related to other official activities have been delegated in accordance with Article 31, shall:

- (a) communicate the outcome of the official controls and other official activities performed by them to the delegating competent authorities on a regular basis and whenever those competent authorities so request;
- (b) immediately inform the delegating competent authorities whenever the outcome of the official controls indicate non-compliance or point to the likelihood of non-compliance, unless specific arrangements established between the competent authority and the delegated body or the natural person concerned provides otherwise; and
- (c) give competent authorities access to their premises and facilities and cooperate and provide assistance.

Article 33

Obligations of the delegating competent authorities

Competent authorities that have delegated certain official control tasks to delegated bodies or natural persons in accordance with Article 28(1), or certain tasks related

to other official activities to delegated bodies or natural persons in accordance with Article 31, shall:

- (a) organise audits or inspections of such bodies or persons, as necessary and avoiding duplication, taking into account any accreditation referred to in point (b)(iv) of Article 29;
- (b) fully or partly withdraw the delegation without delay where:
 - (i) there is evidence that such a delegated body or natural person is failing to properly perform the tasks delegated to it;
 - (ii) the delegated body or the natural person fails to take appropriate and timely action to remedy the shortcomings identified; or
 - (iii) the independence or impartiality of the delegated body or natural person has been shown to be compromised.

This point shall be without prejudice to the competence of the competent authorities to withdraw the delegation for reasons other than those referred to in this Regulation.

CHAPTER IV

Sampling, analyses, tests and diagnoses

Article 34

Methods used for sampling, analyses, tests and diagnoses

1 Methods used for sampling and for laboratory analyses, tests and diagnoses during official controls and other official activities shall comply with Union rules establishing those methods or the performance criteria for those methods.

2 In the absence of the Union rules as referred to in paragraph 1, and in the context of official controls and other official activities, official laboratories shall use one of the following methods according to the suitability for their specific analytical, testing and diagnostic needs:

- a available methods complying with relevant internationally recognised rules or protocols including those that the European Committee for Standardisation (CEN) has accepted; or

relevant methods developed or recommended by the European Union reference laboratories and validated in accordance with internationally accepted scientific protocols;

- b in the absence of the suitable rules or protocols, as referred to in point (a), methods which comply with relevant rules established at national level, or, if no such rules exist, relevant methods developed or recommended by national reference laboratories and validated in accordance with internationally accepted scientific protocols; or

relevant methods developed and validated with inter or intra-laboratory methods validation studies in accordance with internationally accepted scientific protocols.

3 Where laboratory analyses, tests or diagnoses are urgently needed and none of the methods referred to in paragraphs 1 and 2 of this Article exists, the relevant national reference laboratory or, if no such national reference laboratory exists, any other laboratory designated in

accordance with Article 37(1) may use methods other than those referred to in paragraphs 1 and 2 of this Article until the validation of an appropriate method in accordance with internationally accepted scientific protocols.

4 Wherever possible, methods used for laboratory analyses shall be characterised by the relevant criteria set out in Annex III.

5 Samples shall be taken, handled and labelled in such a way as to ensure their legal, scientific and technical validity.

6 The Commission may, by means of implementing acts, lay down rules on:

- a the methods to be used for sampling and for laboratory analyses, tests and diagnoses;
- b performance criteria, analysis, test or diagnosis parameters, measurement uncertainty and procedures for the validation of those methods;
- c the interpretation of analytical, testing and diagnostic results.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 35

Second expert opinion

1 The competent authorities shall ensure that operators, whose animals or goods are subject to sampling, analysis, test or diagnosis in the context of official controls, have the right to a second expert opinion, at the operator's own expense.

The right to a second expert opinion shall entitle the operator to request a documentary review of the sampling, analysis, test or diagnosis by another recognised and appropriately qualified expert.

2 Where relevant, appropriate and technically feasible, having regard in particular to the prevalence and distribution of the hazard in the animals or goods, to the perishability of the samples or the goods and to the amount of available substrate, the competent authorities shall:

- a when taking the sample, and if so requested by the operator, ensure that a sufficient quantity is taken to allow for a second expert opinion and for the review referred to in paragraph 3, should this prove necessary; or
- b where it is not possible to take a sufficient quantity as referred to in point (a), inform the operator thereof.

This paragraph shall not apply when assessing the presence of quarantine pests in plants, plant products or other objects for the purpose of verifying compliance with the rules referred to in point (g) of Article 1(2).

3 Member States may decide that, where there is a dispute between the competent authorities and the operators that is based on the second expert opinion referred to in paragraph 1, the operators may request, at their own expense, the documentary review of the initial analysis, test or diagnosis and, where appropriate, another analysis, test or diagnosis by another official laboratory.

4 The application by the operator for a second expert opinion under paragraph 1 of this Article shall not affect the obligation of competent authorities to take prompt action to eliminate or contain the risks to human, animal and plant health, or to animal welfare or, as regards GMOs

and plant protection products, also to the environment, in accordance with this Regulation and with the rules referred to in Article 1(2).

Article 36

Sampling of animals and goods offered for sale by means of distance communication

- 1 In the case of animals and goods offered for sale by means of distance communication, samples ordered from operators by the competent authorities without identifying themselves may be used for the purposes of an official control.
- 2 Competent authorities, once they are in possession of the samples, shall take all steps to ensure that the operators from whom these samples have been ordered in accordance with paragraph 1:
 - a are informed that such samples have been taken in the context of an official control and, where appropriate, are analysed or tested for the purposes of such official control; and
 - b where the samples referred to in that paragraph are analysed or tested, are able to exercise the right to a second expert opinion, as provided for in Article 35(1).
- 3 Paragraphs 1 and 2 shall apply to delegated bodies and natural persons to which certain official controls tasks have been delegated.

Article 37

Designation of official laboratories

- 1 The competent authorities shall designate official laboratories to carry out the laboratory analyses, tests and diagnoses on samples taken during official controls and other official activities, in the Member State in whose territory those competent authorities operate or in another Member State or a third country that is a Contracting Party to the Agreement on the European Economic Area.
- 2 Competent authorities may designate as an official laboratory a laboratory located in another Member State or third country that is a Contracting Party to the Agreement on the European Economic Area, subject to compliance with the following conditions:
 - a appropriate arrangements are in place under which the competent authorities are enabled to perform the audits and inspections referred to in Article 39(1) or delegate the performance of such audits and inspections to the competent authorities of the Member State or third country that is a Contracting Party to the Agreement on the European Economic Area where the laboratory is located; and
 - b that laboratory is already designated as an official laboratory by the competent authorities of the Member State on whose territory it is located.
- 3 The designation of an official laboratory shall be in writing and shall include a detailed description of:
 - a the tasks that the laboratory carries out as an official laboratory;
 - b the conditions under which it carries out the tasks referred to in point (a); and
 - c the arrangements necessary to ensure efficient and effective coordination and collaboration between the laboratory and the competent authorities.
- 4 The competent authorities may only designate as an official laboratory a laboratory which:

- a has the expertise, equipment and infrastructure required to carry out analyses or tests or diagnoses on samples;
- b has a sufficient number of suitably qualified, trained and experienced staff;
- c ensures that the tasks conferred upon it as set out in paragraph 1 are performed impartially and which is free from any conflict of interest as regards the exercise of its tasks as an official laboratory;
- d can deliver in a timely manner the results of the analysis, test or diagnosis carried out on the samples taken during official controls and other official activities; and
- e operates in accordance with the standard EN ISO/IEC 17025 and is accredited in accordance with that standard by a national accreditation body operating in accordance with Regulation (EC) No 765/2008.

5 The scope of the accreditation of an official laboratory as referred to in point (e) of paragraph 4:

- a shall include those methods of laboratory analysis, test or diagnosis required to be used by the laboratory for analyses, tests or diagnoses, when it operates as an official laboratory;
- b may comprise one or more methods of laboratory analysis, test or diagnosis or groups of methods;
- c may be defined in a flexible manner, so as to allow the scope of accreditation to include modified versions of the methods used by the official laboratory when the accreditation was granted or new methods in addition to those methods, on the basis of the laboratory's own validations without a specific assessment by the national accreditation body prior to the use of those modified or new methods.

6 Where no official laboratory designated in the Union or in a third country that is a Contracting Party to the Agreement on the European Economic Area in accordance with paragraph 1 has the expertise, equipment, infrastructure and staff necessary to perform new or particularly uncommon laboratory analyses, tests or diagnoses, the competent authorities may request a laboratory or diagnostic centre which does not comply with one or more of the requirements set out in paragraphs 3 and 4 to carry out those analyses, tests and diagnoses.

Article 38

Obligations of official laboratories

1 Where the results of an analysis, test or diagnosis carried out on samples taken during official controls or other official activities indicate a risk to human, animal or plant health, or, as regards GMOs and plant protection products, also to the environment, or point to the likelihood of non-compliance, official laboratories shall inform immediately the competent authorities which designated them for that analysis, test or diagnosis and, where relevant, delegated bodies or natural persons to which tasks have been delegated. However, specific arrangements between the competent authorities, delegated bodies or natural persons to which tasks have been delegated and the official laboratories may specify that this information is not required to be provided immediately.

2 Upon request by the European Union reference laboratory or national reference laboratory, official laboratories shall take part in inter-laboratory comparative tests or proficiency tests that are organised for the analyses, tests or diagnoses they perform as official laboratories.

3 Official laboratories shall, upon request of the competent authorities, make available to the public the names of the methods used for analyses, tests or diagnoses performed in the context of official controls and other official activities.

4 Official laboratories shall indicate, at the request of the competent authorities, together with the results, the method used for each analysis, testing or diagnosis, performed in the context of official controls and other official activities.

Article 39

Audits of official laboratories

1 The competent authorities shall organise audits of the official laboratories they have designated in accordance with Article 37(1) on a regular basis and any time they consider that an audit is necessary, unless they find such audits to be redundant considering the accreditation assessment referred to in point (e) of Article 37(4).

2 The competent authorities shall immediately withdraw the designation of an official laboratory, either completely or for certain tasks, where it fails to take appropriate and timely remedial action following the results of an audit provided for in paragraph 1 which disclose any of the following:

- a it no longer complies with the conditions provided for in Article 37(4) and (5);
- b it does not comply with the obligations provided for in Article 38;
- c it is underperforming at inter-laboratory comparative tests referred to in Article 38(2).

Article 40

Derogations from the condition for the mandatory accreditation for certain official laboratories

1 By way of derogation from point (e) of Article 37(4), competent authorities may designate the following as official laboratories irrespective of whether they fulfil the condition provided for in that point:

- a laboratories:
 - (i) whose sole activity is the detection of *Trichinella* in meat;
 - (ii) that only use the methods of detection of *Trichinella* referred to in Article 6 of Commission Implementing Regulation (EU) 2015/1375⁽⁷⁾;
 - (iii) that carry out the detection of *Trichinella* under the supervision of the competent authorities or of an official laboratory designated in accordance with Article 37(1) and accredited in accordance with the standard EN ISO/IEC 17025 for the use of the methods referred to in point (ii) of this point; and
 - (iv) that participate regularly and have satisfactory performance in the inter-laboratory comparative tests or proficiency tests organised by the national reference laboratories for the methods they use for the detection of *Trichinella*;
- b laboratories which only carry out analyses, tests or diagnoses in the context of other official activities, provided that they:
 - (i) only use the methods of laboratory analysis, test and diagnosis referred to in Article 34(1) and point (a) or (b) of Article 34(2);

- (ii) carry out the analyses, tests or diagnoses under the supervision of the competent authorities or of the national reference laboratories in relation to the methods they use;
- (iii) participate regularly and have satisfactory performance in the inter-laboratory comparative tests or proficiency tests organised by the national reference laboratories in relation to the methods they use; and
- (iv) have a quality assurance system in place to ensure sound and reliable results from the methods for laboratory analysis, test and diagnosis used.

2 Where the methods used by the laboratories referred to in point (b) of paragraph 1 of this Article require confirmation of the result of the laboratory analysis, test or diagnosis, the confirmatory laboratory analysis, test or diagnosis shall be carried out by an official laboratory which complies with the requirements set out in point (e) of Article 37(4).

3 The official laboratories designated in accordance with paragraph 1 shall be located in the Member States in whose territory the competent authorities which have designated them are located.

Article 41

Powers to adopt derogations from the condition for the mandatory accreditation of all the methods of laboratory analysis, test and diagnosis used by official laboratories

The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the cases where, and the conditions under which, competent authorities may designate as official laboratories, in accordance with Article 37(1), laboratories which do not fulfil the conditions referred to in point (e) of Article 37(4) in relation to all the methods they use for official controls or other official activities, provided that such laboratories comply with the following conditions:

- (a) they operate and are accredited in accordance with the standard EN ISO/IEC 17025 for the use of one or more methods which are similar to and representative of the other methods they use; and
- (b) they make regular and significant use of the methods for which they have obtained the accreditation referred to in point (a) of this Article; except, as regards the area governed by the rules referred to in point (g) of Article 1(2), where a validated method for the detection of the particular pests of plants referred to in Article 34(1) and (2) does not exist.

Article 42

Temporary derogations from the conditions of the mandatory accreditation for official laboratories

1 By way of derogation from point (a) of Article 37(5), the competent authorities may temporarily designate an existing official laboratory as an official laboratory in accordance with Article 37(1) for the use of a method of laboratory analysis, test or diagnosis for which it has not obtained the accreditation referred to in point (e) of Article 37(4):

- a when the use of that method is newly required by Union rules;

Status: This is the original version (as it was originally adopted).

- b when changes to a method in use require a new accreditation or an extension of the scope of the accreditation obtained by the official laboratory; or
 - c in cases where the need for the use of the method results from an emergency situation or an emerging risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment.
- 2 The temporary designation referred to in paragraph 1 shall be subject to the following conditions:
- a the official laboratory is already accredited in accordance with the standard EN ISO/IEC 17025 for the use of a method which is similar to the one not included within the scope of its accreditation;
 - b a quality assurance system is in place in the official laboratory to ensure sound and reliable results by using a method which is not included within the scope of the existing accreditation;
 - c the analyses, tests or diagnoses are carried out under the supervision of the competent authorities or the national reference laboratory for that method.
- 3 The temporary designation provided for in paragraph 1 shall not exceed a period of one year. It may be renewed once for a further period of one year.
- 4 The official laboratories designated in accordance with paragraph 1 shall be located in the Member States in whose territory the competent authorities which have designated them are located.

CHAPTER V

Official controls on animals and goods entering the Union

Article 43

Official controls on animals and goods entering the Union

Official controls on animals and goods entering the Union shall be organised on a risk basis. In relation to animals and goods referred to in Articles 47 and 48, such official controls shall be performed in accordance with Articles 47 to 64.

Section I

Animals and goods other than those subject to official controls at border control posts under section II

Article 44

Official controls on animals and goods other than those subject to official controls at border control posts under Section II

1 To ascertain compliance with the rules referred to in Article 1(2), the competent authorities shall perform official controls regularly, on a risk basis and with appropriate frequency, on animals and goods entering the Union and to which Articles 47 and 48 do not apply.

2 On animals and goods referred to in paragraph 1 the appropriate frequency of the official controls shall be determined, taking into account:

- a the risks to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, associated with different types of animals and goods;
- b any information indicating the likelihood that consumers might be misled, in particular as to the nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production of goods;
- c the history of compliance with the requirements established by the rules referred to in Article 1(2) applicable to the animals or goods concerned:
 - (i) of the third country and establishment of origin or place of production, as appropriate;
 - (ii) of the exporter;
 - (iii) of the operator responsible for the consignment;
- d the controls that have already been performed on the animals and goods concerned; and
- e the guarantees that the competent authorities of the third country of origin have given with regard to compliance of the animals and goods with the requirements established by the rules referred to in Article 1(2) or with requirements recognised to be at least equivalent thereto.

3 The official controls provided for in paragraph 1 shall be performed at an appropriate place within the customs territory of the Union, including:

- a the point of entry into the Union;
- b a border control post;
- c the point of release for free circulation in the Union;
- d the warehouses and the premises of the operator responsible for the consignment;
- e the place of destination.

4 Notwithstanding paragraphs 1 and 3, the competent authorities at border control posts and other points of entry into the Union shall perform official controls on the following whenever they have reason to believe that their entry into the Union may pose a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment:

- a means of transport, including where empty; and
- b packaging, including pallets.

5 The competent authorities may also perform official controls on goods that are placed under one of the customs procedures defined in point (16)(a), (b) and (c) of Article 5 of Regulation (EU) No 952/2013 and in a temporary storage defined in point (17) of Article 5 of that Regulation.

Article 45

Types of official controls on animals and goods other than those subject to official controls at border control posts under Section II

1 Where official controls are performed in accordance with Article 44(1), they shall:

- a always include a documentary check; and

Status: This is the original version (as it was originally adopted).

- b include identity checks and physical checks depending on the risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment.

2 The competent authorities shall carry out the physical checks referred to in point (b) of paragraph 1 under appropriate conditions allowing investigations to be conducted properly.

3 Where the documentary checks, identity checks or physical checks referred to in paragraph 1 of this Article show that animals and goods do not comply with the rules referred to in Article 1(2), Article 66(1), (3) and (5), Articles 67, 68, and 69, Article 71(1) and (2), Article 72(1) and (2), Articles 137 and 138 shall apply.

4 The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the cases where and the conditions under which competent authorities may request operators to notify the arrival of certain goods entering the Union.

Article 46

Samples taken on animals and goods other than those subject to official controls at border control posts under Section II

1 Where samples on animals and goods are taken, the competent authorities shall, without prejudice to Articles 34 to 42:

- a inform the operators concerned and, where appropriate, the customs authorities; and
- b decide whether the animals or goods need to be detained pending the results of the analysis, test or diagnosis carried out, or whether they can be released provided that the traceability of the animals or goods is ensured.

2 The Commission shall, by means of implementing acts:

- a establish the procedures necessary to ensure the traceability of the animals or goods referred to in point (b) of paragraph 1; and
- b identify the documents that must accompany the animals or goods referred to in paragraph 1 when samples have been taken by the competent authorities.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Section II

Official controls at border control posts on animals and goods

Article 47

Animals and goods subject to official controls at border control posts

1 To ascertain compliance with the rules referred to in Article 1(2), the competent authorities shall perform official controls, at the border control post of first arrival into the Union, on each consignment of the following categories of animals and goods entering the Union:

- a animals;

- b products of animal origin, germinal products and animal by-products;
 - c plants, plant products, and other objects as referred to in the lists established pursuant to Articles 72(1) and 74(1) of Regulation (EU) 2016/2031;
 - d goods from certain third countries for which the Commission has decided, by means of implementing acts provided for in point (b) of paragraph 2 of this Article, that a measure requiring a temporary increase of official controls at their entry into the Union is necessary due to a known or emerging risk or because there is evidence that widespread serious non-compliance with the rules referred to in Article 1(2) might be taking place;
 - e animals and goods which are subject to an emergency measure provided for in acts adopted in accordance with Article 53 of Regulation (EC) No 178/2002, Article 249 of Regulation (EU) 2016/429, or Articles 28(1), 30(1), 40(3), 41(3), 49(1), 53(3) and 54(3) of Regulation (EU) 2016/2031 requiring consignments of those animals or goods, identified by means of their codes from the Combined Nomenclature, to be subject to official controls at their entry into the Union;
 - f animals and goods in relation to whose entry into the Union conditions or measures have been established by acts adopted in accordance with Article 126 or 128 respectively, or with the rules referred to in Article 1(2), which require that compliance with those conditions or measures be ascertained at the entry of the animals or goods into the Union.
- 2 The Commission shall, by means of implementing acts:
- a establish lists which set out all the animals and goods referred to in points (a) and (b) of paragraph 1, indicating their codes from the Combined Nomenclature; and
 - b establish the list of goods belonging to the category referred to in point (d) of paragraph 1, indicating their codes from the Combined Nomenclature, and update it as necessary in relation to the risks referred to in that point.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

3 The Commission is empowered to adopt delegated acts in accordance with Article 144 to amend this Regulation concerning amendments to the categories of consignments referred to in paragraph 1 of this Article, to include composite products, hay and straw, and other products strictly limited to products presenting a newly identified or a significantly increased risk to human, animal or plant health or, as regards GMOs and plant protection products, also to the environment.

4 Unless otherwise provided by the acts establishing the measures or conditions referred to in points (d), (e) and (f) of paragraph 1, this Article shall also apply to consignments of the categories of animals and goods referred to in points (a), (b) and (c) of paragraph 1 when they are of a non-commercial nature.

5 Operators responsible for the consignment shall ensure that animals and goods of the categories referred to in paragraph 1 are presented for official controls at the border control post referred to therein.

Article 48

Animals and goods exempted from official controls at border control posts

The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning rules establishing the cases where, and the

conditions under which, the following categories of animals and goods are exempted from Article 47, and when such exemption is justified:

- (a) goods sent as trade samples or as display items for exhibitions, which are not intended to be placed on the market;
- (b) animals and goods intended for scientific purposes;
- (c) goods on board means of transport operating internationally which are not unloaded and are intended for consumption by the crew and passengers;
- (d) goods which form part of passengers personal luggage and are intended for personal consumption or use;
- (e) small consignments of goods sent to natural persons which are not intended to be placed on the market;
- (f) pet animals as defined in point (11) of Article 4 of Regulation (EU) 2016/429;
- (g) goods which have undergone specific treatment and do not exceed quantities to be established in those delegated acts;
- (h) categories of animals or goods posing a low risk or no specific risk and for which controls at border control posts are therefore not necessary.

Article 49

Official controls at border control posts

1 To verify compliance with the applicable requirements laid down in the rules referred to in Article 1(2), the competent authorities shall perform official controls on the consignments of the categories of animals and goods referred to in Article 47(1) upon arrival of the consignment at the border control post. Those official controls shall include documentary checks, identity checks and physical checks.

- 2 Physical checks shall be performed where those checks concern:
- a animals, except aquatic animals, or meat and edible meat offal, by an official veterinarian, who may be assisted by staff trained in accordance with the requirements established under paragraph 5 in veterinary matters and designated by the competent authorities for that purpose;
 - b aquatic animals, products of animal origin other than the ones referred to in point (a) of this paragraph, germinal products or animal by-products, by an official veterinarian or by staff trained in accordance with the requirements established under paragraph 5 and designated by the competent authorities for that purpose;
 - c plants, plant products and other objects, by an official plant health officer.

3 The competent authorities at border control posts shall systematically perform official controls on consignments of animals being transported and on means of transport to verify compliance with the animal welfare requirements laid down in the rules referred to in Article 1(2). Competent authorities shall put in place arrangements to give priority to official controls on animals being transported and to reduce delays on such controls.

4 The Commission may, by means of implementing acts, lay down rules on the practical arrangements for presentation of consignments of the categories of animals and goods referred to in Article 47(1), the transport units or sub-entities which can constitute an

individual consignment and the maximum number of such transport units or sub-entities in each consignment, taking into account the need to ensure the rapid and efficient handling of the consignments and the official controls to be performed by the competent authorities and, where relevant, international standards. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

5 The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning rules establishing specific training requirements for staff referred to in paragraph 2 of this Article for the performance of the physical checks at the border control posts.

Article 50

Certificates and documents accompanying consignments and split consignments

1 The original official certificates or documents, or electronic equivalents, which are required by the rules referred to in Article 1(2) to accompany consignments of the categories of animals and goods referred in Article 47(1) shall be presented to, and kept by, the competent authorities of the border control post unless otherwise provided for in the rules referred to in Article 1(2).

2 The competent authorities of the border control post shall issue the operator responsible for the consignment with an authenticated paper or electronic copy of the official certificates or documents referred to in paragraph 1 or, if the consignment is split, with individually authenticated paper or electronic copies of such certificates or documents.

3 Consignments shall not be split until official controls have been performed and the Common Health Entry Document (CHED) referred to in Article 56 has been finalised in accordance with Article 56(5) and Article 57.

4 The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning rules establishing the cases where, and the conditions under which, the CHED is required to accompany consignments of the categories of animals and goods referred to in Article 47(1) to the place of destination.

Article 51

Specific rules for official controls at border control posts

1 The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning rules to establish:

- a the cases where, and the conditions under which, the competent authorities of a border control post may authorise the onward transportation of consignments of the categories of animals and goods referred to in Article 47(1) to the place of final destination pending the availability of the results of physical checks, where such checks are required;
- b the time limits and arrangements for carrying out documentary checks and, where necessary, identity checks and physical checks on categories of animals and goods subject to the official controls provided for in Article 47(1) which enter the Union by sea or by air transport from a third country, when those animals or goods are moved from a vessel or aircraft and are transported under customs supervision to another vessel or aircraft in the same port or airport in preparation for onward travel ('transhipped consignments');

- c the cases where, and the conditions under which, identity checks and physical checks of transhipped consignments and of animals arriving by air or sea and staying on the same means of transport for onward travel may be performed at a border control post other than the one of first arrival into the Union;
- d the cases where, and the conditions under which, the transit of consignments of the categories of animals and goods referred to in Article 47(1) may be authorised and certain official controls to be performed at border control posts on such consignments, including the cases and conditions for the storage of goods in specially approved customs warehouses or in free zones;
- e the cases where, and the conditions under which, derogations from the rules on identity checks and physical checks shall apply as regards transhipped consignments and transit of consignments of the goods referred to in point (c) of Article 47(1).

2 The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning rules to establish the cases where, and the conditions under which, derogations from the rules on documentary checks shall apply as regards transhipped consignments and transit of consignments of the goods referred to in point (c) of Article 47(1).

Article 52

Details of documentary checks, identity checks and physical checks

For the purposes of ensuring the uniform implementation of Articles 49, 50 and 51, the Commission shall, by means of implementing acts, lay down detailed rules on the operations to be carried out during and after the documentary checks, identity checks and physical checks referred to in those Articles to ensure the efficient performance of those official controls. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 53

Official controls not performed at border control posts

1 The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning rules establishing the cases where and the conditions under which:

- a identity checks and physical checks on consignments of the categories of animals and goods referred to in Article 47(1) may be performed by competent authorities at control points other than border control posts provided that those control points comply with the requirements provided for in Article 64(3) and in the implementing acts adopted in accordance with Article 64(4);
- b physical checks on consignments which have undergone documentary checks and identity checks at a border control post of first arrival into the Union may be performed at another border control post in a different Member State;
- c identity checks and physical checks on consignments which have undergone documentary checks at a border control post of first arrival into the Union may be performed at another border control post in a different Member State;
- d specific control tasks may be performed by customs authorities or other public authorities, insofar as those tasks are not already falling under the responsibility of those authorities, on:

- (i) consignments referred to in Article 65(2);
- (ii) passengers' personal luggage;
- (iii) goods ordered by sales through distance contracts, including by telephone or via the internet;
- (iv) pet animals which meet the conditions laid down in Article 5 of Regulation (EU) No 576/2013 of the European Parliament and of the Council⁽⁸⁾;
- e documentary checks on consignments of plant, plant products and other objects referred to in point (c) of Article 47(1) may be performed at distance from a border control post.

2 Point (b) of Article 56(3), point (a) of Article 57(2), Article 59(1), points (a) and (d) of Article 60(1) and Articles 62 and 63 shall also apply to the control points referred to in point (a) of paragraph 1 of this Article.

Article 54

Frequency of documentary checks, identity checks and physical checks

1 All consignments of the categories of animals and goods referred to in Article 47(1) shall be subject to documentary checks.

2 Identity checks and physical checks shall be performed on consignments of the categories of animals and goods referred to in Article 47(1) at a frequency dependent on the risk posed by each animal, good or category of animals or goods to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment.

3 The Commission shall, by means of implementing acts, lay down rules for the uniform application of the appropriate frequency rate referred to in paragraph 2. Those rules shall ensure that those frequencies are higher than a zero frequency and shall establish:

- a the criteria and the procedures for determining and modifying the frequency rates of identity checks and physical checks to be performed on consignments of the categories of animals and goods referred to in points (a), (b) and (c) of Article 47(1) and to adjust them to the level of risk associated with those categories, having regard to:
 - (i) information collected by the Commission in accordance with Article 125(1);
 - (ii) the outcome of controls performed by Commission experts in accordance with Article 120(1);
 - (iii) operators' past record as regards compliance with the rules referred to in Article 1(2);
 - (iv) data and information collected via the information management system for official controls (IMSOC) referred to in Article 131;
 - (v) available scientific assessments; and
 - (vi) any other information regarding the risk associated to the categories of animals and goods;
- b the conditions under which Member States may increase the frequency rates of identity checks and physical checks established in accordance with point (a) so as to take account of local risk factors;

Status: This is the original version (as it was originally adopted).

- c the procedures for ensuring that the frequency rates of identity checks and physical checks established in accordance with point (a) are applied in a timely and uniform manner.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

- 4 The Commission shall, by means of implementing acts, lay down rules on:
 - a the frequency of identity checks and physical checks for the categories of goods referred to in point (d) of Article 47(1); and
 - b the frequency of identity checks and physical checks for the categories of animals and goods referred to in points (e) and (f) of Article 47(1) as long as this is not already provided for in the acts referred to therein.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 55

Decisions on consignments

1 A decision shall be taken by the competent authorities on each consignment of the categories of animals and goods referred to in Article 47(1) following the performance of official controls including documentary and, where necessary, identity checks and physical checks, indicating whether the consignment is in compliance with the rules referred to in Article 1(2) and, where relevant, the applicable customs procedure.

- 2 Decisions on consignments shall be taken by:
 - a an official veterinarian where they concern animals, products of animal origin, germinal products or animal by-products; or
 - b an official plant health officer where they concern plants, plant products and other objects.

3 By way of derogation from point (a) of paragraph 2, competent authorities may decide that the decision on consignments of fishery products, live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption, be taken by appropriately trained staff who have been specifically designated by competent authorities for that purpose.

Article 56

Use of the Common Health Entry Document (CHED) by the operator and by the competent authorities

1 For each consignment of the categories of animals and goods referred to in Article 47(1) the operator responsible for the consignment shall complete the relevant part of the CHED, providing the information necessary for the immediate and complete identification of the consignment and its destination.

2 References in this Regulation to the CHED include a reference to its electronic equivalent.

3 The CHED shall be used by:

- a the operators responsible for consignments of the categories of animals and goods referred to in Article 47(1) in order to give prior notification to the competent authorities of the border control post of arrival of those consignments; and
- b the competent authorities of the border control post, in order to:
 - (i) record the outcome of the official controls performed and any decisions taken on that basis, including the decision to reject a consignment;
 - (ii) communicate the information referred to in point (i) through the IMSOC.

4 Operators responsible for the consignment shall give prior notification in accordance with point (a) of paragraph 3 by completing and submitting the relevant part of the CHED into the IMSOC for transmission to the competent authorities of the border control post prior to the physical arrival of the consignment into the Union.

5 The competent authorities of the border control post shall finalise the CHED as soon as:

- a all official controls required by Article 49(1) have been performed;
- b the results from physical checks, where such checks are required, are available; and
- c a decision on the consignment has been taken in accordance with Article 55 and recorded on the CHED.

Article 57

Use of the CHED by customs authorities

1 The placing and handling of consignments of the categories of animals and goods referred to in Article 47(1) under a customs procedure, including the entry or handling in customs warehouses or free zones, shall be subject to the presentation of the CHED by the operator responsible for the consignment to the customs authorities, without prejudice to the exemptions referred to in Article 48 and the rules referred to in Articles 53 and 54. At this stage, the CHED shall have been duly finalised in the IMSOC by the competent authorities of the border control post.

2 Customs authorities shall:

- a not allow the placing of the consignment under a customs procedure different from the one indicated by the competent authorities of the border control post; and
- b without prejudice to the exemptions referred to in Article 48 and the rules referred to in Articles 53 and 54, only allow the release for free circulation of a consignment upon presentation of a duly finalised CHED which confirms that the consignment is in compliance with the applicable rules referred to in Article 1(2).

3 Where a customs declaration is made for a consignment of the categories of animals or goods referred to in Article 47(1) and the CHED is not presented, the customs authorities shall detain the consignment and immediately notify the competent authorities of the border control post. The competent authorities shall take the necessary measures in accordance with Article 66(6).

Article 58

Format, time requirements and specific rules for the use of the CHED

The Commission shall, by means of implementing acts, lay down rules on:

- (a) the format of the CHED and the instructions for its presentation and use, taking into account relevant international standards; and
- (b) the minimum time requirements for prior notification of consignments by operators responsible for the consignment as provided for in point (a) of Article 56(3) in order to enable the competent authorities of the border control post to perform official controls in a timely and effective manner.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 59

Designation of border control posts

1 Member States shall designate border control posts for the purpose of performing official controls on one or more of the categories of animals and goods referred to in Article 47(1).

2 Member States shall notify the Commission before designating a border control post. That notification shall include all the information necessary for the Commission to verify that the proposed border control post complies with the minimum requirements laid down in Article 64.

3 Within three months of receiving the notification referred to in paragraph 2, the Commission shall inform the Member State:

- a whether the designation of the proposed border control post is dependent upon the favourable outcome of a control performed by Commission experts in accordance with Article 116 in order to verify compliance with the minimum requirements laid down in Article 64; and
- b of the date of such a control, which is not to be later than six months from the notification.

4 In cases where the Commission has informed a Member State, in accordance with paragraph 3, that a control is not necessary, the Member State may proceed with the designation.

5 The Member State shall delay designating the border control post until the favourable outcome of the control has been communicated to it by the Commission. The Commission shall communicate the outcome of its control as referred to in point (a) of paragraph 3 at the latest within three months from the date of that control.

Article 60

Listing of border control posts

1 Each Member State shall make available on the internet up-to-date lists of border control posts on its territory, providing the following information for each border control post:

- a its contact details;
- b its opening hours;
- c its exact location and whether it is a port, airport, rail or road entry point; and
- d the categories of animals and goods referred to in Article 47(1) which are included in the scope of its designation.

2 The Commission shall, by means of implementing acts, lay down rules on the format, categories, abbreviations for designations and other information to be used by Member States in the lists of border control posts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 61

Withdrawal of approvals for, and re-designation of, existing border control entities

1 The approval of border inspection posts in accordance with Article 6 of Directive 97/78/EC and Article 6 of Directive 91/496/EEC, the designation of points of entry in accordance with Article 5 of Regulation (EC) No 669/2009 and with Article 13c(4) of Directive 2000/29/EC and the designation of first points of introduction in accordance with Article 5 of Commission Regulation (EU) No 284/2011⁽⁹⁾ shall be withdrawn.

2 Member States may re-designate border inspection posts, designated points of entry, points of entry and first points of introduction referred to in paragraph 1 of this Article as border control posts in accordance with Article 59(1) provided that the minimum requirements referred to in Article 64 are complied with.

3 Article 59(2), (3) and (5) shall not apply to the re-designation referred to in paragraph 2 of this Article.

Article 62

Withdrawal of the designation of border control posts

1 Where border control posts cease to comply with the requirements referred to in Article 64, the Member States shall:

- a withdraw the designation provided for in Article 59(1) for all or for certain categories of animals and goods for which the designation was made; and
- b remove those border control posts from the lists referred to in Article 60(1), for the categories of animals and goods for which the designation is withdrawn.

2 Member States shall inform the Commission and the other Member States of the withdrawal of the designation of a border control post as provided for in paragraph 1 and of the reasons for such withdrawal.

3 The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the cases where, and the procedures by which, border control posts for which the designation has only been partially withdrawn in accordance with point (a) of paragraph 1 of this Article may be re-designated by way of derogation from Article 59.

4 This Article shall be without prejudice to Member States' competence to decide on the withdrawal of designation of border control posts for reasons other than those referred to in this Regulation.

Article 63

Suspension of the designation of border control posts

- 1 A Member State shall suspend the designation of a border control post and order its activities to be stopped, for all or for certain categories of animals and goods for which the designation was made, in cases where such activities may result in a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment. In the case of a serious risk, the suspension shall be with immediate effect.
- 2 Member States shall immediately inform the Commission and the other Member States of any suspension of the designation of a border control post and the reasons for such a suspension.
- 3 Member States shall indicate the suspension of the designation of a border control post in the lists referred to in Article 60(1).
- 4 Member States shall remove the suspension provided for in paragraph 1 as soon as:
 - a the competent authorities are satisfied that the risk referred to in paragraph 1 no longer exists; and
 - b they have communicated to the Commission and to the other Member States the information on the basis of which the suspension is removed.
- 5 This Article shall be without prejudice to Member States' competence to decide on the suspension of designation of border control posts for reasons other than those referred to in this Regulation.

Article 64

Minimum requirements for border control posts

- 1 Border control posts shall be located in the immediate vicinity of the point of entry into the Union and either in a place which is designated by the customs authorities in accordance with Article 135(1) and (2) of Regulation (EU) No 952/2013 or in a free zone.
- 2 The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the cases where and conditions under which a border control post may be situated at a distance other than in the immediate vicinity of the point of entry into the Union in cases of specific geographical constraints.
- 3 Border control posts shall have:
 - a a sufficient number of suitably qualified staff;
 - b premises or other facilities appropriate to the nature and volume of the categories of animals and goods handled;
 - c equipment and premises or other facilities to allow the performance of official controls for each of the categories of animals and goods for which the border control post has been designated;
 - d arrangements in place to ensure, as appropriate, access to any other equipment, premise and service necessary to apply the measures taken in accordance with Articles 65, 66 and 67 in cases of suspicion of non-compliance, non-compliant consignments or consignments presenting a risk;

- e contingency arrangements to ensure the smooth operation of official controls and the effective application of the measures taken in accordance with Articles 65, 66 and 67 in cases of unforeseeable and unexpected conditions or events;
- f the technology and equipment necessary for the efficient operation of the IMSOC and, as appropriate, of other computerised information management systems necessary for the handling and exchange of data and information;
- g access to the services of official laboratories capable of providing analytical, testing and diagnostic results within appropriate deadlines and equipped with the information technology tools necessary to ensure the introduction of the results of analyses, tests or diagnoses carried out into the IMSOC as appropriate;
- h appropriate arrangements for the proper handling of different categories of animals and goods and to prevent risks which may result from cross-contamination; and
- i arrangements to comply with relevant biosecurity standards in order to prevent the spread of diseases into the Union.

4 The Commission may, by means of implementing acts, lay down detailed rules on the requirements under paragraph 3 of this Article to take into account specific features and logistic needs related to the performance of official controls and to the application of the measures taken in accordance with Article 66(3) and (6) and Article 67 in relation to the different categories of animals and goods referred to in Article 47(1). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

5 The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the cases and conditions under which border control posts designated for the imports of unprocessed logs and sawn and chipped wood may be exempted from one or more of the obligations referred to in paragraph 3 of this Article to take into account the needs of competent authorities in charge of official controls operating under specific geographical constraints, while ensuring the proper performance of the controls.

Section III

Action in the event of suspicion of Non-compliance and of Non-compliance of animals and goods entering the union

Article 65

Suspicion of non-compliance and intensified official controls

1 In the event of suspicion of non-compliance of consignments of the categories of animals and goods referred to in Articles 44(1) and 47(1) with the rules referred to in Article 1(2), the competent authorities shall perform official controls in order to confirm or to eliminate that suspicion.

2 Consignments of animals and goods which are not declared by operators to consist of the categories of animals and goods referred to in Article 47(1), shall be subject to official controls by the competent authorities where there is reason to believe that such categories of animals or goods are present in the consignment.

3 The competent authorities shall place the consignments referred to in paragraphs 1 and 2 under official detention pending the outcome of the official controls provided for in those paragraphs.

Where appropriate, those consignments shall be isolated or quarantined and animals shall be sheltered, fed, watered and as necessary treated, pending the outcome of the official controls.

4 Where the competent authorities have reasons to suspect fraudulent or deceptive practices by an operator responsible for the consignment or the official controls give grounds to believe that the rules referred to in Article 1(2) have been seriously or repeatedly infringed, they shall, where appropriate, and in addition to the measures provided for in Article 66(3), intensify as appropriate official controls on consignments with the same origin or use.

5 The competent authorities shall notify the Commission and the Member States through the IMSOC of their decision to perform intensified official controls, as provided for in paragraph 4 of this Article, indicating the reasons for their decision.

6 The Commission shall, by means of implementing acts, lay down rules on the procedures for the coordinated performance by competent authorities of the intensified official controls referred to in paragraphs 4 and 5 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 66

Measures to be taken in cases of non-compliant consignments entering the Union

1 The competent authorities shall place under official detention any consignment of animals or goods entering the Union which does not comply with the rules referred to in Article 1(2) and shall refuse its entry into the Union.

The competent authorities shall isolate or quarantine, as appropriate, any such consignment and the animals belonging to it shall be kept, cared for or treated under appropriate conditions pending any further decision. If possible, the competent authorities shall also take into account the interest of providing special care in respect of certain types of goods.

2 The Commission shall, by means of implementing acts, lay down rules on the practical arrangements for the isolation and quarantine provided for in the second subparagraph of paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

3 The competent authority shall, as regards the consignment referred to in paragraph 1 order, without delay, the operator responsible for the consignment to:

- a destroy the consignment;
- b re-dispatch the consignment outside the Union in accordance with Article 72(1) and (2); or
- c subject the consignment to special treatment in accordance with Article 71(1) and (2) or to any other measure necessary to ensure compliance with the rules referred to in Article 1(2), and, where appropriate, allocate the consignment for purposes other than those for which it was originally intended.

Any action referred to in points (a), (b) and (c) of the first subparagraph shall be performed in compliance with the rules referred to in Article 1(2), including in particular, as regards consignments of live animals, those intended to spare animals any avoidable pain, distress or suffering.

When the consignment consists of plants, plant products or other objects, points (a), (b) and (c) of the first subparagraph shall be applied either to the consignment or to lots thereof.

Before ordering the operator to take action in accordance with (a), (b) and (c) of the first subparagraph, the competent authority shall hear the operator concerned, unless immediate action is necessary in order to respond to a risk to human, animal or plant health, animal welfare or, as regards the GMOs and plant protection products, also to the environment.

4 Where the competent authority orders the operator to take one or more of the actions laid down in point (a), (b) or (c) of the first subparagraph of paragraph 3, that competent authority may exceptionally authorise the action to be taken in respect of a part of the consignment only, provided that the partial destruction, re-dispatch, special treatment, or other measure:

- a is such as to ensure compliance;
- b does not pose a risk to human, animal or plant health or to animal welfare or, as regards GMOs and plant protection products, also to the environment; and
- c does not disrupt official control operations.

5 The competent authorities shall immediately notify any decision to refuse entry of a consignment as provided for in paragraph 1 of this Article, and any order issued in accordance with paragraphs 3 and 6 of this Article and with Article 67 to:

- a the Commission;
- b the competent authorities of the other Member States;
- c the customs authorities;
- d the competent authorities of the third country of origin; and
- e the operator responsible for the consignment.

That notification shall be performed via the IMSOC.

6 If a consignment of the categories of animals or goods referred to in Article 47(1) is not presented for the official controls referred to therein, or is not presented in accordance with the requirements laid down in Articles 50(1) and (3), 56(1), (3) and (4), or with the rules adopted under Article 48, Article 49(4), Article 51, Article 53(1) and Article 58, the competent authorities shall order that such consignment be retained or recalled, and placed under official detention without delay.

Paragraphs 1, 3 and 5 of this Article shall apply to such consignments.

7 The measures referred to in this Article shall be applied at the expense of the operator responsible for the consignment.

Article 67

Measures to be taken on animals or goods entering the Union from third countries presenting a risk

Where official controls indicate that a consignment of animals or goods presents a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, such consignment shall be isolated or quarantined and the animals belonging to it shall be kept, cared for or treated under appropriate conditions pending any further decision.

The competent authorities shall retain the consignment concerned under official detention and shall, without delay, order the operator responsible for that consignment to:

- (a) destroy the consignment in compliance with the rules referred to in Article 1(2), taking all the measures necessary to protect human, animal or plant health, animal welfare or the environment, and as regards live animals including in particular the rules on the sparing of any avoidable pain, distress or suffering; or
- (b) subject the consignment to special treatment in accordance with Article 71(1) and (2).

The measures referred to in this Article shall be applied at the expense of the operator responsible for the consignment.

Article 68

Follow-up of decisions taken in relation to non-compliant consignments entering the Union from third countries

- 1 The competent authorities shall:
 - a invalidate the official certificates and as appropriate other relevant documents accompanying consignments which have been subject to measures pursuant to Article 66(3) and (6) and Article 67; and
 - b cooperate in accordance with Articles 102 to 108 to take any further measures necessary to ensure that it is not possible to reintroduce consignments into the Union which have been refused entry in accordance with Article 66(1).
- 2 The competent authorities in the Member State where the official controls were performed shall supervise the application of the measures ordered in accordance with Article 66(3) and (6) and Article 67 to ensure that the consignment does not give rise to adverse effects on human, animal or plant health, animal welfare, or the environment, during or pending the application of those measures.

Where appropriate, such application shall be completed under the supervision of the competent authorities of another Member State.

Article 69

Failure by the operator to apply the measures ordered by the competent authorities

- 1 The operator responsible for the consignment shall carry out all the measures ordered by the competent authorities in accordance with Article 66(3) and (6) and Article 67 without delay and, at the latest, within 60 days from the day on which the competent authorities notified the operator concerned of their decision in accordance with Article 66(5). The competent authorities may specify a shorter period than the period of 60 days.
- 2 If, after the expiry of the period referred to in paragraph 1, no action has been taken by the operator concerned, the competent authorities shall order:
 - a that the consignment be destroyed or subject to any other appropriate measure;
 - b in the cases referred to in Article 67, that the consignment be destroyed in suitable facilities located as close as possible to the border control post, taking all measures necessary to protect human, animal or plant health, animal welfare or the environment.

3 The competent authorities may extend the period referred to in paragraphs 1 and 2 of this Article for the time necessary to obtain the results of the second expert opinion referred to in Article 35, provided that this is without adverse effects to human, animal and plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment.

4 The measures referred to in this Article shall be applied at the expense of the operator responsible for the consignment.

Article 70

Consistency of application of Articles 66, 67 and 68

The Commission shall, by means of implementing acts, lay down rules to ensure consistency across all border control posts referred to in Article 59(1), and control points referred to in point (a) of Article 53(1), of decisions and measures taken and orders issued by the competent authorities in accordance with Articles 66, 67 and 68 which are to be followed by the competent authorities when responding to common or recurring situations of non-compliance or risk. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 71

Special treatment of consignments

1 The special treatment of consignments provided for in point (c) of Article 66(3) and point (b) of Article 67 may, as appropriate, include:

- a treatment or processing, including decontamination, where appropriate, but excluding dilution, so that the consignment complies with the requirements of the rules referred to in Article 1(2), or with the requirements of a third country of re-dispatch; or
- b treatment in any other manner suitable for safe animal or human consumption or for purposes other than animal or human consumption.

2 The special treatment provided for in paragraph 1 shall:

- a be carried out effectively and ensure the elimination of any risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment;
- b be documented and carried out under the control of the competent authorities or, where appropriate, under the control of the competent authorities of another Member State by mutual agreement; and
- c comply with the requirements laid down in the rules referred to in Article 1(2).

3 The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the requirements and the conditions in accordance with which the special treatment provided for in paragraph 1 of this Article is to take place.

In the absence of rules adopted by delegated acts, such special treatment shall take place in accordance with national law.

Article 72

Re-dispatch of consignments

1 The competent authorities shall allow the re-dispatch of consignments subject to compliance with the following conditions:

- a the destination has been agreed with the operator responsible for the consignment;
- b the operator responsible for the consignment has informed the competent authorities of the Member State in writing that the competent authorities of the third country of origin or, if different, the third country of destination have been informed of the reasons and circumstances for the refusal of the entry into the Union of the consignment of animals or goods concerned;
- c where the third country of destination is not the third country of origin, the operator has obtained the agreement of the competent authorities of that third country of destination and those competent authorities have notified the competent authorities of the Member State that they are prepared to accept the consignment; and
- d in the case of consignments of animals, the re-dispatch is in compliance with animal welfare requirements.

2 The conditions set out in points (b) and (c) of paragraph 1 of this Article shall not apply to consignments of the categories of goods referred to in point (c) of Article 47(1).

Section IV

Approval of the pre-export controls

Article 73

Approval of pre-export controls performed by third countries

1 The Commission may, by means of implementing acts, approve, upon request of a third country, specific pre-export controls that that third country carries out on consignments of animals and goods prior to export to the Union with a view to verifying that the exported consignments satisfy the requirements of the rules referred to in Article 1(2). Such approval shall only apply to consignments originating in the third country concerned and may be granted for one or more categories of animals or goods. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

2 The approval provided for in paragraph 1 shall specify:

- a the maximum frequency of official controls to be performed by the competent authorities of Member States at the entry of the consignments into the Union, where there is no reason to suspect non-compliance with the rules referred to in Article 1(2) or fraudulent or deceptive practices;
- b the official certificates that must accompany consignments entering the Union;
- c a model for the certificates referred to in point (b);
- d the competent authorities of the third country under the responsibility of which pre-export controls must be performed; and

- e where appropriate, any delegated body to which those competent authorities may delegate certain tasks. Such delegation may only be approved if it meets the criteria set out in Articles 28 to 33 or equivalent conditions.

3 The approval provided for in paragraph 1 of this Article may only be granted to a third country if the evidence available and, where appropriate, a Commission control performed in accordance with Article 120, demonstrate that the system of official controls in that third country is able to ensure that:

- a the consignments of the animals or goods exported to the Union meet the requirements of the rules referred to in Article 1(2), or equivalent requirements; and
- b the controls performed in the third country prior to dispatch to the Union are sufficiently effective to replace or reduce the frequency of the documentary, identity checks and physical checks laid down in the rules referred to in Article 1(2).

4 The competent authorities or a delegated body specified in the approval shall:

- a be responsible for contacts with the Union; and
- b ensure that the official certificates referred to in point (b) of paragraph 2 accompany each consignment that is controlled.

5 The Commission shall, by means of implementing acts, lay down detailed rules and criteria for approving pre-export controls performed by third countries in accordance with paragraph 1 of this Article and for official controls performed by the competent authorities of the Member States on animals and goods subject to the approval referred in that paragraph. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 74

Non-compliance with, and withdrawal of, the approval of pre-export controls performed by third countries

1 When official controls on consignments of categories of animal and goods in respect of which specific pre-export controls have been approved in accordance with Article 73(1) reveal serious and recurrent non-compliance with the rules referred to in Article 1(2), Member States shall immediately:

- a notify the Commission and the other Member States and operators concerned via the IMSOC in addition to seeking administrative assistance in accordance with the procedures established in Articles 102 to 108; and
- b increase the number of official controls on consignments from the relevant third country and, where necessary to allow a proper analytical examination of the situation, keep an appropriate number of samples under appropriate storage conditions.

2 The Commission may, by means of implementing acts, withdraw the approval provided for in Article 73(1) where, following the official controls referred to in paragraph 1 of this Article, there are indications that the requirements laid down in Article 73(3) and (4) are no longer being met. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Section V

Cooperation between authorities in relation to consignments from third countries

Article 75

Cooperation between authorities in relation to consignments entering the Union from third countries

1 Competent authorities, customs authorities and other authorities of the Member States dealing with animals and goods entering the Union shall cooperate closely to ensure that the official controls on consignments of animals and goods entering the Union are performed in accordance with the requirements of this Regulation.

For that purpose, competent authorities, customs authorities and other authorities shall:

- a ensure reciprocal access to information which is necessary for the organisation and conduct of their respective activities in relation to animals and goods entering the Union; and
- b ensure the timely exchange of such information, including via electronic means.

2 The Commission shall, by means of implementing acts, lay down rules on uniform cooperation arrangements that competent authorities, customs authorities and other authorities referred to in paragraph 1 are required to put in place to ensure:

- a access by competent authorities to the information necessary for the immediate and complete identification of the consignments of animals and goods entering the Union that are subject to official controls at a border control post in accordance with Article 47(1);
- b the reciprocal update, through exchanges of information or synchronisation of relevant data sets, of information gathered by competent authorities, customs authorities and other authorities on consignments of animals and goods entering the Union; and
- c the swift communication of decisions taken by such authorities on the basis of the information referred to in points (a) and (b).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 76

Cooperation between authorities in relation to consignments not subject to specific controls at borders

1 Paragraphs 2, 3, and 4 of this Article shall apply in the case of consignments of animals and goods other than those subject to controls at entry into the Union as required by Article 47(1) of this Regulation and for which a customs declaration for release for free circulation has been made in accordance with point 12 of Article 5 of Regulation (EU) No 952/2013 and Articles 158 to 202 of that Regulation.

2 Customs authorities shall suspend release for free circulation when they have reason to believe that the consignment may present a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, and immediately notify the competent authorities of such suspension.

3 A consignment whose release for free circulation has been suspended pursuant to paragraph 2 shall be released if, within three working days of the suspension of release, the competent authorities have not requested customs authorities to continue the suspension or have informed customs authorities that no risk is present.

4 Where the competent authorities consider that a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, is present;

- a they shall request the customs authorities not to release the consignment for free circulation and to include the following statement on the commercial invoice accompanying the consignment and on any other relevant accompanying document or the relevant electronic equivalents:

Product presents a risk — release for free circulation not authorised — Regulation (EU) 2017/...;

- b no other customs procedure shall be permitted without the consent of the competent authorities; and
- c Article 66(1), (3), (5) and (6), Articles 67, 68 and 69, Article 71(1) and (2) and Article 72(1) and (2) shall apply.

5 In the case of consignments of animals and goods other than those subject to controls at entry into the Union as required by Article 47(1) and for which no customs declaration for release for free circulation has been made, customs authorities, where they have reason to believe that the consignment may present a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, shall transmit all relevant information to the customs authorities in the Member States of final destination.

Section VI

Specific measures

Article 77

Rules for specific official controls and for measures to be taken following the performance of such controls

1 The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning rules for the performance of specific official controls and on measures in cases of non-compliance, to account for the specificities of the following categories of animals and goods or the arrangements for, and means of, their transport:

- a consignments of fresh fishery products directly landed in ports designated by Member States in accordance with Article 5(1) of Council Regulation (EC) No 1005/2008⁽¹⁰⁾ from a fishing vessel flying a third country flag;
- b consignments of unskinned, furred wild game;
- c consignments of the categories of goods referred to in point (b) of Article 47(1) which are delivered, with or without storage in a specially approved customs warehouses or in free zones, to vessels leaving the Union and intended for ship supply or consumption by the crew and passengers;
- d wood packaging material;
- e feed accompanying animals and intended for the feeding of those animals;

- f animals and goods ordered by sales through distance contracts and delivered from a third country to an address in the Union, and the notification requirements necessary to allow the proper performance of official controls;
- g plant products which, on account of their subsequent destination, may give rise to the risk of spreading infectious or contagious animal diseases;
- h consignments of the categories of animals and goods referred to in points (a), (b) and (c) of Article 47(1) originating from, and returning to, the Union following a refusal of entry by a third country;
- i goods entering the Union in bulk from a third country, irrespective of whether they all originate from that third country;
- j consignments of goods referred to in Article 47(1) coming from the territory of Croatia and transiting through the territory of Bosnia and Herzegovina at Neum ('Neum corridor') before re-entering the territory of Croatia via the points of entry at Klek or Zaton Doli;
- k animals and goods exempted from Article 47 in accordance with Article 48.

2 The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the conditions for monitoring the transport and arrival of consignments of certain animals and goods, from the border control post of arrival to the establishment at the place of destination in the Union, to the border control post at the place of destination or to the border control post of exit.

- 3 The Commission may, by means of implementing acts, lay down rules on:
- a model official certificates and rules for the issuance of such certificates; and
 - b the format of documents that must accompany the categories of animals or goods referred to in paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

CHAPTER VI

Financing of official controls and of other official activities

Article 78

General rules

1 Member States shall ensure that adequate financial resources are available to provide the staff and other resources necessary for the competent authorities to perform official controls and other official activities.

2 This Chapter also applies in the case of delegation of certain official control tasks and other official activities in accordance with Articles 28 and 31.

Article 79

Mandatory fees or charges

1 The competent authorities shall collect fees or charges for the official controls performed in relation to the activities referred to in Chapter II of Annex IV and on animals and

goods referred to in points (a), (b) and (c) of Article 47(1), at border control posts or at control points referred to in point (a) of Article 53(1), either;

- a at the level of the cost calculated in accordance with Article 82(1); or
- b at the amounts provided for in Annex IV.

2 The competent authorities shall collect fees or charges to recover the costs they incur in relation to:

- a official controls performed on animals and goods referred to in points (d), (e) and (f) of Article 47(1);
- b official controls performed at the request of the operator, to obtain the approval provided for in Article 10 of Regulation (EC) No 183/2005;
- c official controls which were not originally planned, and which;
 - (i) have become necessary following the detection of a case of non-compliance by the same operator, during an official control performed in accordance with this Regulation; and
 - (ii) are performed to assess the extent and the impact of the case of non-compliance or to verify that the non-compliance has been remedied.

3 Notwithstanding paragraphs 1 and 2, Member States may, in relation to the activities referred to in Chapter II of Annex IV, on an objective and non-discriminatory basis, reduce the amount of the fees or charges, taking into account:

- a the interests of operators with a low throughput;
- b the traditional methods used for production, processing and distribution;
- c the needs of operators located in regions subject to specific geographical constraints; and
- d the operators' record of compliance with the relevant rules referred to in Article 1(2) as ascertained through official controls.

4 Member States may decide that fees and charges calculated in accordance with point (b) of Article 82(1) shall not be collected below the amount at which, taking into account the cost of collection and the overall income expected from the fees and charges, the collection of that fee or charge would be uneconomical.

5 This Article shall not apply to official controls performed to verify compliance with the rules referred to in points (i) and (j) of Article 1(2).

Article 80

Other fees or charges

Member States may collect fees or charges to cover the costs of official controls and other official activities other than those fees or charges referred to in Article 79, unless prohibited by the legislative provisions applicable in the areas governed by the rules referred to in Article 1(2).

Article 81

Costs

The fees or charges to be collected in accordance with point (a) of Article 79(1) and with Article 79(2) shall be determined on the basis of the following costs, insofar as these result from the official controls concerned:

- (a) the salaries of the staff, including support and administrative staff, involved in the performance of official controls, their social security, pension and insurance costs;
- (b) the cost of facilities and equipment, including maintenance and insurance costs and other associated costs;
- (c) the cost of consumables and tools;
- (d) the cost of services charged to the competent authorities by delegated bodies for official controls delegated to these delegated bodies;
- (e) the cost of training of the staff referred to in point (a), with the exclusion of the training necessary to obtain the qualification necessary to be employed by the competent authorities;
- (f) the cost of travel of the staff referred to in point (a), and associated subsistence costs;
- (g) the cost of sampling and of laboratory analysis, testing and diagnosis charged by official laboratories for those tasks.

Article 82

Calculation of fees or charges

1 Fees or charges collected in accordance with point (a) of Article 79(1) and with Article 79(2) shall be established in accordance with one of the following methods of calculation or a combination of them:

- a at a flat-rate on the basis of the overall costs of official controls borne by the competent authorities over a given period of time, and applied to all operators irrespective of whether any official control is performed during the reference period in relation to each operator charged; in establishing the level of the fees to be charged for each sector, activity and category of operators, the competent authorities shall take into consideration the impact that the type and the size of the activity concerned, and the relevant risk factors, have on the distribution of the overall costs of those official controls; or
- b on the basis of the calculation of the actual costs of each individual official control, and applied to the operators subject to such official control.

2 Travel costs as referred to in point (f) of Article 81 shall be considered for the calculation of the fees or charges referred to in point (a) of Article 79(1) and in Article 79(2) in a manner that does not discriminate between operators on the basis of the distance of their premises from the location of the competent authorities.

3 Where fees or charges are calculated in accordance with point (a) of paragraph 1, the fees or charges collected by competent authorities shall not exceed the overall costs incurred for the official controls performed over the period of time referred to therein.

4 Where fees or charges are calculated in accordance with point (b) of paragraph 1, they shall not exceed the actual cost of the official control performed.

Article 83

Collection and application of fees or charges

1 An operator shall only be charged with a fee or charge for an official control and for another official activity performed on the basis of a complaint if that control leads to the confirmation of non-compliance.

2 Fees or charges collected in accordance with Articles 79 and 80 shall not be directly or indirectly refunded, unless unduly collected.

3 Member States may decide that fees or charges shall be collected by authorities other than the competent authorities or by delegated bodies.

Article 84

Payment of fees or charges

1 The competent authorities shall ensure that the operators receive, upon request, proof of payment of fees or charges in the event that the operators do not otherwise have access to such proof.

2 Fees or charges collected in accordance with Article 79(1) shall be paid by the operator responsible for the consignment or its representative.

Article 85

Transparency

1 Member States shall ensure a high level of transparency on:

- a the fees or charges provided for in point (a) of Article 79(1), Article 79(2) and Article 80, namely on:
 - (i) the method and data used to establish these fees or charges;
 - (ii) the amount of the fees or charges, applied to each category of operators and for each category of official controls or other official activities;
 - (iii) the breakdown of the costs, as referred to in Article 81;
- b the identity of the authorities or bodies responsible for the collection of the fees or charges.

2 Each competent authority shall make available to the public the information referred to in paragraph 1 of this Article for each reference period and the costs to the competent authority for which a fee or charge is due in accordance with point (a) of Article 79(1), Article 79(2) and Article 80.

3 Member States shall consult relevant stakeholders on the general methods used to calculate the fees or charges provided for in point (a) of Article 79(1), Article 79(2) and Article 80.

CHAPTER VII

Official certification

Article 86

General requirements concerning official certification

- 1 Official certification shall result in the issuance of:
 - a official certificates; or
 - b official attestations in the cases provided for in the rules referred to in Article 1(2).
- 2 Where the competent authorities delegate certain tasks related to the issuance of official certificates or official attestations, or to the official supervision referred to in Article 91(1), such delegation shall comply with Articles 28 to 33.

Article 87

Official certificates

Articles 88, 89 and 90 shall apply:

- (a) when the rules referred to in Article 1(2) require the issuance of an official certificate; and
- (b) to official certificates which are necessary for the purposes of exporting consignments of animals and goods to third countries or which are requested from the competent authority of a Member State of dispatch by the competent authority of a Member State of destination in respect of consignments of animals and goods which are to be exported to third countries.

Article 88

Signature and issuance of official certificates

- 1 Official certificates shall be issued by the competent authorities.
- 2 Competent authorities shall designate the certifying officers who are authorised to sign official certificates and shall ensure that these officers:
 - a are impartial, free from any conflict of interest, and in particular are not in a situation which may, directly or indirectly, affect the impartiality of their professional conduct in relation to what is being certified; and
 - b have received appropriate training on the rules with which compliance is certified by an official certificate and on the technical assessment of compliance with those rules as well as with the relevant rules laid down in this Regulation.

3 Official certificates shall be signed by the certifying officer and issued on one of the following grounds:

- a direct knowledge by the certifying officer of up-to-date facts and data relevant for the certification that is obtained through:
 - (i) an official control; or
 - (ii) the acquisition of another official certificate issued by the competent authorities;
- b facts and data relevant for the certification, knowledge of which was ascertained by another person authorised for that purpose by, and acting under the control of, the competent authorities, provided that the certifying officer can verify the accuracy of such facts and data;
- c facts and data relevant for the certification which were obtained from the operators' own control systems, complemented and confirmed by results from regular official controls, where the certifying officer is thus satisfied that the conditions for issuing the official certificate are met.

4 Official certificates shall be signed by the certifying officer and issued only on the basis of point (a) of paragraph 3 of this Article when rules referred to in Article 1(2) so require.

Article 89

Guarantees of reliability for official certificates

1 Official certificates shall:

- a bear a unique code;
- b not be signed by the certifying officer where they are blank or incomplete;
- c be drawn up in one or more of the official languages of the institutions of the Union understood by the certifying officer and, where relevant, in one of the official languages of the Member State of destination;
- d be authentic and accurate;
- e allow for the identification of the person who signed them and the date of issue; and
- f allow the easy verification of the links between the certificate, the issuing authority and the consignment, lot or individual animal or good covered by the certificate.

2 The competent authorities shall take all appropriate measures to prevent the issuance of false or misleading official certificates or the abuse of official certificates.

Article 90

Implementing powers concerning official certificates

The Commission may, by means of implementing acts, lay down rules for the uniform application of Articles 88 and 89 concerning:

- (a) model official certificates and rules for the issuance of such certificates, where requirements are not laid down in the rules referred to in Article 1(2);
- (b) the mechanisms and technical arrangements to ensure the issuance of accurate and reliable official certificates, and prevent risk of fraud;

- (c) the procedures to be followed in the case of withdrawals of official certificates and for the issuance of replacement certificates;
- (d) rules for the production of certified copies of official certificates;
- (e) the format of documents that must accompany animals and goods after official controls have been performed;
- (f) rules for the issuance of electronic certificates and for the use of electronic signatures.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 91

Official attestations

1 When this Regulation or the rules referred to in Article 1(2) require the issuance of official attestations by the operators under the official supervision of the competent authorities, or by the competent authorities themselves, paragraphs 2, 3 and 4 of this Article shall apply.

2 Official attestations shall:

- a be authentic and accurate;
- b be drawn up in one or more of the official languages of the institutions of the Union and, where relevant, in one of the official languages of the Member State of destination; and
- c where they relate to a consignment or a lot, allow the verification of the link between the official attestation and that consignment or lot.

3 Competent authorities shall ensure that the staff performing official controls to supervise the issuance of official attestations or, where the official attestations are issued by the competent authorities, the staff involved in the issuance of those official attestations:

- a are impartial, free from any conflict of interest, and in particular are not in a situation which may, directly or indirectly, affect the impartiality of their professional conduct in relation to what is being certified by the official attestations; and
- b have received appropriate training on:
 - (i) the rules with which compliance is certified by the official attestations and on the technical assessment of compliance with those rules;
 - (ii) the relevant rules laid down in this Regulation.

4 Competent authorities shall perform regular official controls to verify that:

- a the operators issuing the attestations comply with the conditions laid down in the rules referred to in Article 1(2); and
- b the attestation is issued on the basis of relevant, correct and verifiable facts and data.

- (1) 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](#)).
- (2) Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene ([OJ L 35, 8.2.2005, p. 1](#)).
- (3) Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs ([OJ L 338, 22.12.2005, p. 1](#)).
- (4) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy ([OJ L 327, 22.12.2000, p. 1](#)).
- (5) Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals ([OJ L 201, 27.7.2012, p. 60](#)).
- (6) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ([OJ L 353, 31.12.2008, p. 1](#)).
- (7) 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](#)).
- (8) Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 ([OJ L 178, 28.6.2013, p. 1](#)).
- (9) Commission Regulation (EU) No 284/2011 of 22 March 2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China ([OJ L 77, 23.3.2011, p. 25](#)).
- (10) Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, amending Regulations (EEC) 2847/93, (EC) No 1936/2001 and (EC) No 601/2004 and repealing Regulations (EC) No 1093/94 and (EC) No 1447/1999 ([OJ L 286, 29.10.2008, p. 1](#)).