The European Parliament,

— having regard to the Commission proposal to Parliament and the Council (COM(2013)0265),

— having regard to Article 294(2) and Articles 43(2), 114 and 168(4)(b) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0123/2013),

— having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

— having regard to the reasoned opinion submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Luxembourg Chamber of Deputies, asserting that the draft legislative act does not comply with the principle of subsidiarity,

— having regard to the opinion of the European Economic and Social Committee of 16 October 2013 (1),

— having regard to the opinion of the Committee of the Regions of 29 November 2013 (2),

— having regard to Rule 55 of its Rules of Procedure,

— having regard to the report of the Committee on Environment, Public Health and Food Safety and the opinion of the Committee on Agriculture and Rural Development (A7-0162/2014),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

(2) OJ C 114, 15.4.2014, p. 96.

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 and point (b) of Article168(4) 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 (1),

Having regard to the opinion of the Committee of the Regions (2),

Acting in accordance with the ordinary legislative procedure (3),

Whereas:

(1) The Treaty on the Functioning of the European Union ('Treaty') requires a high level of human health protection to be ensured in the definition and implementation of all 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 direct objective the protection of human health.

(2) The Treaty 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 food chain or on the protection of consumers interests in relation to food and food information are carried out in accordance with specific requirements. Union rules exist also to ensure a high level of human, animal and plant health and animal welfare along the 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) and plant protection products. Union rules also guarantee the identity and quality of plant reproductive material. The correct application of those rules, hereinafter collectively referred to as 'Union agri-food chain legislation', contributes to the functioning of the internal market. [Am. 2]
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 (1). In addition to those 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.

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 in animals and animal products and to avoid the spread of infectious diseases of Union concern. It covers areas such as 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.

Article 13 of the Treaty recognises that animals are sentient beings. Union legislation on animal welfare requires animal owners, animal keepers and competent authorities to respect animal welfare requirements guaranteeing their humane treatment and avoiding their unnecessary pain and suffering. Such rules are based on scientific evidence and may indirectly improve the quality and safety of food and feed.

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 guaranteeing the quality and safety of food and feed made from plants.

Union legislation on plant reproductive material regulates the production with a view to placing on the market, and the placing on the market, of plant reproductive material of agricultural, vegetable, forest, fruit and ornamental species and vines. The objective of those rules is to ensure the identity, health and quality of plant reproductive material for its users, and the productivity, diversity, health and quality of the agri-food chain as well as contributing to the protection of biodiversity and the environment. [Am. 3]

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.

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.

Union agri-food chain legislation is based on the principle that operators at all stages of production, processing and distribution within the businesses under their control are responsible for ensuring that the requirements established by Union agri-food chain legislation and which are relevant to their activities are fulfilled.

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.

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Regulation (EC) No 882/2004 of the European Parliament and of the Council (1) 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.

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 Union legislation on plant reproductive material and in 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 (2). 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 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 (3). [Am. 4]

Council Directive 96/23/EC (4) also provides for a very detailed set of rules that establish, inter alia, minimum frequencies of official controls and specific enforcement measures to be adopted in cases of non-compliance.

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 should be more closely integrated, provided that they pursue the same objective with regard to control activities. For that purpose, Regulation (EC) No 882/2004 and other acts currently governing official controls in specific areas should be repealed and replaced by this Regulation. [Am. 5]

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 their application.

For the verification of compliance with the rules on the common organisation of the markets of agricultural products such as 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 the provisions of Council Regulation (EC) No 1234/2007 (5), with the exception of Part II, Title II, Chapter I of that Regulation. [Am. 6]

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.

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Union agri-food chain legislation entrusts the competent authorities of the Member States with specialised tasks to be carried out, not least 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, and in order to ensure the identity and a high quality of plant reproductive material. 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 risks which may arise for human, animal or plant health, animal welfare, or for the environment. Those activities, which include product approval, surveying, surveillance and monitoring, including for epidemiologic purposes, and the eradication and containment of diseases, and other disease control tasks, are governed by the same sectoral rules which are enforced through the official controls. [Am. 7]

Competent authorities should be designated by the Member States in all the areas falling within the scope of this Regulation. While Member States are best placed to decide which competent authority or authorities to designate for each area, and at which level of the administration, they should also be required to designate a single authority that in each area ensures appropriately coordinated communication with other Member States' competent authorities and with the Commission. [Am. 8]

Member States should be allowed to confer upon designated competent authorities the responsibility for official controls in relation to Union rules, including rules regarding alien species which may harm agricultural production or the environment by their invasive character, other than those falling within the scope of this Regulation.[Am. 9]

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 public authorities which act in the public interest, and ensure the quality, consistency and effectiveness of official controls. The designated competent authority, or authorities, should be appropriately resourced and equipped, and offer guarantees of Member States should be able to guarantee their impartiality and professionalism. Competent authorities should ensure the quality, consistency and effectiveness of official controls, by ensuring their independence from any operator operating within the agri-food chain. [Am. 10]

The correct application and enforcement of the rules falling within the scope of this Regulation requires appropriate knowledge of both such rules and the rules of this Regulation. It is therefore important that the staff performing official controls and other official activities are regularly trained on the applicable legislation, according to their area of competence, as well as on the obligations resulting from this Regulation. [Am. 11]

The audits undertaken by the competent authorities, or at the request of the competent authorities, to ensure compliance with this Regulation may be based on international standards, where the requirements of those standards correspond to the requirements of this Regulation. [Am. 12]

Operators should have a the right to appeal against the decisions taken by the competent authorities, and be informed of such a. The competent authorities are to inform operators of this right. [Am. 13]
Competent authorities should perform official controls regularly, 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 situations. In some cases, however, Union agri-food chain legislation requires that official controls be performed irrespective of the level of risk or expected non-compliance in view of the issuance of an official certificate or attestation which is a pre-requisite for the placing on the market or for the movements of animals or goods. In such cases the frequency of the official controls is dictated by the certification or attestation needs.

To preserve the effectiveness of official controls in the verification of compliance, no warning should be given prior to performing controls, unless the nature of the official control activities requires otherwise, as is the case in particular for audit activities.

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 what is necessary for the performance of efficient and effective official controls.

Official controls should be performed by staff free from any conflict of interests, and in particular not engaged, directly or through a spouse, in an economic activity that is subject to the official controls laid down.

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 of animals and goods which are to be moved or placed on the market in another Member State or exported outside the Union. In the latter case, 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.

To ensure that the Union agri-food chain rules are 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 such rules. 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 agri-food chain rules (for example, of veterinary medicinal products) insofar as this is necessary to fully investigate possible violations of those rules and to identify the cause of any such violation.

The competent authorities act in the interest of operators and of the general public by 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 rules is ascertained across the entire agri-food chain through official controls. The competent authorities 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 therefrom. 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.

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(33) It is of the utmost importance that competent authorities 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 detailed information and instructions to staff performing official controls. They should also have appropriate procedures and mechanisms in place to continuously verify that their own action is effective and consistent, and take corrective action when shortcomings are identified.

(34) To facilitate the identification of non-compliance and streamline the taking of corrective action by the operator concerned, the outcome of official controls which identify non-compliance with the rules should be recorded in a report. A copy of that report should also be given to the operator. Where official controls require the continuous or regular presence of the staff of the competent authorities to monitor the operator's activities, a report of each individual inspection or visit to the operator would be disproportionate. In such cases, reports should be prepared with a frequency that enables the competent authorities and the operator to be regularly informed of the level of compliance and immediately notified of any identified shortcomings. In the interests of reducing the administrative burden, it should also be sufficient to record the outcome of official controls at border control posts in the Common Health Entry Document. [Am. 13]

(35) Operators should cooperate fully with competent authorities and delegated bodies to ensure the smooth performance of official controls and to enable the competent authorities to perform other official activities.

(36) This Regulation establishes a single legislative framework for the organisation of official controls to verify compliance with agri-food chain rules in all the areas that such rules cover. 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, 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 minimum frequencies for those controls, specific or additional measures to those provided for in this Regulation that competent authorities should take in relation to non-compliances, 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 mechanisms 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 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.

(37) The competent authorities should be able to delegate some of their tasks to other bodies. Appropriate conditions should be laid down to guarantee 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 ISO standard for the performance of inspections.

(38) 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 state-of-the-art 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 the International Organisation for Standardisation (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 rules.
Operators whose animals or goods are subject to sampling, analysis, test or diagnosis in the context of official controls should have the right to apply for a second expert opinion which should include the taking of a second sample for the purposes of counter-analysis, counter-test or counter-diagnosis unless any such second sampling 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. The IPPC for that reason rejects the use of counter-samples for assessing the presence of quarantine organisms in plants or plant products.

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.

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 ‘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 (1).

While accreditation is the instrument of choice to ensure state-of-the-art 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, in cases where the analyses or tests performed only concern qualitative aspects of plant reproductive material, 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.

In order to ensure flexibility and proportionality of 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. Moreover, accreditation of a laboratory for all the methods it should use as official laboratory might not be immediately available in certain cases where new or recently modified methods should be used, and 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.

Official controls performed on animals and goods entering the Union from third countries are of key importance to ensure that they comply with legislation applicable within the Union and, in particular, with the rules established to protect across the Union human, animal and plant health, animal welfare and, as regards GMOs and plant protection products, the environment. Such official controls should take place as appropriate before or after the animals or goods are released for free circulation within the Union. The frequency of official controls should adequately address risks to health, animal welfare and to the environment, that animals and goods entering the Union could pose, taking into account the history of compliance with the requirements provided for in Union agri-food chain rules, 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.

Given the risks to human, animal or plant health, animal welfare or to the environment that certain animals or goods may pose, those animals or goods should be subject to specific official controls to be performed upon them at 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 phyto-sanitary requirements. Increased controls at 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 the provisions of Council Directive 97/78/EC (1), Council Directive 91/496/EEC (2), Council Directive 2000/29/EC (3) and Commission Regulation (EC) No 669/2009 (4), should be provided for in this Regulation.

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 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 at their entry into the Union.

Official controls performed at border control posts should include documentary and identity checks on all consignments and physical checks performed at a frequency dependent on the risk posed by each consignment of animals or goods.

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, to the environment. This approach should enable the competent authorities to allocate control resources 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 of the consignments entering the Union. The risk-based approach to identity and physical checks should be pursued by making full use of available data sets and information, and of computerised data collection and management systems.

In certain cases, and as long as high levels of human, animal and plant health, animal welfare and protection of the environment in relation to GMOs and plant protection products are guaranteed, official controls normally performed by competent authorities at border control posts could be performed at other control points or by other authorities.

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 result 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.

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 entities should be withdrawn or suspended when they no longer comply with those requirements or when their activities may pose a risk to human, animal or plant health, animal welfare or, in the case of GMOs and plant protection products, to the environment.

To guarantee 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 case of suspicion of non-compliance, and in relation to non-compliant consignments and of consignments which could pose a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment.

In order to avoid inconsistencies and duplications of the official controls effort, to allow consignments which are subject to official controls at border control posts to be timely identified, and to guarantee that controls are performed in an efficient manner, the cooperation and exchange of information amongst competent authorities, customs authorities and other relevant authorities dealing with consignments arriving from third countries should be ensured.

Member States should be required to 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 rules, the system of own controls that they put in place for that purpose needs to 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, at a level appropriate to the enforcement needs at any given moment. To reduce the dependency of the official control system from public finances, competent authorities should be able to collect fees or contributions to costs 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 and plant reproductive material. Fees or contributions to costs 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. [Am. 14]

Fees should cover, but not exceed, the costs incurred by the competent authorities to perform 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 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 will choose for the calculation of the fees, when these are calculated on the basis of overall costs incurred by the competent authorities over a given period of time, and charged on all operators irrespective of whether they are subject to an official control during the reference period, those fees should be calculated so as to reward operators with a consistent good record of compliance with Union food chain legislation.

The direct or indirect refund of fees collected by the competent authorities should be prohibited as it would put operators not benefitting from the refund at a disadvantage and potentially create distortions of competition. However, in order to provide support to micro-enterprises, these should be exempted from the payment of the fees collected in accordance with this Regulation.

The financing of official controls through fees collected from operators should occur in full transparency, so as to enable citizens and businesses to understand the method and data used to establish fees and be informed on the use of fees revenue.
Union agri-food chain rules establish 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.

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 should 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. It is appropriate to lay down a minimum set of rules ensuring that also the issuance of official attestations is performed according to appropriate guarantees of reliability.

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 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.

Regulations (EC) No 1829/2003 (\(^2\)) and (EC) No 1831/2003 (\(^2\)) of the European Parliament and of the Council 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. Experience shows that knowledge and expertise in the testing, evaluation and validation of methods in the context of the authorisation procedure is crucial in order to provide a high-level, state-of-the-art contribution to the efficiency of official controls. Laboratories designated as such under Regulations (EC) No 1829/2003 and (EC) No 1831/2003 should therefore act as European Union reference laboratories for the purposes of this Regulation. [Am. 16]

For the performance of official controls and other official activities on the production and marketing of plant reproductive material 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 areas. For that purpose the Commission should be able to designate, and rely on the expert assistance of, European Union reference centres for plant reproductive material and for animal welfare. [Am. 17]

In order to pursue the objectives of this Regulation and contribute to the smooth functioning of the internal market, ensuring consumer confidence in it, non-compliances with Union 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 by 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 food, or in the case of food fraud, for the purpose of enabling rapid measures to be taken to counter those risks. However, that instrument, while allowing for timely action across all Member States concerned to counter certain serious risks along the 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 agri-food chain rules. [Am. 18]

(63) 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 streamline and simplify cooperation amongst Member States the Commission should 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.

(64) Each Member State should be required to set up and regularly update a multi-annual 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 risk-based and efficient manner across their territory and across the entire agri-food chain, and in compliance with this Regulation.

(65) In order to guarantee the coherence and completeness of MANCPs Member States should designate a single authority responsible for their coordinated preparation and implementation. In order to promote a consistent, uniform and integrated approach to official controls, the Commission should have the power to adopt rules concerning MANCPs which should identify priorities for official controls, effective control procedures, criteria for risk categorisation and performance indicators for assessing MANCPs.

(66) 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 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, the Commission should be able to adopt implementing acts in respect of establishing standard model forms for annual reports.

(67) Commission experts should be able to perform controls in Member States to verify the application of 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.

(68) 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 rules. This principle is enshrined in 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. Concerning plant reproductive material, an equivalence system is in place whereby third countries from which plant reproductive material can be imported are authorised and listed.

(69) 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 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.

(70) 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, 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.

(71) 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, 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 be also addressed to staff of the competent authorities in third countries.

(72) 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 of staff tasked with official controls or other official activities.

(73) 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 Decision 2003/24/EC (1) and currently used for the management of data and information on animals and products of animal origin and official controls thereon. That system should be upgraded and adapted so as to allow its use for all goods for which Union agri-food chain legislation establishes specific requirements or official control modalities. 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 food chain or for animal and plant health. Regulation (EC) No 178/2002 establishes the RASFF, Regulation (EU) …/… (1*) a system for the notification and reporting on the measures on listed diseases and on food fraud, and Regulation (EU) …/… (1**) a system for the notification and reporting of the presence of pests and the notification of non-compliances. All such systems should work in a harmonious, consistent manner that makes use of synergies between the different systems, avoids duplications, simplifies their operation and makes them more efficient. [Am. 19]

(74) 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

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(1*) Number, date, title and, in a footnote, the OJ reference for the Regulation on animal health.

(1**) Number, date, title and, in a footnote, the OJ reference for the Regulation on protective measures against pests of plants.
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 of such computerised system with other information systems operated by public authorities and through which relevant data is exchanged or made available. Moreover, the possibility to use the electronic signatures within the meaning of Directive 1999/93/EC of the European Parliament and the Council (1) should be laid down, in line with the Digital Agenda for Europe.

(74a) In order to minimise administrative burdens and control costs and in order to allow the Union and its Member States to effectively communicate electronically in trade relations with third countries, it is necessary that when exchanging electronic certificates or other electronic data, the Commission and the competent authorities of the Member States use internationally standardised language, message structure and exchange protocols based on guidance for electronic certification in standardised World Wide Web Consortium (W3C) Extensible Markup Language (XML schemas) as well as secure exchange mechanisms between competent authorities as is provided by the UN Centre for Trade Facilitation and Electronic Business (UN/CEFACT). [Am. 20]

(75) The competent authorities should investigate cases where there is a suspicion of non-compliance with Union agri-food legislation and, where non-compliance is established, determine its origin and extent as well as the operators’ responsibilities. They should also take appropriate measures to ensure that the operators concerned remedy the situation and to prevent further non-compliance.

(76) The verification of compliance with 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. Failures 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 and, as regards GMOs and plant protection products, to the environment, independently of the involvement or responsibility of operators or other actors, or lead to situations of serious widespread non-compliance with food chain rules. The Commission should therefore be able to react to serious failures in a Member State’s control system by adopting measures aimed at containing or eliminating those risks from the agri-food chain pending the necessary action to be taken by the concerned Member State to make good the failure in the control system.

(77) Infringements of the rules should be subject to effective, dissuasive and proportionate sanctions at national level throughout the Union. For financial penalties applicable to intentional infringements to be sufficiently dissuasive, they should be set at a level which is likely to offset of at least double the economic advantage sought by the perpetrator through the violation. Member States should also be required to apply appropriate criminal or administrative penalties, or both, in cases where operators fail to cooperate during an official control. [Am. 21]

(77a) Account should be taken of the specific needs of the developing countries, in particular the least developed countries, which should be given support in organising their official controls so that they can meet the criteria for the import of animals and goods into the Union. [Am. 22]


(80) Regulation (EU) No .../... (*) provides a framework for the Union's financing of actions and measures across the agri-food chain in those areas under the multi-annual 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 .../... (**) should be amended to take account of the changes introduced by this Regulation to Regulation (EC) No 882/2004.

(81) 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, inter alia, 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 and physical checks, on the establishment of conditions to be met by certain animals or goods entering the Union from third countries, on additional requirements and tasks of European Union reference laboratories and centres, on additional requirements for national reference laboratories, on criteria for risk categorisation and for performance indicators for the MANCPs, and on the contingency plans for food and feed provided for in Regulation (EC) No 178/2002, the power to adopt acts in accordance with Article 290 of the Treaty 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. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(82) In order to ensure uniform conditions for the implementation of this Regulation, including, inter alia, rules and modalities 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 products 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, 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 (1).

(83) In order to ensure uniform conditions for the implementation of this Regulation, including, inter alia, rules and modalities 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 products 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, 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 (1).

(*) Number, date, title and, in the footnote, the OJ reference for the Regulation 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.

(**) Number of the Regulation 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.

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 rules, cannot be sufficiently achieved by the Member States but can therefore, 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 exceed what is necessary in order to achieve that objective.

HAVE ADOPTED THIS REGULATION:

Title 1
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 performed 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 Commission controls in Member States and in third countries;

(e) the adoption of conditions to be met by 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 following rules, whether established at Union level or by the Member States to apply Union legislation in those areas:

(a) governing food and food safety, food quality and food wholesomeness, at any stage of production, the processing and distribution of food, including rules aimed at guaranteeing 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) governing the deliberate release into the environment and the contained use of GMOs;

(c) governing feed and feed safety, at all stages of production, processing and distribution of feed and the use of feed, including rules aimed at guaranteeing fair practices in trade and protecting consumer health, interests and information;

(d) laying down animal health requirements;

(e) aiming at preventing and minimising risks to human and animal health arising from animal by-products and derived products;

(ea) aiming at preventing and minimising antimicrobial resistance in animals and humans, as well as in the environment;

(f) laying down welfare requirements for animals;
(g) on protective measures against pests of plants;
(h) on the production, with a view to placing on the market, and placing on the market of plant reproductive material;
(i) laying down requirements for the placing on the market and use of plant protection products and the sustainable use of pesticides;
(j) governing organic production and labelling of organic products;
(k) on the use and labelling of protected designations of origin, protected geographical indications and traditional specialties guaranteed;

(ka) laying down requirements on monitoring certain substances and residues thereof in live animals and animal products. [Ams. 25, 26 and 27]

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 applicable to animals and goods:
(a) entering the Union from third countries;
(b) to be exported to third countries.

4. This Regulation shall not apply to official controls for the verification of compliance with:
(a) Regulation (EC) No 1234/2007 in areas other than those under Part II, Title II, Chapter I of that Regulation. However, this Regulation shall apply to official controls on protected designations of origin and protected geographical indications for wine. [Am. 28]
(b) Directive 2010/63/EU of the European Parliament and of the Council (1);


5. Articles 3 to 5, Article 7, Article 11(2) and (3), Article 14, Articles 30 to 33, Articles 36 to 41, Article 76, Titles III and IV, and Articles 129 and 136 of this Regulation 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
Definitions

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

(1) ‘official control’ means any form of control, also including controls of requirements for animals and goods from third countries intended for export to third countries, that the competent authorities perform for the verification of compliance with: [Am. 30]

(a) this Regulation;
(b) the rules referred to in Article 1(2);

(2) ‘other official activities’ means any activity, other than an official control, which is performed by competent authorities in accordance with:

(a) this Regulation;

(b) the rules referred to in article 1(2), except letter (g), to ensure the application of those rules; [Am. 31]

(3) ‘food law’ means food law as defined in point (1) of Article 3 of Regulation (EC) No 178/2002;

(4) ‘feed law’ means the laws, regulations and administrative provisions governing feed in general and feed safety in particular, whether at Union or national level; it covers all stages of production, processing and distribution of feed and the use of feed;

(5) ‘competent authorities’ means:

(a) the central authorities of a Member State responsible for the organisation of organising and carrying out official controls and of other official activities, in accordance with such as issuing certificates and attestations, appointing laboratories, exchanging information in the interest of cooperation between authorities, and taking decisions on measures to remedy breaches of 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;

(6) ‘animals’ means animals as defined in point (1) of Article 4(1) of Regulation (EU) No …/… (*) with the exception of ‘pets’; [Am. 33]

(7) ‘goods’ means any good subject to one or more of the rules referred to in Article 1(2), excluding animals;

(8) ‘food’ means food as defined in Article 2 of Regulation (EC) No 178/2002;

(9) ‘feed’ means feed as defined in point (4) of Article 3 of Regulation (EC) No 178/2002;

(10) ‘animal by-products’ means animal by-products as defined in point (1) of Article 3 of Regulation (EC) No 1069/2009;

(11) ‘derived products’ means derived products as defined in point (2) of Article 3 of Regulation (EC) No 1069/2009;

(12) ‘pests’ means pests as defined in Article 1(1) of Regulation (EU) No …/… (**) ;

(13) ‘plants’ means plants as defined in point (1) of Article 2 of Regulation (EU) No …/… (***) ;

14. ‘plant reproductive material’ means plant reproductive material as defined in point (2) of Article 3 of Regulation (EU) No XXX/XXXX [number, date, title and, in a footnote, the OJ reference for the Regulation on the production and making available on the market of plant reproductive material]; [Am. 34]

(15) ‘plant protection products’ means plant protection products as referred to in Article 2(1) of Regulation (EC) No 1107/2009; for the purposes of this Regulation, ‘plant protection products’ also refers to the active substances referred to in Article 2(2) of Regulation (EC) No 1107/2009 and other substances or preparations referred to in Article 2(3) of that Regulation; [Am. 35]

16. ‘alien species’ means a species, subspecies or lower taxon, introduced outside its natural past or present distribution and includes any part, gametes, seeds, eggs, or propagules of such species, as well as any hybrids, varieties or breeds that might survive and subsequently reproduce; [Am. 36]

‘germinal products’ means germinal products as defined in point (25) of Article 4(1) of Regulation (EU) No … (18);

‘plant products’ means plant products as defined in point (2) of Article 2 of Regulation (EU) No … (19);

‘other objects’ means other objects as defined in point (4) of Article 2 of Regulation (EU) No … (20);

‘risk assessment’ means risk assessment as defined in point (11) of Article 3 of Regulation (EC) No 178/2002;

‘certifying officer’ means:

(a) any official of the competent authorities authorised to sign official certificates by such authorities;

(b) where provided for by the rules referred to in Article 1(2), any other person, who is authorised to sign official certificates by the competent authorities;

‘official certificate’ means any 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);

‘non-compliance’ means non-compliance with:

(a) this Regulation;

(b) rules referred to in Article 1(2);

‘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 the rules referred to in Article 1(2); [Am. 37]

‘operator’ means any natural and legal person subject to one or more obligations provided for in the rules referred to in Article 1(2), except the competent authorities and the other bodies in charge of official controls and other official activities;

‘consignment’ means a number of animals or quantity of goods of the same type, class, or description, covered by the same official certificate, official attestation or any other document, conveyed by the same means of transport and having the same origin; it may consist of one or more lots;

‘inspection’ means a form of official control involving the examination of:

(a) animals or goods;

(b) activities under the control of operators falling within the scope of the rules referred to in Article 1(2) and equipment, means of transport, substances and materials, plant protection products and precautionary measures used to perform those activities; [Am. 38]

(c) places where operators perform their activities;

(ca) the documentation referred to in points (a), (b) and (c); [Am. 39]

‘border control post’ means a place an inspection centre, and the facilities belonging to it, designated by a Member State to perform the official controls provided for in Article 45(1); [Am. 40]


(*) Number of the Regulation on animal health.

(**) Number of the Regulation on protective measures against pests of plants.

(***). Number of the Regulation on protective measures against pests of plants.
'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 objectives;

'rating' means a classification of operators based on an assessment of their conformity with rating criteria;

'official veterinarian' means a veterinarian appointed by the competent authorities and appropriately qualified to perform the official controls and other official activities in accordance with: [Am. 42]

(a) this Regulation;

(b) the rules referred to in Article 1(2);

'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;

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

'long journey' means a journey as defined in point (m) of Article 2 of Regulation (EC) No 1/2005;

'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;

'pesticide application equipment' means any apparatus as defined in point (4) of Article 3 of Directive 2009/128/EC;

'delegated body' means an independent third party, to which the competent authorities have delegated specific official control tasks relating to official controls and other official activities; [Am. 43]

'control authority for organic products production' means a public administrative organisation of a Member State to which the competent authorities have conferred, in whole or in part, their competences for inspections and certification in the organic production sector, in relation to Regulation (EC) No 834/2007, including, where appropriate, the corresponding authority of a third country or operating in a third country; [Am. 44]

'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;

'screening' means a form of official control performed by conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with this Regulation and the rules referred to in Article 1(2);

'targeted screening' means a form of official control involving observation of one or more operators or their activities;

'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 provided for in Articles 15 to 24;

'equivalence' or 'equivalent' means: systems that are broadly the same and meet the same objectives; [Am. 45]

(a) the capability of different systems or measures to meet the same objectives; [Am. 46]

(b) different systems or measures capable of meeting the same objectives; [Am. 47]

'entry into the Union' means the action of bringing animals and goods into one of the territories listed in Annex I;
'documentary check' means the examination of the official certificates, official attestations and other document or 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), Article 54(1), or by implementing acts adopted in accordance with Articles 75(3), 125(4), 127(1) and 128(1);

'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 with the information provided in the official certificates, official attestations and other documents accompanying it;

'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);

'transhipment' means the movement of goods or animals subject to the official controls provided for in Article 45(1) which arrive by sea or by air transport from a third country 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; [Am. 48]

'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 passing through the territory of a third country;

'supervision by the customs authorities' means action as defined in Article 4(13) of Council Regulation (EEC) No 2913/92 (1);

'control by the customs authorities' means customs controls as defined in Article 4(14) of Regulation (EEC) No 2913/92;

'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; [Am. 49]

'additional official controls' means those controls which were not or originally planned and which were decided on the basis of the findings of previous official controls, or other official activities;

'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;

'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 in each of the areas referred to in Article 1(2) over a period of time;

'journey log' means the document set out in points 1 to 5 of Annex II to Regulation (EC) No 1/2005;

'Official auxiliary' means a person qualified, in accordance with Annex IIIa to this Regulation, to act in such a capacity, appointed by the competent authority and working under the authority and responsibility of an official veterinarian. [Am. 50]

Title II
Off icial controls and other official activities in Member States

Chapter I
Competent authorities

Article 3
Designation of competent authorities

1. For each of the areas governed by the rules referred to in Article 1(2), Member States shall designate one or more competent authority or authorities on which they confer the responsibility to perform responsible for planning, organising and where necessary performing official controls and other official activities. [Am. 51]

2. Where, for the same area, a Member State confers the responsibility to perform official controls or other official activities on has 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 be taken to ensure that:

(a) put in place procedures are put in place to ensure efficient and effective coordination between all authorities involved, and the consistency and effectiveness of official controls or other official activities across the whole of its territory; [Am. 53]

(b) designation of a single authority responsible to coordinate the cooperation and the contacts with the Commission and other Member States in relation to the official controls and other official activities performed in that area each of the sectors defined by the Member State, in such a way as to cover all the areas referred to in Article 1(2). [Am. 54]

3. Competent authorities responsible for the verification of compliance with the rules referred to in point (j) of Article 1 (2) may confer specific official control tasks to one or more control authorities for organic products production. In such cases, they shall attribute a code number to each of them. [Am. 55]

4. Member States shall inform the Commission and other Member States of, and of any changes to, the contact details of:

(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 control authorities for organic products referred to in paragraph 3;

(d) the delegated bodies referred to in Article 25(1).

The information referred to in the first subparagraph shall also be made available to the public.

5. Member States may confer to the competent authorities referred to in paragraph 1 the responsibility to carry out controls for the verification of compliance with, or for the application of, rules, including those regulating specific risks which may arise from the presence of alien species in the Union, other than those referred to in Article 1(2). [Am. 56]

6. The Commission may, by means of implementing acts, determine the means by which the information referred to in paragraph 4 is to be made available to the public. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2). The means by which the information referred to in paragraph 4 is to be made available to the public shall in any case include publication on the internet. [Am. 57]
Article 4
General obligations of the competent authorities

1. The competent authorities shall have:

(a) procedures and arrangements in place to ensure the effectiveness and appropriateness of official controls and other official activities;

(b) arrangements in place to ensure the impartiality, independence, quality, consistency and unity of purposes of official controls and other official activities at all levels; they should be in no way connected to or dependent of the operators that they control;

(c) arrangements in place to ensure that staff performing official controls and other official activities are independent, impartial, and free from any conflict of interest, and have no improper connection from which they stand to make economic gain or which might jeopardise their impartiality;

(d) or have access to, an adequate laboratory capacity for analysis, testing and diagnosis;

(e) or have access to, a sufficient number of independent, suitably qualified and experienced staff with regard to the control requirements under Article 1(1) and (2), so that official controls and other official activities can be performed fully, efficiently and effectively;

(f) appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls and other official activities efficiently and effectively;

(g) 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) 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) 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. Staff performing official controls and other official activities shall:

(–a) be officials employed by the competent authorities or by an independent public body delegated by the competent authority to perform official controls or other official activities;

(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;

(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.

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

3. For the purpose of ensuring that the staff of the competent authorities referred to in point (a) of paragraph 1 and in paragraph 2 have the necessary qualifications, skills and knowledge, the Commission shall be empowered to adopt delegated acts in accordance with Article 119 concerning rules for the specific qualification and training requirements of such staff, having regard to the scientific and technical knowledge necessary to perform official controls and other official activities in each of the areas referred to in Article 1(2).

4. When, within the services of activities carried out by 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. [Ams 58 and 341]
Article 5
Audits of the competent authorities

1. Competent authorities shall carry out internal audits or have audits carried out, and shall take appropriate measures in the light of their results, to ensure that they are complying with this Regulation.

Those audits shall be:

(a) subject to independent scrutiny;

(b) carried out in a transparent manner.

2. Competent authorities shall make available the results of the audits referred to in paragraph 1 to the Commission upon justified request. [Am. 59]

3. The Commission may, by means of implementing acts, lay down rules for the conduct of the audits provided for in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 6
Decisions of the competent authorities concerning natural and legal persons

The decisions taken by the competent authorities in accordance with Article 53, Article 64(3) and (5), Articles 65, Article 134(2) and Article 135(1) and (2) concerning natural or legal persons shall be subject to the right of appeal of such persons against those decisions in accordance with national law.

Article 7
Confidentiality obligations of the staff of the competent authorities

1. Competent authorities shall require members of their staff not to disclose, except within the competent authority, information acquired when undertaking their duties in the context of official controls and other official activities which by its nature is covered by professional secrecy, subject to paragraph 2.

2. Unless there is an overriding public interest in its disclosure, or disclosure is required by other Union legislation, information covered by professional secrecy as referred to in paragraph 1 shall include information whose disclosure would undermine:

(a) the purpose of inspections, investigations or audits;

(b) the protection of commercial interests of a natural or legal person;

(c) the protection of ongoing court proceedings and legal advice;

(ca) the decision-making process of competent authorities.

2a. The competent authorities, when determining whether there is an overriding public interest to disclose, shall take into account inter alia the following elements:

(a) possible risks to human, animal or plant health, or to the environment;

(b) the nature, severity and extent of such risks, so as to ensure that disclosure is proportionate in the circumstances.
3. Without prejudice to paragraphs 1 and 2 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 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 the publication or release;

(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 simultaneously and together with such comments.

3a. Competent authorities shall ensure that any information published or made available to the public pursuant to this Article is accurate and that, if any such information subsequently proves to be inaccurate, it is appropriately rectified. [Am. 60]

Chapter II
Official Controls

Article 8
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: [Am. 61]

(a) identified risks associated with:

(i) animals and goods;

(ii) the activities and precautionary measures under the control of operators; [Am. 62]

(iii) the location of the activities or operations of operators;

(iv) the use of products, processes, materials, feed additives or substances that may influence food safety and wholesomeness, feed safety, animal health or animal welfare, plant health or plant reproductive material identity and quality, or, in the case of GMOs and plant protection products, may adversely impact on the environment; [Am. 63]

(iv a) the potential for consumers to be misled as to the nature, quality or substance of a product or the potential for consumers to incur financial loss as a result of receiving misleading information from the operator; [Am. 64]

(iv b) the process requirements according to point (j) of Article 1(2); [Am. 65]

(b) operators undertakings’ past record as regards the results of official controls performed on them and their compliance with the rules referred to in Article 1(2); [Am. 66]

(c) the reliability and results of own controls that have been performed by the operators, or by a third party at their request, for the purpose of ascertaining compliance with the rules referred to in Article 1(2). Transfer of information on these own controls shall be utilised as much as possible, in a manner that minimizes the burden on operators; [Am. 67]

(ca) consumer expectations regarding nature, quality and composition of foods and goods; [Am. 68]

(d) any information that might indicate non-compliance with the rules referred to in Article 1(2);
private quality assurance schemes put in place by operators, which are certified and audited by independent and recognised certification bodies. [Am. 69]

2. Competent authorities shall perform official controls on a regular basis and with appropriate frequency to identify possible intentional violations of the rules referred to in Article 1(2), to verify compliance with the requirements and process criteria according to point (j) of Article 1(2), taking into account, in addition to the criteria referred to in paragraph 1, information regarding such possible intentional violations shared through the mechanisms of administrative assistance provided for in Title IV and any other information pointing to the possibility of such violations. [Am. 70]

2a. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 in order to establish a uniform minimum frequency for carrying out the controls referred to in paragraphs 1 and 2. Where necessary, such minimum frequency, based on risk, shall be established differently for each product, process or activity that is subject to official controls pursuant to this Regulation. [Am. 71]

3. Official controls 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:

(a) the rules referred to in Article 1(2):

(b) the delegated acts adopted by the Commission in accordance with Articles 15 to 24.

4. Official controls shall be performed without prior warning, except where:

(a) prior notification of the operator is necessary; [Am. 72]

(b) the operator has requested such official controls. Such announced controls shall not replace standard controls without prior warning; [Am. 73]

(ba) audits for verification of requirements in accordance with point (j) of Article 1(2) are performed. [Am. 74]

5. Official controls shall be performed as much as possible in a manner that minimises the administrative burden on the operators and operational disruption for operators is kept to the necessary minimum, but without this affecting the quality of the control negatively; to that end, where the same operator is subject to various official controls over the same period, the competent authority shall aggregate them. Where various official controls are applied to operators, Member States shall ensure a coordinated approach with the aim of combining existing control measures. [Am. 75]

6. Competent authorities shall perform official controls with the same care 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;

(c) entering the Union from third countries.

7. To the extent strictly necessary for the organisation of the official controls, Member States of destination may require operators who have animals or goods delivered to them from another Member State to report the arrival of such animals or goods. [Am. 76]
Article 9

Persons, processes and activities, methods and techniques subject to official controls [Am. 77]

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

(a) on animals and goods at all stages of production, processing, marketing, and distribution; [Am. 78]

(b) on substances, materials or other objects which may influence the characteristics or health of animals and goods, at all stages of production, processing and distribution; [Am. 79]

(c) on operators and the activities and operations under their control, on their premises, land, crops and processes, on the storage, transport, and the use of goods and on the keeping of animals; [Am. 80]

(ca) on all documentation, including documentation kept in electronic form, linked to the activity being performed, or to operations including transport. [Am. 81]

Article 10

Transparency of official controls

1. Competent authorities shall perform official controls with a high level of transparency and make available to the public relevant information concerning the organisation and the performance of official controls.

They shall also ensure the regular publication of information, at least once a year, on the following:

(a) type, number and final outcome of official controls;

(b) type and the number of non-compliances detected;

(c) type and number of cases where measures were taken by the competent authorities in accordance with Article 135;

(d) type and number of cases where the penalties referred to in Article 136 were imposed. [Am. 82]

2. To ensure the uniform implementation of the rules provided for in paragraph 1 of this Article, the Commission shall, by means of implementing acts, lay down and update as necessary the format in which the information referred to in that paragraph shall be published. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2) provide Member States with appropriate guidance documents, including a proposal for a standardised reporting format, which shall in any case include publication of those guidance documents on the internet. [Am. 83]

3. Competent authorities shall be entitled to publish or make otherwise available to the public information about the rating of individual operators based on the outcome of the last four official controls, provided that the following conditions are met:

(a) the rating criteria are objective, transparent and publicly available;

(b) appropriate arrangements are in place to ensure the consistency and transparency of the rating process;

(ba) subsequent inspections are carried out without delay if the findings are unfavourable. [Am. 84]

3a. To enable rating systems to be compared between one Member State and another, the Commission shall, by means of delegated acts and in consultation with the stakeholders, lay down guidelines to establish objective criteria which shall be made available to the Member States and which they may use on a voluntary basis. [Am. 85]
Article 11
Documented control and control verification 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 contain detailed instructions for staff performing official controls.

2. Competent authorities shall have procedures in place to verify the consistency and effectiveness of official controls and other official activities that they perform.

3. Competent authorities shall:
   (a) take corrective actions in all cases where the procedures provided for in paragraph 2 identify shortcomings in the consistency and effectiveness of official controls and other official activities;
   (b) update the documented procedures provided for in paragraph 1 as appropriate.

Article 12
Recording of, and reports on, official controls [Am. 86]

1. Competent authorities shall draw up reports on keep documentary records of every official control that they have performed. They shall draw up reports on controls in which this Regulation or the provisions referred to in Article 1(2) were found to have been infringed. [Am. 87]

Those reports shall contain:
   (a) a description of the purpose of the official controls;
   (b) the control methods applied;
   (c) the results of the official controls;
   (d) where appropriate, action that the competent authorities require the operator concerned to take as a result of their official controls.

2. Competent authorities shall provide the operator subject to an official control with a copy of the report provided for in paragraph 1.

3. Where official controls require the continuous or regular presence of staff or representatives of the competent authorities in the operator's premises, the reports 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;
   (b) immediately informed of any shortcoming or non-compliance identified through the official controls.

3a. The outcome of official controls performed at a border control post shall be recorded in the Common Health Entry Document in accordance with Article 54(2)(b). [Am. 88]

Article 13
Official controls, methods and techniques

1. Competent authorities shall perform official controls using control methods and techniques that shall, as appropriate, include screening, targeted screening, verification, inspections, audits, sampling, analysis, diagnosis and tests.

2. Official controls shall include the following, as appropriate [Am. 89]
   (a) an examination of the control systems that operators have put in place and of the results obtained;
(b) an inspection of:

(i) primary producers' installations and other businesses, including their surroundings, premises, offices, equipment, installations and machinery, transport and their animals and goods;

(ii) raw materials, ingredients, processing aids and other products used for the preparation and production of goods or for feeding or treating animals;

(iiia) materials intended to come into contact with food; [Am. 90]

(iii) semi-finished goods;

(iv) cleaning and maintenance products and processes, plant protection products;

(v) labelling, presentation and advertising;

(c) controls on the hygiene conditions in the operators' premises;

(d) an assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), good farming practices and 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); [Am. 91]

(f) interviews with operators and with their staff;

(g) a reading of values recorded by operators' measuring instruments;

(h) controls performed with the competent authorities' own instruments to verify measurements taken by operators;

(i) any other activity required to identify non-compliance.

2a. Specific rules for the performance of official controls shall always take into account not only potential health risks, but also consumer expectations with regard to food composition and the likelihood of fraudulent practices. [Am. 326]

Article 14

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 and staff of the delegated bodies, where specific official control tasks have been delegated in accordance with the provisions of Article 25, access to:

(a) their premises;

(b) their computerised information management systems;

(c) their animals and goods;

(d) their relevant documents and any other relevant information, including the results of potential own tests, that is relevant for the purpose of performing such controls or activities and the control subjects listed in Article 13(2). Every operator shall be able to indicate at least each operator he is supplied by and each operator he is supplying. [Am. 93]

2. During official controls and other official activities, operators shall assist the staff of the competent authorities and the delegated bodies, pursuant to Article 25, in the accomplishment of their control tasks. Operators shall supply sufficient quantities of samples free of charge to the competent authorities. [Am. 94]
3. The operator responsible for the consignment shall:

(a) cooperate fully with the competent authorities to ensure the efficient performance of official controls or other official activities;

(b) make available without delay all requested information concerning the consignment on paper or electronically. \[Am. 95\]

4. The Commission may, by means of implementing acts, lay down rules:

(a) establishing the modalities for access by the competent authorities and the delegated bodies, pursuant to Article 25, to the computerised information management systems referred to in paragraph 1(b); \[Am. 96\]

(b) on the cooperation between operators and competent authorities as referred to in paragraph 3.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 15

Specific rules on official controls and on action to be 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) in relation to products of animal origin intended for human consumption shall always include the verification of compliance with Regulations (EC) No 852/2004 (1), (EC) No 853/2004 and (EC) No 1069/2009 as applicable, and at least of the following, as appropriate:

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

(b) personal hygiene;

(c) HACCP-based procedures;

(d) own-controls procedures;

(e) verification of compliance by the staff with applicable requirements;

(f) verification of the operator’s records and of documents accompanying food, feed and any substance or material entering and leaving the establishment;

(g) consideration of any evidence of the presence of fraudulent practices.

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

(a) the verification by or under the responsibility of an official veterinarian, of the health and welfare of the animals prior to the slaughter or by an official auxiliary working under an official veterinarian’s responsibility;

(b) official controls by or under the responsibility of an official veterinarian or by an official auxiliary working under an official veterinarian’s responsibility, in slaughterhouses, cutting and processing plants and game handling establishments, to verify compliance with the requirements applicable to:

(i) the hygiene of meat production;

(ii) the presence of residues of veterinary medicinal products in products of animal origin intended for human consumption;

(iii) the handling and disposal of animal by-products and of specified risk material;

(iv) the health and welfare of the animals.

1a. For the purposes of the official controls referred to in paragraph 2:

(a) at least one official veterinarian shall be present during both the ante-mortem and post-mortem inspection or, in the case of game-handling establishments, during the post-mortem inspection;

(b) an official veterinarian or an official auxiliary shall be present, with a frequency appropriate to achieving the objectives of this Regulation, in cutting plants when meat is being worked on.

1b. Following the official controls referred to in paragraph 2, actions and measures in accordance with Article 135 in relation to the animals, their welfare and the destination of meat shall be taken by or under the responsibility of the official veterinarian.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning specific rules for the performance of official controls on products of animal origin intended for human consumption and on animals intended for the production of such products to verify compliance with the rules referred to in points (a), (c), (d) and (e) of Article 1(2) applicable to those products and animals, and on action to be taken by the competent authorities following official controls. Those delegated acts shall lay down rules on:

(a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in paragraph 1 and in Article 4, Articles 8 and 9, Article 10(1), Articles 11 to 13, Article 34(1) and (2), and Article 36;

(b) uniform specific requirements for the performance of official controls and uniform minimum frequency of such official controls, having regard, in addition to the criteria referred to in Article 8(1), to the specific hazards and risks which exist in relation to each product of animal origin and the different processes it undergoes;

(c) the cases where and the conditions under which slaughterhouse staff may be involved in official controls appropriately qualified and trained, and employed under the control of the official veterinarian in a unit which is segregated and independent from the production units of the establishment, may assist the official veterinarian when performing the official controls referred to in paragraph 2 in relation to the production of meat from poultry and lagomorphs, and the design and application of tests to assess their performance;

(d) the circumstances in which the competent authorities in relation to specific cases of non-compliance are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph;

(e) criteria to determine when, on the basis of a risk analysis, the conditions and the frequency of the official control tasks to be carried out by the official veterinarian is not required to be present in low throughput slaughterhouses and game handling establishments, during the official controls referred to respecting the minimum requirement laid down in paragraph 1a (a).

Where, in cases of risks which cannot be effectively addressed in the absence of common specifications for the official controls or for the action to be taken by the competent authorities following such official controls, imperative grounds of urgency so require, the procedure provided for in Article 140 shall apply to delegated acts adopted pursuant to this paragraph.

3. The Commission shall take into account the following when adopting delegated acts as provided for in paragraph 2:

(a) the experience gained by competent authorities and food business operators on the application of the procedures referred to in Article 5 of Regulation (EC) No 852/2004;

(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 health and animal health associated with meat and other products of animal origin intended for human consumption;

(da) consideration of any evidence of the presence of fraudulent practices.

4. Insofar as this does not prevent the achievement of the objectives of human health and animal health pursued by the rules referred to in points (a), (c), (d) and (e) of Article 1(2), applicable to products of animal origin intended for human consumption and to animals intended for the production of such products, the Commission shall also take into account the following elements, when adopting delegated acts as provided for in paragraph 2:

(a) the need to facilitate the application of the delegated acts to small businesses in order to ensure an effective application; [Am. 97]

(b) the need to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food;

(c) the needs of food businesses situated in regions that are subject to special geographic constraints.

Article 16
Specific rules on official controls and on action to be taken by the competent authorities in relation to the residues of certain substances in food and feed

The Commission shall be empowered to adopt, in accordance with Article 139 legislative proposals concerning rules on official controls to be performed to verify compliance with the rules referred to in point (a) of Article 1(2) applicable to certain substances whose use on crops or animals or to produce or process food or feed may result in residues of those substances in food or feed, and on action to be taken by the competent authorities following official controls. Such delegated acts shall take account of the need to ensure a minimum level of official controls to prevent the use of those substances in violation of point (a) of Article 1(2), and lay down rules on:

(a) uniform specific requirements for the performance of official controls and uniform minimum frequency of such official controls, having regard, in addition to the criteria referred to in Article 8(1), to the specific hazards and risks related to non-authorised substances and to the non-authorised use of authorised substances;

(b) specific additional criteria and specific additional content to those provided for in Article 108, for the preparation of the relevant parts of the multi-annual national control plan provided for in Article 107(1);

(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 Article 135(2) or additional measures to those provided for in that paragraph.

Article 17
Specific rules on official controls and on action to be taken by the competent authorities in relation to animals, products of animal origin, and germinal products, animal by-products and derived products [Am. 98]

1. Official controls in relation to animals shall include:

(a) verification of measures for protection against biological and chemical hazards to human and animal health;
(b) verification of animal welfare measures, without prejudice to Article 18;

(c) verification of disease control or eradication measures. [Am. 99]

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 legislative proposals concerning 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 on action to be taken by the competent authorities following official controls. Such delegated acts legislative proposals shall take account of animal health risks related to animals, products of animal origin and germinal products, and of human and animal health risks related to animal by-products and derived products, and lay down rules on:

(a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in Article 4, 8, 9, 10(1), Articles 11 and 12, 13, and Article 34(1) and (2) and 36; [Am. 100]

(b) uniform specific requirements for the performance of official controls, and uniform minimum frequency of such official controls, having regard, in addition to the criteria referred to in Article 8(1), to the need to address specific hazards and risks to 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);

(c) the cases where the competent authorities in relation to cases of specific non-compliance are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph.

Article 18
Specific rules on official controls and action to be taken by the competent authorities in relation to the welfare requirements for animals

1. In addition to the general rules on official controls provided for in Article 8, official controls to verify compliance with the rules laying down welfare requirements for animals in case of their transport shall include: [Am. 102]

(a) in 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 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, prior to the journey:

(i) official controls on journey logs to verify that the journey log is realistic and indicates compliance with Regulation (EC) No 1/2005;

(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 57(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 and where applicable Chapter VI of Annex I to Regulation (EC) No 1/2005; [Am. 103]
(ii) official controls to verify that transporters comply with applicable international agreements, including the European Convention for the protection of animals during international transport and have valid transporter authorisations and certificates of competence for drivers and attendants; [Am. 104]

(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;

(iiiia) following official controls under point (c) (i) of this paragraph, where the view of the competent authority is that animals are unfit for transport, they shall be unloaded, watered, fed and rested and veterinary assistance must be sought if necessary, until fit to continue their journey; [Am. 105]

(c) in case of long journeys between Member States and with third countries, official controls performed at any stage of the long journey on a random or targeted basis to verify that declared journey times are realistic and that the journey complies with Regulation (EC) No 1/2005 and in particular that travel times and rest periods have complied with the limits set out in Chapter V of Annex I to Regulation (EC) No 1/2005. [Am. 106]

2. Where the rules referred to in point (f) of Article 1(2) require that certain non-quantifiable standards of animal welfare be met, or where those rules require the adoption of certain practices whose adherence to which cannot be effectively verified through the sole use of the official control methods and techniques referred to in Article 13, official controls performed to verify compliance with those rules may include the use of specific indicators of animal welfare, in the cases and under the conditions that shall be adopted in accordance with point (f) of paragraph 3.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 legislative proposals concerning 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 legislative proposals 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) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in paragraph 1 and Article 4, Articles 8 and 9, Article 10(1) and Articles 11 to 13, 34(1) and (2), and 36; [Am. 108]

(b) uniform specific requirements for the performance of official controls, and uniform minimum frequency of such official controls, having regard, in addition to the criteria referred to in Article 8(1), 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;

(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 Article 135(2) or additional measures to those provided for in that paragraph;

(d) the verification of animal welfare requirements at border control posts and at exit points and the minimum requirements applicable to such exit points;

(e) specific criteria and conditions for the activation of the mechanisms of administrative assistance provided for in Title IV;

(f) the cases and conditions where official controls to verify compliance with animal welfare requirements may shall 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. [Am. 109]
Article 19

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

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 legislative proposals concerning 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 such goods and on action to be taken by the competent authorities following such official controls. Those delegated acts shall take account of plant health risks associated with plants, plant products and other objects in relation to specific pests of plants or operators and lay down rules on: [Am. 328]

(a) specific responsibilities and tasks of the competent authorities, in addition to those provided for in Article 4, Articles 8 and 9, Article 10(1), Articles 11 to 13, Article 34(1) and (2), and Article 36;

(b) uniform specific requirements for the performance of 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) and uniform minimum frequencies of such official controls having regard, in addition to the criteria referred to in Article 8(1), to the specific hazards and risks to plant health in relation to specific plants, plant products and other objects of a particular origin or provenance;

(c) uniform frequencies of official controls performed by competent authorities on operators authorised to issue plant passports in accordance with Article 79(1) of Regulation (EU) No .../... (*) having regard, in addition to the criteria referred to in Article 8(1), to whether those operators have implemented a phytosanitary risk management plan as referred to in Article 86 of Regulation (EU) No .../... (**) for the plants, plant products and other objects they produce;

(d) the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph.

Article 20

Specific rules on official controls and action to be taken by the competent authorities in relation to plant reproductive material

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules for the performance of official controls on plant reproductive material in order to verify compliance with the rules referred to in point (h) of Article 1(2) applicable to such goods and on action to be taken by the competent authorities following such official controls. Those delegated acts shall lay down rules on:

(a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in Articles 4, 8, 9, 10(1), 11, 12, 13, 34(1) and (2), and 36;

(b) uniform specific requirements for the performance of official controls having regard, in addition to the criteria referred to in Article 8(1), to the risks to the health, identity, quality and traceability of certain categories of plant reproductive material or of specific genera or species;

(c) specific criteria and conditions for the activation of the mechanisms of administrative assistance provided for in Title IV;

(d) the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph. [Am. 110]

(*) Number of the Regulation on protective measures against pests of plants.
(**) Number of the Regulation on protective measures against pests of plants.
Article 21
Specific rules on official controls and action to be taken by the competent authorities in relation to GMOs and genetically modified food and feed

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 legislative proposals concerning rules for the performance of official controls on GMOs and genetically modified food and feed performed to verify compliance with the rules referred to in points (a), (b) and (c) of Article 1(2) and on action to be taken by the competent authorities following such official controls. Those delegated acts legislative proposals shall take into account the need to ensure a minimum level of official controls to prevent practices in violation with those rules, and lay down rules on:

(a) specific responsibilities and tasks of the competent authorities, in addition to those provided for in Article 4, Articles 8 and 9, Article 10(1), Articles 11 to 13, Article 34(1) and (2), and Article 36;

(b) uniform specific requirements for the performance of official controls and uniform minimum frequency of such official controls on:

(i) the presence on the market of GMOs and of genetically modified food and feed which have not been authorised in accordance with Directive 2001/18/EC of the European Parliament and the Council (1) or Regulation (EC) No 1829/2003;

(ii) the cultivation of GMOs and the correct application of the monitoring plan referred to in point (e) of Article 13 (2) of Directive 2001/18/EC and in Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, including minimum measures for monitoring and surveillance of potential effects on health, animal health and the environment: [Am. 112]

(iii) the contained use of genetically modified micro-organisms;

(iiiia) minimum measures as regards controls and reporting which aim at avoiding the unintended presence of GMOs, in accordance with Article 26a of Directive 2001/18/EC; [Am. 113]

(c) the circumstances in which the competent authorities in relation to specific cases of non-compliance are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph.

Article 22
Specific rules on official controls and on action to be taken by the competent authorities in relation to plant protection products

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 legislative proposals concerning rules for the performance of official controls to verify compliance with the rules referred to in point (i) of Article 1(2). [Am. 114]

Those delegated acts legislative proposals shall take into account the risks that plant protection products may represent for human health, animal health or the environment, and shall lay down rules on: [Am. 115]

(a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in Article 4, Articles 8 and 9, Article 10(1), Articles 11 to 13, Article 34(1) and (2), and Article 36;

(b) uniform specific requirements for the performance of official controls and uniform minimum frequency of such official controls, concerning the manufacture, placing on the market, entry into the Union, labelling, packaging, transport, storage, parallel trade and use of plant protection products, having regard, in addition to the criteria referred to in Article 8(1), to the need to ensure the safe and sustainable use of plant protection products and to combat illegal trade of such products; [Am. 116]

(c) uniform specific requirements for inspections on pesticide application equipment and uniform minimum frequency of such controls;

(ca) uniform specific requirements for the establishment of a register or database concerning production, packaging and storage facilities; [Am. 117]

(d) the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph;

(e) the design of certification systems to assist the competent authorities in the inspections of pesticide application equipment;

(f) the collection of information, monitoring and reporting on suspected poisonings from plant protection products;

(g) the collection of information, and the monitoring of and reporting on counterfeited plant protection products and illegal trade of plant protection products.

Article 23

Specific rules on official controls and on action to be taken by the competent authorities in relation to organic products and protected designations of origin, protected geographical indications and traditional specialties guaranteed

1. The Commission shall be empowered to adopt delegated acts, in accordance with Article 139 concerning rules for the performance of official controls to verify compliance with the rules referred to in points (j) and (k) of Article 1(2) and on action to be taken by the competent authorities following such official controls.

2. In relation to The Commission shall be empowered to adopt delegated acts, in accordance with Article 27(2) of Regulation (EC) No 834/2007, to verify compliance with the rules referred to in point (j) of Article 1(2), the delegated acts referred to in paragraph 1 and on action to be taken by the competent authorities following such official controls. Those delegated acts shall lay down rules on: [Am. 118]

(a) the specific responsibilities and tasks of the operators, the competent authorities, the delegated bodies to ensure compliance with the provisions of Regulation (EC) No 834/2007, in addition to those provided for in Article 4, Articles 8 and 9, Article 10(1), Articles 11 to 13, Article 34(1) and (2), and Article 36, and in addition to Articles 25, 29, 30 and 32 for the approval and supervision of delegated bodies; [Am. 119]

(b) additional requirements to those referred to in Article 8(1) for risk assessment, and for the establishment of the frequency of official controls, and of sampling as appropriate, taking into account the risk of the occurrence of non-compliance;

(c) the minimum frequency of official controls on operators as defined in point (d) of Article 2 of Council Regulation (EC) No 834/2007, and the cases where and the conditions under which certain such operators are to be exempted from certain official controls;

(d) additional methods and techniques for official controls to those referred to in Article 13 and Article 33(1) to (5) and specific requirements for the performance of official controls aimed at ensuring the traceability of organic products at all stages of the production, preparation and distribution, and at providing assurances as to compliance with the rules referred to in point (j) of Article 1(2);
additional criteria to those referred to in the second subparagraph of Article 135(1) and in Article 30(1) of Regulation (EC) No 834/2007, relating to the measures to be taken in case of the occurrence of non-compliance, and additional measures to those provided for in Article 135(2);

additional requirements to those provided for in point (f) of Article 4(1) in relation to the facilities and equipment necessary to carry out official controls and additional conditions and obligations to those referred to in Articles 25 to 30 and Article 32 for the delegation of official control tasks;

additional reporting obligations to those referred to in Articles 12 and 31 for the competent authorities, the control authorities for organic products, and the delegated bodies in charge of official controls;

additional requirements to those provided for in point (f) of Article 4(1) in relation to the facilities and equipment necessary to carry out official controls and additional conditions and obligations to those referred to in Articles 25 to 30 and Article 32 for the delegation of official control tasks;

specific criteria and conditions for the activation of the mechanisms of administrative assistance provided for in Title IV.

In relation to the rules referred to in point (k) of Article 1(2), the delegated acts referred to in paragraph 1 shall lay down rules on:

additional requirements, methods and techniques to those referred to Articles 11 and 13 for official controls performed to verify compliance with product specifications and labelling requirements;

additional methods and techniques to those referred in Article 13 for the performance of official controls aimed at ensuring the traceability of products falling within the scope of the rules referred to in point (k) of Article 1(2) at all stages of production, preparation and distribution, and at providing assurances as to compliance with those rules;

specific additional criteria and specific additional content to those provided for in Article 108, for the preparation of the relevant parts of the multi-annual national control plan provided for in Article 107(1), and specific additional content of the report provided for in Article 112;

specific criteria and conditions for the activation of the mechanisms of administrative assistance provided for in Title IV;

specific measures to be taken, in addition to those referred to in Article 135(2) in case of non-compliance and of serious or recurrent non-compliance.

Where appropriate, the delegated acts referred to in paragraphs 2 and 3 shall derogate from the provisions of this Regulation referred to in those paragraphs. [Am. 120]

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

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 legislative proposals concerning specific rules 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) and on action to be taken by the competent authorities following such official controls. Those delegated acts shall address newly identified risks which may be posed through food or feed to human or animal health or, in relation to GMOs and plant protection products to the environment, or any such risks emerging from new patterns of production or consumption of food or feed, or which cannot be effectively addressed in the absence of common specifications for the official controls and for the action to be taken by the competent authorities following such official controls, and shall lay down rules on: [Am. 121]

the specific responsibilities and tasks of the competent authorities, in addition to those provided for in Article 4, Articles 8 and 9, Article 10(1), Articles 11 to 13, Article 34(1) and (2), and Article 36;
(b) uniform specific requirements for the performance of official controls and uniform minimum frequency of such official controls, having regard, in addition to the criteria referred to in Article 8(1), to the specific hazards and risks which exist in relation to each category of food and feed and the different processes it undergoes;

(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 Article 135(2) or additional measures to those provided for in that paragraph.

2. Where, in the case of serious risks to human or animal health or to the environment, imperative grounds of urgency so require, the procedure provided for in Article 140 shall apply to delegated acts adopted pursuant to paragraph 1.

**Article 24a**

Specific rules on official controls and on action to be taken by the competent authorities in relation to materials and articles intended to come into contact with food.

The Commission may be empowered to adopt delegated acts in accordance with Article 139 concerning rules on the application of the official controls and on action to be taken by the competent authorities in relation to materials and articles intended to come into contact with food. [Am. 122]

**Chapter III**

Delegation of specific tasks of the competent authorities

**Article 25**

Delegation by the competent authorities of specific official control tasks

1. Competent authorities may delegate specific official control tasks to one or more delegated bodies or natural persons in accordance with the conditions provided for in Articles 26 and 27 respectively. **Competent authorities shall not delegate specific official control tasks to natural persons concerning official controls performed to verify compliance with the rules referred to in point (j) of Article 1(2).** [Am. 123]

2. Competent authorities shall not delegate the decision concerning the measures provided for in point (b) of Article 135 (1) and in Article 135 (2) and (3).

The first subparagraph shall not apply to the measures to be taken in accordance with Article 135 or with the rules provided for in point (c) of Article 23(2) following official controls performed to verify compliance with the rules referred to in point (j) of Article 1(2). [Am. 124]

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 establishing specific official control tasks that may not be delegated in order to preserve the independence or the core functions of the competent authorities.

4. Where competent authorities delegate specific official control tasks for the verification of compliance with the rules referred to in point (j) of Article 1(2) to one or more delegated bodies, they shall attribute a code number to each delegated body and designate authorities responsible for their approval and supervision.

**Article 26**

Conditions for delegating specific official control tasks to delegated bodies

The delegation of specific control tasks to a delegated body referred to in Article 25(1) shall be in writing and shall comply with the following conditions:

(a) the delegation contains a precise description of:

(i) the specific official control tasks that the delegated body may perform;
(ii) the conditions under which it may perform those tasks;

(b) the delegated body:

(i) has the expertise, equipment and infrastructure required to perform the specific official control tasks delegated to it;

(ii) has a sufficient number of suitably qualified and experienced staff;

(iii) is impartial, independent, not directly nor indirectly employed by the operator on which it is performing control activities, and otherwise free from any conflict of interest as regards the exercise of the specific official control tasks delegated to it; [Am. 125]

(iv) works and is accredited in accordance with standard EN ISO/IEC 17020 ‘Requirements for the operation of various types of bodies performing inspection’ or another standard if more relevant to the delegated tasks in question;

(iva) has sufficient powers to perform the official controls delegated to it; [Am. 126]

(c) there are arrangements in place ensuring efficient and effective coordination between the delegating competent authorities and the delegated body.

Article 27
Conditions for delegating specific official control tasks to natural persons

Competent authorities may delegate specific official control tasks to one or more natural persons where the rules provided for in Articles 15 to 24 so allow. Such delegation shall be in writing.

Article 26 shall apply to the delegation of specific official control tasks to natural persons, with the exception of points (b) (ii) and (b)(iv).

Article 28
Obligations of the delegated body and natural person to which specific official control tasks are delegated

Delegated bodies or natural persons to whom specific official control tasks have been delegated in accordance with Article 25(1) shall:

(a) communicate the results of the official controls performed by them to the competent authorities which have delegated the specific official control tasks on a regular basis and whenever those competent authorities so request;

(b) immediately inform the competent authorities which have delegated the specific official control tasks whenever the results of the official controls indicate non-compliance or point to the likelihood of non-compliance.

Article 29
Obligations of the competent authorities delegating specific official control tasks

Competent authorities that have delegated specific official control tasks to delegated bodies or natural persons in accordance with Article 25(1) shall:

(a) organise periodic and unannounced audits or inspections of such bodies or persons as necessary. [Am. 127]

(b) fully or partly withdraw the delegation without delay where:

(i) following an audit or an inspection as provided in point (a), there is evidence that such delegated bodies or natural persons are failing to properly perform the official control tasks delegated to them;
(ii) the delegated body or the natural person fails to take appropriate and timely action to remedy the shortcomings identified during the audits and inspections provided for in point (a);

(iia) the independence or impartiality of the delegated body or natural person have been shown to be compromised.

[Am. 128]

Article 30

Conditions for delegating specific tasks related to other official activities

1. The competent authorities may delegate specific 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;

(b) the conditions laid down in Article 26 are fulfilled with the exception of point (b)(iv).

2. The competent authorities may delegate specific 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;

(b) the conditions laid down in Article 26 are fulfilled with the exception of points (b)(ii) and (b)(iv).

Article 31

Obligations of the delegated body and natural person to which specific tasks related to other official activities are delegated

The delegated body or the natural person to whom specific tasks related to other official activities have been delegated in accordance with Article 30 shall:

(a) communicate the results of the other official activities performed by it to the competent authorities which have delegated the specific tasks related to other official activities on a regular basis and whenever the competent authorities so request;

(b) immediately inform the competent authorities which have delegated the specific tasks related to other official activities whenever the results of the other official activities indicate non-compliance or point to the likelihood of non-compliance.

Article 32

Obligations of the competent authorities delegating specific tasks related to other official activities

Competent authorities that have delegated specific tasks related to other official activities to delegated bodies or natural persons in accordance with Article 30 shall:

(a) organise audits or inspections of such bodies or persons as necessary; [Am. 129]

(b) fully or partly withdraw the delegation without delay where:

(i) following an audit or an inspection as provided for in point (a), there is evidence that such delegated bodies or natural persons are failing to properly perform the tasks related to other official activities delegated to them;

(ii) the delegated bodies or natural persons fail to take appropriate and timely action to remedy the shortcomings identified during the audits and inspections provided for in point (a).
**Chapter IV**

**Sampling, analyses, tests and diagnoses**

**Article 33**

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 referred to in paragraph 1, in the context of official controls, official laboratories shall use state-of-the-art methods for their specific analytical, testing and diagnostic needs, taking into account, in the following order: [Am. 130]

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

(b) in the absence of the rules or protocols referred to in point (a), the relevant methods developed or recommended by the European Union reference laboratories and validated in accordance with internationally accepted scientific protocols;

(c) in the absence of the rules or protocols referred to in point (a) and the methods referred to in point (b), the methods which comply with relevant rules established at national level;

(d) in the absence of the rules or protocols referred to in point (a), the methods referred to in point (b) and the national rules referred to in point (c), the relevant methods developed or recommended by national reference laboratories and validated in accordance with internationally accepted scientific protocols; or,

(e) in the absence of the rules or protocols referred to in point (a), the methods referred to in point (b), the national rules referred to in point (c) and the methods referred to in point (d), the relevant methods validated in accordance with internationally accepted scientific protocols.

3. By way of derogation from paragraph 2, in the context of screening, targeted screening and of other official activities, any of the methods referred to in paragraph 2 may be used in the absence of Union rules referred to in paragraph 1. The same rule shall apply to the other official activities. [Am. 131]

4. Where laboratory analyses, tests or diagnoses are urgently needed in exceptional cases due to a developing emergency situation, and none of the methods referred to in paragraphs 1 and 2 exists, the relevant national reference laboratory or, if no such national reference laboratory exists, any other laboratory designated in accordance with Article 36(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. [Am. 132]

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

6. Samples shall be taken, handled and labelled in such a way as to guarantee their legal, scientific and technical validity. The size of the sample taken must be such as to enable a second expert opinion to be given, where necessary, should an operator so request under Article 34. [Am. 133]

6a. As regards products of animal origin, methods have to be developed and mandatorily established aimed at identifying and tracing breeding material from cloned animals as well as descendants from cloned animals and products derived thereof. [Am. 134]
7. The Commission may, by means of implementing acts, insofar as these matters are not otherwise regulated, lay down rules for:

(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 141(2).

Article 34
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 apply for a second expert opinion, where this is relevant and technically feasible. The operator shall bear the costs of that expert opinion.

Such a right:

(a) shall always entitle the operator to request a documentary review of the sampling, analysis, test or diagnosis by another expert designated by the reference laboratory or, failing that, by another official laboratory which is at least equivalent;

(b) where relevant 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, shall entitle the operator to request and oblige the competent authorities to ensure:

(i) that a sufficient number of other samples be taken for and divided into three parts for the purpose of an initial analysis and, if appropriate, a second expert opinion or, at the request of the operator, and then another final analysis, if there is a discrepancy between the two previous ones;

(ii) where it is not possible to take a sufficient number of samples as referred to in point (i), that an independent second analysis, test or diagnosis on the sample be carried out.

1a. Samples shall be handled and labelled in such a way as to guarantee their legal and technical validity.

2. The application by the operator for a second expert opinion in accordance with paragraph 1 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 for animal welfare or, as regards GMOs and plant protection products, for the environment, in accordance with the rules referred to in Article 1(2) and with this Regulation.

3. The Commission may, by means of implementing acts, lay down procedures for the uniform application of the rules provided for in paragraph 1 and for the presentation and handling of applications for a second expert opinion. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 35
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 those samples are ordered in accordance with paragraph 1: [Am. 141]

(a) are informed that such samples are being taken in the context of an official control and, where appropriate, analysed or tested for the purposes of such official control; and,

(b) where the samples referred to in paragraph 1 are analysed or tested, are entitled to exercise the right to apply for a second expert opinion provided for in Article 34(1).

Article 36
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.

2. Competent authorities may designate as official laboratory a laboratory located in another Member State subject to the following conditions:

(a) appropriate arrangements are in place under which they are enabled to perform the audits and inspections referred to in Article 38(1) or delegate the performance of such audits and inspections to the competent authorities of the Member State where the laboratory is located;

(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 shall be in writing and shall include a detailed description of:

(a) the tasks that the laboratory shall carry out as official laboratory;

(b) the conditions under which it shall carry out those tasks;

(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 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) is independent, impartial and free from any conflict of interest as regards the exercise of its tasks as official laboratory: [Am. 142]

(d) can deliver timely the results of the analysis, test or diagnosis carried out on the samples taken during official controls and other official activities;

(e) operates in accordance with the standard EN ISO/IEC 17025 on ‘General requirements for the competence of testing and calibration laboratories’ and is assessed and accredited in accordance with that standard by a national accreditation body operating in accordance with Regulation (EC) No 765/2008. [Am. 143]

5. The scope of the assessment and accreditation of an official laboratory referred to in point (e) of paragraph 4: [Am. 144]

(a) shall include all the 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 accreditation scope 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.

Where no official laboratory designated in the Union 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 of paragraphs 3 and 4 of this Article to carry out those analyses, tests and diagnoses.

**Article 37**

Obligations of official laboratories

1. Official laboratories shall immediately inform the competent authorities where the results of an analysis, test or diagnosis carried out on samples indicate non-compliance or point to the likelihood of non-compliance by an operator.

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

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

**Article 38**

Audits and inspections of official laboratories

1. The competent authorities shall organise audits or inspections of the official laboratories they have designated in accordance with Article 36(1):

(a) on a regular basis;

(b) any time they consider that an audit or inspection is necessary.

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 or an inspection provided for in paragraph 1 which disclose any of the following:

(a) it no longer complies with the conditions provided for in Article 36(4) and (5);

(b) it does not comply with the obligations provided for in Article 37;

(c) it is underperforming at inter-laboratory comparative tests referred to in Article 37(2).

**Article 39**

Derogations from the condition for the mandatory assessment and accreditation for certain official laboratories [Am. 145]

1. By derogation from point (e) of Article 36(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 for the detection of *Trichinella* the methods referred to in Article 6 of Commission Regulation (EC) No 2075/2005 (1);

(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 36(1), and assessed and accredited in accordance with the standard EN ISO/IEC 17025 on ‘General requirements for the competence of testing and calibration laboratories’ for the use of the methods referred to in point (a)(ii) of this paragraph; [Am. 146]

(b) laboratories carrying out analyses or tests to verify compliance with the rules on plant reproductive material referred to in point (b) of Article 1(2); [Am. 147]

(c) 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 33(1) and points (a), (b) and (c) of Article 33(2);

(ii) carry out the analyses, tests or diagnoses under the supervision of the competent authorities or of the national reference laboratories for the methods they use;

(iii) participate regularly in the inter-laboratory comparative tests organised by the national reference laboratories for the methods they use;

(iv) have a quality assurance system in place to ensure sound and reliable results from the methods for laboratory analysis, test and diagnosis used.

2. Where the methods used by the laboratories referred to in point (c) of paragraph 1 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 of point (e) of Article 36(4).

3. The official laboratories designated in accordance with points (a) and (c) of paragraph 1 shall be located in the Member States in whose territory the competent authorities which have designated them are located.

### Article 40

Powers to adopt derogations from the condition for the mandatory assessment and accreditation of all the methods of laboratory analysis, test and diagnosis used by official laboratories [Am. 148]

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the cases where, and the conditions under which, competent authorities may designate as official laboratories in accordance with Article 36(1) laboratories which do not fulfil the conditions referred to in point (e) of Article 36(4) in relation to all the methods they use, provided that such laboratories comply with the following conditions:

(a) they operate, are assessed and 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;

(b) they make regular and significant use of the methods for which they have obtained the accreditation referred to in point (a).

### Article 41

Temporary derogations from the condition for the mandatory assessment and accreditation of official laboratories [Am. 149]

1. By derogation from point (a) of Article 36(5), the competent authorities may temporarily designate an existing official laboratory as official laboratory in accordance with Article 36(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 36(4):

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

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(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;

(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, to the environment; or

(c) *pending the assessment by, and decision of, the accreditation body.* [Am. 150]

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 from the use of the 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, and may be renewed once for a further period of one year.

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

**Article 41a**

*Official controls on animals and goods entering the Union shall be organised according to risk, and may take place at border control posts in accordance with Section II of this chapter, with a view to checking compliance with the regulatory provisions specific to certain animals or goods, or at an appropriate place in accordance with Section I of this chapter.* [Am. 151]

**Chapter V**

*Official controls on animals and goods entering the Union*

**Section I**

*Animals and goods not subject to specific official controls at borders*

**Article 42**

*Official controls on animals and goods not subject to specific official controls at borders*

1. The competent authorities shall perform official controls regularly on animals and goods entering the Union to ascertain compliance with the rules referred to in Article 1(2).

On animals and goods to which Article 45 does not apply, those official controls shall be performed with appropriate frequency, taking into account:

(a) the risks to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment, associated with different types of animals and goods;

(a) *the likelihood of fraudulent practices which might deceive consumer expectation regarding nature, quality and composition of foods and goods;* [Am. 152]

(b) 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;
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.

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, to the environment:

(a) means of transport, including where empty;
(b) packaging.

The competent authorities may also perform official controls on goods that are placed under one of the customs procedures defined in points (a) to (g) of Article 4(16) of Regulation (EEC) No 2913/92.

Types of official controls on animals and goods not subject to specific official controls at borders

1. The official controls referred to in Article 42(1) shall:

(a) always include a documentary check;
(b) include identity and physical checks depending on the risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, 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, identity and physical checks referred to in paragraph 1 show that animals and goods do not comply with the rules referred to in Article 1(2), Article 64(1), (3), (4) and (5), Articles 65 to 67, Article 69(1) and (2) and Article 70(1) and (2) shall apply.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the cases where and the conditions under which competent authorities may request operators to notify the arrival of certain goods entering the Union.

Samples taken on animals and goods not subject to specific official controls at borders

1. Where samples on animals and goods are taken, the competent authorities shall:

(a) inform the customs authorities and the operators concerned;
(b) decide whether or not the animals or goods can be released before the results of the analysis, test or diagnosis carried out on the samples are available, provided that the traceability of the animals or goods is ensured.

2. The Commission shall, by means of implementing acts:

(a) establish the mechanisms necessary to ensure the traceability of the animals or goods referred to in point (b) of paragraph 1;

(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 141(2).

Section II
Official controls at border Control Posts on animals and goods

Article 45
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 to the Union, on each consignment of the following categories of animals and goods entering the Union from third countries:

(a) animals;

(b) products of animal origin, foods that contain products of animal origin, germinal products and animal by-products; [Am. 153]

(c) plants, plant products, and other objects and materials capable of harbouring or spreading pests of plants as referred to in the lists established pursuant to Articles 68(1) and 69(1) of Regulation (EU) No …/…(*)

(d) goods originating from certain third countries for which the Commission has decided, by means of implementing acts provided for in point (b) of paragraph 2, 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) No …/…(**), or Articles 27(1), 29(1), 40(2), 41(2), 47(1), 49(2) and 50(2) of Regulation (EU) No …/…(***), 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 Articles 125 or 127 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 detailing the animals and goods belonging to the categories referred to in points (a) and (b) of paragraph 1, indicating their codes from the Combined Nomenclature;

(*) Number of the Regulation on protective measures against pests of plants.
(**) Number of the Regulation on animal health.
(***) Number of the Regulation on protective measures against pests of plants.
(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 141(2).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning amendments of the categories of consignments referred to in paragraph 1, to include other products which may give rise to risks to human, animal or plant health or, as regards GMOs and plant protection products, 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.

Article 46
Animals and goods exempted from official controls at border control posts

The Commission shall be empowered to adopt delegated acts in accordance with Article 139, concerning rules establishing the cases where and the conditions under which the following categories of animals and goods are exempted from Article 45:

(a) goods sent as commercial or trade samples or as display items for exhibitions, which are not intended to be placed on the market; [Am. 154]

(b) animals and goods intended for scientific purposes; [Am. 155]

(c) goods that are 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;

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 (10) of Article 4(1) of Regulation (EU) No XXX/XXXX [number of the Regulation on animal health]; [Am. 156]

g) goods which have undergone heat treatment and do not exceed quantities to be defined in those delegated acts;

(h) any other category of animals or goods for which controls at border control posts are not necessary given the risks they pose.

Article 47
Official controls at border control posts

1. The competent authorities shall perform official controls on the consignments of the categories of animals and goods referred to in Article 45(1) upon arrival of the consignment at the border control post. Those official controls shall include documentary, identity and physical checks.

2. All consignments of the categories of animals and goods referred to in Article 45(1) shall be subject to documentary and identity checks.

3. Physical checks shall be performed on consignments of the categories of animals and goods referred to in Article 45 (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, to the environment.
4. Physical checks to verify compliance with animal health and welfare requirements or with plant health requirements laid down in the rules referred to in Article 1(2) shall be performed by, or under the supervision of, staff possessing appropriate qualifications in veterinary or phytosanitary matters respectively, designated by the competent authorities for that purpose.

Where such checks are performed on animals or on products of animal origin, they shall be carried out by an official veterinarian on-site, who may be assisted by specially trained support staff whilst retaining responsibility for the checks carried out. [Am. 157]

5. 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). Arrangements shall be put in place by competent authorities to give priority to official controls on animals being transported and to reduce delays on such controls.

6. The Commission may, by means of implementing acts establish the modalities of presentation of consignments of the categories of goods referred to in Article 45(1), the sub-entities which can constitute an individual consignment and the maximum number of such sub-entities in each consignment, taking into account the need to guarantee the rapid and efficient handling of the consignments and the official controls to be performed by the competent authorities.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 48
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 45(1) shall be presented to, and kept by, the competent authorities of the border control post.

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 54 has been finalised in accordance with Articles 54(4) and 55(1).

Article 49
Specific rules for official controls at border control posts

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 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 45(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 modalities for carrying out documentary, identity and physical checks on transhipped consignments of the categories of goods referred to in Article 45(1);

(c) the cases where and the conditions under which identity 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 45(1) may be authorised and the specific official controls to be performed at border control posts on such consignments, including the cases and conditions for their storage in specially approved free or customs warehouses.
Article 50
Details of documentary, identity and physical checks

For the purposes of ensuring the uniform implementation of the rules laid down in Articles 47, 48 and 49, the Commission shall by means of implementing acts, lay down the details of the operations to be carried out during and after the documentary, identity and physical checks referred to in those rules 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 141(2).

Article 51
Official controls not performed at border control posts of first arrival

1. Competent authorities may perform the identity and physical checks of the animals and goods entering the Union from third countries referred to in Article 45(1) at control points other than border control posts, provided that those control points comply with the requirements provided for in Article 62(3) and in the implementing acts adopted in accordance with Article 62(4). [Am. 158]

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules establishing the cases where and the conditions under which:

(a) identity and physical checks on consignments of the categories of animals and goods referred to in Article 45(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 62(3) and in the implementing acts adopted in accordance with Article 62(4); [Am. 159]

(b) physical checks on consignments which have undergone documentary and identity checks at a border control post of first arrival may be performed at another border control post in a different Member State;

(c) specific control tasks relating to the following may be attributed by competent authorities to customs authorities or other public authorities:

(i) consignments referred to in Article 63(2);

(ii) passengers personal luggage;

(iii) goods ordered by small consignments sent to private individuals or acquired at a distance selling by telephone, post or internet; [Am. 160]

(iiiia) 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 (1). [Am. 161]

2. Point (b) of Article 54(2), point (a) of Article 55(2) and Article 57 and 58, Articles 60 and 61, and Article 62(3) and (4), shall apply to the control points referred to in point (a) of paragraph 1.

Article 52
Frequency of identity and physical checks

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules establishing the categories of animals and goods and the conditions under which, by derogation from Article 47(2) and account taken of the reduced risk, identity checks on consignments of animals and goods referred to in Article 45(1) shall be:

(a) performed at a reduced frequency;

(b) limited to the verification of a consignment’s official seal, where any such seal is present.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules establishing:

(a) the criteria and the procedures for determining and modifying the *minimum* frequency rates of physical checks to be performed on consignments of the categories of animals and goods referred to in points (a), (b) and (c) of Article 45(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 124(1);  

(ii) the outcome of controls performed by Commission experts in accordance with Article 115(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 referred to in Article 130;  

(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 physical checks established in accordance with point (a) so as to take account of local risk factors;  

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

3. The Commission shall, by means of implementing acts, lay down rules establishing:

(a) the *minimum* frequency of physical checks for the categories of goods referred to in point (d) of Article 45(1);  

(b) the *minimum* frequency of physical checks for the categories of animals and goods referred to in points (e) and (f) of Article 45(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 141(2).

Article 53

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 45(1) following the performance of official controls, 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 taken following a physical check to verify compliance with animal health and welfare requirements or with plant health requirements shall be taken by staff possessing appropriate qualifications in veterinary or phytosanitary matters respectively, and designated by the competent authorities for that purpose.

Decisions on consignments of animals and products of animal origin shall be taken by an official veterinarian or under his supervision who may be assisted by specially trained support staff whilst retaining responsibility for the checks carried out.  

2a. Decisions on consignments of animals and products of animal origin shall be recorded in the CHED.  

Article 54

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

1. For each consignment of the categories of animals and goods referred to in Article 45(1) the operator responsible for the consignment shall complete a CHED, providing the information necessary for the immediate and complete identification of the consignment and its destination.
2. The CHED shall be used:

(a) by the operators responsible for consignments of the categories of animals and goods referred to in Article 45(1) in order to give prior notification to the competent authorities of the border control post of the arrival of those consignments;

(b) by 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 or in electronic exchange with the TRACES system.

[Am. 168]

2a. The operators and competent authorities referred to in paragraph 2 may also use a national information system to feed data into the TRACES system. [Am. 169]

3. Operators shall give prior notification in accordance with point (a) of paragraph 2 by completing and submitting the relevant part of the CHED into the TRACES system for transmission to the competent authorities of the border control post prior to the physical arrival of the consignment into the Union.

4. The competent authorities of the border control post shall finalise the CHED record the decision on the consignment in the Common Health Entry Document as soon as: all official controls required by Article 47(1) have been performed.

(a) all official controls required by Article 47(1) have been performed;

(b) the results from physical checks, where such checks are required, are available;

(c) a decision on the consignment has been taken in accordance with Article 53 and recorded on the CHED. [Am. 170]

Article 55
Use of the Common Health Entry Document by customs authorities

1. The placing of consignments of the categories of animals and goods referred to in Article 45(1) under supervision or control by the customs authorities, including the entry or handling in free zones or customs warehouses, shall be subject to the presentation by the operator to the custom authorities of the CHED, or its electronic equivalent, duly finalised in the TRACES system 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;

(b) 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 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 45 (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 64(5).

Article 56
Format, time requirements and specific rules for the use of the Common Health Entry Document

1. The Commission shall, by means of implementing acts, lay down rules establishing:

(a) the format of the CHED and the instructions for its presentation and use;
(b) the minimum time requirements for prior notification of consignments by operators as provided for in point (a) of Article 54(2) 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 141(2).

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 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 45(1) to the place of destination. A copy of the CHED shall in any case accompany consignments of the categories of animals and goods referred to in Article 45(1) to the place of destination. [Am. 171]

Article 57
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 45(1).

2. Member States shall notify the Commission at least three months 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 62.

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 115 in order to verify compliance with the minimum requirements laid down in Article 62;

(b) of the date of such a control.

4. 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.

Article 58
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 and opening hours;

(b) its exact location and whether it is a port, airport, rail or road entry point;

(c) the categories of animals and goods referred to in Article 45(1) which are included in the scope of its designation;

(d) the equipment and premises available for performing official controls on each of the categories of animals and goods for which it is designated;

(e) the volume of the animals and goods handled per calendar year for each of the categories of animals and goods referred to in Article 45(1) for which it is designated.

2. The Commission shall, by means of implementing acts, establish 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 141(2).
Article 59
Withdrawal of approvals for, and re-designation of, existing border control entities


2. Member States may re-designate border inspection posts, designated points of entry and points of entry referred to in paragraph 1 as border control posts in accordance with Article 57(1) provided that the minimum requirements referred to in Article 62 are complied with.

3. Article 57(2) and (3) shall not apply to the re-designation referred to in paragraph 2.

Article 60
Withdrawal of the designation of border control posts

1. Where border control posts cease to comply with the requirements referred to in Article 62, the Member States shall:

(a) withdraw the designation provided for in Article 57(1) for all or for certain categories of animals and goods for which the designation was made;

(b) remove them from the lists referred to in Article 58(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 shall be empowered to adopt delegated acts in accordance with Article 139 concerning the cases where, and the procedures by which, border control posts whose designation has only been partially withdrawn in accordance with point (a) of paragraph 1 may be re-designated by derogation from Article 57.

Article 61
Suspension of the designation of border control posts

1. A Member State shall immediately 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, or to the environment. [Am. 172]

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 58(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;

(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. The Commission may, by means of implementing acts, establish procedures for the exchanges of information and communications referred to in paragraph 2 and in point (b) of paragraph 4.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).
Article 62
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 in a place that is suitably equipped to be designated by the customs authorities, in accordance with Article 38(1) of Regulation (EEC) No 2913/92. [Am. 173]

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the cases where and conditions under which a border control post can be situated at a certain distance from the point of entry into the Union given specific geographical constraints.

3. Border control posts shall have:

   (a) a sufficient number of suitably qualified staff;
   
   (b) premises appropriate for the nature and volume of the categories of animals and goods handled;
   
   (c) equipment and premises 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 guarantee, as appropriate, access to any other equipment, premise and service necessary to apply the measures taken in accordance with Articles 63, 64 and 65 in cases of suspicion, 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 63, 64 and 65 in cases of unforeseeable and unexpected conditions or events;
   
   (f) the technology and equipment necessary for the efficient operation of the TRACES system 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 TRACES system 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;
   
   (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, detail the requirements laid down in paragraph 3 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 64(3) and (5) and Article 65 in relation to the different categories of animals and goods referred to in Article 45(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Section III
Action in case of suspicion of non-compliance and of non-compliance of animals and goods from third countries

Article 63
Suspicion of non-compliance and intensified official controls

1. In case of suspicion of non-compliance of consignments of the categories of animals and goods referred to in Article 45(1) with the rules referred to in Article 1(2), the competent authorities shall perform official controls or delegate the responsibility to other competent authorities in order to confirm or to eliminate that suspicion. [Am. 174]
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 45(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 until they obtain the results 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 treated pending the results of the official controls.

4. Where the competent authorities have reasons to suspect fraudulent behaviour by an operator or 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 64(3), intensify official controls on consignments with the same origin or use as appropriate. [Am. 175]

5. The competent authorities shall notify the Commission and the Member States through the TRACES system of their decision to perform intensified official controls, as provided for in paragraph 4, indicating the purported fraudulent behaviour or serious or repeated infringement.

6. The Commission shall, by means of implementing acts, establish procedures for the coordinated performance by competent authorities of the intensified official controls referred to in paragraphs 4 and 5.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 64
Measures to be taken in cases of non-compliant consignments entering the Union from third countries

1. The competent authorities shall place under official detention any consignment of animals or goods entering the Union from third countries which does not comply with the rules referred to in Article 1(2) When the competent authority ascertains as a result of the official controls performed at the border control posts in accordance with Article 45, that consignments of animals and goods do not comply with the requirements under Article 1(2), it shall issue a report or a decision: ‘Non-compliant consignment’ or ‘Negative control’ which shall be recorded in the CHED. Furthermore the competent authorities shall officially detain said consignment of animals or goods and refuse its entry into the Union. [Am. 176]

As appropriate, any such consignment or part thereof shall be isolated or quarantined and animals belonging to it shall be kept and treated under appropriate conditions pending any further decision. The special needs of other goods shall also be borne in mind. [Am. 177]

2. The Commission shall, by means of implementing acts, lay down the modalities for the isolation and quarantine provided for in the second subparagraph of paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

3. Having, where possible, heard the operator responsible for the consignment the competent authorities shall hear the operator responsible for the consignment the competent authorities. The competent authority may omit this if an immediate decision is necessary either because a delay would be dangerous or such a decision in the public interest. It shall, without delay, order that the operator:

(a) destroy the consignment or part thereof, humanely in the case of live animals, in compliance, where appropriate, with the rules referred to in Article 1(2); or [Am. 179]

(b) re-dispatch the consignment or part thereof outside the Union in accordance with Article 70(1) and (2); or [Am. 180]

(c) subject the consignment or part thereof to special treatment in accordance with Article 69(1) and (2) or to any other measure necessary to ensure compliance with the rules referred to in Article 1(2), and, where appropriate, destines the consignment for purposes other than those for which it was originally intended. [Am. 181]
4. The competent authorities shall immediately notify any decision to refuse entry of a consignment as provided for in paragraph 1 and any order issued pursuant to paragraphs 3 and 5 and Article 65 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;

(e) the operator responsible for the consignment.

That notification shall be performed via the computerized information management system referred to in Article 130(1).

5. If a consignment of the categories of animals or goods referred to in Article 45(1) is not presented for the official controls referred to in that Article, or is not presented in accordance with the requirements laid down in Articles 48(1) and (3) and 54(1), (2) and (3), or with the rules adopted pursuant to Article 46, Article 47(6), Article 49, Article 51(1) and Article 56, the competent authorities shall order that it be retained or recalled, and placed under official detention without delay.

Paragraphs 1, 3 and 4 of this Article shall apply to such consignments.

Article 65

Measures to be taken on animals or goods entering the Union in cases of an attempt to bring non-compliant consignments into the Union from third countries presenting a risk

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

The competent authorities shall retain the consignment in question under official detention and shall, without delay:

(a) order that the operator destroy the consignment, humanely in the case of live animals, in compliance, where appropriate, 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; or

(b) subject the consignment to special treatment in accordance with Article 69(1) and (2).

Article 66

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 other documents accompanying consignments which have been subject to measures pursuant to Article 64(3) and (5) and Article 65;

(b) cooperate in accordance with Title IV 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 64(1).

2. The competent authorities in the Member State where the official controls were performed shall supervise the application of the measures ordered pursuant to Article 64(3) and (5) and Article 65 to ensure that the consignment does not give rise to adverse effects on human, or 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 67

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

1. The operator shall carry out all the measures ordered by the competent authorities in accordance with Article 64 (3) and (5) and 65 without delay and, at the latest, in the case of products, within 60 days from the day on which the competent authorities notified the operator of their decision in accordance with Article 64(4). [Am. 186]

2. If, after the expiry of the 60-day period no action has been taken by the operator, 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 65, 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 34, provided that this is without adverse effects to human, animal and plant health, animal welfare and, as regards GMOs and plant protection products, to the environment.

Article 68

Consistency of application of Articles 64 and 65

The Commission shall, by means of implementing acts, lay down rules to ensure consistency across all border control posts referred to in Article 57(1) and control points referred to in point (a) of Article 51(1) of decisions and measures taken and orders issued by the competent authorities pursuant to Articles 64 and 65, in the form of instructions 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 141(2).

Article 69

Special treatment of consignments

1. The special treatment of consignments provided for in point (c) of Article 64(3) and point (b) of Article 65 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;

(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, to the environment;

(b) be documented and carried out under the control of the competent authorities;

(c) comply with the requirements laid down in the rules referred to in Article 1(2).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the requirements and the conditions in accordance with which the special treatment provided for in paragraph 1 shall take place.

In the absence of rules adopted by delegated act, such special treatment shall take place in accordance with national rules.
Article 70
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 first informed the competent authorities of the third country of origin or third country of destination, if different, 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 competent authorities of the third country of destination have notified the competent authorities of the Member State that they are prepared to accept the consignment;

(d) in the case of consignments of animals the re-dispatch is in compliance with animal welfare requirements.

2. The conditions of points (b) and (c) of paragraph 1 shall not apply to consignments of the categories of goods referred to in point (c) of Article 45(1).

3. The Commission shall, by means of implementing acts, specify the procedures for the information exchanges and notifications referred to in paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

3a. Member States receiving imports which have been authorised by pre-export-controls shall regularly check if the imports actually comply with Union requirements. [Am. 187]

Article 71
Approval of pre-export controls performed by third countries

1. The Commission may, by means of implementing acts, approve specific pre-export controls that a 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). The 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 141(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 behaviour;

(b) the official certificates that must accompany consignments entering the Union;

(c) a model for such certificates;

(d) the competent authorities of the third country under the responsibility of which pre-export controls must be performed;

(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 of Articles 25 to 32 or equivalent conditions.

3. The approval provided for in paragraph 1 may only be granted to a third country if the evidence available and, where appropriate, a Commission control performed in accordance with Article 119, demonstrate that the system of official controls in that third country can 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;
(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 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;

(b) ensure that the official certificates referred to in point (b) of paragraph 2 accompany each consignment controlled.

5. The Commission shall by means of implementing acts establish detailed rules and criteria for approving pre-export controls performed by third countries in accordance with paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 72

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 71(1) reveal serious and recurrent non-compliances 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 TRACES system, including the measures to be applied, in addition to seeking administrative assistance in accordance with the procedures established in Title IV; [Am. 188]

(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, detain a reasonable number of samples under appropriate storage conditions.

2. The Commission may, by means of implementing acts, withdraw the approval provided for in Article 71(1) where, following the official controls referred to in paragraph 1, it appears that the requirements laid down in Article 71(3) and (4) are no longer being met.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 73

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

1. Competent authorities, customs authorities and other authorities of the Member States shall cooperate closely to ensure that the official controls performed 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) guarantee reciprocal access to information which is relevant for the organisation and conduct of their respective activities in relation to animals and goods entering the Union;

(b) ensure the timely exchange of such information, including via electronic means.

1a. The customs authorities shall only release those consignments of animals and goods under Article 45 in respect of which the competent authority at the border control post has carried out the official controls provided for in Article 47 and issued a decision recorded in the CHED. [Am. 189]
2. The Commission shall, by means of implementing acts, adopt uniform rules on the 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 45(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;

(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 141(2).

Article 74

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

1. In the case of consignments of animals and goods other than those subject to controls at entry into the Union as required by Article 45(1) and for which a customs declaration for release for free circulation has been made in accordance with Article 4(17) and Articles 59 to 83 of Regulation (EEC) No 2913/92, paragraphs 2, 3 and 4 shall apply.

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, 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, to the environment, is present:

(a) they shall instruct 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:

‘Product presents a risk — release for free circulation not authorised — Regulation (EU) No …/…. (*)’;

(b) no other customs procedure shall be permitted without the consent of the competent authorities;

(c) Article 64(1), (3), (4) and (5), Articles 65 to 67, Article 69(1) and (2) and Article 70(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 45(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, to the environment, shall transmit all relevant information to the customs authorities in the Member States of final destination.

(*) Number of this Regulation.
Article 75

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

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules for the performance of specific official controls and for the adoption of measures in cases of non-compliance, to account for the specificities of the following categories of animals and goods or their transport modalities and means:

(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 (1) 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 45(1) which are delivered, with or without storage in a specially approved free or customs warehouse, to vessels leaving the Union and intended for ship supply or consumption by the crew and passengers;

(d) wood packaging material; [Am. 190]

(e) feed and food accompanying animals and intended for the feeding of those animals;

(f) animals and goods ordered by distance selling 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 45(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 45(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 the provisions of Article 45 in accordance with Article 46.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 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 or the border control post of exit.

3. The Commission may, by means of implementing acts, lay down rules concerning:

(a) model official certificates and rules for the issuance of such certificates;

(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 141(2).

Chapter VI
Financing of official controls and other official activities

Article 76
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. *With that aim in view they shall collect fees or contributions to the costs or make resources available from general tax revenue.*

2. In addition to the fees collected in accordance with Article 77, Member States may collect fees to cover costs occasioned by official controls other than those referred to in Article 77(1) and (2).

3. This Chapter also applies in the case of delegation of specific official control tasks in accordance with Article 25.

4. Member States shall consult the operators concerned on the methods used to calculate the fees or contributions to the costs. [Am. 191]

Article 77
Mandatory fees or contributions to the costs

1. For the purpose of ensuring that competent authorities are provided with adequate resources for the performance of official controls, the competent authorities shall *may* collect fees or contributions to the costs to recover, some or all of the costs they incur in relation to:

(a) official controls performed to verify that the following operators comply with the rules referred to in Article 1(2):

   (i) food business operators as defined in Article 3(3) of Regulation (EC) No 178/2002 that are either registered or approved, or registered and approved, in accordance with Article 6 of Regulation (EC) No 852/2004;

   (ii) feed business operators as defined in Article 3(6) of Regulation (EC) No 178/2002 registered or approved in accordance with Articles 9 and 10 of Regulation (EC) No 183/2005 of the European Parliament and of the Council (*);

   (iii) professional operators as defined in point (7) of Article 2 of Regulation (EU) No …/…. (**);

   (iv) professional operators as defined in point (6) of Article 3 of Regulation (EU) No XXX/XXXX [number of the Regulation on the production and making available on the market of plant reproductive material];

(b) the official controls performed in view of the issuance of official certificates or to supervise the issuance of official attestations;

(c) official controls performed to verify that the conditions are met:

   (i) to obtain and maintain the approval provided for in Article 6 of Regulation (EC) No 852/2004 or in Articles 9 and 10 of Regulation (EC) No 183/2005;

   (ii) to obtain and maintain the authorisation referred to in Articles 84, 92 and 93 of Regulation (EU) No …/…. (**);

   (iii) to obtain and maintain the authorisation referred to in Article 25 of Regulation (EU) No XXX/XXXX [number of the Regulation on the production and making available on the market of plant reproductive material];

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(**) Number of the Regulation on protective measures against pests of plants.

(***) Number of the Regulation on protective measures against pests of plants.
(d) official controls performed by the competent authorities at the border control posts or at the control points referred to in point (a) of Article 51(1).

2. For the purposes of paragraph 1, the official controls referred to in point (a) of that paragraph shall include official controls performed to verify compliance with measures adopted by the Commission in accordance with Article 137 of this Regulation, Article 53 of Regulation (EC) No 178/2002, Articles 27(1), 29(1), 40(2), 41(2), 47(1), 49(2) and 50(2) of Regulation (EU) No .../.... (*) Articles 41 and 144 of Regulation (EU) No XXX/XXXX [number of the Regulation on the production and making available on the market of plant reproductive material] and Part VI of Regulation (EU) No .../.... (**), unless the decision establishing the measures requires otherwise.

3. For the purposes of paragraph 1:

(a) the official controls referred to in point (a) of that paragraph shall not include official controls performed to verify compliance with temporary restrictions, requirements or other disease control measures adopted by the competent authorities in accordance with Article 55(1), Article 56, Articles 61 and 62, Articles 64 and 65, Article 68(1) and Article 69, and rules adopted pursuant to Article 55(2), Article 63, Article 67 and Article 68(2) of Regulation (EU) No .../.... (***) and Article 16 of Regulation (EU) No .../.... (****);

(aa) the official controls referred to in point (a) of that paragraph shall not include controls performed at the level of primary production as defined in Article 3(17) of Regulation (EC) No 178/2002, including on farm processing. That includes controls to verify compliance with statutory management requirements in the area of public health, animal health, plant health, and animal welfare in accordance with Article 93 of Regulation (EU) No 1306/2013; [Ams 192, 343, 314 and 316]

(b) the official controls referred to in point (a) and (b) of that paragraph shall not include official controls performed to verify compliance with the rules referred to in Article 1(2)(j) and (k).

Article 78

Costs

1. The competent authorities shall collect fees be entitled, when calculating the fees or contributions to the cost in accordance with Article 77, to take the following costs criteria into account:

(a) the salaries of the staff, including support staff, involved in the performance insofar as they correspond to the actual costs of official controls, in accordance with point (b) of Article 79(1), excluding their social security, pension and insurance costs;

(b) the cost of facilities and equipment, including maintenance and insurance costs;

(c) the cost of consumables, services and tools;

(*) Number of the Regulation on protective measures against pests of plants.
(**) Number of the Regulation on animal health.
(***) Number of the Regulation on animal health.
(****) Number of the Regulation on protective measures against pests of plants.
(d) the cost of training of 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;

(e) the cost of travel of the staff for the performance of the official controls referred to in point (a), and associated subsistence costs, calculated in accordance with Article 79(2);

(f) the cost of sampling and of laboratory analysis, testing and diagnosis.

2. If the competent authorities collecting mandatory fees or contributions to the costs in accordance with Article 77 also perform other activities, only the fraction of the cost elements referred to in paragraph 1 of this Article which results from the official controls referred to in Article 77(1) shall be considered for the calculation of the mandatory fees or contribution to the costs. [Am. 193]

Article 79

Calculation of mandatory fees or contributions to the costs

1. The fees or contributions to the costs collected in accordance with Article 77 shall be:

(a) established 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 on each sector, activity and category of operator, 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) calculated on the basis of the actual costs of each individual official control, and applied to the operators subject to such official control; such fee shall not exceed the actual costs of the official control performed and may be partly or entirely expressed as a function of the time employed by the staff of the competent authorities to perform the official controls.

2. Travel costs as referred to in point (e) of Article 78(1) shall be considered for the calculation of the fees or contributions to the costs referred to in Article 77(1) 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 the fees or contributions to the costs are calculated in accordance with point (a) of paragraph 1, the fees or contribution to the costs collected by competent authorities in accordance with Article 77 shall not exceed the overall costs incurred for the official controls performed over the period of time referred to in point (a) of paragraph 1. [Am. 194]

Article 80

Reduction of fees or contributions to the costs for consistently compliant operators

Where fees or contributions to the costs are established in accordance with point (a) of Article 79(1), the rate of the fee to be applied to each operator shall be determined taking into account the operators’ record of compliance with the rules referred to in Article 1(2) as ascertained through official controls, so that fees or contribution to the costs applied to consistently compliant operators are lower than those applied to other operators. [Am. 195]

Article 81

Application of fees or contributions to the costs

1. Operators shall receive proof of the payment of fees or contributions to the costs provided for in Article 77(1).

2. Fees or contributions to the costs collected in accordance with point (d) of Article 77(1) shall be paid by the operator responsible for the consignment or its representative. [Am. 196]
Article 82
Fees refunds and exemption for microenterprises

1. Fees provided for in Article 77 shall not directly or indirectly be refunded, unless unduly collected.

2. Enterprises employing fewer than 10 persons and whose annual turnover or annual balance sheet total does not exceed EUR 2 million shall be exempted from the payment of the fees provided for in Article 77.

3. The costs referred to in Articles 77, 78 and 79 shall not include those incurred for the performance of official controls on the enterprises referred to in paragraph 2.

Member States may exempt small and medium-sized enterprises that fulfil certain objective and non-discriminatory criteria from the payment of fees or cost contributions provided for in Article 77. [Ams 197, 315 and 348]

Article 83
Transparency

1. The competent authorities shall ensure the highest level of transparency of:

(a) the method and data used to establish the fees or contributions to the costs provided for in Article 77(1);

(b) the use of resources collected through such fees or contributions to the costs, including the number of controls performed;

(c) the arrangements in place to ensure an efficient and thrifty use of the resources collected through such fees or contributions to the costs.

2. Each competent authority shall make available to the public the following information for each reference period:

(a) the costs to the competent authority for which a fee is due in accordance with Article 77(1), indicating the breakdown of such costs per activity referred to in Article 77(1) and per cost element referred to in Article 78(1);

(b) the amount of the fees or contributions to the costs provided for in Article 77(1) applied to each category of operators, and for each category of official controls;

(c) the method used to establish the fees or contributions to the costs provided for in Article 77(1), including the data and estimates used for the establishment of the flat rate fees or contribution to the costs referred to in point (a) of Article 79(1);

(d) where point (a) of Article 79(1) applies, the method used to adjust the level of the fees or contributions to the costs in accordance with Article 80;

(e) the overall amount of fees or contributions to the costs corresponding to the exemption referred to in Article 82(2). [Am. 198]

Article 84
Expenses arising from additional official controls and from enforcement measures

Competent authorities shall charge fees or contributions to the costs to cover the additional costs they have incurred as a result of: [Am. 199]

(a) additional official controls:

(i) which have become necessary following the detection of a non-compliance during an official control performed in accordance with this Regulation;
(ii) performed to assess the extent and the impact of the non-compliance or to verify that the non-compliance has been remedied;

(b) official controls performed at the request of the operator;

(c) corrective action taken by the competent authorities, or by a third party upon request by the competent authorities, where an operator has failed to carry out corrective action ordered by the competent authorities in accordance with Article 135 to remedy the non-compliance;

(d) official controls performed and action taken by the competent authorities in accordance with Articles 64 to 67, 69 and 70, and corrective action taken by a third party upon request by the competent authorities, in cases where the operator has failed to carry out corrective action ordered by the competent authorities in accordance with Article 64(3) and (5), Article 65 and Article 67.

Chapter VII
Official certification

Article 85
General requirements concerning official certification

1. In accordance with rules referred to in Article 1(2), official certification shall take the form of:

(a) official certificates; or,

(b) official attestations,

(ba) official health attestations. [Am. 200]

2. Where the competent authorities delegate specific tasks related to the issuance of official certificates or official attestations, or to the official supervision referred to in Article 90(1) such delegation shall comply with Articles 25 to 32.

Article 86
Official certificates

1. When the rules referred to in Article 1(2) require the issuance of an official certificate, Articles 87, 88 and 89 shall apply.

2. Articles 87 to 89 shall also apply to official certificates which are necessary for the purposes of exporting consignments of animals and goods to third countries.

2a. Regarding the issuance of an official certificate for products referred to in point (j) of Article 1(2), in addition to compliance with Article 85(2), the delegated body shall work and be accredited in accordance with standard EN ISO/IEC 17065: 2012. [Am. 201]

Article 87
Signature and issuance of official certificates

1. Official certificates shall be issued by the competent authorities or delegated bodies pursuant to Articles 25 to 32. [Am. 202]

2. Competent authorities shall designate the certifying officers who are authorised to sign official certificates. Certifying officers shall:

(a) be free from conflict of interest in relation to what is being certified and act independently and impartially; [Am. 203]

(b) receive appropriate training on the rules with which compliance is certified by the official certificate as well as on the provisions of this Chapter.
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 facts and data relevant for the certification, 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 when rules referred to in Article 1(2) so require.

Article 88
Guarantees of reliability for official certificates

1. Official certificates shall:

(a) not be signed by the certifying officer where they are blank or incomplete;

(b) be drawn up in one of the official languages of the institutions of the Union that is understood by the certifying officer and, where relevant, in one of the official languages of the Member State of destination;

(c) be authentic and accurate;

(d) enable the identification of the person who signed them and the date of issue; [Am. 204]

(e) allow the easy verification of the link between the certificate, the issuing authority and the consignment, lot or individual animal or good covered by the certificate. [Am. 205]

2. The competent authorities shall take all measures necessary to prevent and penalise the issuance of false or misleading official certificates or the abuse of official certificates. Such measures shall include where appropriate:

(a) the temporary suspension of the certifying officer from its duties;

(b) the withdrawal of the authorisation to sign official certificates;

(c) any other necessary measure to prevent that the offence referred to in the first sentence of this paragraph is repeated.

Article 89
Implementing powers for official certificates

The Commission may, by means of implementing acts, lay down rules for the uniform application of Articles 87 and 88 concerning:

(a) model official certificates and rules for the issuance of such certificates;

(b) the mechanisms and the legal 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 production 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 141(2).

**Article 90**

**Official attestations**

1. When 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 of the official languages of the institutions of the Union or in any of the official languages of a Member State; [Am. 206]

   (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 certification procedure or, where the official attestations are issued by the competent authorities, the staff involved in the issuance of those official attestations:

   (a) are independent, impartial and free from any conflict of interest in relation to what is being certified by the official attestations; [Am. 207]

   (b) receive appropriate training on:

      (i) the rules with which compliance is certified by the official attestations;

      (ii) the 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);

   (b) the attestation is issued on the basis of relevant, correct and verifiable facts and data.

  

**Title III**

**Reference laboratories and centres**

**Article 91**

**Designation of European Union reference laboratories**

1. The Commission may, by means of implementing acts, designate European Union reference laboratories in the areas governed by the rules referred to in Article 1(2) where the effectiveness of official controls also depends on the quality, uniformity and reliability of: [Am. 208]

   (a) the methods of analysis, test or diagnosis employed by the official laboratories designated in accordance with Article 36 (1);
(b) the results of the analyses, tests and diagnoses performed by those official laboratories.

2. The designations provided for in paragraph 1 shall:

(a) follow a public selection process;

(b) be reviewed regularly every five years; [Am. 209]

(ba) be made only to laboratories that hold a supporting letter from the authority competent in the field in question. [Am. 317]

2a. The Commission may, where it considers appropriate, designate more than one reference laboratory for the same disease and thus promote the rotation of national laboratories meeting the requirements of paragraph 3 of this Article. [Am. 210]

3. European Union reference laboratories shall:

(a) operate in accordance with the standard EN ISO/IEC 17025 on ‘General requirements for the competence of testing and calibration laboratories’ and be assessed and accredited in accordance with that standard by a national accreditation body, operating in accordance with Regulation (EC) No 765/2008;

(b) be independent, impartial and free of conflict of interests as regards the exercise of its tasks as European Union reference laboratories; [Am. 211]

(c) have 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 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 to perform their tasks in emergency situations;

(g) where relevant, be equipped to comply with relevant biosecurity standards;

(ga) where relevant, cooperate with Union research centres and Commission services to develop high standards in methods of laboratory analysis, testing and diagnosis; [Am. 212]

(gb) be able to receive a financial contribution from the Union in accordance with Council Decision 90/424/EEC (1);

[Am. 213]

(gc) ensure that their staff respect the confidential nature of certain subjects, results or communications. [Am. 214]

3a. By way of derogation from paragraphs 1 and 2 of this Article, the reference laboratories referred to in Article 32 (1) of Regulation (EC) No 1829/2003 and Article 21(1) of Regulation (EC) No 1831/2003 shall be European Union reference laboratories having the tasks and responsibilities set out in Article 92 of this Regulation, as regards, respectively:

(a) GMOs and genetically modified food and feed;

(b) feed additives. [Am. 215]

Article 92
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 36(1) and of the analytical, testing and diagnostic data generated by them.

2. European Union reference laboratories shall be responsible, in accordance with annual or multiannual work programmes approved by the Commission, for the following tasks:

(a) providing national reference laboratories with details of methods of laboratory analysis, test or diagnosis, including reference methods;

(aa) providing reference material free of charge and for unrestricted use, in respect of animal health, strains and serums, to the national reference laboratories to facilitate the adjustment and harmonisation of methods of analysis, testing and diagnosis; [Am. 216]

(b) 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 and by ensuring appropriate follow-up of such comparative testing in accordance, where available, with internationally accepted protocols; they shall inform the competent authorities of the follow-up and results of such inter-laboratory comparative testing; [Am. 217]

(c) coordinating practical arrangements necessary to apply new methods of laboratory analysis, test or diagnosis, and informing national reference laboratories of advances in this field;

(d) conducting training courses free of charge for the benefit of staff from national reference laboratories and, if needed, conducting training courses for the benefit of staff from other official laboratories, as well as of experts from third countries; [Am. 218]

(e) providing scientific and technical assistance to the Commission within the scope of their mission;

(f) providing information on relevant Union, national and international research activities to national reference laboratories;

(g) collaborating within the scope of their mission with laboratories in third countries and with the European Food Safety Authority, the European Medicines Agency and the European Centre for Disease Prevention and Control;

(h) assisting actively in the diagnosis of outbreaks in Member States of foodborne, 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; [Am. 219]

(i) coordinating or performing tests for the verification of the quality of reagents used for the diagnosis of animal, zoonotic or foodborne diseases;

(j) where relevant for their area of competence, establishing and maintaining:

(ii) reference collections of pests of plants or reference strains of pathogenic agents; [Am. 220]

(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.
2a. Paragraphs 1 and 2 of this Article shall apply without prejudice to Article 32, first paragraph, of Regulation (EC) No 1829/2003 and the rules adopted under the fourth and fifth paragraphs of Article 32 of that Regulation, in addition to Article 21, first paragraph, of Regulation (EC) No 1831/2003 and the rules adopted under the third and fourth paragraphs of Article 21 of that Regulation. [Am. 221]

3. European Union reference laboratories shall publish the list of the national reference laboratories designated by the Member States in accordance with Article 98(1).

**Article 92a**

1. The Commission shall, by means of delegated acts, designate a European Union reference laboratory for food authenticity.

2. Member States may designate national reference laboratories as part of a network of laboratories working within the Union. [Am. 222]

**Article 93**

Designation of European Union reference centres for plant reproductive material

1. The Commission may, by means of implementing acts, designate European Union reference centres that shall support the activities of the Commission, the Member States and the European Plant Variety Agency (EPCA) in relation to the application of the rules referred to in point (b) of Article 11(2).

2. The designations provided for in paragraph 1 shall:

   (a) follow a public selection process;

   (b) be reviewed regularly.

3. European Union reference centres for plant reproductive material shall:

   (a) possess a high level of scientific and technical expertise in inspection, sampling and testing of plant reproductive material;

   (b) have suitably qualified staff with adequate training in the areas referred to in point (a) and support staff as appropriate;

   (c) possess or have access to the infrastructure, the equipment and the products necessary to carry out the tasks assigned to them;

   (d) ensure that their staff have good knowledge of international standards and practices in the areas referred to in point (a) and that the latest developments in research at national, Union and international level in those areas are taken into account in their work. [Am. 223]

**Article 94**

Responsibilities and tasks European Union reference centres for plant reproductive material

The European Union reference centres designated in accordance with Article 93(1) shall be responsible, in accordance with annual or multiannual work programmes approved by the Commission for the following tasks:

(a) providing scientific and technical expertise, within the scope of their mission, on:

   (i) field inspection, sampling and testing performed for the certification of plant reproductive material;
(ii) post-certification tests of plant reproductive material;

(iii) tests on standard material categories of plant reproductive material;

(b) organising comparative tests and field trials on plant reproductive material;

(c) conducting training courses for the benefit of staff of the competent authorities and of experts from third countries;

(d) contributing to the development of certification and post-certification test protocols for plant reproductive material, and of performance indicators for the certification of plant reproductive material;

(e) disseminating research findings and technical innovations in the fields within the scope of their mission. [Am. 224]

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 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). [Am. 225]

2. The designations provided for in paragraph 1 shall:

(a) follow a public selection process;

(b) be reviewed regularly.

3. European Union reference centres for animal welfare shall:

(a) have suitably qualified staff with a high level of scientific and technical expertise in human-animal relationship, animal behaviour, animal physiology, animal health and nutrition related to animal welfare, and animal welfare aspects related to the commercial and scientific use of animals, taking ethical aspects into consideration. [Am. 226]

(b) have suitably qualified staff with adequate training in the areas referred to in point (a) and in ethical issues related to animals and support staff as appropriate. [Am. 227]

(c) possess or have access to the infrastructure, the equipment and products necessary to carry out the tasks assigned to them;

(d) ensure that their staff have good knowledge of international standards and practices in the areas referred to in point (a) and that the latest developments in research at national, Union and international level 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 designated in accordance with Article 95(1) shall be responsible, in accordance with annual or multiannual work programmes approved by the Commission for the following tasks:

(a) providing scientific and technical expertise within the scope of their mission to the national scientific support networks or bodies provided for in Article 20 of Regulation (EC) No 1099/2009;

(b) providing scientific and technical expertise for the development and application of the animal welfare indicators referred to in point (f) of Article 18(3);
(ba) coordinating a network of institutions with recognised knowledge on animal welfare that could assist the competent authorities and stakeholders in implementing relevant Union legislation; [Am. 228]

c) developing or coordinating methods for the assessment of the level of welfare of animals and of methods for the improvement of the welfare of animals; [Am. 229]

d) coordinating the carrying out of scientific and technical studies on the welfare of animals used for commercial or scientific purposes; [Am. 230]

(e) conducting training courses for the benefit of staff of the national scientific support networks or bodies referred to in point (a), of staff of the competent authorities and of experts from third countries;

(f) disseminating research findings and technical innovations and collaborating with Union research bodies in the fields within the scope of their mission.

Article 96a

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 any intentional violations of the rules referred to in Article 1(2).

2. The designations provided for in paragraph 1 shall follow a public selection process and be reviewed regularly.

3. European Union reference centres for the authenticity and integrity of the agri-food chain shall:

(a) possess a high level of scientific and technical expertise in the sectors governed by the rules referred to in Article 1(2) and in applied forensic science in those sectors, thus having the ability to carry out or coordinate research at the highest levels on the authenticity and integrity of goods and to develop, apply and validate the methods to be used for the detection of intentional violations of the rules referred to in Article 1(2);

(b) have suitably qualified staff with adequate training in the areas referred to in point (a) and the necessary support staff;

(c) possess or have access to the infrastructure, the equipment and the products necessary to carry out the tasks assigned to them;

(d) ensure that their staff have good knowledge of international standards and practices in the subjects referred to in point (a) and that the latest research developments at national, Union and international level in those areas are taken into account in their work. [Am. 231]

Article 96b

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

The European Union reference centres designated under Article 96a(1) shall be responsible, in accordance with the annual or multiannual work programmes approved by the Commission, for the following activities:

(a) providing specific knowledge of the authenticity and integrity of goods and methods for detecting intentional violations of the rules referred to in Article 1(1), 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 intentional violations, for economic reasons, of the rules referred to in Article 1(2) and helping to develop specific official control techniques and protocols;

(c) where necessary, performing the tasks referred to in points (a) to (g) of Article 92(2);

(d) where necessary, establishing and storing collections or databases of authenticated reference materials, to be used to verify the authenticity or integrity of goods;

(e) disseminating research findings and technical innovations in the fields within the scope of their missions. [Am. 232]

Article 97
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 91;

   (b) European Union reference centres for plant reproductive material provided for in Article 93; [Am. 233]

   (c) European Union reference centres for animal welfare provided for in Article 95.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the establishment of requirements, responsibilities and tasks for the European Union reference laboratories, the European Union reference centres for plant reproductive material and the European Union reference centres for animal welfare in addition to those laid down in Article 91(3), Article 92, 93(3), Article 95(3) and Article 96. [Am. 234]

3. European Union reference laboratories and European Union reference centres shall be subject to Commission controls to verify compliance with the requirements of Article 91(3), Article 92, 93(3), Article 95(3) and Article 96. [Am. 235]

4. If the Commission controls referred to in paragraph 3 show non-compliance with the requirements laid down in Article 91(3), Article 92, Article 95(3) and Article 96, the Commission shall, after having received the comments of the European Union reference laboratory or European Union reference centre:

   (a) withdraw the designation of that laboratory or centre; or,

   (b) take any other appropriate measure.

Article 98
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 91(1).

A Member State may designate a laboratory situated in another Member State or in a third country that is a Contracting Party to the European Free Trade Association (EFTA).

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 36(4), Article 36(5), Article 38, Article 41(1), points (a) and (b) of Article 41(2) and Article 41(3) shall apply to national reference laboratories.

3. National reference laboratories shall:

   (a) be independent, impartial and free of conflict of interests as regards the exercise of its tasks as national reference laboratories.[Am. 236]
(b) have 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 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 to perform their tasks in emergency situations;

(f) where relevant, be equipped to comply with 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 that information available to the public;

(c) update that information 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 shall be empowered to adopt delegated acts in accordance with Article 139 concerning the establishment of requirements for national reference laboratories in addition to those laid down in paragraphs 2 and 3.

6a. This Article shall apply without prejudice to Article 32, second paragraph, of Regulation (EC) No 1829/2003 and the rules adopted under the fourth and fifth paragraphs of Article 32 of that Regulation, in addition to Annex II to Regulation (EC) No 1831/2003 and the rules adopted under the third and fourth paragraphs of Article 21 of that Regulation. [Am. 237]

Article 99

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 36(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 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 coordinated control plans adopted in accordance with Article 111;
(f) where relevant, establish and maintain up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents;

(fa) assist actively in the diagnosis of outbreaks on national territory of animal, foodborne or zoonotic diseases by carrying out confirmatory diagnosis, characterisation and epizootic or taxonomic studies on pathogen isolates or pest specimens, as specified for the national reference laboratories of the Union in point (h) of Article 92(2).

[Am. 238]

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the establishment of responsibilities and tasks for national reference laboratories in addition to those provided in paragraph 1.

2a. This Article shall apply without prejudice to Article 32, second paragraph, of Regulation (EC) No 1829/2003 and the rules adopted under the fourth and fifth paragraphs of Article 32 of that Regulation, in addition to Annex II to Regulation (EC) No 1831/2003 and the rules adopted under the third and fourth paragraphs of Article 21 of that Regulation. [Am. 239]

Title IV
Administrative assistance and cooperation

Article 100
General rules

1. The competent authorities in the Member States concerned shall provide each other with administrative assistance in accordance with Articles 102 to 105, 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, participation by the competent authorities of a Member State in on-the-spot official controls that the competent authorities of another Member State perform. [Am. 240]

3. The provisions of this Title shall not prejudice national rules:

(a) applicable to the release of documents that are the object of, or related to, judicial proceedings;

(b) aimed at the protection of natural or legal persons’ commercial interests.

4. All communications between competent authorities in accordance with Articles 102 to 105 shall be in writing.

5. 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 102(1);

(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 141(2). [Am. 241]

5a. Communications between competent authorities conducted in accordance with the provisions of this title shall be without prejudice to Commission Regulation (EU) No 16/2011 (1) regarding communications through the Rapid Alert System for Food and Feed. [Am. 242]

Article 101
Liaison bodies

1. Each Member State shall designate one or more liaison bodies responsible for the exchange of communications between competent authorities in accordance with Articles 102 to 105.

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. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the establishment of minimum requirements that liaison bodies designated in accordance with paragraph 1 are required to comply with.

4. Member States shall communicate to the Commission and other Member States the details of their liaison bodies designated in accordance with paragraph 1, and any subsequent modification of those details.

5. 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 4.

6. All requests for assistance pursuant to Article 102(1), and notifications and communications pursuant to Articles 103, 104 and 105 shall be transmitted by a liaison body to its correspondent in the Member State to which the request or the notification is addressed.

7. The Commission shall, by means of implementing acts, establish the specificiations of the technical tools and the procedures for communication between liaison bodies designated in accordance with paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2). [Am. 243]

Article 102
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 motivated 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) indicate within 15 days from the date of receipt of the request, the time necessary to provide an informed response to the request; [Am. 244]

(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:

(a) shall at all times be able to produce written authority stating their identity and their official capacity;

(b) shall have access 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;

(c) may not, on their own initiative, exercise the powers of enquiry conferred on officials of the requested competent authorities.
Article 103
Assistance without request

1. When the competent authorities in a Member State become aware of a 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 delay.

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

(a) shall acknowledge receipt of the notification without delay;

(b) shall indicate within 15 working days from the date of receipt of the notification: [Am. 245]

   (i) what investigations they intend to carry out; or,

   (ii) the reasons why they consider that no investigations are necessary;

(c) where investigations referred to in point (b) are considered necessary, they shall investigate the matter and inform the notifying competent authorities without delay of the results and, where appropriate, of any measures taken.

Article 104
Assistance in the event of non-compliance

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, to the environment, or to constitute a 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 them to undertake appropriate investigations.

1a. The other concerned Member States referred to in paragraph 1 shall, in the case of infringements of Regulation (EC) No 1/2005 include:

(a) the Member State that granted the authorisation to the transporter;

(b) where a deficiency in the means of transport is involved in the failure to observe the requirements of that Regulation, the Member State that granted the certificate of approval of the means of transport;

(c) where the driver is involved in the failure to observe the requirements of that Regulation, the Member State that issued the driver’s certificate of competence. [Am. 246]

2. The notified competent authorities shall without delay:

(a) acknowledge receipt of the notification;

(b) indicate what investigations they intend to carry out;

(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;

(c) inform all relevant, concerned stakeholders, as specified in national food safety contingency plans. [Am. 247]

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:

(a) the competent authorities from the two Member States shall 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 102(3);
(b) they shall 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 with the rules referred to in Article 1(2), 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 105
Assistance by third countries

1. When competent authorities receive information from a third country indicating non-compliance or a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment, they shall, without delay:

(a) notify such information to the competent authorities in other concerned Member States;

(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;

(c) relevant Union and national rules applicable to the communication of personal data to third countries are complied with.

Article 106
Coordinated assistance and follow-up by the Commission

1. The Commission shall coordinate without delay the measures and actions undertaken by competent authorities in accordance with this Title where:

(a) information available to the Commission 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) information available to the Commission 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; and,

(c) 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).

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 shall be empowered to adopt delegated acts in accordance with Article 139 to establish rules for the rapid exchange of information in the cases referred to in paragraph 1.
Title V
Planning and reporting

Article 107
Multi-annual national control plans (MANCP) and single authority 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 a multi-annual national control plan, the preparation and implementation of which are coordinated across their territory.

2. Member States shall designate a single the authority or authorities responsible for:

   (a) the coordination of the preparation of the plan referred to in paragraph 1 across all competent authorities responsible for the official controls;

   (b) ensuring that such plan is coherent and consistently implemented.

Article 108
Content of the multi-annual national control plans

1. Multi-annual national control plans shall be prepared so as to ensure that:

   (a) 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 8 and in the rules provided for in Articles 15 to 24;

   (b) there is efficient prioritisation of official controls and efficient allocation of control resources.

2. Multi-annual national control plans shall contain general information on the structure and organisation of the systems of official control in the Member State concerned, for each of the sectors concerned and shall contain at least information on the following:

   (a) the strategic objectives of the multi-annual national control plan 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 4(1);

   (h) the training of staff of the competent authorities;

   (i) the documented procedures provided for in Article 11(1);

   (j) the organisation and operation of contingency plans in accordance with the rules referred to Article 1(2);

   (k) the organisation of cooperation and mutual assistance between competent authorities in the Member States.
Article 109
Preparation and implementation of multi-annual control plans

1. Member States shall ensure that the multi-annual national control plan provided for in Article 107(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.

1a. The multi-annual national control plan may be prepared in consultation with relevant operators, with a view to ensuring a risk-based approach to official controls. [Am. 250]

2. The multi-annual national control plan shall be updated every time it is necessary to adjust it to changes to the rules referred to in Article 1(2), and shall be reviewed on a regular basis to take account at least of the following factors:

(a) the emergence of new diseases, pests of plants or other risks to human or plant animal health, animal welfare or, in the case of GMOs and plant protection products, to the environment; [Am. 251]

(b) significant changes to the structure, management or operation of the competent authorities in the Member State;

(c) the results of Member States' official controls;

(d) the results of Commission controls performed in the Member State in accordance with Article 115(1);

(e) scientific findings;

(f) the outcome of official controls performed by the competent authorities of third country in a Member State.

3. Member States shall provide the Commission with an up-to-date version of their multi-annual national control plan on request.

Article 110
Delegated powers for multi-annual national control plans

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the multi-annual national control plan provided for in Article 107(1).

Those delegated acts shall lay down rules on:

(a) criteria for the risk categorisation of the operators' activities;

(b) priorities for official controls based on the criteria laid down in Article 8 and in the rules provided for in Articles 15 to 24;

(c) procedures to maximise the effectiveness of official controls;

(d) the main performance indicators to be applied by the competent authorities in assessing the multi-annual national control plan and its implementation. [Am. 252]

Article 111
Coordinated control plans 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 shall be empowered to adopt delegated acts in accordance with Article 139 concerning:

(a) the preparation, organisation and the implementation of coordinated control plans of limited duration in one of the areas governed by the rules referred to in Article 1(2); [Am. 253]
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; \[\text{Am. 254}\]

(ba) the role of stakeholders in the development and implementation of the coordinated control plans. \[\text{Am. 255}\]

Article 112
Annual reports by the Member States

1. By 30 June every year, each Member State shall submit to the Commission a report setting out:

(a) any amendments made to its multi-annual national control plan to take account of the factors referred to in Article 109(2);

(b) the results of official controls performed in the previous year under its multi-annual national control plan;

(c) the type and number of cases of non-compliance with the rules referred to in Article 1(2) detected in the previous year by the competent authorities, specified per sector, and with an adequate level of detail; \[\text{Am. 256}\]

(d) the measures taken to ensure the effective operation of its multi-annual national control plan, including enforcement action and the results of such measures;

(da) the information on fees referred to in paragraph 2 of Article 83 on transparency. \[\text{Am. 257}\]

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 paragraph 1.

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 141(2).

Article 113
Annual reports by the Commission

1. The Commission shall, by 31 December every second year after the entry into force of this Regulation, 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 112, which shall include the information on fees referred to in paragraph 2 of Article 83 on transparency; \[\text{Am. 259}\]

(b) the results of Commission controls performed in accordance with Article 115(1);

(c) any other relevant information.

2. The annual report provided for in paragraph 1 may, where appropriate, shall include recommendations on possible improvements to official control systems in Member States and specific official controls in certain areas. \[\text{Am. 260}\]
Article 114
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 operational 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);

(c) channels and procedures for sharing information between competent authorities and other parties concerned as appropriate.

3. Member States shall review their contingency plans for food and feed regularly 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 shall be empowered to adopt delegated acts in accordance with Article 139 concerning:

(a) rules for the establishment of the contingency plans provided for in paragraph 1 to the extent necessary to ensure the consistent and efficient use of the general plan for crisis management provided for in Article 55(1) of Regulation (EC) No 178/2002;

(b) the role of stakeholders in the establishment and operation of those contingency plans.

Title VI
Union activities

Chapter I
Commission controls

Article 115
Commission controls in Member States

1. Commission experts shall perform controls 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 and of the competent authorities which operate them;

(c) investigate and collect information:

(i) on official controls and enforcement practices;

(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.
2. The controls provided for in paragraph 1 shall be organised in cooperation with the competent authorities of the Member States and 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 116
Reports by the Commission on controls by its experts in Member States

1. The Commission shall:

(a) prepare a draft report on the findings of controls performed in accordance with Article 115(1);

(b) send to the Member State where those controls were 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 115(1);

(d) make publicly available the final report referred to in point (c) and the comments of the Member State referred to in point (b).

2. Where appropriate, the Commission may recommend in its final reports provided for in paragraph 1 corrective or preventive action to be taken by the Member States to address the specific or systemic shortcomings identified by its experts during controls performed in accordance with Article 115(1).

Article 117
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 115(1);

(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 to the Member States sufficiently well in advance. [Am. 261]

Article 118
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 by the controls performed by the Commission experts in accordance to Article 115(1);

(b) give all necessary assistance and provide all documentation and other technical support that Commission experts request to enable them to perform controls efficiently and effectively;

(c) ensure that 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 119
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 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, zoonoses and plant health, and procedures for notifying the Commission and relevant international bodies of outbreaks of animal diseases and pests of plants; [Am. 263]

(g) the extent and operation of official controls performed on animals, plants and their products arriving from other third countries;

(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 information referred to in Article 124(1);

(b) where appropriate, the written records on the official controls it performs.

4. The Commission may appoint experts from Member States to assist its own experts during the controls provided for in paragraph 1.

Article 120
Frequency of Commission controls in third countries

The frequency of controls performed by the Commission in third countries shall be determined on the basis of:

(a) a risk assessment of the animal and goods exported to the Union from them;

(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 results of controls already performed by the Commission experts or by other inspection bodies;
(e) the results of official controls on animals and goods entering the Union from the third country and of any other official controls that competent authorities of Member States have performed;

(f) information received from the European Food Safety Authority 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;

(iv) European and Mediterranean Plant Protection Organisation;

(v) the secretariat of the International Plant Protection Convention;

(vi) Organisation for Economic Co-operation 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;

(ha) the likelihood of fraudulent practices which might deceive consumer expectations regarding the nature, quality and composition of foods and goods; [Am. 264]

(i) the need to investigate or respond to emergency situations in individual third countries.

Article 121
Reports by the Commission on controls by its experts in third countries

The Commission shall report on the findings of each control performed in accordance with Articles 119 and 120.

Its report shall, where appropriate, contain recommendations.

The Commission shall make its reports publicly available.

Article 122
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 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.

Article 123
Third-country controls in Member States

1. Member States shall inform the Commission of:

(a) planned controls in their territory by the competent authorities of third countries;

(b) the intended schedule and scope of such controls.
2. Commission experts may participate in the controls referred to in paragraph 1, at the request of either of the following:

(a) the competent authorities of Member States where those controls are being performed;

(b) the competent authorities of the third country performing those controls.

The participation by Commission experts and the final schedule and scope of the controls referred to in paragraph 1 shall be organised in close cooperation between the Commission and the competent authorities of the Member State 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) ensure uniformity with regard to controls performed by the competent authorities of third countries.

Chapter II

Conditions for the entry into the Union of animals and goods

Article 124

Information on third countries’ control systems

1. The Commission shall request third countries intending 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 regulations 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 second paragraph of Article 121;

(f) where relevant, results of official controls performed on animals and goods intended to be exported to the Union;

(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 second paragraph of Article 121.

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 and structure of the third country.
Article 125
Establishment of additional conditions for entry into the Union of animals and goods

1. The Commission shall be empowered to adopt delegated acts, in accordance with Article 139 concerning the conditions to be respected by animals and goods entering the Union from third countries where these 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) and of Article 6 of Regulation (EC) No 853/2004, or with requirements recognised to be at least equivalent.

2. The conditions 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;

(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;

(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 and plant protection products, of the environment, equivalent to that ensured by complying with the requirements referred to in paragraph 1. [Am. 266]

3. Where, in case of risks arising from animals and goods entering the Union from third countries to human health, animal health or, as regards GMOs and plant protection products, to the environment, imperative grounds of urgency so require, the procedure provided for in Article 140 shall apply to delegated acts adopted pursuant to paragraph 1.

4. The Commission may, by means of implementing acts, lay down rules concerning 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).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 126
Inclusion in the list of third countries referred to in point (a) of Article 125(2)

1. The inclusion of a third country or region thereof in the list referred to in point (a) of Article 125(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 that purpose by the third country concerned, accompanied by appropriate evidence and guarantees that the concerned animals and goods from that third country comply with the relevant requirements referred to in Article 123(1) or with requirements equivalent thereto. Those implementing acts shall be adopted and updated in accordance with the examination procedure referred to in Article 141(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;
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 for the environment in relation to GMOs and plant protection products;

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 for the environment in relation to GMOs and plant protection products;

e) the guarantees given by a 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 125(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 its updated versions 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) any other information or data on the capability of the third country to ensure that only animals or goods which offer the same or an equivalent level of protection as that afforded by the relevant requirements referred to in Article 125(1) enter the Union.

Article 127

Establishment of 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, Article 249 of Regulation (EU) No …/… (*) and in Articles 27(1), 29(1), 40(2), 41(2), 47(1), 49(2) and 50(2) of Regulation (EU) No …/… (**), 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, may pose a risk to human, or animal or plant health or, as regards GMOs and plant protection products, to the environment, or where there is evidence that widespread serious non-compliance with the rules referred to in Article 1(2) might be taking place, the Commission shall adopt, by means of implementing delegated acts in accordance with Article 139, 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 141(2). [Am. 267]

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 or dispatched from the concerned third countries or regions thereof;

(b) the requirement that the animals and goods referred to in paragraph 1 originating 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 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 originating 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;

(*) Number of the Regulation on animal health.
(**) Number of the Regulation on protective measures against pests of plants.
(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 124;

(b) any other information that the third countries concerned have provided;

(c) where necessary, the results of Commission controls provided for in Article 119(1).

4. On duly justified imperative grounds of urgency relating to human health and animal health or, as regards GMOs and plant protection products, to the protection of the environment, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 141(3).

Article 128
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 124(1);

(b) where appropriate, the satisfactory outcome of a control performed in accordance with Article 119(1);

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

2. The implementing acts referred to in paragraph 1 shall set out the modalities governing 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 must 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 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 141(2).

Article 128a
Supporting developing countries

1. With a view to ensuring that developing countries can comply with this Regulation, measures may be taken, and may be implemented for as long as they continue to have a demonstrable impact, to support the following activities:

— compliance with the conditions governing the entry into the Union of animals and goods;

— drafting of guidelines on the organisation of official controls on products to be exported to the Union;

— sending of European Union or Member State experts to developing countries to assist with the organisation of official controls;
— involvement of control staff from developing countries in training programmes or courses.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 setting out provisions covering the forms of support for developing countries referred to in paragraph 1. [Am. 268]

Chapter III
Training of staff of the competent authorities

Article 129
Training and exchange of staff of the competent authorities

1. The Commission shall 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 violations of the provisions of this Regulation and of the rules referred to in Article 1(2). [Am. 269]

The Commission shall organise those activities in cooperation with Member States. [Am. 270]

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 is disseminated as necessary and appropriately used in the staff training activities referred to in Article 4(2) and (3).

Training activities aimed at disseminating such knowledge shall be included in the training programmes referred to in Article 4(2).

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 shall, by means of implementing acts, lay down rules for the organisation of the training activities referred to in paragraph 1 and of the programmes referred to in paragraph 5.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).
Chapter IV
Information management systems

Article 130
Information management system for official controls (IMSOC)

1. The Commission shall set up and manage a computerised information management system for the integrated operation of the mechanisms and tools through which data, information and documents concerning official controls are automatically forwarded from databases in the Member States and managed and handled and automatically exchanged (the IMSOC), taking into account existing national systems.

1a. When forwarding electronic certificates or other electronic documents, the Commission and Member States shall use standard international programming languages, message structures and transmission protocols and safe transmission procedures.

2. The IMSOC shall:

(a) integrate fully and provide the necessary updates to the TRACES system as established by Decision 2003/24/EC;

(b) integrate fully and provide the necessary updates to 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) …/…, Article 97 of Regulation (EU) …/….

(c) provide appropriate linkages between the TRACES system and the systems referred to in point (b) to allow, as necessary, the efficient exchange and update of data between those systems and between the TRACES system and those systems.

2a. When exchanging electronic data, such as electronic certificates, the Commission and the competent authorities of the Member States shall use internationally standardised language, message structure and exchange protocols.

Article 131
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 the rules referred to in Article 1(2) and the delegated acts provided for in Articles 15 to 24 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 and information in accordance with Title IV;

(c) provide a tool to collect and manage the reports on official controls provided by the 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 Regulation (EC) No 1/2005, of official certificates and of the common health entry document referred to in Article 54 of this Regulation.

(*) Number of the Regulation on animal health.
(**) Number of the Regulation on protective measures against pests of plants.
Article 132
Use of the IMSOC in case of animals and goods subject to specific official controls

1. In 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 shall not apply to goods subject to the rules referred to in Article 1(2)(g) and (h).

However, the Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning when and to what extent the first subparagraph shall apply to the goods referred to in the second subparagraph.

2. In 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 result of controls performed on those animals and goods.

3. In case of animals or goods subject to the official controls referred to in Title II, Chapter V, Sections I and II, 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 14(4) and 73(2) and with other relevant Union rules;

(c) support and operate the procedures referred to in point (a) of Article 52(2) and in Article 63(6).

Article 133
Empowerment for the adoption of rules for the functioning of the IMSOC

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the establishment of:

(a) the technical specifications and the specific rules for the functioning of the IMSOC and of its components;

(b) contingency arrangements to be applied in case of unavailability of any of the functionalities of the IMSOC;

(c) the cases where and the conditions under which concerned third countries and international organisations may be granted partial access to the functionalities of the IMSOC and the modalities of such access;

(d) the cases where and the conditions under which exemptions from the use of the TRACES system can be granted to occasional users;

(e) the rules concerning an electronic system under which electronic certificates issued by the competent authorities of third countries shall be accepted by the competent authorities.
Title VII
Enforcement action

Chapter I
Action by the competent authorities and penalties

Article 134
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 and, as regards GMOs and plant protection products, to the environment. Given the increasing frequency of fraud in the food area, more emphasis shall be put on tackling practices which mislead consumers as to the nature or the quality of the food they purchase and consume. [Am. 336]

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 for its purposes, the investigation referred to in paragraph 2 shall include:

(a) the performance of intensified official controls on animals, goods and operators for an appropriate period, in keeping with the nature of the risk; [Am. 274]

(b) the official detention of animals and goods and of any unauthorised substances or products as appropriate.

Article 135
Investigations and measures in case of established non-compliance

1. Where the non-compliance is established, the competent authorities shall:

(a) perform any further investigation necessary to determine the origin and extent of the non-compliance and to establish the operator's responsibilities;

(b) take appropriate measures to ensure that the operator remedies the non-compliance and prevents further occurrences of it. [Am. 275]

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

2. When acting in accordance with paragraph 1, competent authorities shall, as appropriate:

(a) order or perform treatments on animals;

(aa) where the outcome of the official controls on journey logs provided for in point (i) of paragraph (b) of Article 18(1) is not satisfactory, require the organiser to change the arrangements for the intended long journey so that it complies with Regulation (EC) No 1/2005; [Am. 276]

(b) order the unloading, transfer to another means of transport, holding and in suitable accommodation with appropriate care of animals, quarantine periods, the postponement of the slaughter of animals, that veterinary assistance must be sought if necessary. [Am. 277]

(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, prohibit their return to the Member State of dispatch or order their return to the Member State of dispatch;

(e) order that the operator increases the frequency of own controls;
(ea) require business operators carrying out the killing of animals or any related operations falling within the scope of Regulation (EC) No 1099/2009 to amend their standard operating procedures and, in particular, slow down or stop production; [Am. 278]

(f) order that certain activities of the operator concerned 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 approval of the establishment, plant, holding or means of transport concerned, or of the authorisation of a transporter or of the certificate of competence of the driver; [Am. 279]

(k) order the slaughter or killing of animals provided that this is the most appropriate measure to safeguard human health and animal health and welfare;

(l) take any other measure the competent authorities deem appropriate to ensure compliance with the rules referred to in Article 1(2).

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 rights of appeal against such decisions and on the applicable procedure and time limits.

4. All expenditure incurred pursuant to this Article shall be borne by the responsible operators.

Article 136
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 applied. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those rules to the Commission by the date referred to in the second subparagraph of Article 162(1) and shall notify it without delay of any subsequent amendment affecting them.

Irrespective of the financial advantage sought, the severity of the penalties should also reflect the degree of risk of damage to consumers’ health. [Am. 280]

2. Member States shall ensure that financial penalties applicable to intentional violations of this Regulation and of the rules referred to in Article 1(2) are set at least offset double the economic advantage sought through the violation. [Am. 281]

3. Member States shall ensure in particular that penalties are provided for in the following cases:

(a) where operators fail to cooperate during official controls or other official activities;

(b) false or misleading official certification and declarations; [Am. 282]

(c) fraudulent production or use of official certificates, official labels, official marks and other official attestations;

(ca) where consumers’ health is damaged. [Am. 283]
Article 136a
Reporting of breaches

1. Member States shall ensure that competent authorities establish effective and reliable mechanisms to encourage reporting of potential or actual breaches of this Regulation and of national measures related to this Regulation to competent authorities.

2. The mechanisms referred to in paragraph 1 shall include at least:

(a) specific procedures for the receipt of reports on breaches and their follow-up;

(b) appropriate protection for employees of institutions who report breaches committed within the institution against retaliation, discrimination or other types of unfair treatment at a minimum;

(c) protection of personal data concerning both the person who reports the breaches and the natural person who is allegedly responsible for a breach, in accordance with Directive 95/46/EC;

(d) clear rules that ensure that confidentiality is guaranteed in all cases in relation to the person who reports the breaches committed within the institution, unless disclosure is required by national law in the context of further investigations or subsequent judicial proceedings.

3. Member States shall require institutions to have in place appropriate procedures for their employees to report breaches internally through a specific, independent and autonomous channel. Such a channel may also be provided through arrangements provided for by social partners. The same protection as referred to in points (b), (c) and (d) of paragraph 2 shall apply. [Am. 284]

Chapter II
Union enforcement measures

Article 137
Serious failure in a Member State’s control system

1. Where the Commission has evidence of a serious failure in a Member State’s control systems and such failure may constitute a possible and widespread risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, 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 the failure in the control system 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 failure in the official 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 failure 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 failure in the control system is eliminated.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).
2. The measures referred to in paragraph 1 shall be adopted only after the Member State concerned has failed to correct the situation upon request and within the 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, to the protection of the environment, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 141(3).

Title VIII
Common provisions

Chapter I
Procedural provisions

Article 138
Amendment of Annexes and references to European standards

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning amendments to Annexes II and III to this Regulation, in order to take into account changes to the rules referred to in Article 1(2), technical progress and scientific developments.

2. In order to keep up-to-date the references to the European standards referred to in point (b)(iv) of Article 26, point (e) of Article 36(4) and point (a) of Article 91(3), the Commission shall be empowered to adopt delegated acts amending those references in the event that CEN amends them.

Article 139
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 delegation of power referred to in Article 15(2), Article 17, Article 23(1), Article 23(2), Article 24a, Article 25(3), Article 40, Article 43(4), Article 45(3), Article 46, Article 49, Article 51(1), Article 52(1) and (2), Article 56(2), Article 60 (3), Article 62(2), Article 69(3), Article 75(1) and (2), Article 97(2), Article 98(6), Article 99(2), Article 101(3), Article 106 (3), Article 111, Article 114(4), Article 125(1), Article 127(1), Article 128a(2), the third subparagraph of Article 132(1), Article 133, Article 138(1) and (2), Article 143(2), Article 144(3) and Article 153(3) shall be conferred on the Commission for an indeterminate period of time 5 years from ... (*) 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 identical duration, unless the European Parliament or Council opposes such an extension not later than 3 months before the end of each period. [Am. 285]

2a. For the period during which these delegated powers are exercised, it is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council. [Am. 286]

(*) Date of entry into force of this amending Act.
The delegation of powers referred to in Article 15(2), Article 17, Article 23(1), Article 23(2), Article 24a, Article 25 (3), Article 40, Article 43(4), Article 45(3), Article 46, Article 49, Article 51(1), Article 52(1) and (2), Article 56(2), Article 60(3), Article 62(2), Article 69(3), Article 75(1) and (2), Article 97(2), Article 98(6), Article 99(2), Article 101(3), Article 106(3), Article 111, Article 114(4), Article 125(1), Article 127(1), Article 128a(2), the third subparagraph of Article 132(1), Article 133, Article 138(1) and (2), Article 143(2), Article 144(3) and Article 153(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.

As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

A delegated act adopted pursuant to Article 15(2), Article 17, Article 23(1), Article 23(2), Article 24a, Article 25(3), Article 40, Article 43(4), Article 45(3), Article 46, Article 49, Article 51(1), Article 52(1) and (2), Article 56(2), Article 60(3), Article 62(2), Article 69(3), Article 75(1) and (2), Article 97(2), Article 98(6), Article 99(2), Article 101(3), Article 106(3), Article 111, Article 114(4) and 125(1), Article 127(1), Article 128a(2), the third subparagraph of Article 132(1), Article 133, Article 138(1) and (2), Article 143(2), Article 144(3) and Article 153(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 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 the Council.

Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 139(5). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or by the Council.

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. That Committee shall be a Committee within the meaning of Regulation (EU) No 182/2011. This shall apply with the exception of cases covered by Article 23, which requires the Commission to be assisted by committees set up under Regulation (EC) No 834/2007, Regulation (EU) No 1151/2012 regarding DOP, protected geographical indications ('PGI') and traditional speciality guaranteed ('TSG') food product designations, Regulation (EC) No 1234/2007 regarding DOP and PGI wine designations and Regulation (EC) No 110/2008 of the European Parliament and of the Council (1) regarding the geographical indications of spirit drinks. [Am. 287]

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

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

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 142
Repeals

1. Regulation (EC) No 882/2004, Directives 89/608/EEC and 96/93/EC and Decision 92/438/EEC are repealed as from … (*)

However, Articles 14 to 17 and 26 to 29 of Regulation (EC) No 882/2004 shall continue to apply until … (**) The designation of each of the European Union reference laboratories referred to in Annex VII to Regulation (EC) No 882/2004 shall continue to apply until the designation, in each of the areas concerned, of a European Union reference laboratory pursuant to Article 91(2) of this Regulation. [Am. 288]

1a. The designation of each of the European Union reference laboratories referred to in Annex VII to Regulation (EC) No 882/2004 shall continue to apply until such time as, in each of the areas concerned, a European Union reference laboratory is designated in accordance with Article 91(2) of this Regulation, without prejudice to Article 91(3a) thereof. [Am. 289]


3. References to the repealed acts shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex IV.

Article 143
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 45(2), Article 46, points (b), (c) and (d) of Article 49, Article 52(1) and (2), point (a) of Article 56(1) of this Regulation shall continue to apply until the date to be determined in the delegated act adopted in accordance with paragraph 2.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the date on which the provisions referred to in paragraph 1 shall no longer apply. That date shall be the date of the application of the corresponding rules to be established pursuant to the delegated or implementing acts provided for in Article 45(2), Article 46, points (b), (c) and (d) of Article 49, Article 52(1) and (2) and point (a) of Article 56(1) of this Regulation.

(*) Date of entry into force of this Regulation + 1 year.
(**) Date of entry into force of this Regulation + 3 years.
(***) Date of entry into force of this Regulation + 3 years.
Article 144

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 to Annexes II, III and IV to that Directive until the date to be determined in the delegated act adopted in accordance with paragraph 3.

2. Article 29(1) and (2) of Directive 96/23/EC shall continue to apply until the date to be determined in the delegated act adopted in accordance with paragraph 3.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the date on which the competent authorities shall cease to perform official controls in accordance with paragraph 1, and on which Article 29(1) and (2) of Directive 96/23/EC shall no longer apply. That date shall be the date of the application of the corresponding rules to be established pursuant to the delegated or implementing acts provided for in Articles 16 and 111 of this Regulation.

Article 145

Amendments to Directive 98/58/EC

Directive 98/58/EC is amended as follows:

(a) Article 2 is amended as follows:

(i) point 3 is deleted;

(ii) the following second subparagraph is added:

'The definition of "competent authorities" laid down in point (5) of Article 2 of Regulation (EU) No …/[…(*) shall also apply.'

(b) Article 6 is amended as follows:

(i) paragraph 1 is deleted;

(ii) paragraph 2 is replaced by the following:

'2. Member States shall submit to the Commission by 30 June 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) point (a) of paragraph 3 is deleted;

(d) Article 7 is deleted.

Article 146

Amendments to Directive 1999/74/EC

Directive 1999/74/EC is amended as follows:

(a) Article 8 is amended as follows:

(i) paragraph 1 is deleted;

(ii) paragraph 2 is replaced by the following:

'Member States shall submit to the Commission by 30 June 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.'

(*) Number of this Regulation.
(iii) point (a) of paragraph 3 is deleted;

(b) Article 9 is deleted.

Article 147
Amendments to Regulation (EC) No 999/2001

Regulation (EC) No 999/2001 is amended as follows:
(a) Articles 19 and 21 are deleted;
(b) In Annex X, Chapters A and B are deleted.

Article 148
Amendments to Regulation (EC) No 1829/2003

Regulation (EC) No 1829/2003 is amended as follows:
(a) Article 32 is amended as follows:
(i) the first and second subparagraphs are deleted
(ii) the third subparagraph is replaced by the following:

‘Applicants for authorisation of genetically modified food and feed shall contribute to supporting the costs of the tasks of the European Union reference laboratory and the national reference laboratories designated in accordance with Articles 91(1) and 98(1) of Regulation (EU) No XXX/XXXX [number of this Regulation] for that area.’

(iii) in the fifth subparagraph the words ‘and the annex’ shall be deleted.
(iv) in the sixth subparagraph the words ‘and adapting the Annex’ shall be deleted.
(b) the Annex is deleted. [Am. 291]

Article 149
Amendments to Regulation (EC) No 1831/2003

Regulation (EC) No 1831/2003 is amended as follows:
(a) in Article 7, paragraph 3(f) is replaced by the following

‘a written statement that three samples of the feed additive have been sent by the applicant directly to the European Union reference laboratory referred to in Article 21.’

(b) Article 21 is amended as follows:
(i) the first, third and fourth paragraphs are deleted;
(ii) paragraph 2 is replaced by the following:

‘Applicants for the authorisation of additives shall contribute to supporting the cost of the tasks of the European Union reference laboratories and the national reference laboratories designated in accordance with Articles 91(1) and 98(1) of Regulation (EU) No XXX/XXXX [number of this Regulation] for that area.’

(c) Annex II is deleted. [Am. 292]

Article 150
Amendments to Regulation (EC) No 1/2005

Regulation (EC) No 1/2005 is amended as follows:
(a) Article 2 is amended as follows:
(i) points (d), (f), (i) and (p) are deleted;
(ii) the following second subparagraph is added:

'The definitions of “competent authorities”, “border control post”, “official veterinarian” and “exit point” laid down in points (5), (29), (32), and (36) of Article 2 of Regulation (EU) No .../... (*) shall also apply.'

(*) Of L ..., ..., p. ...;

(b) Articles 14 to 16, Article 21, Article 22(2), Articles 23 and 24 and Article 26 are deleted shall continue to apply until the legislative proposals referred to in Article 18 are established; [Am. 293]

(c) Article 27 is amended as follows:

(i) paragraph 1 is deleted;

(ii) paragraph 2 is replaced by the following:

‘2. Member States shall submit to the Commission by 30 June 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.’;

(d) Article 28 is deleted.

Article 151
Amendments to Regulation (EC) No 396/2005 and related transitional measures

1. Regulation (EC) No 396/2005 is amended as follows:

(a) Articles 26 and 27, Article 28(1) and (2) and Article 30 are deleted;

(b) the introductory phrase of Article 31(1) is replaced by the following:

‘1. Member States shall submit the following information concerning the previous calendar year to the Commission, the Authority and the other Member States by 30 June each year:’.

2. Article 26, Article 27(1) and Article 30 of Regulation (EC) No 396/2005 shall continue to apply until the date of the application of the corresponding rules to be determined in the delegated act adopted in accordance with paragraph 3 established pursuant to the legislative proposals referred to in Article 16 of this Regulation. [Am. 294]

3. The Commission shall be empowered to adopt delegated acts in accordance to Article 139 concerning the date on which Articles 26, 27(1) and 30 referred to in paragraph 2 shall no longer apply. That date shall be the date of the application of the corresponding rules to be established pursuant to the delegated acts provided for in Article 16 of this Regulation. [Am. 295]

Article 152
Amendments to Directive 2007/43/EC

Directive 2007/43/EC is amended as follows:

(a) Article 2 is amended as follows:

(i) in paragraph 1, points (c) and (d) are deleted;

(+)* Number of this Regulation.
(ii) the following paragraph 3 is added:

3. The definitions of “competent authorities” and of “official veterinarian” laid down in points (5) and (32) of Article 2 of Regulation (EU) No …/…. (+) (*) shall also apply.

(*) OJ L …, …, p. …;

(b) Article 7 is amended as follows:

(i) paragraph 1 is deleted;

(ii) paragraph 2 is replaced by the following:

2. Member States shall submit to the Commission by 30 June 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 153
Amendments to Regulation (EC) No 834/2007 and related transitional measures

1. Regulation (EC) No 834/2007 is amended as follows:

(a) Article 2 is amended as follows:

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

‘(n) “competent authorities” means competent authorities as defined in point (5) of Article 2 of Regulation (EU) No …/…. (+) (*)

(*) OJ L …, …, p. …;

(ii) point (o) is deleted;

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

‘(p) “control body” means a delegated body as defined in point (38) of Article 2 of Regulation (EU) No …/…. (+);’

(b) in point (a) of Article 24(1), ‘Article 27(10)’ is replaced by ‘Articles 3(3) and 25(4) of Regulation (EU) No …/…. (+);’

(c) Article 27 is amended as follows:

(i) paragraph 1 is replaced by the following:

‘1. Official controls to verify compliance with this Regulation shall be performed in accordance with Regulation (EC) No 882/2004:’

(ii) paragraphs 3 to 6 and 8 to 14 are deleted; [Am. 296]

(+*) Number of this Regulation.
(+*) Number of this Regulation.
(+*) Number of this Regulation.
(d) in Article 29(1), ‘Article 27(4)’ is replaced by ‘Articles 3(3) and 25(4) of Regulation (EU) No …/…. (+)’;

(e) in Article 30, paragraph 2 is deleted.

2. **Articles Paragraphs 3 to 14 of Article 27 and paragraph 2 of Article 30(2) of Regulation (EC) No 834/2007 shall continue to apply until the date to be determined in the delegated act to be adopted in accordance with paragraph 3.** [Ams. 297 and 298]

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the date on which the provisions referred to in paragraph 2 shall no longer apply. That date shall be the date of the application of the corresponding rules to be established pursuant to the delegated acts provided for in Article 23(2) of this Regulation.

**Article 154**  
Amendments to Directive 2008/119/EC

Directive 2008/119/EC is amended as follows:

(a) Article 2 is amended as follows:

(i) point 2 is deleted;

(ii) the following second subparagraph is added:

‘The definition of “competent authorities” laid down in point (5) of Article 2 of Regulation (EU) No …/… (+) (*) shall also apply.

(*) OJ L …, …, p. …’;

(b) Article 7 is amended as follows:

(i) paragraphs 1 and 2 are deleted;

(ii) paragraph 3 is replaced by the following:

‘3. Member States shall submit to the Commission by 30 June 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) Article 9 is deleted.

**Article 155**  
Amendments to Directive 2008/120/EC

Directive 2008/120/EC is amended as follows:

(a) Article 2 is amended as follows:

(i) point 10 is deleted;
(ii) the following second subparagraph is added:

> ‘The definition of “competent authorities” laid down in point (5) of Article 2 of Regulation (EU) No …/…. (+) (*) shall also apply.

(*) OJ L …, …, p. …;

(b) Article 8 is amended as follows:

(i) paragraphs 1 and 2 are deleted;

(ii) paragraph 3 is replaced by the following:

> ‘Member States shall submit to the Commission by 30 June 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) Article 10 is deleted.

Article 156

Amendments to Regulation (EC) No 1099/2009

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

(a) Article 2 is amended as follows:

(i) point (q) is deleted;

(ii) the following second subparagraph is added:

> ‘In addition to the definitions referred to in the first subparagraph, the definition of “competent authorities” laid down in point (5) of Article 2 of Regulation (EU) No …/…. (+) (*) shall also apply.

(*) OJ L …, …, p. …;

(b) Article 22 is deleted.

Article 157

Amendments to Regulation (EC) No 1069/2009

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

(a) Article 3 is amended as follows:

(i) points 10 and 15 are deleted;

(ii) the following second subparagraph is added:

> ‘The definition of “competent authorities” and “transit” laid down in points (5) and (50) of Article 2 of Regulation (EU) No …/…. (+) (*) shall also apply.

(*) OJ L …, …, p. …;
(b) Articles 45, 49 and 50 are deleted.

Article 158
Amendments to Regulation (EC) No 1107/2009

Article 68 of Regulation (EC) No 1107/2009 is amended as follows:

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

‘Member States shall finalise and submit to the Commission by 30 June each year a report on the scope and the results of the official controls performed in order to verify compliance with this Regulation.’;

(b) the second and third paragraphs are deleted.

Article 159
Amendments to Directive 2009/128/EC and related transitional measures

1. Directive 2009/128/EC is amended as follows:

(a) in Article 8, paragraph 1, the second subparagraph of paragraph 2 and paragraphs 3, 4, 6 and 7 are deleted;

(b) Annex II is deleted.

2. Paragraph 1, the second subparagraph of paragraph 2 and paragraphs 3, 4 and 6 of Article 8 and Annex II of Directive 2009/128/EC shall continue to apply until the date to be determined in the delegated act of the application of the corresponding rules to be adopted in accordance with paragraph 3 established pursuant to the legislative proposals referred to in Article 22 of this Regulation. [Am. 299]

3. The Commission shall be empowered to adopt delegated acts in accordance to Article 130 concerning the date on which the provisions referred to in paragraph 2 shall no longer apply. That date shall be the date of the application of the corresponding rules to be established pursuant to the delegated acts provided for in Article 22 of this Regulation. [Am. 300]

Article 160
Amendments to Regulation (EU) No 1151/2012

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

(a) Article 36 is amended as follows:

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

(ii) paragraphs 1 and 2 are deleted;

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

‘3. official controls performed in accordance with Regulation (EU) No …/… (+) (‘) shall cover:

(‘) OJ L …, p. …;

(b) Article 37 is amended as follows:

(i) 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 3 of Regulation (EU) No …/… (+); or,
(b) delegated bodies within the meaning of point 38 of Article 2 of Regulation (EU) No …./…. (+);

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

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

(c) Articles 38 and 39 are deleted.

Article 161

Amendments to Regulation (EU) No …./2013 (+)

Regulation (EU) No …./2013 (+) is amended as follows:

(a) Article 29 is amended as follows:

(i) the heading is replaced by the following:

‘European Union reference laboratories and centres’;

(ii) paragraph 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 91 of Regulation (EU) No …./…. (+) (*);

(b) the European Union reference centres for plant reproductive material referred to in Article 93 of that Regulation [Am. 301]

(c) the European Union reference centres for animal welfare referred to in Article 95 of that Regulation;

(ca) the European Union reference centres for the authenticity and integrity of the agri-food chain. [Am. 302]

(*) OJ L …, …, p. …;

(iii) in paragraph 2, point (a) is replaced by the following:

‘(a) costs of personnel, regardless its status, directly involved in activities of the laboratories or centres which are carried out in their capacity of Union reference laboratory or centre’;

(b) the following Article 29a is added:

‘Article 29a

Accreditation of national reference laboratories for plant health

1. Grants may be awarded to the national reference laboratories referred to in Article 98 of Regulation (EU) No …./…. (+) for costs incurred for obtaining accreditation according to the standard EN ISO/IEC 17025 for the use of methods of laboratory analysis, test and diagnosis to verify compliance with the rules on protective measures against pests of plants.

(*) Number of this Regulation.
(+ Number of the Regulation 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.
(+ Number of the Regulation 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.
(+ Number of this Regulation.
(+ Number of this Regulation.
2. The grants referred to in paragraph 1 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. '[Am. 303]

Article 162
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 5, it shall apply from … (+).

No later than one year after entry into force of this Regulation, the Commission shall provide a comprehensive guidance document, to assist operators and national authorities to effectively implement this Regulation. [Am. 304]

1a. No later than five years after the entry into force of this Regulation, the Commission shall submit a report to the European Parliament and the Council to present the experience gained from the application of this Regulation and consider in particular the reduction of administrative burden on private sector and the efficiency and effectiveness of controls carried out by competent authorities. [Am. 305]

2. In the area covered by the rules referred to in point (g) of Article 1(2), this Regulation, shall apply from … (+), with the following exceptions:

(a) Articles 91 and 92 and Articles 97 to 99 shall apply in accordance with paragraph 1;
(b) Article 33(1), (2), (3) and (4), point (e) of Article 36(4) and Article 36(5) shall apply from … (+).

3. In the area covered by the rules referred to in point (h) of Article 1(2), this Regulation, shall apply from [date of application of the Regulation on the production and making available on the market of plant reproductive material], with the following exceptions:

(a) Articles 93, 94 and 97 shall apply in accordance with paragraph 1;
(b) Article 33(1), (2), (3) and (4) shall apply from [date of entry into force of this Regulation + 5 years]. [Am. 306]

4. Article 15(1), Article 18(1), Articles 45 to 62 and Articles 76 to 84, point (b) of Article 150, points (b) and (c) (i) of Article 152, point (b)(i) of Article 154, and point (b)(i) of Article 155 and point (b) of Article 156 shall apply from … (+). Point (b) of Article 150 and point (b) of Article 156 shall not apply until the delegated acts that replace them are in force. [Am. 307]

5. Article 161 shall apply from … (+).

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

Done at

For the European Parliament
The President

For the Council
The President

(+): Date of entry into force of this Regulation + 1 year.
(+): Date of application of the Regulation on protective measures against pests of plants.
(+): Date of entry into force of this Regulation + 5 years.
(+): Date of entry into force this Regulation + 3 years.
(+): Date of entry into force of this Regulation.
ANNEX I

TERRITORIES REFERRED TO IN POINT 45 OF ARTICLE 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 Italian Republic
12. The territory of the Republic of Cyprus
13. The territory of the Republic of Latvia
14. The territory of the Republic of Lithuania
15. The territory of the Grand Duchy of Luxembourg
16. The territory of Hungary
17. The territory of the Republic of Malta
18. The territory of the Kingdom of the Netherlands in Europe
19. The territory of the Republic of Austria
20. The territory of the Republic of Poland
21. The territory of the Portuguese Republic
22. The territory of Romania
23. The territory of the Republic of Slovenia
24. The territory of the Slovak Republic
25. The territory of the Republic of Finland
26. The territory of the Kingdom of Sweden
27. The territory of the United Kingdom of Great Britain and Northern Ireland

For the purpose of the official controls performed by the competent authorities to verify the compliance with the rules referred to in point (g) of Article 1(2) and other official activities carried out in relation to point (g) of Article 1(2), references to third countries shall be read as references to third countries and to the territories listed in Annex I of Regulation (EU) No …/…(*) and references to the Union territory shall be read as references to the Union territory without the territories listed in that Annex.

(*) Number of the Regulation on protective measures against pests of plants.
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, diagnosis and testing

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

5a. The risks posed by antimicrobial resistance to human and animal health [Am. 309]

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, and to the environment, and to the identity and quality of plant reproductive material [Am. 310]

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, test 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, test and diagnosis
11. Any other activity or information required for the effective functioning of the official controls.
ANNEX IIa

OFFICIAL AUXILIARIES

1. The competent authority may appoint as official auxiliaries only persons who have undergone training and passed a test in accordance with the following requirements.

2. The competent authority must make arrangements for such tests. To be eligible for these tests, candidates must prove that they have received:

   (a) at least 500 hours of theoretical training and at least 400 hours of practical training, covering the areas specified in paragraph 5; and

   (b) such additional training as is required to enable official auxiliaries to undertake their duties competently.

3. The practical training referred to in point (a) of paragraph 2 is to take place in slaughterhouses and cutting plants, under the supervision of an official veterinarian, and on holdings and in other relevant establishments.

4. Training and tests are to concern principally red meat or poultry meat. However, persons who undergo training for one of the two categories and passed the test, need only undergo abridged training to pass the test for the other category. Training and test should cover wild game, farmed game and lagomorphs, where appropriate.

5. Training for official auxiliaries is to cover, and tests are to confirm knowledge of, the following subjects:

   (a) in relation to holdings:

      (i) theoretical part:

      — familiarity with the farming industry organisation, production methods, international trade, etc.,

      — good livestock husbandry practices,

      — basic knowledge of diseases, in particular zoonoses-viruses, bacteria, parasites, etc.,

      — monitoring for disease, use of medicines and vaccines, residue testing,

      — hygiene and health inspection,

      — animal welfare on the farm and during transport,

      — environmental requirements — in buildings, on farms and in general,

      — relevant laws, regulations and administrative provisions,

      — consumer concerns and quality control;

      (ii) practical part:

      — visits to holdings of different types and using different rearing methods,

      — visits to production establishments,

      — observation of the loading and unloading of animals,

      — laboratory demonstrations,

      — veterinary checks,

      — documentation;
(b) in relation to slaughterhouses and cutting plants:

(i) theoretical part:

— familiarity with the meat industry organisation, production methods, international trade and slaughter and cutting technology,

— basic knowledge of hygiene and good hygienic practices, and in particular industrial hygiene, slaughter, cutting and storage hygiene, hygiene of work,

— HACCP and the audit of HACCP-based procedures,

— animal welfare on unloading after transport and at the slaughterhouse,

— basic knowledge of the anatomy and physiology of slaughtered animals,

— basic knowledge of the pathology of slaughtered animals,

— basic knowledge of the pathological anatomy of slaughtered animals,

— relevant knowledge concerning TSEs and other important zoonoses and zoonotic agents,

— knowledge of methods and procedures for the slaughter, inspection, preparation, wrapping, packaging and transport of fresh meat,

— basic knowledge of microbiology,

— ante-mortem inspection,

— examination for trichinosis,

— post-mortem inspection,

— administrative tasks,

— knowledge of the relevant laws, regulations and administrative provisions,

— sampling procedure,

— fraud aspects;

(ii) practical part:

— animal identification,

— age checks,

— inspection and assessment of slaughtered animals,

— post-mortem inspection in a slaughterhouse,

— examination for trichinosis,

— identification of animal species by examination of typical parts of the animal,

— identifying and commenting on parts of slaughtered animals in which changes have occurred,

— hygiene control, including the audit of the good hygiene practices and the HACCP-based procedures,
— recording the results of ante-mortem inspection,
— sampling,
— traceability of meat,
— documentation.

6. Official auxiliaries are to maintain up-to-date knowledge and to keep abreast of new developments through regular continuing education activities and professional literature. The official auxiliary is, wherever possible, to undertake annual continuing education activities.

7. Persons already appointed as official auxiliaries must have adequate knowledge of the subjects mentioned in paragraph 5. Where necessary, they are to acquire this knowledge through continuing education activities. The competent authority is to make adequate provision in this regard.

8. However, when official auxiliaries carry out only sampling and analysis in connection with examinations for trichinosis, the competent authority need only ensure that they receive training appropriate to these tasks. [Am. 311]
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(e) of paragraph 1 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, then they 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.
ANNEX IV

CORRELATION TABLE REFERRED TO IN ARTICLE 142(3)


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### Directive 89/608/EEC

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### Decision 92/438/EEC

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