

## III

(Preparatory Acts)

## COUNCIL

## POSITION (EU) No 1/2017 OF THE COUNCIL AT FIRST READING

with a view to the adoption of a Regulation of the European Parliament and of the Council 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)

Adopted by the Council on 19 December 2016

(Text with EEA relevance)

(2017/C 55/01)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2), Article 114 and Article 168(4)(b) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Having regard to the opinion of the Committee of the Regions <sup>(2)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(3)</sup>,

Whereas:

- (1) The Treaty on the Functioning of the European Union (TFEU) requires a high level of protection of human and animal health and of the environment to be ensured in the definition and implementation of Union policies and activities. The achievement of that objective should, inter alia, be pursued via measures in the veterinary and phytosanitary fields which have as their final objective the protection of human health.

<sup>(1)</sup> OJ C 67, 6.3.2014, p. 166.

<sup>(2)</sup> OJ C 114, 15.4.2014, p. 96.

<sup>(3)</sup> Position of the European Parliament of 15 April 2014 and position of the Council at first reading of 19 December 2016. Position of the European Parliament of ... (not yet published in the Official Journal).

- (2) The TFEU also provides that the Union is to contribute to the attainment of a high level of consumer protection by the measures it adopts in the context of the completion of the internal market.
- (3) Union legislation provides for a set of harmonised rules to ensure that food and feed are safe and wholesome, and that activities which might have an impact on the safety of the agri-food chain or on the protection of consumers' interests in relation to food and food information are performed in accordance with specific requirements. Union rules exist also to ensure a high level of human, animal and plant health as well as animal welfare along the agri-food chain and in all those areas of activity where a key objective is the fight against the possible spread of animal diseases, in some cases transmissible to humans, or of pests injurious to plants or plant products, and to ensure the protection of the environment from risks that might arise from genetically modified organisms (GMOs) or plant protection products. The correct application of those rules, hereinafter collectively referred to as 'Union agri-food chain legislation', contributes to the functioning of the internal market.
- (4) The basic Union rules with regard to food and feed law are laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council <sup>(1)</sup>. In addition to those basic rules, more specific food and feed law covers different areas such as animal nutrition, including medicated feedingstuffs, food and feed hygiene, zoonoses, animal by-products, residues of veterinary medicinal products, contaminants, control and eradication of animal diseases with a human health impact, food and feed labelling, plant protection products, food and feed additives, vitamins, mineral salts, trace elements and other additives, food contact materials, quality and compositional requirements, drinking water, ionisation, novel foods and GMOs.
- (5) Union legislation on animal health aims to ensure high standards of human and animal health in the Union, the rational development of the agriculture and aquaculture sectors, and to increase productivity. That legislation is necessary to contribute to the completion of the internal market for animals and animal products and to avoid the spread of infectious diseases of Union concern. It covers areas that include intra-Union trade, entry into the Union, disease eradication, veterinary controls and notification of diseases, and also contributes to the safety of food and feed.
- (6) Transmissible animal diseases, including by micro-organisms that have developed resistance to antimicrobials, may have a significant impact on public health, food and feed safety, and animal health and welfare. In order to ensure high standards of animal and public health in the Union, rules on animal health measures and on feed and food safety are laid down at Union level. Compliance with those rules, including the rules that are intended to tackle the problem of antimicrobial resistance, should be subjected to the official controls provided for in this Regulation. Additionally, Union legislation provides for rules on the placing on the market and use of veterinary medicinal products which contribute to coherent action at Union level directed at enforcing the prudent use of antimicrobials at farm level and at minimising the development of antimicrobial resistance in animals and its transmission through food of animal origin. Actions number 2 and 3 advocated by the Communication of 15 November 2011 from the Commission to the European Parliament and to the Council entitled 'Action plan against the rising threats from Antimicrobial Resistance' emphasise the essential role played by the specific Union rules in the area of veterinary medicinal products. Compliance with those specific rules should be subjected to the controls provided for in that Union legislation and, therefore, does not fall within the scope of this Regulation.
- (7) Article 13 TFEU recognises that animals are sentient beings. Union legislation on animal welfare requires animal owners, animal keepers and competent authorities to respect welfare requirements of animals to ensure their humane treatment and avoid causing them unnecessary pain and suffering. Those rules are based on scientific evidence and may improve the quality and safety of food of animal origin.
- (8) Union legislation on plant health regulates the entry, establishment and spread of pests of plants that do not exist, or are not widely present, in the Union. Its objective is to protect the health of Union crops and of public and private green space and forests while simultaneously safeguarding the Union's biodiversity and environment, and ensure the quality of plants and plant products and safety of food and feed made from plants.

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

- (9) Union legislation on plant protection products regulates the authorisation, placing on the market, use and control of plant protection products and of any active substances, safeners, synergists, co-formulants and adjuvants, which they might contain or of which they might consist. The objective of those rules is to ensure a high level of protection of both human and animal health and of the environment through evaluation of the risks posed by plant protection products, while improving the functioning of the Union market through harmonisation of the rules for their placing on the market and while also improving agricultural production.
- (10) Directive 2001/18/EC of the European Parliament and of the Council <sup>(1)</sup> and Regulation (EC) No 1829/2003 of the European Parliament and of the Council <sup>(2)</sup> provide for the prior authorisation, traceability and labelling of GMOs and genetically modified food and feed. GMOs which are not for the purpose of direct consumption, such as seeds used as source material for the production of food and feed, are able to be authorised under Directive 2001/18/EC or under Regulation (EC) No 1829/2003. Irrespective of the legal basis under which GMOs could be authorised, the same rules on official controls should apply.
- (11) Union legislation on organic production and labelling of organic products provides a basis for the sustainable development of organic production and aims to contribute to the protection of natural resources, biodiversity and animal welfare, and the development of rural areas.
- (12) Union legislation on agricultural quality schemes for agricultural products and foodstuffs identifies products and foodstuffs farmed and produced to exact specifications whilst encouraging diverse agricultural production, protecting product names and informing consumers about the specific character of agricultural products and foodstuffs.
- (13) Union agri-food chain legislation is based on the principle that operators at all the stages of production, processing and distribution which are under their control are responsible for ensuring compliance with the requirements relevant to their activities established by Union agri-food chain legislation.
- (14) Union rules on marketing standards for fishery and aquaculture products ensure sustainable products and the realisation of the full potential of the internal market; they facilitate marketing activities based on fair competition, thereby helping to improve the profitability of production. These rules ensure compliance with the same requirement both for imports and products originating from within the Union. Union rules on marketing standards for agricultural products contribute to improving the economic conditions for the production and marketing and the quality of such products.
- (15) The responsibility to enforce Union agri-food chain legislation lies with Member States, whose competent authorities monitor and verify, through the organisation of official controls, that relevant Union requirements are effectively complied with and enforced.
- (16) Regulation (EC) No 882/2004 of the European Parliament and of the Council <sup>(3)</sup> has established a single legislative framework for the organisation of official controls. That framework has significantly improved the efficiency of official controls, the enforcement of Union agri-food chain legislation and the level of protection against risks to human, animal and plant health and animal welfare in the Union and the level of protection of the environment from risks that might arise from GMOs and plant protection products. It has also provided a consolidated legal framework to support an integrated approach towards the performance of official controls along the agri-food chain.

<sup>(1)</sup> Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

<sup>(2)</sup> Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

<sup>(3)</sup> Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with food and feed law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

- (17) There are a number of provisions in Union agri-food chain legislation, the enforcement of which has not, or has only partially, been governed by Regulation (EC) No 882/2004. In particular, specific official control rules were kept in place in Regulation (EC) No 1069/2009 of the European Parliament and of the Council <sup>(1)</sup>. Plant health also largely falls outside the scope of Regulation (EC) No 882/2004 with certain rules on official controls being laid down in Council Directive 2000/29/EC <sup>(2)</sup>.
- (18) Council Directive 96/23/EC <sup>(3)</sup> also provides a very detailed set of rules that establish, inter alia, the minimum frequency of official controls and specific enforcement measures to be adopted in cases of non-compliance.
- (19) In order to rationalise and simplify the overall legislative framework, whilst simultaneously pursuing the objective of better regulation, the rules applicable to official controls in specific areas should be integrated into a single legislative framework for official controls. For that purpose, Regulation (EC) No 882/2004 and other Union acts currently governing official controls in specific areas should be repealed and replaced by this Regulation.
- (20) This Regulation should seek to establish a harmonised Union framework for the organisation of official controls, and official activities other than official controls, along the entire agri-food chain, taking into account the rules on official controls laid down in Regulation (EC) No 882/2004 and in relevant sectoral legislation, and the experience gained from the application of those rules.
- (21) The rules which set out the requirements for the sustainable use of plant protection products laid down in Directive 2009/128/EC of the European Parliament and of the Council <sup>(4)</sup> include, in Article 8 thereof, provisions on the inspection of application equipment, which will continue to apply while the rules on official controls of this Regulation do not apply to those inspection activities.
- (22) For the verification of compliance with the rules on the common organisation of the markets of agricultural products (arable crops, wine, olive oil, fruit and vegetables, hops, milk and milk products, beef and veal, sheepmeat and goatmeat and honey), a well-established and specific control system is already in place. This Regulation should therefore not apply to the verification of compliance with Regulation (EU) No 1308/2013 of the European Parliament and of the Council <sup>(5)</sup> governing the common organisations of the markets in agricultural products, except where the controls carried out in relation to marketing standards under Regulation (EU) No 1306/2013 of the European Parliament and of the Council <sup>(6)</sup> indicate possible cases of fraudulent or deceptive practices.
- (23) Certain definitions currently set out in Regulation (EC) No 882/2004 should be adapted to take account of the broader scope of this Regulation, to align them with those set out in other Union acts, and to clarify or, where appropriate, replace terminology having different meanings in different sectors.
- (24) Where Union agri-food chain legislation requires the competent authorities to verify that the operators comply with the relevant Union rules and that the animals or goods meet specific requirements for the purpose of issuing official certificates or attestations, such verification of compliance should be considered as an official control.

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

<sup>(2)</sup> Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169, 10.7.2000, p. 1).

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

<sup>(4)</sup> Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71).

<sup>(5)</sup> Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

<sup>(6)</sup> Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 (OJ L 347, 20.12.2013, p. 549).

- (25) Union agri-food chain legislation entrusts additionally the competent authorities of the Member States with specialised tasks to be carried out for the protection of animal health, plant health and animal welfare and for the protection of the environment in relation to GMOs and plant protection products. Those tasks are the public interest activities which the competent authorities of the Member States are required to carry out for the purpose of eliminating, containing or reducing any hazard which may arise for human, animal or plant health, animal welfare or also for the environment. Those other official activities, which include the granting of authorisations or approvals, the epidemiological surveillance and monitoring, eradication and containment of diseases or pests, as well as the issuance of official certificates or attestations, are governed by the same sectoral rules which are enforced through the official controls and therefore by this Regulation.
- (26) Competent authorities should be designated by the Member States for all the areas that fall within the scope of this Regulation. While Member States are best placed to identify and decide which are the competent authority or authorities to designate for each area or part thereof, they should also be required to designate a single authority that for each area or part of area ensures appropriately coordinated communication with other Member States' competent authorities and with the Commission.
- (27) For the performance of official controls aimed at verifying the correct application of Union agri-food chain legislation, and of the other official activities entrusted to Member State authorities by Union agri-food chain legislation, Member States should designate competent authorities which act in the public interest, are appropriately resourced and equipped, and offer guarantees of impartiality and professionalism. Competent authorities should ensure the quality, consistency and effectiveness of official controls.
- (28) The correct application and enforcement of the rules falling within the scope of this Regulation require appropriate knowledge of both those rules and the rules of this Regulation. It is therefore important that the staff performing official controls and other official activities is regularly trained on the applicable legislation, in accordance with their area of competence, as well as on the obligations resulting from this Regulation.
- (29) The competent authorities should carry out internal audits or have audits carried out on their behalf, to ascertain compliance with this Regulation. Those audits should be carried out in a transparent manner and be subject to independent scrutiny.
- (30) Operators should have the right, subject to national law, to appeal against the decisions taken by the competent authorities. The competent authorities should inform operators of that right.
- (31) The competent authorities should ensure that the staff responsible for official controls does not disclose information acquired during the performance of those controls where that information is covered by professional secrecy. Unless there is an overriding interest to justify disclosure, professional secrecy should include information which would undermine the purpose of inspections, investigations or audits, the protection of commercial interests or the protection of court proceedings and legal advice. However, professional secrecy should not prevent competent authorities from publishing factual information on the outcome of official controls regarding individual operators when the operator concerned has been allowed to comment upon it prior to the disclosure and such comments have been taken into account, or released alongside the information being disclosed by the competent authorities. The need to respect professional secrecy is also without prejudice to the obligation for competent authorities to inform the general public where there are reasonable grounds to suspect that a food or feed may present a risk for health under Article 10 of Regulation (EC) No 178/2002. The right of individuals to the protection of their personal data as provided for in Directive 95/46/EC of the European Parliament and of the Council <sup>(1)</sup> should not be affected by this Regulation. These rules should also be without prejudice to situations where disclosure is required by Union or national legislation.
- (32) Competent authorities should perform official controls regularly, on a risk basis and with appropriate frequency, on all the sectors and in relation to all operators, activities, animals and goods governed by Union agri-food chain legislation. The frequency of official controls should be established by the competent authorities having regard to the need to adjust the control effort to the risk and to the level of compliance expected in the different

<sup>(1)</sup> Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

situations, including the possible violations of the Union agri-food chain legislation perpetrated through fraudulent or deceptive practices. Accordingly, the likelihood of non-compliance with all the areas of the Union agri-food chain legislation which fall within the scope of this Regulation should be taken into account when adjusting the control efforts. In some cases, however, and in view of the issuance of an official certificate or attestation which is a prerequisite for the placing on the market or for the movements of animals or goods, Union agri-food chain legislation requires that official controls be performed irrespective of the level of risk or the likelihood of non-compliance. In such cases, the frequency of the official controls is dictated by the certification or attestation needs.

- (33) To preserve the effectiveness of official controls in the verification of compliance, no notice should be given prior to performing controls, unless such prior notice is absolutely necessary for the controls to be carried out (for example, in the case of those official controls performed in slaughterhouses during slaughter operations which require the continuous or regular presence of staff or representatives of the competent authorities in the operator's premises) or the nature of the official control activities requires otherwise (as is particularly the case with regard to audit activities).
- (34) Official controls should be thorough and effective and should ensure that Union legislation is applied correctly. Given that official controls may represent a burden for operators, competent authorities should organise and conduct official control activities taking their interests into account and limiting the said burden to that which is necessary for the performance of efficient and effective official controls.
- (35) Official controls should be performed by staff who are independent, that is free from any conflict of interest, and in particular who are not in a situation which, directly or indirectly, could affect their ability to carry out their professional duties in an impartial manner. Appropriate arrangements should also be in place to ensure impartiality in cases where official controls are performed on animals, goods, places or activities which belong to a public authority or body.
- (36) Official controls should be performed with the same level of care by the competent authorities of the Member State irrespective of whether the rules being enforced apply to activities which are only relevant on the territory of that Member State or to activities which will have an impact on the compliance with Union legislation on animals and goods which are to be moved or placed on the market in another Member State or exported outside the Union. In the case of exports outside the Union, competent authorities may also be required, in accordance with Union legislation, to verify the conformity of animals and goods with requirements established by the third country of destination of such animals or goods. Furthermore, as regards the establishments of models for export certificates, the relevant implementing powers provided for in this Regulation should only apply where such certification is provided for in Union law, and in particular in bilateral agreements concluded between the Union and a third country or an association of third countries.
- (37) Without prejudice to traceability requirements laid down in sectorial legislation, and to the extent strictly necessary for organising official controls, operators should be able, in exceptional circumstances, to be required by the competent authorities of a Member State to report the arrival of animals and goods from another Member State.
- (38) To ensure that the Union agri-food chain legislation is correctly enforced, the competent authorities should have the power to perform official controls at all stages of production, processing and distribution of animals and goods concerned by that legislation. To ensure that official controls are thoroughly conducted and effective, the competent authorities should also have the power to perform official controls at all stages of production and distribution of goods, substances, materials or objects which are not governed by Union agri-food chain legislation insofar as it is necessary to fully investigate possible infringements of that legislation and to identify the cause of any such infringement. In order to perform those official controls efficiently, competent authorities should draw up and maintain a list or register of the operators to be controlled.
- (39) The competent authorities act in the interest of operators and of the general public ensuring that the high standards of protection established by Union agri-food chain legislation are consistently preserved and protected through appropriate enforcement action, and that compliance with such legislation is verified across the entire agri-food chain through official controls. The competent authorities, as well as delegated bodies and natural

persons to which certain tasks have been delegated, should therefore be accountable to the operators and to the general public for the efficiency and effectiveness of the official controls they perform. They should provide access to information concerning the organisation and performance of official controls and other official activities, and regularly publish information concerning official controls and the results obtained. Competent authorities should also, subject to certain conditions, be entitled to publish or to make available information about the rating of individual operators based on the outcome of official controls. The use of rating schemes by Member States should be allowed and encouraged as a means to increase transparency along the agri-food chain, provided that appropriate guarantees of fairness, consistency, transparency and objectiveness are offered by such schemes. The competent authorities should have the necessary arrangements in place in order for the rating to reflect accurately the actual level of compliance; in particular, competent authorities should be encouraged to ensure that the rating is based on the outcome of several official controls or, when the rating is based on the outcome of one single official control and the findings are unfavourable, that subsequent official controls are carried out within a reasonable time. The transparency of rating criteria is particularly necessary so that best practices can be compared and, in time, the development of a consistent approach at Union level considered.

- (40) It is of importance that competent authorities as well as delegated bodies and natural persons to which certain tasks have been delegated, ensure and verify the effectiveness and the consistency of the official controls they perform. For that purpose they should act on the basis of written documented procedures and should provide information and instructions to staff performing official controls. They should also have appropriate documented procedures and mechanisms in place to verify continuously that their own action is effective and consistent, and take corrective action when shortcomings are identified.
- (41) To facilitate the identification of cases of non-compliance and to streamline the taking of corrective action by the operator concerned, the outcome of official controls should be recorded in a written form and a copy should be given to the operator on request. Where official controls require the continuous or regular presence of the staff of the competent authorities to monitor the operator's activities, a written record of each individual inspection or visit to the operator would be disproportionate. In such cases, written records should be prepared with a frequency that enables the competent authorities and the operator to be informed regularly of the level of compliance and promptly notified of any identified shortcomings or non-compliance.
- (42) Operators should cooperate fully with competent authorities, delegated bodies or natural persons to which certain tasks have been delegated, to ensure the smooth performance of official controls and to enable the competent authorities to perform other official activities. Operators responsible for a consignment entering the Union should provide all available information related to that consignment. All operators should provide to the competent authorities at least the information needed to identify themselves, their activities and the operators which they supply and which supply them.
- (43) This Regulation establishes a single legislative framework for the organisation of official controls to verify compliance with Union agri-food chain legislation in all the areas that such legislation covers. In some of those areas, Union legislation lays down detailed requirements to be complied with which require special skills and specific means for the performance of official controls. To avoid diverging enforcement practices which could generate uneven protection of human, animal and plant health, animal welfare and, as regards GMOs and plant protection products, also of the environment, disrupt the functioning of the internal market for animals and goods falling within the scope of this Regulation and distort competition, the Commission should be able to supplement the rules laid down in this Regulation through the adoption of specific official control rules capable of catering for the needs of controls of those areas. In particular, such rules should lay down specific requirements for the performance of official controls and the minimum frequency for such controls, specific or additional measures to those provided for in this Regulation that competent authorities should take in relation to cases of non-compliance, specific responsibilities and tasks of the competent authorities in addition to those provided for in this Regulation and specific criteria for triggering the administrative assistance mechanism provided for in this Regulation. In other cases, such additional rules might become necessary in order to provide a more detailed framework for the performance of official controls in relation to food and feed, where new information emerges about risks to human or animal health or, in relation to GMOs and plant protection products, also to the environment, indicating that in the absence of common specifications for the performance of official controls across the Member States, the controls would fail to deliver the expected level of protection against those risks, as provided for by Union agri-food chain legislation.

- (44) To enable the efficient organisation of the official controls covered by this Regulation, Member States should have the discretion to identify the most appropriate staff to perform such controls provided that a high level of protection of human, animal and plant health and animal welfare is ensured throughout the agri-food chain and that international standards and obligations are met. However, in certain cases, where their specific skills are necessary to ensure a sound outcome of the official controls, Member States should be required to refer to official veterinarians, plant health officers or other specifically designated persons. That should be without prejudice to the possibility for Member States to also use official veterinarians (including for official controls on poultry and lagomorphs) plant health officers or other specifically designated persons in cases where this is not required in accordance with this Regulation.
- (45) For the purpose of developing new control methods and techniques in relation to official controls on meat production, competent authorities should be allowed to adopt national measures to implement pilot projects that are limited in time and scope. Such measures should ensure that competent authorities verify that operators comply with all the fundamental provisions applicable to meat production, including the requirement that meat is safe and fit for human consumption. In order to ensure that the Commission and the Member States have the possibility to assess the impact of such national measures and express their opinion before they are adopted, and take therefore the most appropriate action, those measures should be notified to the Commission in accordance with and for the purposes of Articles 5 and 6 of Directive (EU) 2015/1535 of the European Parliament and of the Council <sup>(1)</sup>.
- (46) The competent authorities should be able to delegate some of their tasks to other bodies. Appropriate conditions should be laid down to ensure that the impartiality, quality and consistency of the official controls and of the other official activities are preserved. The delegated body should in particular be accredited according to the International Organisation for Standardisation (ISO) standard for the performance of inspections.
- (47) To ensure the reliability and consistency of official controls and other official activities across the Union, the methods used for sampling and for laboratory analyses, tests and diagnoses should meet scientific standards, satisfy the specific analytical, testing and diagnostic need of the laboratory concerned, and offer sound and reliable analytical, test and diagnostic results. Clear rules should be established for the choice of the method to be used where more than one is available from different sources, such as ISO, the European and Mediterranean Plant Protection Organisation (EPPO), the International Plant Protection Convention (IPPC), the World Organisation for Animal Health (OIE), European Union and national reference laboratories, or national law.
- (48) Operators whose animals or goods are subject to sampling, analysis, test or diagnosis in the context of official controls should have the right to a second expert opinion, at their own expense. Such a right should allow the operator to request a documentary review by another expert of the initial sampling, analysis, test or diagnosis, as well as a second analysis, test or diagnosis of the parts of the sampling material taken initially unless any such second analysis, test or diagnosis is technically impossible or irrelevant. Such would be the case, in particular, where the prevalence of the hazard is particularly low in the animal or good or its distribution particularly sparse or irregular for the purpose of assessing the presence of quarantine organisms or, as the case may be, for performing a microbiological analysis.
- (49) For the purposes of performing official controls on trade which take place through the internet or other remote means, competent authorities should be able to obtain samples through anonymously placed orders (also known as mystery shopping) which can then be analysed, tested or subject to a verification of compliance. All steps should be taken by the competent authorities to preserve the rights of the operators to a second expert opinion.
- (50) Laboratories designated by the competent authorities to carry out analyses, tests and diagnoses on samples taken in the context of official controls and other official activities should possess the expertise, equipment, infrastructure and staff to carry out such tasks to the highest standards. To ensure sound and reliable results, those laboratories should be accredited for the use of these methods according to standard EN ISO/IEC 17025 on

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



'General requirements for the competence of testing and calibration laboratories'. The accreditation should be delivered by a national accreditation body operating in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council <sup>(1)</sup>.

- (51) While accreditation is the instrument of choice to ensure high performance by official laboratories, it is also a complex and costly process, which would result in a disproportionate burden for the laboratory in cases where the method of laboratory analysis, test or diagnosis is particularly simple to perform and does not require specialised procedures or equipment, as is the case for the detection of *Trichinella* in the context of the inspection and, under certain conditions, in cases where the laboratory only carries out analyses, tests or diagnoses in the context of other official activities and not of official controls.
- (52) In order to ensure the flexibility and proportionality of the approach, in particular for animal health or plant health laboratories, provision should be made for the adoption of derogations aimed at allowing certain laboratories not to be accredited for all the methods they use. That happens in particular where validated methods for detecting particular pests of plants are not available. Moreover, accreditation of a laboratory for all the methods that it should use as an official laboratory might not be immediately available in cases where new or recently modified methods are to be used, in cases of emerging risks or in emergency situations. Under certain conditions, official laboratories should therefore be allowed to carry out analyses, tests and diagnoses for the competent authorities before they obtain the relevant accreditation.
- (53) Official controls performed on animals and goods entering the Union from third countries are of key importance since these controls ensure compliance with legislation applicable within the Union and, in particular, with the rules established to protect human, animal and plant health, animal welfare and, as regards GMOs and plant protection products, also the environment. Such official controls should take place before the animals or goods are released for free circulation within the Union. The frequency of official controls should adequately address risks to human, animal and plant health, animal welfare and to the environment that animals and goods entering the Union might pose, taking into account the operator's history of compliance with the requirements provided for in Union agri-food chain legislation, the controls already performed on those animals and goods in the third country concerned, and the guarantees given by that third country that animals and goods exported to the Union meet the requirements laid down in Union legislation.
- (54) It is necessary to provide for the categories of animals and goods which should always be presented at a border control post for official controls to be performed prior to their entry into the Union. It is also necessary to provide for the possibility of requiring that other categories of goods be subject temporarily to the same requirement by virtue of specific measures to that effect, and for the possibility of requiring that certain other categories of goods, and in particular certain foodstuffs containing both products of plant origin and processed products of animal origin (composite products), always be presented for official controls at a border control post prior to their entry into the Union.
- (55) Given the risks to human, animal or plant health, animal welfare or to the environment that certain animals or goods may pose, they should be subject to specific official controls to be performed upon them on their entry into the Union. Current Union rules require the performance of official controls at Union borders to verify that human health, animal health and animal welfare standards applicable to animals, products of animal origin, germinal products and animal by-products are met and that plants and plant products comply with phytosanitary requirements. Increased controls on entry into the Union are also performed on certain other goods where emerging or known risks so warrant. The specificities of such controls, currently governed by Council Directives 97/78/EC <sup>(2)</sup>, 91/496/EEC <sup>(3)</sup> and 2000/29/EC and Commission Regulation (EC) No 669/2009 <sup>(4)</sup> should be provided for in this Regulation.

<sup>(1)</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

<sup>(2)</sup> Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

<sup>(3)</sup> Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC (OJ L 268, 24.9.1991, p. 56).

<sup>(4)</sup> Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and the Council as regards the increased level of official controls on imports of certain food and feed of non-animal origin and amending Decision 2006/504/EC (OJ L 194, 25.7.2009, p. 11).

- (56) In order to reinforce the efficiency of the Union's official control system, ensure an optimal allocation of official control resources assigned to border controls and facilitate the enforcement of Union agri-food chain legislation, a common integrated system of official controls at border control posts, replacing the current fragmented control frameworks, should be established to handle all consignments which, given the risk they may carry, should be controlled on their entry into the Union.
- (57) Official controls should be performed on consignments upon their arrival at border control posts. Those official controls should include documentary checks on all consignments, including where appropriate checks by electronic means, as well as identity checks and physical checks performed at an appropriate frequency dependent on the risk posed by each consignment of animals or goods.
- (58) The frequency of physical checks should be determined and modified on the basis of risks to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment. That approach should enable the competent authorities to allocate resources for controls where the risk is highest. The frequency of identity checks should also be subject to reduction or limited to the verification of a consignment's official seal where this is justified by a reduced risk posed by the consignments entering the Union. The risk-based approach to identity checks and physical checks should be pursued by making use of available data sets and information, and of computerised data collection and management systems.
- (59) In certain cases, and provided that high levels of human, animal and plant health, animal welfare and, in relation to GMOs and plant protection products, also protection of the environment are ensured, official controls normally performed by competent authorities at border control posts could be performed at other control points or by other authorities.
- (60) For the purpose of organising an efficient system of official controls, consignments arriving from third countries which require controls at their entry into the Union should be accompanied by a common health entry document (CHED), to be used for the prior notification of the arrival of consignments at the border control post, and to record the outcome of official controls performed and of decisions taken by the competent authorities in relation to the consignment which they accompany. The same document should be used by the operator to obtain clearance by customs authorities once all official controls have been performed.
- (61) In some Member States, due to specific geographical constraints, such as long coasts or borders, the minimum requirements for border control posts are difficult to fulfil on a permanent basis. Imports of unprocessed logs of wood are usually done in large volumes through specialised ports or control points and with an irregular frequency which make it difficult to have permanently staffed and fully equipped border control posts. Derogations from minimum requirements for border control posts should be allowed to ensure effective official controls on specific unprocessed logs of wood.
- (62) Official controls on animals and goods entering the Union from third countries should be performed at border control posts designated by Member States in accordance with a set of minimum requirements. The designation of such posts should be withdrawn or suspended when they no longer comply with the minimum requirements or when their activities could pose a risk to human, animal or plant health, animal welfare or, in the case of GMOs and plant protection products, also to the environment. The decision whether to withdraw or suspend such a designation would need to take account of the degree of seriousness of the risk and of the principle of proportionality.
- (63) To ensure the uniform application of official control rules on consignments arriving from third countries, common rules should be established to govern the actions that the competent authorities and operators should take in the event of suspicion of non-compliance, and in relation to non-compliant consignments and of consignments which might pose a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment.
- (64) In order to avoid inconsistencies and duplications in carrying out official controls, to allow consignments which are subject to official controls at border control posts and at other control points to be timely identified and to ensure that controls are performed in an efficient manner, cooperation and exchange of information amongst competent authorities, customs authorities and other relevant authorities dealing with consignments arriving from third countries should be ensured.

- (65) Member States should ensure that adequate financial resources are always available in order to appropriately staff and equip the competent authorities performing official controls and other official activities. Although operators are primarily responsible for ensuring that their activities are carried out in compliance with Union agri-food chain legislation, the system of own controls that they put in place for that purpose should be complemented by a dedicated system of official controls maintained by each Member State to ensure effective market surveillance along the agri-food chain. Such a system is, by its very nature, complex and resource-demanding and should be provided with a stable influx of resources for official controls, and at a level appropriate to the enforcement needs at any given moment. To reduce the dependency of the official control system on public finances, competent authorities should collect fees or charges to cover the costs they incur when performing official controls on certain operators and for certain activities for which Union agri-food chain legislation requires registration or approval in accordance with Union rules on the hygiene of food and feed or rules governing plant health. Fees or charges should also be collected from operators to compensate the costs of official controls performed in view of issuing an official certificate or attestation and costs of official controls performed by the competent authorities at border control posts.
- (66) Fees or charges should cover, but not exceed, the costs, including overhead costs, incurred by the competent authorities to perform official controls. Overhead costs could include the costs of the support and organisation necessary for planning and carrying out the official controls. Such costs should be calculated on the basis of each individual official control or on the basis of all official controls performed over a given period of time. Where fees or charges are applied on the basis of the actual cost of individual official controls, operators with a good record of compliance should bear lower overall charges than non-compliant ones, as they should be subject to less frequent official controls. In order to promote compliance with Union legislation by all operators irrespective of the method (based on actual costs or on a flat rate) that each Member State has chosen for the calculation of the fees or charges, when fees or charges are calculated on the basis of overall costs incurred by the competent authorities over a given period of time, and imposed on all operators irrespective of whether they are subject to an official control during the reference period, those fees or charges should be calculated so as to reward operators with a consistent good record of compliance with Union agri-food chain legislation.
- (67) The direct or indirect refund of fees or charges collected by the competent authorities should be prohibited as it would put at a disadvantage operators not benefitting from the refund and potentially create distortions of competition.
- (68) The financing of official controls through fees or charges collected from operators should be fully transparent, so as to enable citizens and businesses to understand the method and data used to establish fees or charges.
- (69) Union agri-food chain legislation establishes the cases where the placing on the market or the movement of certain animals or goods should be accompanied by an official certificate signed by the certifying officer. It is appropriate to establish a common set of rules laying down the obligations of the competent authorities and the certifying officers with regard to the issuance of official certificates as well as the characteristics that official certificates should have to ensure their reliability.
- (70) In other cases, the rules falling within the scope of this Regulation provide that the placing on the market or the movement of certain animals or goods are to be accompanied by an official label, official mark or other official attestation issued by the operators under the official supervision of the competent authorities or by the competent authorities themselves. Official attestations include, for example, plant passports, organic logos and identification marks, where these are required by Union legislation, and marks of protected designations of origin, protected geographical indications or traditional specialities guaranteed. It is appropriate to lay down a minimum set of rules to ensure that also the issuance of official attestations is able to be performed in accordance with appropriate guarantees of reliability.
- (71) Official controls and other official activities should be based on analytical, testing and diagnostic methods that meet state-of-the-art scientific standards and offer sound, reliable and comparable results across the Union. The methods used by official laboratories as well as the quality and uniformity of analytical, testing and diagnostic

data generated by them should therefore be improved continuously. For that purpose, the Commission should be able to designate, and rely on the expert assistance of, European Union reference laboratories in all those areas of the agri-food chain where there is the need for precise and reliable analytical, testing and diagnostic results. The European Union reference laboratories should in particular ensure that national reference laboratories and official laboratories are provided with up-to-date information on available methods, organise or participate actively in inter-laboratory comparative tests and offer training courses for national reference laboratories or official laboratories.

- (72) The first paragraph of Article 32 of Regulation (EC) No 1829/2003 and the first paragraph of Article 21 of Regulation (EC) No 1831/2003 of the European Parliament and of the Council <sup>(1)</sup> confer respectively on the European Union reference laboratory for genetically modified food and feed and on the European Union reference laboratory for feed additives specific tasks as part of the authorisation procedure for genetically modified food or feed, or feed additives, relating, in particular, to the testing, evaluation and validation of the method of detection or analysis proposed by applicants. Those laboratories therefore should act as European Union reference laboratories for the purposes of this Regulation.
- (73) For the performance of official controls and other official activities which are aimed at identifying possible violations to the rules including those perpetrated through fraudulent or deceptive practices, and in the field of animal welfare, the competent authorities should have access to updated, reliable and consistent technical data, to research findings, new techniques and expertise necessary for the correct application of Union legislation applicable in those two areas. For that purpose, the Commission should be able to designate, and rely on the expert assistance of, European Union reference centres for the authenticity and integrity of the agri-food chain and for animal welfare.
- (74) In order to pursue the objectives of this Regulation and contribute to the smooth functioning of the internal market, ensuring consumer confidence in it, cases of non-compliance with Union agri-food chain legislation requiring enforcement action in more than one Member State should be pursued efficiently and consistently. The rapid alert system for food and feed (RASFF) established pursuant to Article 50 of Regulation (EC) No 178/2002 already enables competent authorities to rapidly exchange and disseminate information on serious direct or indirect risks to human health in relation to food or feed, or serious risks to human or animal health or to the environment in relation to feed, for the purpose of enabling rapid measures to be taken to counter those serious risks. However, that instrument, while allowing for timely action across all Member States concerned to counter certain serious risks along the agri-food chain, cannot serve the purpose of enabling effective cross border assistance and cooperation between competent authorities to ensure that cases of non-compliance with Union agri-food chain legislation which have a cross-border dimension are effectively pursued not only in the Member State where the non-compliance is first detected but also in the Member State where the non-compliance originated. In particular, administrative assistance and cooperation should enable competent authorities to share information, detect, investigate and take effective and proportionate action to pursue cross-border violations of Union agri-food chain legislation also in cases where potential fraudulent or deceptive practices have or could have a cross-border dimension.
- (75) Requests for administrative assistance and all notifications should be given appropriate follow-up. In order to facilitate administrative assistance and cooperation, Member States should be required to designate one or more liaison bodies to assist and coordinate communication flows between competent authorities in different Member States. In order to ensure uniform conditions for the implementation of this Regulation and to streamline and simplify cooperation between Member States, implementing powers should be conferred on the Commission to adopt implementing acts establishing the specifications of the technical tools to be used, the procedures for communication between liaison bodies and a standard format for requests for assistance, notifications and responses.
- (76) Each Member State should be required to set up and regularly update a multiannual national control plan (MANCP) covering all the areas governed by Union agri-food chain legislation and containing information on the structure and organisation of its system of official controls. Such MANCPs are the instrument through which each Member State should ensure that official controls are performed in a manner that is risk-based and efficient

<sup>(1)</sup> Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

across their territory and across the entire agri-food chain, and in compliance with this Regulation. Appropriate consultation with relevant stakeholders in advance of the preparation of the plans should ensure their fitness for purpose.

- (77) In order to ensure the coherence and completeness of the MANCP each Member State should designate a single body tasked with coordinating the preparation of its MANCP and collecting, as necessary, the information on its implementation, review and update.
- (78) Member States should be required to submit an annual report to the Commission with information on control activities and the implementation of the MANCPs. In order to ensure uniform conditions for the implementation of this Regulation and to facilitate the collection and transmission of comparable data, the subsequent compilation of such data into Union-wide statistics and the preparation of reports by the Commission on the operation of official controls across the Union, implementing powers should be conferred on the Commission to adopt implementing acts in respect of establishing standard model forms for annual reports.
- (79) Commission experts should be able to perform controls, including audits, in Member States to verify the application of the relevant Union legislation and the functioning of national control systems and competent authorities. Commission controls should also serve to investigate and collect information on enforcement practices or problems, emergencies and new developments in Member States. At the request of the Member States concerned, Commission experts should also be able to participate in controls performed by the competent authorities of third countries on the territory of that Member State; such controls should be organised in close cooperation between the Member States concerned and the Commission.
- (80) Animals and goods from third countries should comply with the same requirements which apply to Union animals and goods, or with requirements which are recognised to be at least equivalent in relation to the objectives pursued by Union agri-food chain legislation. This principle is enshrined in Article 11 of Regulation (EC) No 178/2002, which requires that food and feed imported into the Union comply with the relevant requirements of the Union's food law or with requirements considered to be at least equivalent thereto. Specific requirements to apply that principle are provided for in Union rules on protective measures against pests of plants, which prohibit the introduction into the Union of certain pests which are not present (or only present to a limited extent) in the Union, in Union rules laying down animal health requirements, which allow the entry of animals and of certain products of animal origin into the Union only from third countries which are included in a list set up for that purpose, and in Union rules for the organisation of official controls on products of animal origin intended for human consumption, which also provide for the establishment of a list of third countries from which those products can enter the Union.
- (81) In order to ensure that animals and goods entering the Union from third countries comply with all the requirements laid down in Union agri-food chain legislation or with requirements considered equivalent, in addition to the requirements established by Union rules on protective measures against pests of plants, Union rules laying down animal health requirements and Union rules laying down specific hygiene rules for food of animal origin to ensure that the requirements laid down in Union agri-food chain legislation in relation to phytosanitary and veterinary concerns are met, the Commission should be allowed to establish conditions for the entry of animals and goods into the Union to the extent necessary to ensure that those animals and goods comply with all relevant requirements of Union agri-food chain legislation or equivalent requirements. Such conditions should apply to animals or goods or categories of animals or goods from all third countries or from certain third countries or regions thereof.
- (82) Where, in specific cases, there is evidence that certain animals or goods originating from a third country, a group of third countries, or regions thereof, give rise to risks to human, animal or plant health or, as regards GMOs and plant protection products, also to the environment or where there is evidence that widespread serious non-compliance with Union agri-food chain legislation might be taking place, the Commission should be able to adopt measures to contain such risks.

- (83) The performance of effective and efficient official controls and other official activities, and ultimately the safety and health of humans, animals and plants, and the protection of the environment, also depends on the availability to the control authorities of well trained staff possessing an appropriate knowledge of all the matters relevant for the correct application of Union legislation. Appropriate and dedicated training should be provided by the Commission to promote a uniform approach to official controls and other official activities by the competent authorities. To promote the knowledge of Union agri-food chain legislation and requirements in third countries, such training should also be addressed to staff of the competent authorities in third countries. In the latter case, the training activities should be designed to take into account the specific needs of developing countries, to support their controls and enforcement actions so that they can meet the requirements applicable to import of animals and goods into the Union.
- (84) To promote the sharing of experience and best practices among competent authorities, the Commission should also be able to organise, in cooperation with the Member States, programmes for the exchange between Member States of staff tasked with official controls or other official activities.
- (85) It is important for the performance of effective official controls and other official activities that the competent authorities in the Member States, the Commission and, where relevant, operators be able to exchange data and information related to official controls or results therefrom rapidly and efficiently. Several information systems are established by Union legislation and managed by the Commission to allow such data and information to be handled and managed through Union-wide computerised and internet-based tools. A system dedicated to recording and tracing official control results is the Trade Control and Expert System (Traces system), established by Commission Decisions 2003/24/EC <sup>(1)</sup> and 2004/292/EC <sup>(2)</sup> in accordance with Council Directive 90/425/EEC <sup>(3)</sup> and currently used for the management of data and information on animals and products of animal origin and official controls thereon. This Regulation should allow that system to be maintained and upgraded so as to allow its use for all goods for which Union agri-food chain legislation establishes specific requirements or practical arrangements for official controls. Dedicated computerised systems also exist for the rapid exchange of information between Member States and with the Commission on risks which might arise in the agri-food chain or for animal and plant health. Article 50 of Regulation (EC) No 178/2002 establishes the RASFF which is a system for notifying direct or indirect risk to human health deriving from food or feed, Article 20 of Regulation (EU) 2016/429 of the European Parliament and of the Council <sup>(4)</sup> a system for the notification and reporting on the measures on listed diseases, and Article 103 of Regulation (EU) 2016/2031 of the European Parliament and of the Council <sup>(5)</sup> a system for the notification and reporting of the presence of pests and the notification of cases of non-compliance. All such systems should work in a harmonious and consistent manner that makes use of synergies between the different systems, avoids duplications, simplifies their operation and makes them more efficient.
- (86) To support a more efficient management of official controls, a computerised information system integrating and upgrading as necessary all relevant existing information systems should be set up by the Commission, allowing for the use of advanced communication and certification tools, and for the most efficient use of the data and information related to official controls. In view of avoiding unnecessary duplications of information requirements, the design of such computerised system should take into account the need to ensure, wherever appropriate, the compatibility and inter-operability of such a computerised system with other information systems operated by public authorities and through which relevant data is automatically exchanged or made available. Moreover, the possibility to use electronic signatures within the meaning of Directive 1999/93/EC of

<sup>(1)</sup> Commission Decision 2003/24/EC of 30 December 2002 concerning the development of an integrated computerised veterinary system (OJ L 8, 14.1.2003, p. 44).

<sup>(2)</sup> Commission Decision 2004/292/EC of 30 March 2004 on the introduction of the Traces system and amending Decision 92/486/EEC (OJ L 94, 31.3.2004, p. 63).

<sup>(3)</sup> Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (OJ L 224, 18.8.1990, p. 29).

<sup>(4)</sup> Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).

<sup>(5)</sup> Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

the European Parliament and the Council <sup>(1)</sup> should be provided for, in line with the Digital Agenda for Europe. The European Data Protection Supervisor should be consulted during the development stage of any new functionality of such computerised system, as well as during the development of relevant implementing measures which might affect the processing of personal data and privacy.

- (87) In order to ensure uniform conditions for the implementation of this Regulation regarding the proper functioning of the computerised information system, its technical specifications, as well as the duties and prerogatives of the various actors and users involved, taking into account in particular the need to minimise administrative burdens by using, as appropriate, internationally standardised language, message structure and exchange protocols, implementing powers should be conferred on the Commission.
- (88) The competent authorities should investigate cases where there is a suspicion of non-compliance with Union agri-food chain legislation and, where non-compliance is established, determine its origin and extent as well as the operators' responsibilities. The competent authorities should also take appropriate measures to ensure that the operators concerned remedy the situation and to prevent further non-compliance. The organisation and performance of investigations and enforcement actions by the competent authorities should duly take into account potential risks and the likelihood of fraudulent or deceptive practices along the agri-food chain.
- (89) The verification of compliance with Union agri-food chain legislation through official controls is of fundamental importance to ensure that, across the Union, the objectives of that legislation are effectively achieved. Disruptions in a Member State's control systems can in certain cases substantially hinder the achievement of those objectives and lead to the emergence of risks to human, animal and plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, independently of the involvement or responsibility of operators or other actors, or lead to situations of widespread serious non-compliance with Union agri-food chain legislation. In order to ensure uniform conditions for the implementation of this Regulation, the Commission should be able, in the event of serious disruptions in a Member State's control system, to react by adopting measures aimed at containing or eliminating those risks from the agri-food chain, pending the necessary action to be taken by the Member State concerned to remedy the disruption in the control system. Implementing powers should therefore be conferred on the Commission.
- (90) Infringements of the rules of the Union agri-food chain legislation and of this Regulation should be subject to effective, dissuasive and proportionate penalties at national level throughout the Union, the severity of which takes account, inter alia, of the potential damage to human health that may result from infringements, including in cases where operators fail to cooperate during an official control and in cases where false or misleading official certificates or attestations are produced or used. For financial penalties applicable to violations of the rules perpetrated through fraudulent or deceptive practices to be sufficiently deterrent, they should be set at a level which seeks to exceed the undue advantage for the perpetrator resulting from those practices.
- (91) Any person should be able to bring new information to the attention of competent authorities which assists them in detecting, and imposing penalties in cases of, infringements of this Regulation and of the rules referred to in Article 1(2). However, whistleblowing could be deterred by the lack of clear procedures or for fear of retaliation. Reporting of infringements of this Regulation is a useful tool to ensure that a competent authority is able to detect and impose penalties for infringements. This Regulation should therefore ensure that adequate arrangements are in place to enable any person to alert the competent authorities to possible infringements of this Regulation and to protect that person from retaliation.
- (92) This Regulation covers areas that are already covered in certain acts currently in force. To avoid duplications and to establish a coherent legislative framework, the following acts should be repealed and replaced by this

<sup>(1)</sup> Directive 1999/93/EC of the European Parliament and the Council of 13 December 1999 on a Community framework for electronic signatures (OJ L 13, 19.1.2000, p. 12).

Regulation: Regulation (EC) No 882/2004 and Regulation (EC) No 854/2004 of the European Parliament and of the Council <sup>(1)</sup>, Council Directives 89/608/EEC <sup>(2)</sup>, 89/662/EEC <sup>(3)</sup>, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC <sup>(4)</sup> and 97/78/EC and Council Decision 92/438/EEC <sup>(5)</sup>.

- (93) In order to ensure consistency, the following acts should be amended: Regulation (EC) No 999/2001 of the European Parliament and of the Council <sup>(6)</sup>, Council Regulation (EC) No 1/2005 <sup>(7)</sup>, Regulation (EC) No 396/2005 of the European Parliament and of the Council <sup>(8)</sup>, Regulation (EC) No 1069/2009, Council Regulation (EC) No 1099/2009 <sup>(9)</sup>, Regulation (EC) No 1107/2009 of the European Parliament and of the Council <sup>(10)</sup>, Regulation (EU) No 1151/2012 of the European Parliament and of the Council <sup>(11)</sup>, and Council Directives 98/58/EC <sup>(12)</sup>, 1999/74/EC <sup>(13)</sup>, 2007/43/EC <sup>(14)</sup>, 2008/119/EC <sup>(15)</sup> and 2008/120/EC <sup>(16)</sup>.
- (94) Regulation (EU) No 652/2014 of the European Parliament and of the Council <sup>(17)</sup> provides a framework for the Union's financing of actions and measures across the agri-food chain in those areas under the multiannual financial framework 2014-2020. Some of those acts and measures aim to improve the performance of official controls and other official activities across the Union. Regulation (EU) No 652/2014 should be amended to take account of the repeal of Regulation (EC) No 882/2004 by this Regulation.
- (95) Considering the specific situation as regards the plant sector, which has so far not been subject to the same level of controls as other goods under this Regulation, it is essential that the introduction of the new system be as smooth and seamless as possible. For that reason, it is necessary to introduce specific provisions regarding the timing of the adoption of relevant delegated acts. It is also clear that it is justified to have an exemption from the obligation of documentary checks to be carried out at border control posts for the plant sector in the case of

<sup>(1)</sup> Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

<sup>(2)</sup> Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters (OJ L 351, 2.12.1989, p. 34).

<sup>(3)</sup> Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (OJ L 395, 30.12.1989, p. 13).

<sup>(4)</sup> Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products (OJ L 13, 16.1.1997, p. 28).

<sup>(5)</sup> Council Decision 92/438/EEC of 13 July 1992 on computerization of veterinary import procedures (Shift project), amending Directives 90/675/EEC, 91/496/EEC, 91/628/EEC and Decision 90/424/EEC, and repealing Decision 88/192/EEC (OJ L 243, 25.8.1992, p. 27).

<sup>(6)</sup> Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

<sup>(7)</sup> Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (OJ L 3, 5.1.2005, p. 1).

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

<sup>(9)</sup> Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, p. 1).

<sup>(10)</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

<sup>(11)</sup> Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs (OJ L 343, 14.12.2012, p. 1).

<sup>(12)</sup> Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes (OJ L 221, 8.8.1998, p. 23).

<sup>(13)</sup> Council Directive 1999/74/EC of 19 July 1999 laying down minimum standards for the protection of laying hens (OJ L 203, 3.8.1999, p. 53).

<sup>(14)</sup> Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production (OJ L 182, 12.7.2007, p. 19).

<sup>(15)</sup> Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves (OJ L 10, 15.1.2009, p. 7).

<sup>(16)</sup> Council Directive 2008/120/EC of 18 December 2008 laying down minimum standards for the protection of pigs (OJ L 47, 18.2.2009, p. 5).

<sup>(17)</sup> Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC (OJ L 189, 27.6.2014, p. 1).



plants, plant products and other objects posing a low level of risk and to permit documentary checks at a distance from border control posts for plants, plant products and other objects where such checks at a distance are able to provide an equal level of assurance.

- (96) In order to amend the references to European standards, and Annexes II and III to this Regulation to take into account of legislative and technical and scientific developments, and to supplement this Regulation with specific rules governing official controls and other official activities in the areas it covers, including rules on the qualification and training of staff, on additional responsibilities and tasks of the competent authorities, on the cases where the accreditation of laboratories is not required, on certain exemptions from official controls at the borders, on the criteria to be used to determine the frequency of identity checks and physical checks, on the establishment of conditions to be fulfilled by certain animals or goods entering the Union from third countries, on additional requirements and tasks of European Union reference laboratories and centres and on additional requirements for national reference laboratories' the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making <sup>(1)</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
- (97) In order to ensure uniform conditions for the implementation of this Regulation regarding the designation of European Union reference laboratories and of the European Union reference centres for the authenticity and integrity of the agri-food chain and for animal welfare, the adoption of the programme of the Commission controls in the Member States, and the performance of increased official controls in the event of infringements of Union agri-food chain legislation which require coordinated assistance and follow-up by the Commission, implementing powers should be conferred on the Commission.
- (98) In order to ensure uniform conditions for the implementation of this Regulation, including rules and practical arrangements in respect of audits, the format of certificates and other documents, the establishment of computerised information management systems, the cooperation between operators and competent authorities and amongst competent authorities, customs authorities and other authorities, the methods of sampling and of laboratory analysis, test and diagnosis as well as their validation and interpretation, traceability, the listing of animals or goods subject to controls as well the listing of countries or regions that can export certain animals and goods to the Union, prior notification of consignments, exchanges of information, border control posts, isolation and quarantine, approval of pre-export controls performed by third countries, measures to contain a risk or put an end to a widespread serious non-compliance relating to certain animals or goods originating from a third country or a region thereof, the recognition of third countries or regions that offer equivalent guarantees to those applied in the Union and its repeal, training activities and exchange programmes of staff amongst Member States and on the contingency plans for food and feed for the application of the general plan for crisis management provided for in Article 55(1) of Regulation (EC) No 178/2002, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council <sup>(2)</sup>.
- (99) Since the objective of this Regulation, namely to ensure a harmonised approach with regard to official controls and other official activities performed in view of ensuring the application of Union agri-food chain legislation, cannot be sufficiently achieved by the Member States but can rather, by reason of its effect, complexity, trans-border and international character, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

<sup>(1)</sup> OJ L 123, 12.5.2016, p. 1.

<sup>(2)</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

HAVE ADOPTED THIS REGULATION:

TITLE I

SUBJECT MATTER, SCOPE AND DEFINITIONS

*Article 1*

**Subject matter and scope**

1. This Regulation lays down rules for:
  - (a) the performance of official controls and other official activities by the competent authorities of the Member States;
  - (b) the financing of official controls;
  - (c) the administrative assistance and cooperation between Member States in view of the correct application of the rules referred to in paragraph 2;
  - (d) the performance of controls by the Commission in Member States and in third countries;
  - (e) the adoption of conditions to be fulfilled with respect to animals and goods entering the Union from a third country;
  - (f) the establishment of a computerised information system to manage information and data in relation to official controls.
2. This Regulation shall apply to the official controls performed for the verification of compliance with the rules, whether established at Union level or by the Member States, to apply Union legislation, in the areas of:
  - (a) food and food safety, integrity and wholesomeness at any stage of production, processing and distribution of food, including rules aimed at ensuring fair practices in trade and protecting consumer interests and information, and the manufacture and use of materials and articles intended to come into contact with food;
  - (b) deliberate release into the environment of genetically modified organisms (GMOs) for the purpose of food and feed production;
  - (c) feed and feed safety at any stage of production, processing and distribution of feed and the use of feed, including rules aimed at ensuring fair practices in trade and protecting consumer health, interests and information;
  - (d) animal health requirements;
  - (e) prevention and minimisation of risks to human and animal health arising from animal by-products and derived products;
  - (f) welfare requirements for animals;
  - (g) protective measures against pests of plants;
  - (h) requirements for the placing on the market and use of plant protection products and the sustainable use of pesticides, with the exception of pesticides application equipment;
  - (i) organic production and labelling of organic products;
  - (j) use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed.
3. This Regulation shall also apply to official controls performed for the verification of compliance with requirements laid down in the rules referred to in paragraph 2 where those requirements are applicable to animals and goods entering the Union or to be exported from the Union.

4. This Regulation shall not apply to official controls for the verification of compliance with:
- (a) Regulation (EU) No 1308/2013; however, this Regulation shall apply to checks pursuant to Article 89 of Regulation (EU) No 1306/2013, where those checks identify possible fraudulent or deceptive practices in respect of the marketing standards referred to in Articles 73 to 91 of Regulation (EU) No 1308/2013;
  - (b) Directive 2010/63/EU of the European Parliament and of the Council <sup>(1)</sup>;
  - (c) Directive 2001/82/EC of the European Parliament and of the Council <sup>(2)</sup>.
5. Articles 4, 5, 6, 8, Article 12(2) and (3), Articles 15, 18 to 27, 31 to 34, 37 to 42 and 78, Articles 86 to 108, point (b) of Article 112, Article 130 and Articles 131 to 141 shall also apply to other official activities performed by the competent authorities in accordance with this Regulation or with the rules referred to in paragraph 2 of this Article.

## Article 2

### Official controls and other official activities

1. For the purposes of this Regulation, 'official controls' means activities performed by the competent authorities, or by the delegated bodies or the natural persons to which certain official control tasks have been delegated in accordance with this Regulation, in order to verify:
- (a) compliance by the operators with this Regulation and with the rules referred to in Article 1(2); and
  - (b) that animals or goods meet the requirements laid down in the rules referred to in Article 1(2), including for the issuance of an official certificate or official attestation.
2. For the purposes of this Regulation, 'other official activities' means activities, other than official controls, which are performed by the competent authorities, or by the delegated bodies or the natural persons to which certain other official activities have been delegated in accordance with this Regulation, and with the rules referred to in Article 1(2), including activities aimed at verifying the presence of animal diseases or pests of plants, preventing or containing the spread of such animal diseases or pests of plants, eradicating those animal diseases or pests of plants, granting authorisations or approvals, and issuing official certificates or official attestations.

## Article 3

### Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) 'food law' means food law as defined in point (1) of Article 3 of Regulation (EC) No 178/2002;
- (2) 'feed law' means the laws, regulations and administrative provisions governing feed in general and feed safety in particular, whether at Union or national level at any stage of production, processing and distribution or use of feed;
- (3) 'competent authorities' means:
  - (a) the central authorities of a Member State responsible for the organisation of official controls and of other official activities, in accordance with this Regulation and the rules referred to in Article 1(2);
  - (b) any other authority to which that responsibility has been conferred;
  - (c) where appropriate, the corresponding authorities of a third country;

<sup>(1)</sup> Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

<sup>(2)</sup> Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

- (4) 'organic control authority' means a public administrative organisation for organic production and labelling of organic products of a Member State to which the competent authorities have conferred, in whole or in part, their competences in relation to the application of Council Regulation (EC) No 834/2007 <sup>(1)</sup>, including, where appropriate, the corresponding authority of a third country or operating in a third country;
- (5) 'delegated body' means a separate legal person to which the competent authorities have delegated certain official control tasks or certain tasks related to other official activities;
- (6) 'control verification procedures' means the arrangements put in place and actions performed by the competent authorities for the purpose of ensuring that official controls and other official activities are consistent and effective;
- (7) 'control system' means a system comprising the competent authorities and the resources, structures, arrangements and procedures set up in a Member State to ensure that official controls are performed in accordance with this Regulation and with the rules referred to in Articles 18 to 27;
- (8) 'control plan' means a description established by the competent authorities containing information on the structure and organisation of the official control system, and of its operation and the detailed planning of official controls to be performed, over a period of time, in each of the areas governed by the rules referred to in Article 1(2);
- (9) 'animals' means animals as defined in point (1) of Article 4 of Regulation (EU) 2016/429;
- (10) 'animal disease' means disease as defined in point (16) of Article 4 of Regulation (EU) 2016/429;
- (11) 'goods' means all that is subject to one or more of the rules referred to in Article 1(2), excluding animals;
- (12) 'food' means food as defined in Article 2 of Regulation (EC) No 178/2002;
- (13) 'feed' means feed as defined in point (4) of Article 3 of Regulation (EC) No 178/2002;
- (14) 'animal by-products' means animal by-products as defined in point (1) of Article 3 of Regulation (EC) No 1069/2009;
- (15) 'derived products' means derived products as defined in point (2) of Article 3 of Regulation (EC) No 1069/2009;
- (16) 'plants' means plants as defined in point (1) of Article 2 of Regulation (EU) 2016/2031;
- (17) 'pests of plants' means pests as defined in Article 1(1) of Regulation (EU) 2016/2031;
- (18) 'plant protection products' means plant protection products as referred to in Article 2(1) of Regulation (EC) No 1107/2009;
- (19) 'products of animal origin' means products of animal origin as defined in point 8.1 of Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council <sup>(2)</sup>;
- (20) 'germinal products' means germinal products as defined in point (28) of Article 4 of Regulation (EU) 2016/429;
- (21) 'plant products' means plant products as defined in point (2) of Article 2 of Regulation (EU) 2016/2031;
- (22) 'other objects' means other objects as defined in point (5) of Article 2 of Regulation (EU) 2016/2031;
- (23) 'hazard' means any agent or condition with the potential to have an adverse effect on human, animal or plant health, animal welfare or the environment;
- (24) 'risk' means a function of the probability of an adverse effect on human, animal or plant health, animal welfare or the environment and of the severity of that effect, consequential to a hazard;
- (25) 'official certification' means the procedure by which assurance concerning compliance with one or more requirements laid down in the rules referred to in Article 1(2) is provided by the competent authorities;

<sup>(1)</sup> Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L 189, 20.7.2007, p. 1).

<sup>(2)</sup> Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

- (26) 'certifying officer' means:
- (a) any official of the competent authorities authorised to sign official certificates by such authorities; or
  - (b) any other natural person who is authorised by the competent authorities to sign official certificates in accordance with the rules referred to in Article 1(2);
- (27) 'official certificate' means a paper or electronic document signed by the certifying officer and providing assurance concerning compliance with one or more requirements laid down in the rules referred to in Article 1(2);
- (28) 'official attestation' means any label, mark or other form of attestation issued by the operators under the supervision, through dedicated official controls, of the competent authorities or by the competent authorities themselves, and providing assurance concerning compliance with one or more requirements laid down in this Regulation or in the rules referred to in Article 1(2);
- (29) 'operator' means any natural or legal person subject to one or more of the obligations provided for in the rules referred to in Article 1(2);
- (30) 'audit' means a systematic and independent examination to determine whether activities and the related results of such activities comply with planned arrangements and whether these arrangements are applied effectively and are suitable to achieve the objectives;
- (31) 'rating' means a classification of operators based on an assessment of their conformity with rating criteria;
- (32) 'official veterinarian' means a veterinarian appointed by a competent authority, either as staff or otherwise, and appropriately qualified to perform official controls and other official activities in accordance with this Regulation and the relevant rules referred to in Article 1(2);
- (33) 'official plant health officer' means a natural person appointed by a competent authority, either as staff or otherwise, and appropriately trained to perform official controls and other official activities in accordance with this Regulation and the relevant rules referred to in point (g) of Article 1(2);
- (34) 'specified risk material' means specified risk material as defined in point (g) of Article 3(1) of Regulation (EC) No 999/2001;
- (35) 'long journey' means a long journey as defined in point (m) of Article 2 of Regulation (EC) No 1/2005;
- (36) 'pesticide application equipment' means pesticide application equipment as defined in point (4) of Article 3 of Directive 2009/128/EC;
- (37) 'consignment' means a number of animals or quantity of goods covered by the same official certificate, official attestation or any other document, conveyed by the same means of transport and coming from the same territory or third country, and, except for goods subject to the rules referred to in point (g) of Article 1(2), being of the same type, class or description;
- (38) 'border control post' means a place, and the facilities belonging to it, designated by a Member State for the performance of the official controls provided for in Article 47(1);
- (39) 'exit point' means a border control post or any other place designated by a Member State where animals, falling within the scope of Regulation (EC) No 1/2005, leave the customs territory of the Union;
- (40) 'entering the Union' or 'entry into the Union' means the action of bringing animals and goods into one of the territories that are listed in Annex I to this Regulation from outside these territories, except in relation to the rules referred to in point (g) of Article 1(2) for which these terms mean the action of bringing goods into the 'Union territory' as defined in the second subparagraph of Article 1(3) of Regulation (EU) 2016/2031;
- (41) 'documentary check' means the examination of the official certificates, official attestations and other documents including documents of a commercial nature, which are required to accompany the consignment as provided for by the rules referred to in Article 1(2), by Article 56(1) or by implementing acts adopted in accordance with Articles 77(3), 126(3), 128(1) and 129(1);

- (42) 'identity check' means a visual inspection to verify that the content and the labelling of a consignment, including the marks on animals, seals and means of transport, correspond to the information provided in the official certificates, official attestations and other documents accompanying it;
- (43) 'physical check' means a check on animals or goods and, as appropriate, checks on packaging, the means of transport, labelling and temperature, the sampling for analysis, testing or diagnosis and any other check necessary to verify compliance with the rules referred to in Article 1(2);
- (44) 'transit' means movement from one third country to another third country passing under customs supervision through one of the territories listed in Annex I or from one of the territories listed in Annex I to another territory listed in Annex I after passing through the territory of a third country, except in relation to the rules referred to in point (g) of Article 1(2), for which it means one of the following:
- (a) movement from one third country to another third country, as defined in the first subparagraph of Article 1(3) of Regulation (EU) 2016/2031 passing under customs supervision through the 'Union territory', as defined in the second subparagraph of Article 1(3) of that Regulation; or
  - (b) movement from the 'Union territory' to another part of the 'Union territory', as defined in the second subparagraph of Article 1(3) of Regulation (EU) 2016/2031, passing through the territory of a third country as defined in the first subparagraph of Article 1(3) of that Regulation;
- (45) 'supervision by the customs authorities' means customs supervision as defined in point (27) of Article 5 of Regulation (EU) No 952/2013 of the European Parliament and of the Council <sup>(1)</sup>;
- (46) 'control by the customs authorities' means customs controls as defined in point (3) of Article 5 of Regulation (EU) No 952/2013;
- (47) 'official detention' means the procedure by which the competent authorities ensure that animals and goods subject to official controls are not moved or tampered with pending a decision on their destination; it includes storage by operators in accordance with the instructions and under the control of the competent authorities;
- (48) 'journey log' means the document set out in points 1 to 5 of Annex II to Regulation (EC) No 1/2005;
- (49) 'official auxiliary' means a representative of the competent authorities trained in accordance with the requirements established under Article 18 and employed to perform certain official control tasks or certain tasks related to other official activities;
- (50) 'meat and edible meat offal' means, for the purpose of point (a) of Article 49(2) of this Regulation, the products listed in sub-Chapters 0201 to 0208 of Chapter 2 of Section I of Part Two of Annex I to Council Regulation (EEC) No 2658/87 <sup>(2)</sup>;
- (51) 'health mark' means a mark applied after the official controls referred to in points (a) and (c) of Article 18(2) have been performed and which attests that the meat is fit for human consumption.

## 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.

<sup>(1)</sup> Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

<sup>(2)</sup> Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

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 <sup>(1)</sup> and Article 6 of Regulation (EC) No 183/2005 of the European Parliament and of the Council <sup>(2)</sup>;
  - (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;

<sup>(1)</sup> 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).

<sup>(2)</sup> 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).

- (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 preselection 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 <sup>(1)</sup>;

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

- (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;
- (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 multiannual 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 <sup>(1)</sup>;

<sup>(1)</sup> 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).

- (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 <sup>(1)</sup>; 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 <sup>(2)</sup>.

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;

<sup>(1)</sup> 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).

<sup>(2)</sup> 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).

- (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 <sup>(1)</sup>;
  - (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.

<sup>(1)</sup> 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).

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;
- (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
  - (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 <sup>(1)</sup>;
  - (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.

<sup>(1)</sup> 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).

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;
- (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 <sup>(1)</sup> 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.

<sup>(1)</sup> 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).

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) .../... (\*)’;

- (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.

(\*) Number of the Regulation contained in document ST 10755/16 (2013/0140(COD)).

## 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 <sup>(1)</sup> 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).

<sup>(1)</sup> 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) No 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).

## 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.

### TITLE III

#### REFERENCE LABORATORIES AND REFERENCE CENTRES

##### *Article 92*

#### **Decision to establish a European Union reference laboratory**

1. In the areas governed by the rules referred to in Article 1(2), a European Union reference laboratory shall be established where the effectiveness of official controls and other official activities also depends on the quality, uniformity and reliability of:

- (a) the methods of analysis, test or diagnosis employed by the official laboratories designated in accordance with Article 37(1); and
- (b) the results of the analyses, tests and diagnoses performed by those official laboratories.

2. A European Union reference laboratory shall be established where there is a recognised need to promote uniform practices in relation to the development or use of the methods referred to in point (a) of paragraph 1.

3. The Commission shall review regularly the mandate and operation of the European Union reference laboratories.

4. The Commission shall supplement this Regulation by adopting the decision to establish a European Union reference laboratory by means of a delegated act in accordance with Article 144.

##### *Article 93*

#### **Designation of European Union reference laboratories**

1. The Commission shall, by means of implementing acts, designate European Union reference laboratories in the cases where a decision has been taken to establish such a laboratory in accordance with Article 92.

2. The designations provided for in paragraph 1 shall:

- (a) follow a public selection process; and
- (b) be limited in time and with a minimum period of five years, or reviewed regularly.

3. European Union reference laboratories shall:
- (a) operate in accordance with standard EN ISO/IEC 17025 and be accredited in accordance with that standard by a national accreditation body, operating in accordance with Regulation (EC) No 765/2008. The scope of that accreditation:
    - (i) shall include all the methods of laboratory analysis, test or diagnosis required to be used by the laboratory when it operates as an European Union reference laboratory;
    - (ii) may comprise one or more methods of laboratory analysis, test or diagnosis or groups of methods;
    - (iii) may be defined in a flexible manner, so as to allow the scope of the accreditation to include modified versions of the methods used by the European Union reference 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, prior to the use of those modified or new methods, by the national accreditation body of the Member State where the European Union reference laboratory is located;
  - (b) be impartial, free from any conflict of interest, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as European Union reference laboratories;
  - (c) have, or have contractual access to, suitably qualified staff with adequate training in analytical, testing and diagnostic techniques applied in their area of competence, and support staff as appropriate;
  - (d) possess, or have access to, the infrastructure, equipment and products necessary to carry out the tasks assigned to them;
  - (e) ensure that their staff and any contractually engaged staff have good knowledge of international standards and practices and that the latest developments in research at national, Union and international level are taken into account in their work;
  - (f) be equipped, or have access to, the necessary equipment to perform their tasks in emergency situations; and
  - (g) where relevant, be equipped to comply with relevant biosecurity standards.

4. By way of derogation from point (a) of paragraph 3 of this Article, for the area governed by the rules referred to in point (g) of Article 1(2), the Commission may designate official laboratories, designated as such by the competent authorities on the basis of a derogation adopted pursuant to Article 41, as European Union reference laboratories irrespective of whether they fulfil the conditions provided for in point (a) of paragraph 3 of this Article.

5. By way of derogation from paragraphs 1 and 2 of this Article, the laboratories referred to in the first paragraph of Article 32 of Regulation (EC) No 1829/2003 and the first paragraph of the Article 21 of Regulation (EC) No 1831/2003 shall be the European Union reference laboratories having the responsibilities and performing the tasks referred to in Article 94 of this Regulation in the areas respectively of:

- (a) GMOs and genetically modified food and feed; and
- (b) feed additives.

6. The confidentiality obligations of staff, referred to in Article 8, shall apply *mutatis mutandis* to staff of the European Union reference laboratories.

#### Article 94

### Responsibilities and tasks of European Union reference laboratories

1. European Union reference laboratories shall contribute to the improvement and harmonisation of methods of analysis, test or diagnosis to be used by official laboratories designated in accordance with Article 37(1) and of the analytical, testing and diagnostic data generated by them.

2. European Union reference laboratories designated in accordance with Article 93(1) shall be responsible for the following tasks insofar as they are included in the reference laboratories' annual or multiannual work programmes that have been established in conformity with the objectives and priorities of the relevant work programmes adopted by the Commission in accordance with Article 36 of Regulation (EU) No 652/2014:

- (a) providing national reference laboratories with details and guidance on the methods of laboratory analysis, testing or diagnosis, including reference methods;
- (b) providing reference materials to national reference laboratories;
- (c) coordinating the application by the national reference laboratories and, if necessary, by other official laboratories of the methods referred to in point (a), in particular, by organising regular inter-laboratory comparative testing or proficiency tests and by ensuring appropriate follow-up of such comparative testing or proficiency tests in accordance, where available, with internationally accepted protocols, and informing the Commission and the Member States of the results and follow-up to the inter-laboratory comparative testing or proficiency tests;
- (d) coordinating practical arrangements necessary to apply new methods of laboratory analysis, testing or diagnosis, and informing national reference laboratories of advances in this field;
- (e) conducting training courses for staff from national reference laboratories and, if needed, from other official laboratories, as well as of experts from third countries;
- (f) providing scientific and technical assistance to the Commission within the scope of their mission;
- (g) providing information on relevant national, Union and international research activities to national reference laboratories;
- (h) collaborating within the scope of their mission with laboratories in third countries and with the European Food Safety Authority (EFSA), the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC);
- (i) assisting actively in the diagnosis of outbreaks in Member States of food-borne, zoonotic or animal diseases, or of pests of plants, by carrying out confirmatory diagnosis, characterisation and taxonomic or epizootic studies on pathogen isolates or pest specimens;
- (j) coordinating or performing tests for the verification of the quality of reagents and lots of reagents used for the diagnosis of food-borne, zoonotic or animal diseases and pests of plants;
- (k) where relevant for their area of competence, establishing and maintaining:
  - (i) reference collections of pests of plants and/or reference strains of pathogenic agents;
  - (ii) reference collections of materials intended to come into contact with food used to calibrate analytical equipment and provide samples thereof to national reference laboratories;
  - (iii) up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents; and
- (l) where relevant for their area of competence, cooperate among themselves and with the Commission, as appropriate, to develop methods of analysis, testing or diagnosis of high standards.

As regards point (i) of point (k), the European Union reference laboratory may establish and maintain those reference collections and reference strains by contractual outsourcing to other official laboratories and to scientific organisations.

3. European Union reference laboratories shall publish the list of the national reference laboratories designated by the Member States in accordance with Article 100(1).

#### *Article 95*

#### **Designation of European Union reference centres for animal welfare**

1. The Commission shall, by means of implementing acts, designate European Union reference centres for animal welfare that shall support the activities of the Commission and of the Member States in relation to the application of the rules referred to in point (f) of Article 1(2).

2. The designations provided for in paragraph 1 shall:
  - (a) follow a public selection process; and
  - (b) be limited in time or reviewed regularly.
3. European Union reference centres for animal welfare shall:
  - (a) act impartially as regards the exercise of their tasks as European Union reference centres;
  - (b) possess a high level of scientific and technical expertise in human-animal relationship, animal behaviour, animal physiology, animal genetics, animal health and nutrition related to animal welfare, and animal welfare aspects related to the commercial and scientific use of animals;
  - (c) have suitably qualified staff with adequate training in the areas referred to in point (b) and in ethical issues related to animals and support staff as appropriate;
  - (d) possess, or have access to, the infrastructure, the equipment and products necessary to carry out the tasks assigned to them; and
  - (e) ensure that their staff have good knowledge of international standards and practices in the areas referred to in point (b) and that the latest developments in research at national, Union and international level, including studies performed and actions undertaken by other European Union reference centres for animal welfare, in those areas are taken into account in their work.

#### *Article 96*

#### **Responsibilities and tasks of European Union reference centres for animal welfare**

The European Union reference centres for animal welfare shall be responsible for the following supporting tasks insofar as they are included in the reference centres' annual or multiannual work programmes that have been established in conformity with the objectives and priorities of the relevant work programmes adopted by the Commission in accordance with Article 36 of Regulation (EU) No 652/2014:

- (a) providing scientific and technical expertise within the scope of their mission including, where appropriate in the form of coordinated assistance, to relevant national support networks and bodies in the area governed by the rules referred to in point (f) of Article 1(2);
- (b) providing scientific and technical expertise for the development and application of the animal welfare indicators referred to in point (e) of Article 21(8);
- (c) developing or coordinating the development of methods for the assessment of the level of welfare of animals and of methods for the improvement of the welfare of animals;
- (d) carrying out scientific and technical studies on the welfare of animals used for commercial or scientific purposes;
- (e) conducting training courses for staff of the national scientific support networks or bodies referred to in point (a), for staff of the competent authorities and for experts from third countries; and
- (f) disseminating research findings and technical innovations and collaborating with Union research bodies in the fields within the scope of their mission.

#### *Article 97*

#### **Designation of European Union reference centres for the authenticity and integrity of the agri-food chain**

1. The Commission may, by means of implementing acts, designate European Union reference centres that shall support the activities of the Commission and of the Member States to prevent, detect and combat violations of the rules referred to in Article 1(2) perpetrated through fraudulent or deceptive practices.

2. The designations provided for in paragraph 1 shall:
  - (a) follow a public selection process; and
  - (b) be limited in time or reviewed regularly.
3. European Union reference centres for the authenticity and integrity of the agri-food chain shall:
  - (a) act impartially as regards the exercise of their tasks as European Union reference centres;
  - (b) possess a high level of scientific and technical expertise in the areas governed by the rules referred to in Article 1(2) and in applied forensic science in those areas, in order to have the ability to carry out or coordinate research at the highest level on the authenticity and integrity of goods and to develop, apply and validate the methods to be used for the detection of violations of the rules referred to in Article 1(2) perpetrated through fraudulent or deceptive practices;
  - (c) have suitably qualified staff with adequate training in the areas referred to in point (b) and the necessary support staff;
  - (d) possess, or have access to, the infrastructure, the equipment and the products necessary to carry out the tasks assigned to them; and
  - (e) ensure that their staff have good knowledge of international standards and practices in the areas referred to in point (b) and that the latest research developments at national, Union and international level in those areas are taken into account in their work.

#### Article 98

#### **Responsibilities and tasks of European Union reference centres for the authenticity and integrity of the agri-food chain**

The European Union reference centres for the authenticity and integrity of the agri-food chain shall be responsible for the following supporting tasks insofar as they are included in the reference centres' annual or multiannual work programmes that have been established in conformity with the objectives and priorities of the relevant work programmes adopted by the Commission in accordance with Article 36 of Regulation (EU) No 652/2014:

- (a) providing specialised knowledge in relation to the authenticity and integrity of the agri-food chain and to the methods for detecting violations of the rules referred to in Article 1(2) of this Regulation perpetrated through fraudulent or deceptive practices, in relation to the forensic science applied to the areas governed by these rules;
- (b) providing specific analyses designed to identify the segments of the agri-food chain that are potentially subject to violations of the rules referred to in Article 1(2) of this Regulation perpetrated through fraudulent or deceptive practices and helping to develop specific official control techniques and protocols;
- (c) where necessary, performing the tasks referred to in points (a) to (h) of Article 94(2) of this Regulation, thereby avoiding duplication with the tasks of European Union reference laboratories designated in accordance with Article 93 of this Regulation;
- (d) where necessary, establishing and maintaining collections or databases of authenticated reference materials, to be used to detect violations of the rules referred to in Article 1(2) of this Regulation perpetrated through fraudulent or deceptive practices; and
- (e) disseminating research findings and technical innovations in the fields within the scope of their mission.

#### Article 99

#### **Obligations of the Commission**

1. The Commission shall publish and update, whenever necessary, the list of:
  - (a) European Union reference laboratories provided for in Article 93;

- (b) European Union reference centres for animal welfare provided for in Article 95;
  - (c) European Union reference centres for the authenticity and integrity of the agri-food chain provided for in Article 97.
2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the establishment of requirements, responsibilities and tasks for the European Union reference laboratories, the European Union reference centres for animal welfare and European Union reference centres for the authenticity and integrity of the agri-food chain in addition to those laid down in Article 93(3), Article 94, Article 95(3), Article 96, Article 97(3) and Article 98. Such delegated acts shall be limited to situations of new or emerging risks, new or emerging animal diseases or pests of plants or where new legal requirements so warrant.
3. European Union reference laboratories and European Union reference centres shall be subject to Commission controls to verify compliance with the requirements of Article 93(3), Article 94, and Articles 95(3) and 97(3).
4. If the Commission controls referred to in paragraph 3 of this Article show non-compliance with the requirements laid down in Article 93(3), Article 94, and Articles 95(3) and 97(3), the Commission shall, after having received the comments of the European Union reference laboratory or European Union reference centre:
- (a) by means of an implementing act, withdraw the designation of that laboratory or centre; or
  - (b) take any other appropriate measure.

#### Article 100

#### **Designation of national reference laboratories**

1. Member States shall designate one or more national reference laboratories for each European Union reference laboratory designated in accordance with Article 93(1).

Member States may designate a national reference laboratory also in the cases where there is no corresponding European Union reference laboratory.

A Member State may designate a laboratory situated in another Member State or in a third country that is a Contracting Party to the Agreement on the European Economic Area.

A single laboratory may be designated as a national reference laboratory for more than one Member State.

2. The requirements provided for in point (e) of Article 37(4), Article 37(5), Article 39 and Article 42(1), points (a) and (b) of Article 42(2) and Article 42(3) shall apply to national reference laboratories.

By way of derogation from point (e) of Article 37(4), for the area governed by the rules referred to in point (g) of Article 1(2), competent authorities may designate official laboratories, designated as such by the competent authorities on the basis of a derogation adopted under Article 41, as national reference laboratories irrespective of whether they fulfil the condition provided for in point (e) of Article 37(4).

3. National reference laboratories shall:

- (a) be impartial, free from any conflict of interests, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as national reference laboratories;
- (b) have, or have contractual access to, suitably qualified staff with adequate training in analytical, testing and diagnostic techniques in their area of competence, and support staff as appropriate;
- (c) possess, or have access to, the infrastructure, equipment and products needed to carry out the tasks assigned to them;
- (d) ensure that their staff and any contractually engaged staff have good knowledge of international standards and practices and that the latest developments in research at national, Union and international level are taken into account in their work;

- (e) be equipped with, or have access to, the necessary equipment to perform their tasks in emergency situations; and
  - (f) where relevant, be equipped to comply with relevant biosecurity standards.
4. Member States shall:
- (a) communicate the name and address of each national reference laboratory to the Commission, the relevant European Union reference laboratory and other Member States;
  - (b) make the information referred to in point (a) available to the public; and
  - (c) update the information referred to in point (a) whenever necessary.
5. Member States that have more than one national reference laboratory for a European Union reference laboratory shall ensure that such laboratories work closely together, so as to ensure efficient coordination between them, with other national laboratories and with the European Union reference laboratory.
6. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the establishment of requirements for national reference laboratories in addition to those laid down in paragraphs 2 and 3 of this Article. Such delegated acts shall be limited to ensuring coherence with any additional requirements adopted in accordance with Article 99(2).

#### *Article 101*

#### **Responsibilities and tasks of national reference laboratories**

1. National reference laboratories shall, in their area of competence:
- (a) collaborate with the European Union reference laboratories, and participate in training courses and in inter-laboratory comparative tests organised by these laboratories;
  - (b) coordinate the activities of official laboratories designated in accordance with Article 37(1) with a view of harmonising and improving the methods of laboratory analysis, test or diagnosis and their use;
  - (c) where appropriate, organise inter-laboratory comparative testing or proficiency tests between official laboratories, ensure an appropriate follow-up of such tests and inform the competent authorities of the results of such tests and follow-up;
  - (d) ensure the dissemination to the competent authorities and official laboratories of information that the European Union reference laboratory supplies;
  - (e) provide within the scope of their mission scientific and technical assistance to the competent authorities for the implementation of MANCPs referred to in Article 109 and of coordinated control programmes adopted in accordance with Article 112;
  - (f) where relevant, validate the reagents and lots of reagents, establish and maintain up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents;
  - (g) where necessary, conduct training courses for the staff of official laboratories designated under Article 37(1); and
  - (h) assist actively the Member State having designated them in the diagnosis of outbreaks of food-borne, zoonotic or animal diseases or of pests of plants and in case of non-compliance of consignments, by carrying out confirmatory diagnoses, characterisation and epizootic or taxonomic studies on pathogen isolates or pest specimens.
2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the establishment of responsibilities and tasks for national reference laboratories in addition to those provided for in paragraph 1 of this Article. Such delegated acts shall be limited to ensuring coherence with any additional responsibilities and tasks adopted in accordance with Article 99(2).

## TITLE IV

## ADMINISTRATIVE ASSISTANCE AND COOPERATION

*Article 102***General rules**

1. The competent authorities in the Member States concerned shall provide each other with administrative assistance in accordance with Articles 104 to 107, in order to ensure the correct application of the rules referred to in Article 1(2) in cases which have relevance in more than one Member State.
  2. Administrative assistance shall include, where appropriate, and, by agreement between the competent authorities concerned, participation by the competent authorities of a Member State in on-the-spot official controls that the competent authorities of another Member State perform.
  3. This Title shall be without prejudice to national law:
    - (a) applicable to the release of documents and information that are the object of, or related to, judicial investigations and court proceedings, including criminal investigations; and
    - (b) aimed at the protection of natural or legal persons' commercial interests.
  4. Member States shall take measures to facilitate the transmission, from other law enforcement authorities, public prosecutors and judicial authorities, to the competent authorities, of information on possible non-compliance with the rules referred to in Article 1(2) which is relevant for the application of this Title and which may constitute:
    - (a) a risk to human, animal or plant health, or to animal welfare, or, as regards GMOs and plant protection products, also to the environment; or
    - (b) a possible violation of the rules referred to in Article 1(2) perpetrated through fraudulent or deceptive practices.
  5. All communications between competent authorities in accordance with Articles 104 to 107 shall be in writing, on paper or in electronic form.
  6. In order to streamline and simplify communication exchanges, the Commission shall, by means of implementing acts, establish a standard format for:
    - (a) the requests for assistance provided for in Article 104(1); and
    - (b) the communication of common and recurrent notifications and responses.
- Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

*Article 103***Liaison bodies**

1. Each Member State shall designate one or more liaison bodies acting as contact points responsible for facilitating the exchange of communications between competent authorities in accordance with Articles 104 to 107.
2. The designation of liaison bodies shall not preclude direct contacts, exchange of information or cooperation between the staff of competent authorities in different Member States.
3. Member States shall communicate to the Commission and other Member States the contact details of their liaison bodies designated in accordance with paragraph 1, and any subsequent modification of those details.
4. The Commission shall publish and update on its website the list of liaison bodies communicated to it by the Member States in accordance with paragraph 3.
5. All requests for assistance pursuant to Article 104(1), and notifications and communications pursuant to Articles 105, 106 and 107 shall be transmitted by a liaison body to its correspondent in the Member State to which the request or the notification is addressed.



6. The Commission shall, by means of implementing acts, establish the specifications of the technical tools and the procedures for communication between liaison bodies designated in accordance with paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

#### *Article 104*

##### **Assistance on request**

1. Where the competent authorities in a Member State consider that, for the performance of official controls or for the effective follow-up to such controls in their territory, they require data or information from the competent authorities of another Member State, they shall issue a reasoned request for administrative assistance to the competent authorities of that Member State. The requested competent authorities shall:

- (a) acknowledge receipt of the request without delay;
- (b) where the requesting competent authority so specifies, indicate within ten working days from the date of receipt of the request, the estimated time necessary to provide an informed response to the request; and
- (c) perform official controls or investigations necessary to provide the requesting competent authorities without delay with all necessary information and documents to enable them to take informed decisions and verify compliance with Union rules within their jurisdiction.

2. Documents may be transmitted in their original form or copies may be provided.

3. By agreement between the requesting competent authorities and the requested competent authorities, staff designated by the former may be present during the official controls and investigations referred to in point (c) of paragraph 1 performed by the requested competent authorities.

In such cases the staff of the requesting competent authorities shall:

- (a) at all times be able to produce written authority stating their identity and their official capacity;
- (b) be granted access by the operator to the same premises and documents as the staff of the requested competent authorities, through their intermediary, and for the sole purpose of the administrative enquiry being carried out; and
- (c) not, on their own initiative, exercise the powers of enquiry conferred on officials of the requested competent authorities.

#### *Article 105*

##### **Assistance without request in the event of non-compliance**

1. When the competent authorities in a Member State become aware of a case of non-compliance, and if such non-compliance may have implications for another Member State, they shall notify such information to the competent authorities of that other Member State without being requested to do so and without undue delay.

2. The competent authorities notified in accordance with paragraph 1 shall:

- (a) acknowledge receipt of the notification without undue delay;
- (b) where the notifying competent authority so specifies, indicate within ten working days from the date of receipt of the notification:
  - (i) what investigations they intend to carry out; or
  - (ii) the reasons why they consider that no investigations are necessary; and
- (c) where investigations referred to in point (b) are considered necessary, investigate the matter and inform the notifying competent authorities without delay of the results and, where appropriate, of any measures taken.

*Article 106***Assistance in the event of non-compliance creating a risk or a repeated or potentially serious infringement**

1. Where, during official controls performed on animals or goods originating in another Member State, the competent authorities establish that such animals or goods do not comply with the rules referred to in Article 1(2) in such a way as to create a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, or to constitute a potentially serious infringement of those rules, they shall, without delay, notify the competent authorities of the Member State of dispatch and of any other concerned Member State in order to enable those competent authorities to undertake appropriate investigations.
2. The notified competent authorities shall without delay:
  - (a) acknowledge receipt of the notification;
  - (b) where the notifying competent authority so specifies, indicate what investigations they intend to carry out; and
  - (c) investigate the matter, take all necessary measures and inform the notifying competent authorities of the nature of the investigations and official controls performed, of the decisions taken and of the reasons for such decisions.
3. If the notifying competent authorities have reason to believe that the investigations performed or the measures taken by the notified competent authorities do not adequately address the non-compliance established, they shall request the notified competent authorities to complement the official controls performed or the measures taken. In such cases the competent authorities from the two Member States shall:
  - (a) seek an agreed approach with the aim of appropriately addressing the non-compliance, including through joint official controls and investigations performed in accordance with Article 104(3); and
  - (b) inform the Commission without delay where they are not able to agree on appropriate measures.
4. When official controls performed on animals or goods originating in another Member State show repeated cases of non-compliance as referred to in paragraph 1, the competent authorities of the Member State of destination shall inform the Commission and the competent authorities of the other Member States without delay.

*Article 107***Assistance on the basis of information provided by third countries**

1. When competent authorities receive information from a third country indicating non-compliance with rules referred to in Article 1(2) or a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, they shall, without delay:
  - (a) notify such information to the competent authorities in other concerned Member States; and
  - (b) communicate such information to the Commission where it is or may be relevant at Union level.
2. Information obtained through official controls and investigations performed in accordance with this Regulation may be communicated to the third country referred to in paragraph 1, provided that:
  - (a) the competent authorities which have provided the information consent to such communication;
  - (b) the third country has undertaken to provide the assistance necessary to gather evidence of practices that are or appear to be non-compliant with Union rules or that pose a risk to humans, animals or plants or the environment; and
  - (c) relevant Union and national rules applicable to the communication of personal data to third countries are complied with.

*Article 108***Coordinated assistance and follow-up by the Commission**

1. Where the competent authorities in the Member States concerned are unable to agree on appropriate action to address the non-compliance with the rules referred to in Article 1(2), the Commission shall coordinate without delay the measures and actions undertaken by competent authorities in accordance with this Title where information available to the Commission either:
  - (a) reports activities that are, or appear to be, non-compliant with the rules referred to in Article 1(2), and such activities have, or might have, ramifications in more than one Member State; or
  - (b) indicates that the same, or similar, activities that are, or appear to be, non-compliant with the rules referred to in Article 1(2) might be taking place in more than one Member State.
2. In the cases referred to in paragraph 1, the Commission may:
  - (a) in collaboration with the Member State concerned, send an inspection team to perform an on-the-spot official control;
  - (b) request, by means of implementing acts, that the competent authorities in the Member State of dispatch and, where appropriate, in other Member States concerned, appropriately intensify official controls and report to it on the measures taken by them;
  - (c) take any other appropriate measure in accordance with 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 by establishing rules for the rapid exchange of information in the cases referred to in paragraph 1.

## TITLE V

## PLANNING AND REPORTING

*Article 109***Multiannual national control plans (MANCPs) and a single body for the MANCP**

1. Member States shall ensure that official controls governed by this Regulation are performed by the competent authorities on the basis of an MANCP, the preparation and implementation of which are coordinated across their territory.
2. Member States shall designate a single body tasked with:
  - (a) coordinating the preparation of the MANCP across all competent authorities responsible for the official controls;
  - (b) ensuring that the MANCP is coherent;
  - (c) collecting the information on the implementation of the MANCP in view of submitting the annual reporting referred to in Article 113 and of its review and update as necessary in accordance with Article 111(2).

*Article 110***Content of the MANCPs**

1. MANCPs shall be prepared so as to ensure that official controls are planned in all the areas governed by the rules referred to in Article 1(2) and in accordance with the criteria laid down in Article 9 and with the rules provided for in Articles 18 to 27.
2. MANCPs shall contain general information on the structure and organisation of the systems of official control in the Member State concerned in each of the areas covered, and shall contain information on at least the following:
  - (a) the strategic objectives of the MANCP and on how the prioritisation of official controls and allocation of resources reflect these objectives;

- (b) the risk categorisation of the official controls;
- (c) the designation of competent authorities and their tasks at central, regional and local level, and on resources available to those authorities;
- (d) where appropriate, the delegation of tasks to delegated bodies;
- (e) the general organisation and management of official controls at national, regional and local level, including official controls in individual establishments;
- (f) control systems applied to different sectors and coordination between the different services of competent authorities responsible for official controls in those sectors;
- (g) procedures and arrangements in place to ensure compliance with the obligations of the competent authorities provided for in Article 5(1);
- (h) the training of staff of the competent authorities;
- (i) the documented procedures provided for in Article 12(1);
- (j) the general organisation and operation of contingency plans in accordance with the rules referred to in Article 1(2); and
- (k) the general organisation of cooperation and mutual assistance between competent authorities in the Member States.

#### *Article 111*

##### **Preparation, update and review of MANCPs**

1. Member States shall ensure that the MANCP provided for in Article 109(1) is made available to the public, with the exception of those parts of the plan the disclosure of which could undermine the effectiveness of official controls.
2. The MANCP shall be regularly updated to adjust it to changes to the rules referred to in Article 1(2), and reviewed to take account at least of the following factors:
  - (a) the emergence of new diseases, pests of plants or other risks to human, animal or plant health, animal welfare or, in the case of GMOs and plant protection products, also to the environment;
  - (b) significant changes to the structure, management or operation of the competent authorities in the Member State;
  - (c) the outcome of Member States' official controls;
  - (d) the outcome of Commission controls performed in the Member State in accordance with Article 116(1);
  - (e) scientific findings; and
  - (f) the outcome of official controls performed by the competent authorities of a third country in a Member State.
3. Member States shall provide the Commission, upon request, with the latest up-to-date version of their respective MANCP.

#### *Article 112*

##### **Coordinated control programmes and information and data collection**

With a view to conducting Union-wide targeted assessment of the state of application of the rules referred to in Article 1(2) or establishing the prevalence of certain hazards across the Union, the Commission may adopt implementing acts concerning:

- (a) the implementation of coordinated control programmes of limited duration in one of the areas governed by the rules referred to in Article 1(2);
- (b) the organisation, on an ad hoc basis, of the collection of data and information in relation to the application of a specific set of the rules referred to in Article 1(2) or regarding the prevalence of certain hazards.

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

#### *Article 113*

##### **Annual reports by the Member States**

1. By 31 August every year, each Member State shall submit to the Commission a report setting out:
  - (a) any amendments made to its MANCP to take account of the factors referred to in Article 111(2);
  - (b) the outcome of official controls performed in the previous year under its MANCP;
  - (c) the type and number of cases of non-compliance with the rules referred to in Article 1(2), per area, detected in the previous year by the competent authorities;
  - (d) the measures taken to ensure the effective operation of its MANCP, including enforcement action and the results of such measures, and
  - (e) a link to the web page of the competent authority containing the public information on fees or charges referred to in Article 85(2).
2. In order to ensure the uniform presentation of the annual reports provided for in paragraph 1, the Commission shall, by means of implementing acts, adopt and update as necessary standard model forms for the submission of the information and data referred to in that paragraph.

Those implementing acts shall, whenever possible, allow the use of the standard model forms adopted by the Commission for the submission of other reports on official controls that the competent authorities are required to submit to the Commission in accordance with the rules referred to in Article 1(2). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

#### *Article 114*

##### **Annual reports by the Commission**

1. By 31 January every year, the Commission shall make available to the public an annual report on the operation of official controls in the Member States, taking into account:
  - (a) the annual reports submitted by the Member States in accordance with Article 113; and
  - (b) the results of Commission controls performed in accordance with Article 116(1).
2. The annual report provided for in paragraph 1 may, where appropriate, include recommendations on possible improvements to official control systems in Member States and to certain official controls in certain areas.

#### *Article 115*

##### **Contingency plans for food and feed**

1. For the application of the general plan for crisis management provided for in Article 55(1) of Regulation (EC) No 178/2002, Member States shall draw up contingency plans for food and feed setting out measures to be applied without delay when food or feed is found to pose a serious risk to human or animal health either directly or through the environment.
2. The contingency plans for food and feed provided for in paragraph 1 shall specify:
  - (a) the competent authorities to be involved;
  - (b) the powers and responsibilities of the authorities referred to in point (a); and
  - (c) channels and procedures for sharing information between competent authorities and other parties concerned as appropriate.

3. Member States shall review regularly their contingency plans for food and feed to take into account changes in the organisation of the competent authorities and experience gained from implementing the plan and simulation exercises.
4. The Commission may adopt implementing acts concerning:
  - (a) rules for the establishment of the contingency plans provided for in paragraph 1 of this Article to the extent necessary to ensure the consistent and effective use of the general plan for crisis management provided for in Article 55(1) of Regulation (EC) No 178/2002; and
  - (b) the role of stakeholders in the establishment and operation of those contingency plans.

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

## TITLE VI

### UNION ACTIVITIES

#### CHAPTER I

#### **Commission controls**

##### *Article 116*

#### **Commission controls in Member States**

1. Commission experts shall perform controls, including audits, in each Member State to:
  - (a) verify the application of the rules referred to in Article 1(2) and those provided for in this Regulation;
  - (b) verify the functioning of national control systems in the areas governed by the rules referred to in Article 1(2) and those provided for in this Regulation, and of the competent authorities which operate them;
  - (c) investigate and collect information:
    - (i) on official controls and enforcement practices in the areas governed by the rules referred to in Article 1(2) and those provided for in this Regulation;
    - (ii) on important or recurring problems with the application or enforcement of the rules referred to in Article 1(2);
    - (iii) in relation to emergency situations, emerging problems or new developments in the Member States in the areas governed by the rules referred to in Article 1(2) and those provided for in this Regulation.
2. The controls provided for in paragraph 1 shall be organised in cooperation with the competent authorities of the Member States and shall be performed on a regular basis.
3. The controls provided for in paragraph 1 may include on-the-spot verifications. The Commission experts may accompany the staff of the competent authorities performing official controls.
4. Experts from the Member States may assist the Commission experts. National experts accompanying Commission experts shall be given the same rights of access as the Commission experts.

##### *Article 117*

#### **Reports by the Commission on controls in Member States**

The Commission shall:

- (a) prepare a draft report on the findings and on recommendations addressing the shortcomings identified by its experts during controls performed in accordance with Article 116(1);
- (b) send to the Member State where those controls have been performed a copy of the draft report provided for in point (a) for its comments;

- (c) take the comments of the Member State referred to in point (b) into account in preparing the final report on the findings of the controls performed by its experts in the Member States as provided for in Article 116(1); and
- (d) make publicly available the final report referred to in point (c) and the comments of the Member State referred to in point (b).

*Article 118*

**Programme of the Commission controls in Member States**

1. The Commission shall, by means of implementing acts:
  - (a) establish an annual or multiannual control programme for the controls to be performed by its experts in the Member States as provided for in Article 116(1); and
  - (b) by the end of each year, communicate to the Member States the annual control programme or any update to the multiannual control programme for the following year.
2. The Commission may, by means of implementing acts, amend its control programme to take account of developments in the areas governed by the rules referred to in Article 1(2). Any such amendment shall be communicated without delay to the Member States.

*Article 119*

**Obligations of the Member States as regards Commission controls**

Member States shall:

- (a) take appropriate follow-up measures to remedy any specific or systemic shortcomings identified through the controls performed by the Commission experts in accordance with Article 116(1);
- (b) give the necessary technical assistance and provide the available documentation, including the results of the audits referred to in Article 6, upon justified request, and other technical support that Commission experts request to enable them to perform controls efficiently and effectively; and
- (c) give the necessary assistance to ensure that the Commission experts have access to all premises or parts of premises, animals and goods, and to information, including computing systems, relevant for the execution of their duties.

*Article 120*

**Commission controls in third countries**

1. Commission experts may perform controls in third countries in order to:
  - (a) verify the compliance or equivalence of third-country legislation and systems, including official certification and the issuance of official certificates, official labels, official marks and other official attestations, with the requirements laid down in the rules referred to in Article 1(2);
  - (b) verify the capacity of the third country control system to ensure that consignments of animals and goods exported to the Union comply with relevant requirements established by the rules referred to in Article 1(2) or with requirements recognised to be at least equivalent thereto;
  - (c) collect information and data to elucidate the causes of recurring or emerging problems in relation to exports of animals and goods from a third country.
2. The controls provided for in paragraph 1 shall have particular regard to:
  - (a) the legislation of the third country;
  - (b) the organisation of the third country's competent authorities, their powers and independence, the supervision to which they are subject and the authority they have to enforce the applicable legislation effectively;

- (c) the training of staff of the competent authority of the third country in the performance of official controls;
  - (d) the resources including analytical, testing and diagnostic facilities available to competent authorities;
  - (e) the existence and operation of documented control procedures and control systems based on priorities;
  - (f) where applicable, the situation regarding animal health, animal welfare, zoonoses and plant health, and procedures for notifying the Commission and relevant international bodies of outbreaks of animal diseases and pests of plants;
  - (g) the extent and operation of controls performed by the competent authority of the third country on animals, plants and their products arriving from other third countries; and
  - (h) the assurances which the third country can give regarding compliance with, or equivalence to, the requirements laid down in the rules referred to in Article 1(2).
3. In order to facilitate the efficiency and effectiveness of the controls provided for in paragraph 1, the Commission may, prior to performing such controls, request that the third country concerned provide:
- (a) the necessary information referred to in Article 125(1); and
  - (b) where appropriate and necessary, the written records on the controls its competent authorities perform.
4. The Commission may appoint experts from Member States to assist its own experts during the controls provided for in paragraph 1.

#### *Article 121*

#### **Frequency of Commission controls in third countries**

The frequency of Commission controls in third countries referred to in Article 120 shall be determined on the basis of the following criteria:

- (a) a risk assessment of the animals and goods exported to the Union from the third country concerned;
- (b) the rules referred to in Article 1(2);
- (c) the volume and nature of animals and goods entering the Union from the third country concerned;
- (d) the outcome of controls already performed by the Commission experts or by other inspection bodies;
- (e) the outcome of official controls on animals and goods entering the Union from the third country concerned and of any other official controls that competent authorities of Member States have performed;
- (f) information received from the EFSA or similar bodies;
- (g) information received from internationally recognised bodies such as:
  - (i) the World Health Organisation;
  - (ii) the Codex Alimentarius Commission;
  - (iii) the World Organisation for Animal Health (OIE);
  - (iv) European and Mediterranean Plant Protection Organisation and any other regional plant protection organisations established under the International Plant Protection Convention (IPPC);
  - (v) the secretariat of the IPPC;
  - (vi) Organisation for Economic Cooperation and Development;
  - (vii) United Nations Economic Commission for Europe;
  - (viii) the secretariat of the Cartagena Protocol on Biosafety to the Convention on Biological Biodiversity;



- (h) evidence of emerging disease situations or other circumstances that might result in animals and goods entering the Union from a third country presenting health or environmental risks or a risk of fraudulent or deceptive practices;
- (i) the need to investigate or respond to emergency situations in individual third countries.

#### *Article 122*

### **Reports by the Commission on controls in third countries**

The Commission shall report on the findings of each control performed in accordance with Articles 120 and 121. Its report shall, where appropriate, contain recommendations.

The Commission shall make its reports publicly available.

#### *Article 123*

### **Programme of the Commission controls in third countries**

The Commission shall communicate its programme of controls in third countries to Member States in advance and shall report on the results. The Commission may amend that programme to take account of developments in the areas governed by the rules referred to in Article 1(2). Any such amendment shall be communicated to the Member States in advance.

#### *Article 124*

### **Third-country controls in Member States**

1. Member States shall inform the Commission of planned controls in the areas governed by the rules referred to in Article 1(2) on their territory, by the competent authorities of third countries.
2. Commission experts may participate in the controls referred to in paragraph 1, at the request of the competent authorities of Member States where those controls are being performed.
3. The participation by Commission experts in the controls referred to in paragraph 1 shall serve in particular to:
  - (a) provide advice on the rules referred to in Article 1(2);
  - (b) provide information and data available at Union level that may be useful for the control performed by the competent authorities of the third country;
  - (c) facilitate consistency and uniformity with regard to controls performed by the competent authorities of third countries in different Member States.

#### *CHAPTER II*

### ***Conditions for the entry into the Union of animals and goods***

#### *Article 125*

### **Information on third countries' control systems**

1. The Commission shall request third countries which intend to export animals and goods to the Union to provide the following accurate and up-to-date information on the general organisation and management of sanitary and phytosanitary control systems in their territory:
  - (a) any sanitary or phytosanitary rules adopted or proposed within their territory;
  - (b) risk-assessment procedures and factors taken into consideration for the assessment of risks and for the determination of the appropriate level of sanitary or phytosanitary protection;

- (c) any control and inspection procedures and mechanisms, including, where relevant, on animals or goods arriving from other third countries;
  - (d) official certification mechanisms;
  - (e) where appropriate, any measures taken following recommendations provided for in the first paragraph of Article 122;
  - (f) where relevant, results of controls performed on animals and goods intended to be exported to the Union; and
  - (g) where relevant, information on changes made to the structure and functioning of control systems adopted to meet Union sanitary or phytosanitary requirements or recommendations provided for in the first paragraph of Article 122.
2. The request for information referred to in paragraph 1 shall be proportionate, taking account of the nature of the animals and goods to be exported to the Union and of the specific situation in, and structure of, the third country.

#### *Article 126*

#### **Establishment of additional conditions for entry into the Union of animals and goods**

1. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the conditions to be respected by animals and goods entering the Union from third countries which are necessary to ensure that the animals and goods comply with the relevant requirements established by the rules referred to in Article 1(2), with the exception of points (d), (e), (g) and (h) of Article 1(2), or with requirements recognised to be at least equivalent thereto.
2. The conditions laid down in the delegated acts referred to in paragraph 1 shall identify animals and goods by referring to their codes from the Combined Nomenclature and may include:
- (a) the requirement that certain animals and goods shall only enter the Union from a third country or region of a third country which appears on a list drawn up by the Commission for that purpose;
  - (b) the requirement that consignments of certain animals and goods from third countries be dispatched from, and obtained or prepared in, establishments which comply with the relevant requirements referred to in paragraph 1 or with requirements recognised to be at least equivalent thereto;
  - (c) the requirement that consignments of certain animals and goods be accompanied by an official certificate, an official attestation, or by any other evidence that the consignments comply with the relevant requirements referred to in paragraph 1 or with requirements recognised to be at least equivalent thereto, including the results of the analysis performed by an accredited laboratory;
  - (d) the obligation to provide the evidence referred to in point (c) in accordance with a specific format;
  - (e) any other requirement necessary to ensure that certain animals and goods offer a level of protection of health and, as regards GMOs, also of the environment, equivalent to that ensured by the requirements referred to in paragraph 1.
3. The Commission may, by means of implementing acts, lay down rules on the format and type of official certificates, official attestations, or evidence required in accordance with the rules provided for in point (c) of paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

#### *Article 127*

#### **Inclusion in the list of third countries referred to in point (a) of Article 126(2)**

1. The inclusion of a third country or region thereof in the list referred to in point (a) of Article 126(2) shall be made in accordance with paragraphs 2 and 3 of this Article.

2. The Commission shall approve, by means of implementing acts, the request transmitted to it for the purpose referred to in paragraph 1 of this Article by the third country concerned, accompanied by appropriate evidence and guarantees that the animals and goods concerned from that third country comply with the relevant requirements referred to in Article 126(1) or with requirements equivalent thereto. Those implementing acts shall be adopted and updated in accordance with the examination procedure referred to in Article 145(2).
3. The Commission shall decide on the request referred to in paragraph 2 taking into account, as appropriate:
- (a) the third country's legislation in the sector concerned;
  - (b) the structure and organisation of the competent authorities of the third country and its control services, the powers available to them, the guarantees that can be provided with regard to the application and enforcement of the legislation of the third country applicable to the sector concerned, and the reliability of the official certification procedures;
  - (c) the performance by the competent authorities of the third country of adequate official controls and other activities to assess the presence of hazards for human, animal or plant health, for animal welfare or, in relation to GMOs and plant protection products, also for the environment;
  - (d) the regularity and rapidity of information supplied by the third country on the presence of hazards for human, animal or plant health, for animal welfare or, in relation to GMOs and plant protection products, also for the environment;
  - (e) the guarantees given by the third country that:
    - (i) conditions applied to the establishments from which animals or goods are exported to the Union comply with requirements that are equivalent to those referred to in Article 126(1);
    - (ii) a list of the establishments referred to in point (i) is drawn up and kept up to date;
    - (iii) the list of establishments referred to in point (i) and updates thereof are communicated to the Commission without delay;
    - (iv) the establishments referred to in point (i) are the subject of regular and effective controls by the competent authorities of the third country;
  - (f) the findings of controls performed by the Commission in the third country in accordance with Article 120(1);
  - (g) any other information or data on the capability of the third country to ensure that only animals or goods which provide the same or an equivalent level of protection as that afforded by the relevant requirements referred to in Article 126(1) enter the Union.
4. The Commission shall delete the reference to a third country or a region of a third country from the list referred to in point (a) of Article 126(2) where the conditions for inclusion on the list cease to be met. The procedure referred to in paragraph 2 of this Article shall apply.

#### *Article 128*

#### **Special measures regarding the entry into the Union of certain animals and goods**

1. Where, in cases other than those referred to in Article 53 of Regulation (EC) No 178/2002 and Article 249 of Regulation (EU) 2016/429, there is evidence that the entry into the Union of certain animals or goods originating from a third country, a region thereof or a group of third countries, pose a risk to human, animal or plant health or, as regards GMOs, also to the environment, or where there is evidence that widespread serious non-compliance with the rules referred to in Article 1(2) of this Regulation is taking place, the Commission shall adopt, by means of implementing acts, the measures necessary to contain such risk or put an end to the identified non-compliance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2) of this Regulation.

2. The measures referred to in paragraph 1 shall identify animals and goods by referring to their codes from the Combined Nomenclature, and may include:
- (a) the prohibition of entry into the Union of the animals and goods referred to in paragraph 1 originating in or dispatched from the third countries concerned or regions thereof;
  - (b) the requirement that the animals and goods referred to in paragraph 1 originating in or dispatched from certain third countries or regions thereof be subject, prior to dispatch, to specific treatment or controls;
  - (c) the requirement that the animals and goods referred to in paragraph 1 originating in or dispatched from certain third countries or regions thereof be subject, upon entry into the Union, to specific treatment or controls;
  - (d) the requirement that consignments of the animals and goods referred to in paragraph 1 of this Article originating in or dispatched from certain third countries or regions thereof, be accompanied by an official certificate, an official attestation, or by any other evidence that the consignment complies with requirements established by the rules referred to in Article 1(2) or with requirements recognised to be at least equivalent thereto;
  - (e) the requirement that the evidence referred to in point (d) be provided in accordance with a specific format;
  - (f) other measures necessary to contain the risk.
3. When adopting the measures referred to in paragraph 2, account shall be taken of:
- (a) the information collected in accordance with Article 125;
  - (b) any other information that the third countries concerned have provided; and
  - (c) where necessary, the results of Commission controls provided for in Article 120(1).
4. On duly justified imperative grounds of urgency relating to human health and animal health or, as regards GMOs and plant protection products, also to the protection of the environment, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 145(3).

#### *Article 129*

#### **Equivalence**

1. In the areas governed by the rules referred to in Article 1(2), with the exclusion of points (d), (e), (g), and (h) of Article 1(2), the Commission may, by means of implementing acts, recognise that measures applied in a third country, or regions thereof, are equivalent to the requirements laid down in those rules, on the basis of:

- (a) a thorough examination of information and data provided by the third country concerned pursuant to Article 125(1); and
- (b) where appropriate, the satisfactory outcome of a control performed in accordance with Article 120(1).

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

2. The implementing acts referred to in paragraph 1 shall set out the practical arrangements for the entry of animals and goods into the Union from the third country concerned, or regions thereof, and may include:

- (a) the nature and content of the official certificates or attestations that have to accompany the animals or goods;
- (b) specific requirements applicable to the entry into the Union of the animals or goods and the official controls to be performed at entry into the Union;
- (c) where necessary, procedures for drawing up and amending lists of regions or establishments in the third country concerned from which the entry of animals and goods into the Union is permitted.

3. The Commission shall, by means of implementing acts, repeal without delay the implementing acts provided for in paragraph 1 of this Article where any of the conditions for the recognition of equivalence cease to be fulfilled. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

## CHAPTER III

**Training of staff of the competent authorities and of other authorities**

## Article 130

**Training and exchange of staff**

1. The Commission may organise training activities for the staff of the competent authorities and, where appropriate, for staff of other authorities of the Member States involved in investigations of possible infringements of this Regulation and of the rules referred to in Article 1(2).

The Commission shall organise those activities in cooperation with the Member States concerned.

2. The training activities referred to in paragraph 1 shall facilitate the development of a harmonised approach to official controls and other official activities in Member States. They shall include, as appropriate, training on:

- (a) this Regulation and the rules referred to in Article 1(2);
- (b) control methods and techniques relevant for the official controls and for the other official activities of the competent authorities;
- (c) production, processing and marketing methods and techniques.

3. The training activities referred to in paragraph 1 may be open to staff of the competent authorities of third countries and may be organised outside the Union.

4. Competent authorities shall ensure that the knowledge acquired through the training activities referred to in paragraph 1 of this Article is disseminated as necessary and appropriately used in the staff training activities referred to in Article 5(4).

Training activities aimed at disseminating such knowledge shall be included in the training programmes referred to in Article 5(4).

5. The Commission may organise, in cooperation with the Member States, programmes for the exchange of staff of the competent authorities performing official controls or other official activities between two or more Member States.

Such exchange may take place through the temporary secondment of staff of the competent authorities from one Member State to the other or through the exchange of such staff between the relevant competent authorities.

6. The Commission may, by means of implementing acts, lay down rules on the organisation of the training activities referred to in paragraph 1, and of the programmes referred to in paragraph 5, of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

## CHAPTER IV

**Information management system**

## Article 131

**Information management system for official controls (IMSOC)**

1. The Commission shall, in collaboration with the Member States, set up and manage a computerised information management system for official controls (IMSOC) for the integrated operation of the mechanisms and tools through which data, information and documents concerning official controls and other official activities are managed, handled, and automatically exchanged.

2. The processing of personal data by the Member States and the Commission through the IMSOC and any one of its components shall only be carried out for the purpose of performing official controls and other official activities in accordance with this Regulation and with the rules referred to in Article 1(2).

*Article 132***General functionalities of the IMSOC**

The IMSOC shall:

- (a) allow for the computerised handling and exchange of information, data and documents necessary for the performance of official controls, resulting from the performance of official controls or the recording of the performance or outcome of official controls in all cases where this Regulation, the rules referred to in Article 1(2) or the delegated and implementing acts provided for in Articles 16 to 27 provide for the exchange among competent authorities, between the competent authorities and the Commission, and where appropriate with other authorities and the operators, of such information, data and documents;
- (b) provide a mechanism for the exchange of data, information and documents in accordance with Articles 102 to 108;
- (c) provide a tool to collect and manage the reports on official controls provided by Member States to the Commission;
- (d) allow for the production, handling and transmission, including in electronic form, of the journey log referred to in Article 5(4) of Regulation (EC) No 1/2005, of the records obtained by the navigation system referred to in Article 6(9) of that Regulation, of official certificates and of the CHED referred to in Article 56 of this Regulation; and
- (e) integrate the existing computerised systems managed by the Commission and used for the rapid exchange of data, information and documents in relation to risks to human, animal health and welfare, and plant health, as established by Article 50 of Regulation (EC) No 178/2002, Article 20 of Regulation (EU) 2016/429 and Article 103 of Regulation (EU) 2016/2031 and provide appropriate links between those systems and its other components.

*Article 133***Use of the IMSOC in the case of animals and goods subject to certain official controls**

1. In the case of animals or goods whose movements within the Union or placing on the market are subject to specific requirements or procedures established by the rules referred to in Article 1(2), the IMSOC shall enable the competent authorities at the place of dispatch and other competent authorities responsible for performing official controls on those animals or goods to exchange, in real time, data, information and documents concerning animals or goods being moved from one Member State to another and on official controls performed.

The first subparagraph of this paragraph shall not apply to goods subject to the rules referred to in points (g) and (h) of Article 1(2).

2. In the case of exported animals and goods for which Union rules apply in relation to the issuance of the export certificate, the IMSOC shall enable the competent authorities of the place of dispatch and other competent authorities responsible for performing official controls to exchange, in real time, data, information and documents concerning such animals and goods and the outcome of controls performed on those animals and goods.

3. In the case of animals or goods subject to the official controls referred to in Articles 44 to 64, the IMSOC shall:

- (a) enable the competent authorities at the border control posts and other competent authorities responsible for performing official controls on those animals or goods to exchange, in real time, data, information and documents concerning those animals and goods and on controls performed on those animals or goods;
- (b) enable the competent authorities at the border control posts to share and exchange relevant data, information and documents with customs authorities and other authorities responsible for performing controls on animals or goods entering the Union from third countries, and with operators involved in entry procedures, in accordance with the rules adopted pursuant to Articles 15(4) and 75(2) and with other relevant Union rules; and
- (c) support and operate the procedures referred to in point (a) of Article 54(3) and in Article 65(6).

4. The IMSOC shall, for the purpose of this Article, integrate the existing Traces system.

#### *Article 134*

### **The functioning of the IMSOC**

The Commission shall adopt implementing acts for the functioning of the IMSOC which lay down:

- (a) the technical specifications of the IMSOC and its system components, including the electronic data exchange mechanism for exchanges with existing national systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures;
- (b) the specific rules for the functioning of the IMSOC and of its system components to ensure protection of personal data and security of exchange of information;
- (c) the specific rules for the functioning and use of the IMSOC and of its components, including the rules to update and create the necessary links between the systems referred to in point (e) of Article 132 and in Article 133(4);
- (d) contingency arrangements to be applied in the event of unavailability of any of the functionalities of the IMSOC;
- (e) the cases where, and the conditions under which, the third countries and international organisations concerned may be granted partial access to the functionalities of the IMSOC and the practical arrangements of such access;
- (f) the cases where, and the conditions under which, the data, information and documents are to be transmitted using the IMSOC;
- (g) the rules concerning an electronic system under which electronic certificates issued by the competent authorities of third countries are to be accepted by the competent authorities; and
- (h) the cases where, and the conditions under which, exemptions from the use of the IMSOC can be granted to occasional users.

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

#### *Article 135*

### **Data protection**

1. Directive 95/46/EC and Regulation (EC) No 45/2001 of the European Parliament and of the Council (\*) shall apply to the extent that the information processed through the IMSOC contains personal data as defined in point (a) of Article 2 of Directive 95/46/EC and in point (a) of Article 2 of Regulation (EC) No 45/2001.
2. In relation to their responsibilities to transmit the relevant information to the IMSOC and the processing of any personal data that might result from that activity, the competent authorities of the Member States shall be regarded as controllers as defined in point (d) of Article 2 of Directive 95/46/EC.
3. In relation to its responsibility to manage the IMSOC and the processing of any personal data that might result from that activity, the Commission shall be regarded as controller as defined in point (d) of Article 2 of Regulation (EC) No 45/2001.
4. Member States may restrict the rights and obligations under Article 6(1), Article 10, Article 11(1) and Article 12 of Directive 95/46/EC as necessary to safeguard the interest referred to in points (d) and (f) of Article 13(1) of that Directive.
5. The Commission may restrict the rights and obligations under Article 4(1), Article 11, Article 12(1) and Articles 13 to 17 of Regulation (EC) No 45/2001 where such restriction constitutes a necessary measure to safeguard the interests referred to in points (a) and (e) of Article 20(1) of that Regulation during the period in which actions are being planned or performed to verify compliance with food or feed law or to ensure the enforcement of food or feed law in the specific case to which the information relates.

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(\*) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

*Article 136***Data security**

Member States and the Commission shall ensure that the IMSOC complies with the rules on data security adopted by the Commission under Article 17 of Directive 95/46/EC and Article 22 of Regulation (EC) No 45/2001 respectively.

## TITLE VII

## ENFORCEMENT ACTION

## CHAPTER I

***Actions by the competent authorities and penalties****Article 137***General obligations of the competent authorities as regards enforcement action**

1. When acting in accordance with this Chapter, the competent authorities shall give priority to action to be taken to eliminate or contain risks to human, animal and plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment.
2. In case of suspicion of non-compliance, the competent authorities shall perform an investigation in order to confirm or to eliminate that suspicion.
3. Where necessary, actions taken in accordance with paragraph 2 shall include:
  - (a) the performance of intensified official controls on animals, goods and operators for an appropriate period;
  - (b) the official detention of animals and goods and of any unauthorised substances or products as appropriate.

*Article 138***Actions in the event of established non-compliance**

1. Where the non-compliance is established, the competent authorities shall take:
  - (a) any action necessary to determine the origin and extent of the non-compliance and to establish the operator's responsibilities; and
  - (b) appropriate measures to ensure that the operator concerned remedies the non-compliance and prevents further occurrences of such non-compliance.

When deciding which measures to take, the competent authorities shall take account of the nature of that non-compliance and the operator's past record with regard to compliance.

2. When acting in accordance with paragraph 1 of this Article, competent authorities shall take any measure they deem appropriate to ensure compliance with the rules referred to in Article 1(2), including, but not limited, to the following:
  - (a) order or perform treatments on animals;
  - (b) order the unloading, transfer to another means of transport, holding and care of animals, quarantine periods, the postponement of the slaughter of animals, and, if necessary, order that veterinary assistance be sought;
  - (c) order treatments on goods, the alteration of labels or corrective information to be provided to consumers;



- (d) restrict or prohibit the placing on the market, the movement, the entry into the Union or the export of animals and goods; and prohibit their return to the Member State of dispatch or order their return to the Member State of dispatch;
  - (e) order the operator to increase the frequency of own controls;
  - (f) order certain activities of the operator concerned to be subject to increased or systematic official controls;
  - (g) order the recall, withdrawal, removal and destruction of goods, authorising, where appropriate, the use of the goods for purposes other than those for which they were originally intended;
  - (h) order the isolation or closure, for an appropriate period of time, of all or part of the business of the operator concerned, or its establishments, holdings or other premises;
  - (i) order the cessation for an appropriate period of time of all or part of the activities of the operator concerned and, where relevant, of the internet sites it operates or employs;
  - (j) order the suspension or withdrawal of the registration or approval of the establishment, plant, holding or means of transport concerned, of the authorisation of a transporter or of the certificate of competence of the driver;
  - (k) order the slaughter or killing of animals provided that this is the most appropriate measure to safeguard human health as well as animal health and welfare.
3. The competent authorities shall provide the operator concerned, or its representative, with:
- (a) written notification of their decision concerning the action or measure to be taken in accordance with paragraphs 1 and 2, together with the reasons for that decision; and
  - (b) information on any right of appeal against such decisions and on the applicable procedure and time limits with respect to such right of appeal.
4. All expenditure incurred under this Article shall be borne by the responsible operators.
5. The competent authorities, in the case of issuance of false or misleading official certificates or in the case of abuse of official certificates, shall take appropriate measures, including:
- (a) the temporary suspension of the certifying officer from its duties;
  - (b) the withdrawal of the authorisation to sign official certificates;
  - (c) any other measure to prevent a reoccurrence of the offences referred to in Article 89(2).

#### *Article 139*

#### **Penalties**

1. Member States shall lay down the rules on penalties applicable to infringements of this Regulation and take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, by 14 December 2019, notify those provisions to the Commission and shall notify it without delay of any subsequent amendment affecting them.
2. Member States shall ensure that financial penalties for violations of this Regulation and of the rules referred to in Article 1(2), perpetrated through fraudulent or deceptive practices, reflect, in accordance with national law, at least either the economic advantage for the operator or, as appropriate, a percentage of the operator's turnover.

#### *Article 140*

#### **Reporting of infringements**

1. Member States shall ensure that competent authorities have effective mechanisms to enable reporting of actual or potential infringements of this Regulation.

2. The mechanisms referred to in paragraph 1 shall include at least:
  - (a) procedures for the receipt of reports of infringements and their follow-up;
  - (b) appropriate protection for persons reporting an infringement against retaliation, discrimination or other types of unfair treatment; and
  - (c) protection of personal data of the person reporting an infringement in accordance with Union and national law.

## CHAPTER II

### **Union enforcement measures**

#### Article 141

#### **Serious disruption in a Member State's control system**

1. Where the Commission has evidence of a serious disruption in a Member State's control system and such disruption may constitute a widespread risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment, or result in a widespread infringement of the rules referred to in Article 1(2), it shall, by means of implementing acts, adopt one or more of the following measures, to be applied until such disruption is eliminated:
  - (a) the prohibition to make available on the market or to transport, move or otherwise handle certain animals or goods concerned by the disruption in the control system;
  - (b) special conditions for the activities, animals or goods referred to in point (a);
  - (c) the suspension of the operation of official controls in border control posts or other control points concerned by the disruption in the official control system or the withdrawal of such border control posts or other control points;
  - (d) other appropriate temporary measures necessary to contain that risk until the disruption in the control system is eliminated.

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

2. The measures referred to in paragraph 1 shall be adopted only where the Member State concerned has not corrected the situation upon request and within the appropriate time limit set by the Commission.
3. On duly justified imperative grounds of urgency relating to human and animal health or, as regards GMOs and plant protection products, also to the protection of the environment, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 145(3).

## TITLE VIII

### COMMON PROVISIONS

#### CHAPTER I

#### **Procedural provisions**

#### Article 142

#### **Amendment of Annexes and references to European standards**

1. The Commission is empowered to adopt delegated acts in accordance with Article 144 to amend this Regulation concerning amendments to Annexes II and III, in order to take into account changes to the rules referred to in Article 1(2), technical progress and scientific developments.
2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to amend this Regulation concerning the references to the European standards referred to in point (b)(iv) of Article 29, point (e) of Article 37(4) and point (a) of Article 93(3), in the event that CEN amends those standards.

*Article 143***Data protection**

1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.
2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.

*Article 144***Exercise of the delegation**

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Articles 18(7) and 21(8), Article 41, Articles 45(4) and 47(3), Article 48, Article 50(4), Article 51, and Articles 53(1), 62(3), 64(2) and (5), 77(1) and (2), 99(2), 100(6), 101(2), 126(1), 142(1) and (2), 149(2), 150(3), 154(3), 155(3) and 165(3) shall be conferred on the Commission for a period of five years from the date of entry into force of this Regulation. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
3. The delegation of power referred to in Articles 18(7) and 21(8), Article 41, Articles 45(4) and 47(3), Article 48, Article 50(4), Article 51, and Articles 53(1), 62(3), 64(2) and (5), 77(1) and (2), 99(2), 100(6), 101(2), 126(1), 142(1) and (2), 149(2), 150(3), 154(3), 155(3) and 165(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Articles 18(7) and 21(8), Article 41, Articles 45(4) and 47(3), Article 48, Article 50(4), Article 51, and Articles 53(1), 62(3), 64(2) and (5), 77(1) and (2), 99(2), 100(6), 101(2), 126(1), 142(1) and (2), 149(2), 150(3), 154(3), 155(3) and 165(3) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

*Article 145***Committee procedure**

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002, except in respect of Articles 25 and 26 of this Regulation for which the Commission shall be assisted respectively by the committees established pursuant to Regulation (EC) No 834/2007 and to Regulation (EU) No 1151/2012. Those committees shall be committees within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

## CHAPTER II

### **Transitional and final provisions**

#### *Article 146*

#### **Repeals**

1. Regulations (EC) No 854/2004 and (EC) No 882/2004, Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Decision 92/438/EEC, are repealed with effect from 14 December 2019.
2. References to the repealed acts shall be construed as references to this Regulation and shall be read in accordance with the correlation tables in Annex V.

#### *Article 147*

### **Relation with Regulation (EC) No 882/2004**

The designation of each of the European Union reference laboratories referred to in Annex VII to Regulation (EC) No 882/2004 shall remain effective until a designation of a European Union reference laboratory in the same area takes place in accordance with Article 93 of this Regulation.

#### *Article 148*

### **Relation with Regulations (EC) No 852/2004 and (EC) No 853/2004 regarding approval of food business establishments**

1. Competent authorities shall establish procedures for food business operators to follow when applying for the approval of their establishments in accordance with Regulations (EC) No 852/2004 and (EC) No 853/2004.
2. Upon receipt of an application for approval from a food business operator, the competent authority shall make an on-site visit.
3. The competent authority shall approve an establishment for the activities concerned only if the food business operator has demonstrated that it complies with the relevant requirements of food law.
4. The competent authority may grant conditional approval if it appears that the establishment meets all the infrastructure and equipment requirements. It shall grant full approval only if it appears from a new official control of the establishment, carried out within three months of granting conditional approval, that the establishment meets the other relevant requirements of food law. If clear progress has been made but the establishment still does not meet all of the relevant requirements, the competent authority may prolong the conditional approval. However, conditional approval shall not exceed a total of six months, except in the case of factory and freezer vessels flying the flag of Member States, for which such conditional approval shall not exceed a total of 12 months.
5. The competent authority shall keep the approval of establishments under review when carrying out official controls.

*Article 149***Transitional measures related to the repeals of Directives 91/496/EEC and 97/78/EC**

1. The relevant provisions of Directives 91/496/EEC and 97/78/EC which govern matters referred to in Article 47(2), Article 48, points (b), (c) and (d) of Article 51(1), point (a) of Article 53(1), Article 54(1) and (3), and point (a) of Article 58 of this Regulation shall continue to apply instead of the corresponding provisions of this Regulation until 14 December 2022 or an earlier date to be determined in the delegated act adopted in accordance with paragraph 2 of this Article.
2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to amend this Regulation concerning the date referred to in paragraph 1 of this Article. That date shall be the date of application of the corresponding rules to be established pursuant to the delegated or implementing acts provided for in Article 47(2), Article 48, points (b), (c) and (d) of Article 51(1), point (a) of Article 53(1), Article 54(1) and (3), and point (a) of Article 58.

*Article 150***Transitional measures related to the repeal of Directive 96/23/EC**

1. Competent authorities shall continue to perform the official controls necessary to detect the presence of the substances and groups of residues listed in Annex I to Directive 96/23/EC, in accordance with Annexes II, III and IV to that Directive, instead of the corresponding provisions of this Regulation, until 14 December 2022 or an earlier date to be determined in the delegated act adopted in accordance with paragraph 3 of this Article.
2. Article 29(1) and (2) of Directive 96/23/EC shall continue to apply instead of the corresponding provisions of this Regulation until 14 December 2022 or an earlier date to be determined in the delegated act adopted in accordance with paragraph 3 of this Article.
3. The Commission is empowered to adopt delegated acts in accordance with Article 144 to amend this Regulation concerning the earlier date referred to in paragraphs 1 and 2 of this Article. That date shall be the date of application of the corresponding rules to be established pursuant to the delegated or implementing acts provided for in Articles 19 and 112.

*Article 151***Amendments to Directive 98/58/EC**

Directive 98/58/EC is amended as follows:

- (1) Article 2, point (3) is replaced by the following:

‘3. “competent authorities” means competent authorities as defined in Article 3(3) of Regulation (EU) .../... of the European Parliament and of the Council (\*) (\*\*)

(\*\*) Regulation (EU) .../... of the European Parliament and of the Council of ... 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) (OJ L ... ..);

- (2) Article 6 is amended as follows:

(a) paragraph 1 is deleted;

(\*) Number of the Regulation.

(b) paragraph 2 is replaced by the following:

‘2. Member States shall submit to the Commission by 31 August each year an annual report for the previous year on the inspections carried out by the competent authority to check compliance with the requirements of this Directive. The report shall be accompanied by an analysis of the most serious findings of non-compliance and a national action plan to prevent or decrease their occurrence for the forthcoming years. The Commission shall submit summaries of those reports to the Member States.’;

(c) in paragraph 3, point (a) is deleted;

(3) Article 7 is deleted.

#### Article 152

### Amendments to Directive 1999/74/EC

Directive 1999/74/EC is amended as follows:

(1) Article 8 is amended as follows:

(a) paragraph 1 is deleted;

(b) paragraph 2 is replaced by the following:

‘2. Member States shall submit to the Commission by 31 August each year an annual report for the previous year on the inspections carried out by the competent authority to check compliance with the requirements of this Directive. The report shall be accompanied by an analysis of the most serious findings of non-compliance and a national action plan to prevent or decrease their occurrence for the forthcoming years. The Commission shall submit summaries of these reports to the Member States.’;

(c) in paragraph 3, point (a) is deleted;

(2) Article 9 is deleted.

#### Article 153

### Amendments to Regulation (EC) No 999/2001

Regulation (EC) No 999/2001 is amended as follows:

(1) Articles 19 and 21 are deleted;

(2) in Annex X, Chapters A and B are deleted.

#### Article 154

### Amendments to Regulation (EC) No 1/2005 and related transitional measures

1. Regulation (EC) No 1/2005 is amended as follows:

(1) Article 2 is amended as follows:

(a) point (d) is replaced by the following:

‘(d) “border inspection post” means a border control post as defined in Article 3(38) of Regulation (EU) .../... of the European Parliament and of the Council (\*) (\*\*)

(\*\*) Regulation (EU) .../... of the European Parliament and of the Council of... 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) (OJ L ... ..);

(\*) Number of the Regulation.

(b) point (f) is replaced the following:

‘(f) “competent authority” means competent authorities as defined in Article 3(3) of Regulation (EU) .../... (\*)’;

(c) point (i) is replaced by the following:

‘(i) “exit point” means an exit point as defined in Article 3(39) of Regulation (EU) .../... (\*)’;

(d) point (p) is replaced by the following:

‘(p) “official veterinarian” means an official veterinarian as defined in Article 3(32) of Regulation (EU) .../... (\*)’.

(2) Articles 14, 15, 16 and 21, Article 22(2), and Articles 23, 24 and 26 are deleted.

(3) Article 27 is amended as follows:

(a) paragraph 1 is deleted;

(b) paragraph 2 is replaced by the following:

‘2. Member States shall submit to the Commission by 31 August each year an annual report for the previous year on the inspections carried by the competent authority to verify compliance with the requirements of this Regulation. The report shall be accompanied by an analysis of the major deficiencies detected and an action plan to address them.’;

(4) Article 28 is deleted.

2. Articles 14, 15, 16 and 21, Article 22(2), and Articles 23, 24 and 26 of Regulation (EC) No 1/2005 shall continue to apply, instead of the corresponding provisions of this Regulation, until 14 December 2022 or an earlier date to be determined in the delegated act adopted in accordance with paragraph 3 of this Article.

3. The Commission is empowered to adopt delegated acts in accordance with Article 144 to amend this Regulation concerning the date referred to in paragraph 2 of this Article. That date shall be the date of application of the corresponding rules to be established pursuant to the delegated or implementing acts provided for in Article 21.

#### *Article 155*

#### **Amendments to Regulation (EC) No 396/2005 and related transitional measures**

1. Articles 26 and 27, Article 28(1) and (2) and Article 30 of Regulation (EC) No 396/2005 are deleted.

2. Article 26, Article 27(1) and Article 30 of Regulation (EC) No 396/2005 shall continue to apply instead of the corresponding provisions of this Regulation until 14 December 2022 or an earlier date to be determined in the delegated act adopted in accordance with paragraph 3 of this Article.

3. The Commission is empowered to adopt delegated acts in accordance with Article 144 to amend this Regulation concerning the date referred to in paragraph 2 of this Article. That date shall be the date of application of the corresponding rules to be established pursuant to the delegated or implementing acts provided for in Article 19.

#### *Article 156*

#### **Amendments to Directive 2007/43/EC**

Directive 2007/43/EC is amended as follows:

(1) In Article 2(1), points (c) and (d) are replaced by the following:

‘(c) “competent authorities” means competent authorities as defined in Article 3(3) of Regulation (EU) .../... of the European Parliament and of the Council (\*\*) (\*\*\*)’;

(\*) Number of the Regulation contained in document ST 10755/16 (2013/0140(COD)).

(\*\*) Number of the Regulation.

(d) 'official veterinarian' means an official veterinarian as defined in Article 3(32) of Regulation (EU) .../... (\*);

(\*\*\*) Regulation (EU) .../... of the European Parliament and of the Council of ... 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) (OJ L ... ..);

(2) Article 7 is amended as follows:

(a) paragraph 1 is deleted;

(b) paragraph 2 is replaced by the following:

'2. Member States shall submit to the Commission by 31 August each year an annual report for the previous year on the inspections carried out by the competent authority to check compliance with the requirements of this Directive. The report shall be accompanied by an analysis of the most serious findings of non-compliance and a national action plan to prevent or decrease their occurrence for the forthcoming years. The Commission shall submit summaries of those reports to the Member States.'

#### Article 157

### Amendments to Directive 2008/119/EC

Directive 2008/119/EC is amended as follows:

(1) In Article 2, point (2) is replaced by the following:

'2. "competent authorities" means competent authorities as defined in Article 3(3) of Regulation (EU) .../... of the European Parliament and of the Council (\*\*) (\*\*\*).

(\*\*\*) Regulation (EU) .../... of the European Parliament and of the Council of... 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) (OJ L ... ..);

(2) Article 7 is amended as follows:

(a) paragraphs 1 and 2 are deleted;

(b) paragraph 3 is replaced by the following:

'3. Member States shall submit to the Commission by 31 August each year an annual report for the previous year on the inspections carried out by the competent authority to check compliance with the requirements of this Directive. The report shall be accompanied by an analysis of the most serious findings of non-compliance and a national action plan to prevent or decrease their occurrence for the forthcoming years. The Commission shall submit summaries of those reports to the Member States.'

(3) Article 9 is deleted.

(\*) Number of the Regulation contained in document ST 10755/16 (2013/0140(COD)).

(\*\*) Number of the Regulation.



## Article 158

**Amendments to Directive 2008/120/EC**

Directive 2008/120/EC is amended as follows:

(1) In Article 2, point (10) is replaced by the following:

‘10. “competent authorities” means competent authorities as defined in Article 3(3) of Regulation (EU) .../... of the European Parliament and of the Council (\*) (\*\*).

(\*\*) Regulation (EU) .../... of the European Parliament and of the Council of... 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) (OJ L ... ..);

(2) Article 8 is amended as follows:

(a) paragraphs 1 and 2 are deleted;

(b) paragraph 3 is replaced by the following:

‘3. Member States shall submit to the Commission by 31 August each year an annual report for the previous year on the inspections carried out by the competent authority to check compliance with the requirements of this Directive. The report shall be accompanied by an analysis of the most serious findings of non-compliance and a national action plan to prevent or decrease their occurrence for the forthcoming years. The Commission shall submit summaries of those reports to the Member States.’;

(3) Article 10 is deleted.

## Article 159

**Amendments to Regulation (EC) No 1099/2009**

Regulation (EC) No 1099/2009 is amended as follows:

(1) In Article 2, point (q) is replaced by the following:

‘(q) “competent authorities” means competent authorities as defined in point (3) of Article 3 of Regulation (EU) .../... of the European Parliament and of the Council (\*) (\*\*).

(\*\*) Regulation (EU) .../... of the European Parliament and of the Council of... 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) (OJ L ... ..);

(2) Article 22 is deleted.

(\*) Number of the Regulation.

*Article 160***Amendments to Regulation (EC) No 1069/2009**

Regulation (EC) No 1069/2009 is amended as follows:

(1) Article 3 is amended as follows:

(a) point (10) is replaced by the following:

‘10. “competent authority” means competent authorities as defined in point (3) of Article 3 of Regulation (EU) .../... of the European Parliament and of the Council (\*) (\*\*).

(\*\*) Regulation (EU) .../... of the European Parliament and of the Council of... 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) (OJ L ... ..);

(b) point (15) is replaced by the following:

‘15. “transit” means transit as defined in Article 3(44) of Regulation (EU) .../... (\*\*).’;

(2) Articles 45, 49 and 50 are deleted.

*Article 161***Amendments to Regulation (EC) No 1107/2009**

Regulation (EC) No 1107/2009 is amended as follows:

(1) Article 68 is amended as follows:

(a) the first paragraph is replaced by the following:

‘Member States shall submit to the Commission by 31 August each year a report, for the previous year, on the scope and the outcome of the official controls performed in order to verify compliance with this Regulation’;

(b) the second and third paragraphs are deleted.

(2) point (n) of Article 78(1) is deleted.

*Article 162***Amendments to Regulation (EU) No 1151/2012**

Regulation (EU) No 1151/2012 is amended as follows:

(1) Article 36 is amended as follows:

(a) the heading is replaced by the following: ‘Content of official controls’;

(b) paragraphs 1 and 2 are deleted;

(\*) Number of the Regulation.

(\*\*) Number of the Regulation contained in document ST 10755/16 (2013/0140(COD)).

(c) in paragraph 3, the introductory phrase is replaced by the following:

‘3. Official controls performed in accordance with Regulation (EU) .../... of the European Parliament and of the Council (\*) (\*\*) shall cover:

(\*\*) Regulation (EU) .../... of the European Parliament and of the Council of ... 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) (O) L ... ..’;

(2) Article 37 is amended as follows:

(a) in paragraph 1, the first subparagraph is replaced by the following:

‘1. In respect of protected designations of origin, protected geographical indications and traditional specialities guaranteed that designate products originating within the Union, verification of compliance with the product specification, before placing the product on the market, shall be carried out by:

- (a) the competent authorities designated in accordance with Article 4 of Regulation (EU) .../... (\*\*); or
- (b) delegated bodies as defined in Article 3(5) of Regulation (EU) .../... (\*\*);

(b) in paragraph 3, the first subparagraph is deleted;

(c) in paragraph 4, the words ‘paragraphs 1 and 2’ are replaced by the words: ‘paragraph 2’;

(3) Article 38 is deleted;

(4) Article 39 is replaced by the following:

‘Article 39

#### **Delegated bodies performing controls in third countries**

The delegated bodies performing controls in the third countries referred to in paragraph 2(b) of Article 37 shall be accredited to the relevant harmonised standard for “Conformity assessment — Requirements for bodies certifying products, processes and services”. These delegated bodies may be accredited either by a national accreditation body outside the Union, in accordance with Regulation (EC) No 765/2008, or by an accreditation body outside the Union that is a signatory of a multilateral recognition arrangement under the auspices of the International Accreditation Forum.’

#### *Article 163*

#### **Amendments to Regulation (EU) No 652/2014**

Regulation (EU) No 652/2014 is amended as follows:

(1) Article 30(1) is replaced by the following:

‘1. To cover the costs they incur to implement the work programmes approved by the Commission, grants may be awarded to:

- (a) the European Union reference laboratories referred to in Article 93 of Regulation (EU) .../... of the European Parliament and of the Council (\*) (\*\*\*\*) and to the European Union reference centres referred to in Article 29 of Regulation (EU) 2016/1012 of the European Parliament and of the Council (\*\*\*\*);

(\*) Number of the Regulation.

(\*\*\*\*) Number of the Regulation contained in document ST 10755/16 (2013/0140(COD)).

- (b) the European Union reference centres for animal welfare referred to in Article 95 of Regulation (EU) .../... (\*);
- (c) the European Union reference centres for the authenticity and integrity of the agri-food chain referred to in Article 97 of Regulation (EU) .../... (\*).

(\*\*\*) Regulation (EU) .../... of the European Parliament and of the Council of... 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) (OJ L ... ..).

(\*\*\*\*) Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016 on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products thereof and amending Regulation (EU) No 652/2014, Council Directives 89/608/EEC and 90/425/EEC and repealing certain acts in the area of animal breeding (“Animal Breeding Regulation”) (OJ L 171, 29.6.2016, p. 66).;

- (2) the following Article is inserted:

‘Article 30a

#### **Accreditation of national reference laboratories for plant health**

1. Grants may be awarded to the national reference laboratories referred to in Article 100 of Regulation (EU) .../... (\*) for costs incurred for obtaining accreditation according to the standard EN ISO/IEC 17025 on “General requirements for the competence of testing and calibration laboratories” for the use of methods of laboratory analysis, test and diagnosis to verify compliance with the rules on protective measures against pests of plants.

2. Grants may be awarded to a single national reference laboratory in each Member State for each European Union reference laboratory for plant health, up to three years after the designation of that European Union reference laboratory.’.

#### *Article 164*

#### **Amendments to Regulation (EU) 2016/429 and related transitional provisions**

1. Regulation (EU) 2016/429 is amended as follows:

- (1) Article 4 is amended as follows:

- (a) point (33) is replaced by the following:

‘(33) “official control” means any form of control performed in accordance with Regulation (EU) .../... of the European Parliament and of the Council (\*\*) (\*\*\*);

(\*\*\*) Regulation (EU) .../... of the European Parliament and of the Council of... 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) (OJ L ... ..);

(\*) Number of the Regulation contained in document ST 10755/16 (2013/0140(COD)).

(\*\*) Number of the Regulation.

(b) point (51) is replaced by the following:

‘(51) “Traces” means a system component integrated into the IMSOC as referred to in Articles 131 to 136 of Regulation (EU) .../... (\*);’;

(c) point (53) is replaced by the following:

‘(53) “official veterinarian” means an official veterinarian as defined in Article 3(32) of Regulation (EU) .../... (\*);’;

(d) point (55) is replaced by the following:

‘(55) “competent authority” means the central veterinary authority of a Member State responsible for the organisation of official controls and any other official activities in accordance with this Regulation and Regulation (EU) .../... (\*), or any other authority to which that responsibility has been delegated;’;

(2) in Article 229, paragraph (2) is replaced by the following:

‘2. The operators responsible for the consignment in question shall present consignments of animals, germinal products and products of animal origin from third countries or territories for the purposes of official control as provided for in Article 47 of Regulation (EU) .../... (\*);’;

(3) Article 281 is deleted.

2. The following provisions shall continue to apply in relation to the matters governed by Regulation (EU) 2016/429, until the date of application of that Regulation:

(a) Article 9 of Directive 89/662/EEC;

(b) Article 10 of Directive 90/425/EEC;

(c) Article 18(1), (3), (4), (5), (6), (7) and (8) of Directive 91/496/EEC;

(d) Article 22(1), (3), (4), (5), (6) and (7) of Directive 97/78/EC.

3. Having regard to Article 14 of Regulation (EU) 2016/429 and notwithstanding the date of application provided for in that Regulation, for the purpose of Article 31(2) of this Regulation, the condition for its application shall be considered to be fulfilled already from 14 December 2019.

#### Article 165

### Amendments to Regulation (EU) 2016/2031 and related transitional provisions

1. Regulation (EU) 2016/2031 is amended as follows:

(1) Article 2, point (6) is replaced by the following:

‘(6) “competent authority” means competent authorities as defined in Article 3(3) of Regulation (EU) .../... of the European Parliament and of the Council (\*\*) (\*\*\*)’;

(\*\*\*) Regulation (EU) .../... of the European Parliament and of the Council of... 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) (OJ L ... ..);’;

(\*) Number of the Regulation contained in document ST 10755/16 (2013/0140(COD)).

(\*\*) Number of the Regulation.

- (2) Article 10 is replaced by the following:

*Article 10*

**Official confirmation by the competent authorities of the presence of a Union quarantine pest**

Where a competent authority suspects, or has received evidence concerning, the presence of a Union quarantine pest, or a pest subject to measures adopted pursuant to Article 30(1), in a part of the territory of the respective Member State where that pest was previously not known to be present, or in a consignment of plants, plant products or other objects introduced into, intended to be introduced into, or moved within the Union territory, it shall immediately take any measures necessary to confirm on the basis of a diagnosis of an official laboratory as referred to in Article 37 of Regulation (EU) .../... (\*) (“to officially confirm”), whether that pest is present or not.

Pending the official confirmation of the presence of that pest, the Member States concerned shall, where applicable, take phytosanitary measures to eliminate the risk of spread of that pest.

The suspicion or evidence referred to in the first paragraph of this Article may be based on any information received pursuant to Articles 14 and 15, or from any other source.;

- (3) in Article 11, the second paragraph is replaced by the following:

‘Notifications under the first paragraph shall be made by the single authority, as referred to in Article 4(2) of Regulation (EU) .../... (\*), of the Member State concerned and through the electronic notification system referred to in Article 103.;

- (4) in Article 25(2), point (a) is replaced by the following:

‘(a) the roles and responsibilities of the bodies involved in the execution of the plan, in case of a confirmed or suspected presence of the priority pest concerned, as well as the chain of command and procedures for the coordination of actions to be taken by competent authorities, other public authorities, as referred to in Article 4(2) of Regulation (EU) .../... (\*), delegated bodies or natural persons involved, as referred to in Article 28(1) of that Regulation, laboratories and professional operators, including the coordination with neighbouring Member States and neighbouring third countries, where appropriate.;

- (5) in Article 41, paragraph 4 is replaced by the following:

‘4. In the event that plants, plant products or other objects have been introduced into, or moved within, the Union territory in violation of paragraph 1 of this Article, Member States shall adopt the necessary measures, as referred to in Article 66(3) of Regulation (EU) .../... (\*), and shall notify the Commission and other Member States through the electronic notification system referred to in Article 103.

Where applicable, that notification shall also be made to the third country from which the plants, plant products or other objects were introduced into the Union territory.;

- (6) in Article 44, paragraph 2 is replaced by the following:

‘2. Where appropriate, the Commission shall carry out investigations in the third country concerned and in accordance with Article 120 of Regulation (EU) .../... (\*), to verify whether the conditions referred to in points (a) and (b) of the first subparagraph of paragraph 1 of this Article are fulfilled.;

- (7) in Article 49(6), the third subparagraph is replaced by the following:

‘Member States shall notify, through the electronic notification system referred to in Article 103 of this Regulation, the Commission and the other Member States of any case where the introduction of a plant, plant product or other object into the Union territory was refused, or its movement within the Union territory prohibited, because the Member State concerned considered that the prohibition referred to in point (c) of the second subparagraph of paragraph 2 of this Article was violated. Where applicable, that notification shall include the measures taken by that Member State on the plants, plant products or other objects concerned pursuant to Article 66(3) of Regulation (EU) .../... (\*).;

(\*) Number of the Regulation contained in document ST 10755/16 (2013/0140(COD)).

(8) in Article 76, paragraphs 4 and 5 are replaced by the following:

‘4. In the case of a third country which is not a contracting party to the IPPC, the competent authority shall only accept the phytosanitary certificates issued by the authorities which are competent in accordance with the national rules of that third country and notified to the Commission. The Commission shall inform the Member States and the operators, through the electronic notification system referred to in Article 103, in accordance with point (a) of Article 132 of Regulation (EU) .../... (\*), of the notifications received.

The Commission is empowered to adopt delegated acts, in accordance with Article 105, to supplement this Regulation concerning the conditions for acceptance referred to in the first subparagraph of this paragraph, to ensure the reliability of those certificates.

5. Electronic phytosanitary certificates shall only be accepted when provided through, or in electronic exchange with, the IMSOC referred to in Article 131(1) of Regulation (EU) .../... (\*);

(9) in Article 77(1), the first subparagraph is replaced by the following:

‘1. Where a phytosanitary certificate has been issued in accordance with Article 71(1), (2) and (3), and the competent authority concerned concludes that the conditions referred to in Article 76 are not fulfilled, it shall invalidate that phytosanitary certificate and ensure that it does not accompany any longer those plants, plant products or other objects concerned. In that case, and in respect of the plants, plant products or other objects concerned, the competent authority shall take one of the measures set out in Article 66(3) of Regulation (EU) .../... (\*);

(10) in Article 91(1), the second subparagraph is replaced by the following:

‘Authorised operators implementing an approved pest risk management plan may be subject to inspections with a reduced frequency, as referred to in point (b) of Article 22(3) of Regulation (EU) .../... (\*);

(11) in Article 94(1), the first subparagraph is replaced by the following:

‘1. By way of derogation from Article 87 of this Regulation, where a plant, plant product or other object, introduced into the Union territory from a third country which, for movement within the Union territory, requires a plant passport pursuant to Article 79(1) and 80(1) of this Regulation, the passport shall be issued if the checks under Article 49(1) of Regulation (EU) .../... (\*) concerning its introduction have been completed satisfactorily and have led to the conclusion that the plant, plant product or other object concerned fulfils the substantive requirements for issuance of a plant passport in accordance with to Article 85 of this Regulation and, where appropriate, Article 86 of this Regulation.’;

(12) in Article 100, paragraph 5 is replaced by the following:

‘5. Electronic phytosanitary certificates for export shall be provided through, or in electronic exchange with, the IMSOC.’;

(13) in Article 101, paragraph 6 is replaced by the following:

‘6. Electronic phytosanitary certificates for re-export shall be provided through, or in electronic exchange with, the IMSOC.’;

(14) in Article 102, paragraph 4 is replaced by the following:

‘4. The pre-export certificate shall accompany the plants, plant products and other objects concerned during their movement within the Union territory, unless the information contained in it is exchanged between the Member States concerned through, or in electronic exchange with, the IMSOC.’;

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(\*) Number of the Regulation contained in document ST 10755/16 (2013/0140(COD)).

(15) Article 103 is replaced by the following:

*'Article 103*

#### **Establishment of electronic notification system**

The Commission shall establish an electronic system for the submission of notifications by the Member States.

That system shall be connected to, and compatible with, the IMSOC.;

(16) in Article 109, paragraph 1 is replaced by the following:

*'Directive 2000/29/EC is repealed, without prejudice to Article 165(2), (3) and (4) of Regulation (EU) .../... (\*).'*

2. The relevant Articles of Directive 2000/29/EC shall continue to apply in relation to the matters governed by Article 47(2), Article 48, points (b), (c) and (d) of Article 51(1), point (a) of Article 53(1), Article 54(1) and (3), and point (a) of Article 58 of this Regulation instead of these latter provisions, until 14 December 2022 or an earlier date, after the date of application of this Regulation, to be determined in the delegated act adopted in accordance with paragraph 3 of this Article.

3. The Commission is empowered to adopt delegated acts in accordance with Article 144 to amend this Regulation concerning the date referred to in paragraph 2 of this Article.

4. Without prejudice to paragraphs 2 and 3 of this Article and the date of application provided for in Article 167(1), the Commission shall adopt the delegated acts referred to in points (a) and (e) of Article 53(1), as regards goods referred to in point (c) of Article 47(1), at the latest 12 months before their date of application.

#### *Article 166*

#### **Transitional measures for the adoption of delegated and implementing acts**

Without prejudice to the dates of application referred to in Article 167 and transitional provisions provided for in this Chapter, the Commission is empowered to adopt delegated and implementing acts provided for in this Regulation as from... [the date of entry into force referred to in Article 167(1)]. Such acts shall apply from the date of application in accordance with Article 167, without prejudice to any transitional rules provided for in this Chapter.

#### *Article 167*

#### **Entry into force and application**

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

Unless otherwise provided for in paragraphs 2 to 4, it shall apply from 14 December 2019.

2. In the area governed by the rules referred to in point (g) of Article 1(2), Article 34(1), (2) and (3), point (e) of Article 37(4) and Article 37(5) shall apply from ... [Date of entry into force of this Regulation + 5 years].

3. Articles 92 to 101 of this Regulation shall apply from ... [Date of entry into force this Regulation + 1 year], instead of Articles 32 and 33 of Regulation (EC) No 882/2004, which is repealed by this Regulation.

4. Article 163 shall apply from ... [Date of entry into force of this Regulation].

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(\*) Number of the Regulation contained in document ST 10755/16 (2013/0140(COD)).



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

Done at...

*For the Council*

*The President*

*For the European Parliament*

*The President*

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## ANNEX I

TERRITORIES REFERRED TO IN POINT 40 OF ARTICLE 3, EXCEPT FOR THE APPLICATION OF POINT (G) OF ARTICLE 1(2)

1. The territory of the Kingdom of Belgium
  2. The territory of the Republic of Bulgaria
  3. The territory of the Czech Republic
  4. The territory of the Kingdom of Denmark with the exception of the Faroe Islands and Greenland
  5. The territory of the Federal Republic of Germany
  6. The territory of the Republic of Estonia
  7. The territory of Ireland
  8. The territory of the Hellenic Republic
  9. The territory of the Kingdom of Spain with the exception of Ceuta and Melilla
  10. The territory of the French Republic
  11. The territory of the Republic of Croatia
  12. The territory of the Italian Republic
  13. The territory of the Republic of Cyprus
  14. The territory of the Republic of Latvia
  15. The territory of the Republic of Lithuania
  16. The territory of the Grand Duchy of Luxembourg
  17. The territory of Hungary
  18. The territory of the Republic of Malta
  19. The territory of the Kingdom of the Netherlands in Europe
  20. The territory of the Republic of Austria
  21. The territory of the Republic of Poland
  22. The territory of the Portuguese Republic
  23. The territory of Romania
  24. The territory of the Republic of Slovenia
  25. The territory of the Slovak Republic
  26. The territory of the Republic of Finland
  27. The territory of the Kingdom of Sweden
  28. The territory of the United Kingdom of Great Britain and Northern Ireland
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## ANNEX II

## TRAINING OF STAFF OF THE COMPETENT AUTHORITIES

## CHAPTER I

***Subject matter for the training of staff performing official controls and other official activities***

1. Different control methods and techniques, such as inspection, verification, screening, targeted screening, sampling, and laboratory analysis, testing and diagnosis
2. Control procedures
3. The rules referred to in Article 1(2)
4. Assessment of non-compliance with the rules referred to in Article 1(2)
5. The hazards in the production, processing and distribution of animals and goods
6. The different stages of production, processing and distribution, and the possible risks to human health, and where appropriate to the health of animals and plants, to the welfare of animals, to the environment
7. The evaluation of the application of HACCP procedures and of good agricultural practices
8. Management systems such as quality assurance programmes that the operators manage and their assessment in so far as these are relevant for the requirements set out in the rules referred to in Article 1(2)
9. Official certification systems
10. Contingency arrangements for emergencies, including communication between Member States and the Commission
11. Legal proceedings and implications of official controls
12. Examination of written, documentary material and other records, including those related to inter-laboratory comparative testing, accreditation and risk assessment, which may be relevant to the assessment of compliance with the rules referred to in Article 1(2); this may include financial and commercial aspects
13. Control procedures and requirements for entry into the Union of animals and goods arriving from third countries
14. Any other area necessary to ensure that official controls are performed in accordance with this Regulation

## CHAPTER II

***Subject areas for control procedures***

1. The organisation of the competent authorities and the relationship between central competent authorities and authorities to which they have conferred tasks to perform official controls or other official activities
2. The relationship between competent authorities and delegated bodies or natural persons to which they have delegated tasks related to official controls or other official activities
3. A statement on the objectives to be achieved
4. Tasks, responsibilities and duties of staff
5. Sampling procedures, control methods and techniques, including laboratory analysis, testing and diagnosis, interpretation of results and consequent decisions
6. Screening and targeted screening programmes
7. Mutual assistance in the event that official controls require more than one Member State to take action

8. Action to be taken following official controls
  9. Cooperation with other services and departments that may have relevant responsibilities or with operators
  10. Verification of the appropriateness of methods of sampling and of laboratory analysis, testing and diagnosis
  11. Any other activity or information required for the effective functioning of the official controls
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## ANNEX III

## CHARACTERISATION OF METHODS OF ANALYSIS

1. Methods of analysis and measurement results should be characterised by the following criteria:
    - (a) accuracy (trueness and precision),
    - (b) applicability (matrix and concentration range),
    - (c) limit of detection,
    - (d) limit of quantification,
    - (e) precision,
    - (f) repeatability,
    - (g) reproducibility,
    - (h) recovery,
    - (i) selectivity,
    - (j) sensitivity,
    - (k) linearity,
    - (l) measurement uncertainty,
    - (m) other criteria that may be selected as required.
  2. The precision values referred to in point 1(e) shall either be obtained from a collaborative trial which has been conducted in accordance with an internationally recognised protocol on collaborative trials (e.g. ISO 5725 'Accuracy (trueness and precision) of measurement methods and results') or, where performance criteria for analytical methods have been established, be based on criteria compliance tests. The repeatability and reproducibility values shall be expressed in an internationally recognised form (e.g. the 95 % confidence intervals as defined by ISO 5725 'Accuracy (trueness and precision) of measurement methods and results'). The results from the collaborative trial shall be published or freely available.
  3. Methods of analysis which are applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities.
  4. In situations where methods of analysis can only be validated within a single laboratory, those methods should be validated in accordance with internationally accepted scientific protocols or guidelines or, where performance criteria for analytical methods have been established, be based on criteria compliance tests.
  5. Methods of analysis adopted under this Regulation should be edited in the standard layout for methods of analysis recommended by the ISO.
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## ANNEX IV

## CHAPTER I

*Fees or charges for the official controls on consignments of animals and goods entering the Union*

- I. CONSIGNMENTS OF LIVE ANIMALS
- (a) Bovine animals, equidae, pigs, sheep, goats, poultry, rabbits and small game birds or ground game, wild boar and wild ruminants:
- EUR 55 per consignment, up to 6 tonnes, and
  - EUR 9 per tonne, over 6 and up to 46 tonnes, or
  - EUR 420 per consignment, over 46 tonnes.
- (b) Animals of other species:
- EUR 55 per consignment, up to 46 tonnes, or
  - EUR 420 per consignment, over 46 tonnes.
- II. CONSIGNMENTS OF MEAT
- EUR 55 per consignment, up to 6 tonnes, and
  - EUR 9 per tonne, over 6 and up to 46 tonnes, or
  - EUR 420 per consignment, over 46 tonnes.
- III. CONSIGNMENTS OF FISHERY PRODUCTS
- (a) Fishery products not in bulk:
- (i) EUR 55 per consignment, up to 6 tonnes; and
  - (ii) EUR 9 per tonne, over 6 and up to 46 tonnes; or
  - (iii) EUR 420 per consignment, over 46 tonnes.
- (b) Fishery products, transported as break bulk shipment:
- (i) EUR 600 per vessel, with a cargo of fishery products up to 500 tonnes;
  - (ii) EUR 1 200 per vessel, with a cargo of fishery products over 500 and up to 1 000 tonnes;
  - (iii) EUR 2 400 per vessel, with a cargo of fishery products over 1 000 and up to 2 000 tonnes;
  - (iv) EUR 3 600 per vessel, with a cargo of fishery products of more than 2 000 tonnes.
- IV. CONSIGNMENTS OF MEAT PRODUCTS, POULTRYMEAT, WILD GAME MEAT, RABBIT MEAT OR FARMED GAME MEAT
- (a) EUR 55 per consignment, up to 6 tonnes; and
  - (b) EUR 9 per tonne, over 6 and up to 46 tonnes; or
  - (c) EUR 420 per consignment, over 46 tonnes.
- V. CONSIGNMENTS OF OTHER PRODUCTS OF ANIMAL ORIGIN DIFFERENT FROM MEAT PRODUCTS FOR HUMAN CONSUMPTION
- (a) Other products of animal origin for human consumption not in bulk;
- (i) EUR 55 per consignment, up to 6 tonnes; and
  - (ii) EUR 9 per tonne, over 6 and up to 46 tonnes; or
  - (iii) EUR 420 per consignment, over 46 tonnes.

- (b) Other products of animal origin for human consumption transported as break bulk shipment:
  - (i) EUR 600 per vessel, with a cargo of products up to 500 tonnes;
  - (ii) EUR 1 200 per vessel, with a cargo of products over 500 and up to 1 000 tonnes;
  - (iii) EUR 2 400 per vessel, with a cargo of products over 1 000 and up to 2 000 tonnes;
  - (iv) EUR 3 600 per vessel, with a cargo of products of more than 2 000 tonnes.

VI. CONSIGNMENTS OF ANIMAL BY-PRODUCTS AND FEED OF ANIMAL ORIGIN

- (a) Consignment of animal by-product and feed of animal origin transported not in bulk:
  - (i) EUR 55 per consignment, up to 6 tonnes; and
  - (ii) EUR 9 per tonne, over 6 and up to 46 tonnes; or
  - (iii) EUR 420 per consignment, over 46 tonnes.
- (b) Animal by-products and feed of animal origin, transported as break bulk shipment:
  - (i) EUR 600 per vessel, with a cargo of products up to 500 tonnes;
  - (ii) EUR 1 200 per vessel, with a cargo of products over 500 and up to 1 000 tonnes;
  - (iii) EUR 2 400 per vessel, with a cargo of products over 1 000 and up to 2 000 tonnes;
  - (iv) EUR 3 600 per vessel, with a cargo products of more than 2 000 tonnes.

VII. CONSIGNMENTS OF ANIMALS AND GOODS FROM THIRD COUNTRIES TRANSITING OR TRANSHIPPED

EUR 30 for consignment increased by EUR 20 per quarter of an hour for every member of staff involved in the controls.

VIII. CONSIGNMENTS OF PLANTS, PLANT PRODUCTS AND OTHER PRODUCTS, OBJECTS AND MATERIALS CAPABLE OF HARBOURING OR SPREADING PESTS OF PLANTS

- (a) For documentary checks: EUR 7 per consignment.
- (b) For identity checks:
  - (i) EUR 7 per consignment up to a size of a truck load, a railway wagon load or the load of a container of comparable size;
  - (ii) EUR 14 per consignment bigger than the above size.
- (c) For plant health checks, in accordance with the following specifications:
  - (i) cuttings, seedlings (except forestry reproductive material), young plants of strawberries or of vegetables:
    - EUR 17,5 per consignment up to 10 000 in number,
    - EUR 0,70 per consignment for each additional 1 000 units,
    - EUR 140 per consignment maximum fee;
  - (ii) shrubs, trees (other than cut Christmas trees), other woody nursery plants including forest reproductive material (other than seed):
    - EUR 17,5 per consignment up to 10 000 in number,
    - EUR 0,44 per consignment for each additional 1 000 units,
    - EUR 140 per consignment maximum fee;
  - (iii) bulbs, corms, rhizomes, tubers, intended for planting (other than tubers of potatoes):
    - EUR 17,5 per consignment up to 200 kg of weight,
    - EUR 0,16 per consignment for each additional 10 kg,
    - EUR 140 per consignment maximum fee;

- (iv) seeds, tissue cultures:
  - EUR 7,5 per consignment up to 100 kg of weight,
  - EUR 0,175 per consignment for each additional 10 kg,
  - EUR 140 per consignment maximum fee;
- (v) other plants intended for planting, not specified elsewhere in this point:
  - EUR 17,5 per consignment up to 5 000 in number,
  - EUR 0,18 per consignment for each additional 100 units,
  - EUR 140 per consignment maximum fee;
- (vi) cut flowers:
  - EUR 17,5 per consignment up to 20 000 in number,
  - EUR 0,14 per consignment for each additional 1 000 units,
  - EUR 140 per consignment maximum fee;
- (vii) branches with foliage, parts of conifers (other than cut Christmas trees):
  - EUR 17,5 per consignment up to 100 kg of weight,
  - EUR 1,75 per consignment for each additional 100 kg,
  - EUR 140 per consignment maximum fee;
- (viii) cut Christmas trees:
  - EUR 17,5 per consignment up to 1 000 in number,
  - EUR 1,75 per consignment for each additional 100 units,
  - EUR 140 per consignment maximum fee;
- (ix) leaves of plants, such as herbs, spices and leafy vegetables:
  - EUR 17,5 per consignment up to 100 kg of weight,
  - EUR 1,75 per consignment for each additional 10 kg,
  - EUR 140 per consignment maximum fee;
- (x) fruits, vegetables (other than leafy vegetables):
  - EUR 17,5 per consignment up to 25 000 kg of weight,
  - EUR 0,7 per consignment for each additional 1 000 kg,
- (xi) tubers of potatoes:
  - EUR 52,5 per lot up to 25 000 kg of weight,
  - EUR 52,5 per lot for each additional 25 000 kg;
- (xii) wood (other than bark):
  - EUR 17,5 per consignment up to 1 000 m<sup>3</sup> of volume,
  - EUR 0,175 per consignment for each additional 10 m<sup>3</sup>;
- (xiii) soil and growing medium, bark:
  - EUR 17,5 per consignment up to 25 000 kg of weight,
  - EUR 0,7 per consignment for each additional 1 000 kg,
  - EUR 140 per consignment maximum fee;



- (xiv) grain:
  - EUR 17,5 per consignment up to 25 000 kg of weight,
  - EUR 0,7 per consignment for each additional 1 000 kg,
  - EUR 700 per consignment maximum fee;
- (xv) other plants or plant products not specified elsewhere in this point:
  - EUR 17,5 per consignment.

Where a consignment does not consist exclusively of products coming under the description of the relevant indent, those parts thereof consisting of products coming under the description of the relevant indent (lot or lots) shall be treated as a separate consignment.

## CHAPTER II

### ***Fees or charges for the official controls in slaughterhouses, cutting plants, game-processing plants, milk production and producing and placing on the market fishery products and aquaculture products***

#### I. FEES OR CHARGES FOR THE OFFICIAL CONTROLS IN SLAUGHTERHOUSES

- (a) Beef meat:
  - (i) adult bovine animals: 5 EUR/animal;
  - (ii) young bovine animals: 2 EUR/animal;
- (b) solipeds/equidae meat: 3 EUR/animal;
- (c) pigmeat: animals of a carcass weight:
  - (i) of less than 25 kg: 0,5 EUR/animal;
  - (ii) equal to or greater than 25 kg: 1 EUR/animal;
- (d) sheepmeat and goatmeat: animals of a carcass weight:
  - (i) of less than 12 kg: 0,15 EUR/animal;
  - (ii) equal to or greater than 12 kg: 0,25 EUR/animal;
- (e) poultrymeat:
  - (i) poultry of genus *Gallus* and guinea fowl: 0,005 EUR/animal;
  - (ii) ducks and geese: 0,01 EUR/animal;
  - (iii) turkeys: 0,025 EUR/animal;
  - (iv) farmed rabbit meat: 0,005 EUR/animal;
  - (v) quails and partridges: 0,002 EUR/animal.

#### II. FEES OR CHARGES FOR THE OFFICIAL CONTROLS IN CUTTING PLANTS

Per tonne of meat:

- (a) beef, veal, pig, solipeds/equidae, sheep and goatmeat: 2 EUR;
- (b) poultry and farmed rabbit meat: 1,5 EUR;
- (c) farmed and wild game meat:
  - small game birds and ground game: 1,5 EUR,
  - ratites (ostrich, emu, nandou): 3 EUR,
  - boar and ruminants: 2 EUR.

## III. FEES OR CHARGES FOR THE OFFICIAL CONTROLS IN GAME-PROCESSING PLANTS

- (a) small game birds: 0,005 EUR/animal;
- (b) small ground game: 0,01 EUR/animal;
- (c) ratites: 0,5 EUR/animal;
- (d) land mammals:
  - (i) boar: 1,5 EUR/animal;
  - (ii) ruminants: 0,5 EUR/animal.

## IV. FEES OR CHARGES FOR THE OFFICIAL CONTROLS ON MILK PRODUCTION

- (a) 1 EUR per 30 tonnes;
- and
- (b) 0,5 EUR/tonne thereafter.

## V. FEES OR CHARGES FOR THE OFFICIAL CONTROLS ON PRODUCING AND PLACING ON THE MARKET FISHERY PRODUCTS AND AQUACULTURE PRODUCTS

- (a) First placing on the market of fishery and aquaculture products:
    - (i) 1 EUR/tonne for the first 50 tonnes in the month;
    - (ii) 0,5 EUR/tonne thereafter.
  - (b) First sale in fish market
    - (i) 0,5 EUR/tonne for the first 50 tonnes in the month;
    - (ii) 0,25 EUR/tonne thereafter;
  - (c) First sale in case of lack of or insufficient gradation for freshness and/or size:
    - (i) 1 EUR/tonne for the first 50 tonnes in the month;
    - (ii) 0,5 EUR/tonne thereafter.
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