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Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [...]/2013 [*Office of Publications, please insert number of 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*], and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation)**

(Text with EEA relevance)

{SWD(2013) 166 final}

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## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

#### 1.1. Background of the proposal

In order to afford European Union (EU) citizens a high level of human, animal and plant health, and guarantee the functioning of the internal market, Union legislation provides for a set of harmonised rules to prevent, eliminate or reduce the level of health risk to humans, animals and plants, which may arise along the 'agri-food chain', this term being used in a very broad sense, to comprehend all those processes, products and activities which relate to food, its production and handling, and the rules which (directly or indirectly, e.g. through the safety requirements for feed) ensure that it is safe and fit for human consumption. It also includes rules referred to as veterinary and phytosanitary legislation, which deal with risks to animal health and plant health in general, and rules on the identity, health and quality of plant reproductive material. Thus this vast *acquis* governs health risks in the strict sense (risks to the integrity of humans, animals and plants from pests, diseases, microbial and chemical contaminants and other hazards) and also the preservation of inherent qualities required to ensure a safe start of plant production and regulated production methods (i.e. animal welfare, organic farming, geographical indications, plant reproductive material). It also includes rules established to ensure the provision of information to consumers and to guarantee fair commercial practices in agri-food chain products' trade.

To ensure that this extensive set of rules is enforced by the Member States (MS) across the EU in a harmonised manner, **a legislative framework for the organisation of official controls** has been established through Regulation (EC) No 882/2004 ('the Regulation')<sup>1</sup>.

The proposal revises the legislation on official controls to overcome shortcomings identified in its wording and in its application. It aims to put in place a robust, transparent and sustainable regulatory framework that is better 'fit for purpose'. The proposal replaces and repeals the Regulation and a number of sectoral acts and provisions which will be made redundant by its adoption.

As the proposal is part of a comprehensive package, which also includes three major reviews to modernise the animal health, plant health and plant reproductive material *acquis*, it also aims to modernise and integrate the system of official controls in a manner that consistently accompanies the upgrade of EU policies in these sectors.

In order to rationalise and simplify the overall legislative framework, whilst simultaneously pursuing the objective of better regulation, the proposal integrates the rules currently applicable to official controls in specific areas currently governed by separate sets of rules (e.g. controls on residues of veterinary medicinal products in live animals and animal products, and plant health controls) into the framework of the Regulation.

Based on an extensive review of the provisions of the Regulation, which highlighted a number of cases where the burden of organising and performing official controls could be reduced by eliminating redundant requirements (e.g. separate reporting from official controls on residues of veterinary medicinal products) or allowing a proportionate and flexible approach to some specific situations (e.g. not requiring full accreditation of official laboratories in case of emergencies), the proposal introduces such changes.

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

As regards official controls performed on goods arriving from third countries, the provisions of the Regulation currently apply together with sectoral provisions which govern respectively the imports of animals and animal origin products, those of plant and plant products, and the controls on food and feed for which a specific risk requires increased attention at the borders.

The report adopted by the Commission in December 2010<sup>2</sup> on the effectiveness and consistency of sanitary and phytosanitary controls on imports of food, feed, animals and plants, whilst concluding that the comprehensive body of legislation currently in place allows the EU to deal with emerging risks or emergency situations without causing distortions to trade, also found that the Union's system of import controls could be made more consistent by reviewing and consolidating the existing sectoral acts with regard to official controls. The report indicates that this recommendation would bring benefits for MS and operators handling goods from third countries, by enabling a more efficient prioritisation of controls and a better allocation of public resources employed on import controls. The review of the Regulation was considered a good opportunity to take account of the findings of the report and consolidate controls where possible. The proposal includes therefore a set of common and comprehensive rules applicable to controls performed on animals and goods from third countries.

**As regards the financing of official controls**, the Regulation confirms the general principle according to which MS should allocate appropriate financial resources to official controls, and also the obligation for MS to collect, in certain areas, so-called 'control fees' to recover from business operators the costs incurred for the performance of official controls. Current rules require that mandatory inspection fees be charged only for official control activities on businesses handling meat, fishery products, and milk and for the approval of feed establishments and for (most) controls at borders. Historically, these were the areas where methods of controls by MS competent authorities (CAs) were first harmonised at EU level; the legislator assumed that in those areas operators benefiting from the added value represented by the assurances provided by the official controls should be called upon to compensate the costs incurred by the States because of such controls.

The proposal maintains the system of mandatory fees while introducing the changes necessary to address the shortcomings of the current system. External research<sup>3</sup> carried out in 2009 to evaluate the application of the financing mechanism established by the Regulation indeed pointed to the existence of problems regarding the application of the relevant rules (Articles 26 to 29), and concluded that the overall objective of ensuring that competent authorities are provided with adequate financial resources to perform official controls is not being met throughout the EU with a subsequent impact on delivery of controls. It also pointed out the unfairness of a system of mandatory fees whereby only certain sectors would contribute to the financing of official controls, and which would not discriminate effectively between compliant and non-compliant behaviour. The 2009 report recommended reviewing Articles 26 to 29 of the Regulation.

Throughout the consultation period stakeholders have contributed fully, both to the evaluation studies and the preparation of the Impact Assessment (IA).

## **1.2. Objectives of the proposal**

The general objectives of the revision coincide with the Treaty objectives to safeguard the single market while ensuring delivery of a high level of health protection. They also reflect

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<sup>2</sup> COM/2010/785/Final.

<sup>3</sup> 'Fees or charges collected by Member States to cover the costs occasioned by official controls'. FCEC 2009.

the Commission's priority objective of ensuring proper enforcement of EU law, which is also the original objective of the Regulation on official controls.

More specifically, the proposal aims to modernise and sharpen enforcement tools, and in particular official controls, as laid down in the existing Regulation, to simplify the legislative framework, make it easier to use and more efficient (for example with regard to administrative cooperation). As to the financing of official controls, the proposal aims to ensure the availability of stable and appropriate resources, ensure equity and fairness in the financing of official controls and improve transparency.

Effective official controls are necessary to ensure the correct enforcement of the legislation which governs the 'agri-food chain', and thus to ensure delivery on the objectives above.

The efficient operation of the EU system of official controls is important for both EU exports and imports. The EU's ability to export towards third countries relies on the reputation of the high production standards and added value that the EU goods can prove to have compared to the ones produced outside Europe. This can only be achieved by reliable and trusted official controls which ensure that the EU agri-food chain safety and quality standards are consistently enforced and corresponding expectations from trade partners met.

As regards imports, it is essential that all food on the EU market is safe. Controls performed by the MS CAs on goods arriving from third countries offer adequate guarantees that they meet equivalent safety requirements. The relevant import control rules must comply with the WTO Sanitary and Phytosanitary (SPS) Agreement, in particular with the provisions laid down in Annex C to the SPS Agreement.

### **1.3. Regulatory Framework**

The responsibility to enforce EU agri-food chain legislation lies with the MS, whose authorities monitor and verify that the relevant requirements are effectively applied, complied with and enforced across the Union. In doing that they verify that operators' activities and goods placed on the EU market (either EU produced or imported from third countries) are in compliance with the relevant EU food chain standards and requirements.

Harmonised EU rules to govern official control activities performed by MS are established in the Regulation with the aim of creating an integrated and uniform approach to official controls along the food chain. The Regulation provides for a general framework for official controls in the sectors of feed and food law, animal health and animal welfare rules, laying down rules governing both the organisation and the financing of such controls.

Despite the above integrated approach, for historical reasons official controls for animal health purposes (both on domestic and imported goods) and official controls on residues of veterinary medicinal products, remained regulated separately. Moreover, certain sectors pertaining to the food chain were not included in the scope of the Regulation - i.e. plant health, plant reproductive material (PRM), animal by-products (ABP) - and specific sectoral regimes were developed for them.

This proposal intends to establish a unique set of rules applicable to official controls in all these sectors.

### **1.4. Consistency with other policies and objectives of the Union**

This initiative pursues the objectives of the Communication on Smart Regulation in the European Union. One of the aims of the review is to simplify legislative burdens in light of comments made by MS and food business operators on the existing regime.

The proposal is consistent with the reviews of the animal health, the legislation on measures against pests of plants, and the PRM legislation, which are adopted by the Commission at the same time. It also intends to ensure that the provisions of the Regulation complement in a consistent manner those applicable to veterinary medicinal products, also currently being reviewed. A thorough analysis on the alignment of this EU sectoral legislation with overarching provisions of the Regulation was conducted so as to integrate the system of official controls in a manner that also consistently accompanies the upgrade of EU policies in these sectors.

The proposal also seeks to align the framework of official controls, in particular the terminology used, to the modernised customs code.

With a view to the Europe 2020 strategy, the provision of effective controls along the food chain will ensure safe food and feed while fostering competitiveness of business operators, rewarding compliant business operators and ensuring user-pays principles across all sectors. To this end, the exemption of micro-enterprises from mandatory control fees fulfils the Commission's commitment to lower the burden on very small businesses, in line with its new policy on 'Minimizing regulatory burden for SMEs – Adapting EU regulation to the needs of micro-enterprises'<sup>4</sup>.

## **2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS**

### **2.1. Consultation process**

#### *2.1.1. Consultation methods, main sectors targeted and general profile of respondents*

The Working Group created within the context of the Standing Committee for the Food Chain and Animal Health to discuss matters related to the application of the Regulation met several times to discuss the on-going review. Member States were also consulted in the context of two studies contracted out by the Commission in the area of the financing of official controls (the 2009 study mentioned above, and a second in 2011 exploring further the shortcomings identified<sup>5</sup>). Member States have also been consulted within other fora and frameworks on the following specific issues relating to official controls: accreditation of official laboratories, official controls on residues of veterinary medicinal products in live animals and animal products, veterinary border controls, animal health, plant health and plant reproductive material. The main problems identified and the provisional options were also presented and discussed at meetings of the Heads of Food Safety Agencies and services on 29 June - 1 July 2011 and on 8 December 2011.

Stakeholders (industry association representatives and NGOs) have been consulted during the evaluation studies and the preparation of the IA. Two ad hoc Working groups, on the review of the system of official controls and the review of the rules governing the financing of such controls respectively, were convened under the Advisory Group on the Food Chain and Animal Health and Plant Health. Progress was also presented and discussed in the plenaries of the aforementioned Advisory Group and on invitation at meetings of several industry representative bodies. In addition to discussions with MS, stakeholder consultation was an equally important element of the two external contractor studies on the financing of official controls.

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<sup>4</sup> COM (2011)803.

<sup>5</sup> 'Preparatory work to support the impact assessment on reviewing the rules on the financing of official controls'. GHK Consulting Ltd working with ADAS UK Ltd. 2011.

### *2.1.2. Data Collection*

Audit Reports by the Food and Veterinary Office (FVO), the Commission service tasked with appraising Union controls in the MS, were extensively used to inform the review. They provide information and data on the organisation and functioning of control systems in the Member States and on the application of agri-food legislation. The findings of each audit carried out by the FVO are set out in an audit report, which is made available to the public.

As regards the financing of official controls, the 2011 study highlighted the difficulty in obtaining exact figures from Member States to quantify the overall control costs and the corresponding resourcing problem. However the report did highlight the diverse spread of cost recovery within MS and certain problems with the application of EU rules.

### *2.1.3. Summary of responses and how they have been taken into account*

All stakeholders and Member States welcomed the proposal to review the Regulation and the objective of establishing a clearer, simpler and more efficient legislative framework for the organisation of official controls and of other official activities along the entire agri-food chain, whilst taking into account the specificities of each sector. Indeed, there was almost unanimous consensus that the review should take account of relevant official control rules in sectoral legislation and of any experience gained and lessons learnt since the Regulation entered into force.

As regards the rules on the financing of official controls, views varied according to the current practices in each Member States and, from businesses' perspective, on whether they are currently being charged or not through mandatory fees.

If a general preoccupation emerged regarding the proposal to expand the list of mandatory fees, most respondents would agree as to the unfairness of collecting such fees only from certain operators and all would accept the importance of appropriately resourcing national control systems. The proposal was prepared with a view to striking the right policy balance, by ensuring that the new rules do not add an unaffordable or disproportionate burden on each operator, whilst securing stable appropriate revenues for the competent authorities and their control systems.

Both stakeholders and Member States agree that the 'risk-based controls' principle in the Regulation (i.e. that where resources are finite these are to be used selectively and the selection should be based on the hazard and risks associated with the specific business activity, or product, the operator's record of compliance and reliability, indications of possible non-compliance) should be kept and reinforced, in particular in those areas where current rules create obstacles to the efficient allocation of control resources, namely border controls and controls on residues of veterinary medicinal products. The proposal does this by repealing the special rules governing the latter and by replacing the currently fragmented framework applicable to official controls on different categories of products from third countries with a common set of rules.

Member States and operators alike welcomed the envisaged enhancements to the transparency requirements laid down in the Regulation. Thus, one of the specific objectives of the review is that the system of controls should provide MS with a clear guidance as to how they are expected to deliver on the obligation to ensure a 'high level of transparency' of their activities, so that citizens can have access to basic information and data on enforcement work along the agri-food chain. Transparency was also reported to be a concern in relation to the financing of official controls (the fees system), which should be transparent and allow the public, and more specifically, the operators to understand how the fees are calculated and how revenue

therefrom is employed. Operators clearly see transparency as a driver to accountability and efficiency of the system of official controls as a whole.

There was general agreement amongst industry contributors and Member States alike that steps should be taken to improve the functionality of administrative assistance between Member States with a view to improving the main instrument through which cross border violations of food chain rules can be investigated and pursued and application of Union rules made more effective. In response, the proposal makes clear the responsibility of Member States when the need for administrative assistance arises.

## 2.2. Impact Assessment

The options developed and assessed looked both at the design of the legislative framework and at the rules on the financing of national control systems.

A preliminary analysis focused on two possible changes to the current rules on control fees, specifically aiming to:

- repeal Union rules on control fees (thus leaving it to MS to decide how to ensure the appropriate funding of control activities and whether to charge inspection fees or not) [Option 1A], or
- maintain current EU rules on fees, including on mandatory fees, and exempting micro-enterprises<sup>6</sup> therefrom [Option 1B].

Both abovementioned options would substantially alter the current framework as regards the financing of national control systems and were found not to be viable.

The following options were further assessed by comparison with the *status quo*:

**Option 2 – Streamline.** The legislative framework is improved by clarifying, simplifying and streamlining existing provisions on controls in the sectors currently covered by the Regulation, and by ensuring full cost recovery where mandatory fees are already provided for, with the possibility for Member States to refund fees paid by micro-enterprises.

**Option 3 – Streamline + Integrate.** The legislative framework is improved and streamlined as described under Option 2, the scope of the Regulation is widened such that plant health and PRM, and animal by-products (ABP) are included (therefore completing the 'integration' of food chain official controls). Full cost recovery is ensured where mandatory fees are already provided for in the existing Regulation, as well as in the fields of plant health, where mandatory fees are introduced for official controls linked to plant passport obligations and PRM, where mandatory fees are introduced with regards to certification. Member States will have the possibility to refund fees paid by micro-enterprises.

**Option 4 – Streamline + Integrate + broader cost recovery.** The legislative framework is improved and streamlined, and plant health, PRM, and ABP are included in its scope as described under Option 3. Mandatory fees are extended to cover all controls performed on feed and food businesses registered and or approved in accordance with food and feed hygiene Regulations as well as operators defined in plant health and PRM law. MS have the possibility to refund fees paid by micro-enterprises.

Option 4 was retained and substantially informs the present proposal. However, the exemption of micro-enterprises from mandatory control fees is required to fulfil the

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<sup>6</sup> Enterprises with less than 10 employees and or a turnover or balance sheet equal to or less than EUR 2 million.

Commission's commitment to lower the burden on very small businesses, in line with its new policy on 'Minimizing regulatory burden for SMEs – Adapting EU regulation to the needs of micro-enterprises'<sup>7</sup>.

Therefore the (optional) refund mechanism designed to alleviate micro-enterprises from the financial burden of fees, has been replaced with a mandatory exemption of those enterprises from the fees.

### **3. LEGAL ELEMENTS OF THE PROPOSAL**

#### **3.1. Legal basis**

The Regulation was based on Articles 37, 95 and 152(4)(b) of the EC Treaty, now Article 43, 114 and 168(4)(b) respectively of the TFEU. Likewise, the proposal is based on these latter Articles.

The Common Agricultural Policy (CAP), which is based on Article 43 of the TFEU, is qualified by the Lisbon Treaty as shared competence between the EU and its MS. However, the majority of agricultural activity, as well as ancillary activities upstream and downstream, have been regulated at the EU level. This means that legislation is predominantly a role for the institutions of the European Union. Article 114 provides the legal basis for the establishment and functioning of the internal market for food products while ensuring a high level of protection of consumers and the approximation of provisions laid down by the law, regulation or administrative actions in this respect. Article 168(4)(b) stipulates that in order to meet common safety concerns 'measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health' should be adopted by the EU.

#### **3.2. Subsidiarity principle**

The existence of a harmonised EU legislative framework to govern the organisation and performance of official controls along the food chain is necessary to ensure the uniform application of the agri-food chain rules across the EU and the smooth functioning of the internal market. This rationale, which is still valid, underpins the existing rules on official controls. As the problems identified by this review are linked to the current design of the EU legislative framework, its reform cannot be achieved by MS acting alone. The intervention of the European legislator is required.

European added value test - The added value of a single, uniform set of EU rules to govern official controls lies in the fact that it offers national enforcers (and their operators) a framework within which CAs can rely on enforcement activities carried out in another MS, and on the reproducibility and scientific and technical soundness of control results. It also ensures that EU agri-food chain standards necessary for the functioning of the single market are applied uniformly and consistently in the different Member States and sectors.

As to the financing of controls, common EU rules ensure that CAs can count on a reliable flux of resources to maintain the control effort at a level justified by the risks and by enforcement needs (including the level of non-compliance). Provisions on fees in particular ensure that business activities monitored through dedicated national control systems, which benefit directly from efficiently performed controls, participate to the financing of the latter, so as to minimise the dependency of control funding from public finances. Common EU rules are necessary also to prevent discriminatory treatment between operators located in a Member State where the user-pays rule (and thus fees) applies and those located in a Member State

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<sup>7</sup> COM (2011)803.



where this is not the case. Only common EU rules can ensure a uniform approach to pursue this objective.

### **3.3. Proportionality principle**

EU action should not go beyond what is necessary to achieve the objectives set. The present exercise has looked at a broad range of options, including that of harmonising fee levels across Member States, and that of de-regulating the matter. The analysis sought to design the most proportionate solution to ensure a sufficient and steady flux of dedicated resources for official controls, whilst leaving MS the time and flexibility necessary to cater for their internal arrangements and the specificities of their business population.

### **3.4. Choice of instruments**

Proposed instrument: Regulation.

Other types of measure would not be appropriate for the following reason(s).

The existing provisions have been demonstrated to provide an appropriate framework for MS, however despite this, inconsistency of interpretation has arisen as discussed previously. A Directive would have led to still greater inconsistency leading to uncertainty for Member States' CAs and operators. A Regulation provides a consistent approach for Member States to follow and reduces the administrative burden as operators do not need to familiarise themselves with the individual national legislation in the Member States.

Soft law instruments such as guidelines are considered not sufficient to tackle differences in the interpretation and application of the legislation.

## **4. BUDGETARY IMPLICATION**

The proposal does not imply incurring any expenditure which is not already foreseen in the financial statement of the common financial framework. No additional human resources are envisaged either.

## **5. OPTIONAL ELEMENTS**

### **TITLE I: SUBJECT MATTER, SCOPE, AND DEFINITIONS**

The scope of the Regulation will be expanded to cover controls performed to verify compliance with the legislation concerning measures against pests of plants, rules governing the production, with a view of placing on the market, of plant reproductive material and rules on animal by-products.

Moreover, it will be clarified that certain Articles of the Regulation also apply to official activities, other than official controls. These are the public interest activities entrusted to competent authorities of the MS for the purpose of eliminating, containing or reducing risks which may arise for the health of humans, animals or plants, or for the welfare of animals. These activities, which notably include various modalities of surveying, surveillance and monitoring (including epidemiologic), and eradication, containment, and other diseases control tasks, are governed by the same sectoral rules which are enforced through the official controls.

Existing definitions will be adjusted to give account of the broader scope of the Regulation in terms of sectors and activities covered by it. New definitions will be introduced, some by cross-referring to sectoral rules.

Finally, it will be clarified that the Regulation shall also apply to official controls performed for the verification of the requirements applicable to animals and goods arriving from third countries, and to animals and goods to be exported to third countries.

Empowerment provisions will allow the Commission to adopt delegated acts to lay down sector specific rules for such goods in order to take account of the specific official controls needs of certain areas of the agri-food chain and of risks to health.

## **TITLE II: OFFICIAL CONTROLS AND OTHER OFFICIAL ACTIVITIES IN MEMBER STATES**

### **CHAPTER I: COMPETENT AUTHORITIES**

The structure of this Chapter will remain largely unaltered. The terminology will be adjusted to give account of the broader scope of the Regulation (both in terms of sectors and activities covered). However, some changes will be necessary to address certain shortcomings and provide the competent authorities with the most efficient tools to perform official controls and other official activities.

### **CHAPTER II: SAMPLING, ANALYSIS, TESTING AND DIAGNOSIS.**

The existing provisions on the second expert opinion will be clarified so that this right will be applicable in the case of official controls only and that it includes each time, a documentary review of the sampling, analysis, testing or diagnosis by another expert and, where relevant and technically feasible, a sufficient number of other samples offered to the operator for another expert opinion or, if this is not possible, another analysis, test or diagnosis carried out on the existing sample. An empowerment will allow the Commission to adopt implementing rules in order to ensure a uniform application.

Requirements on methods of sampling and of laboratory analysis, testing and diagnosis will become applicable to official controls and to other official activities in all the sectors covered by the Regulation (e.g. to surveillance, monitoring and survey activities in the plant health and animal health sectors). A 5 years transitional period will thus be foreseen for the plant health and plant propagating material sectors.

The rules for the choice of the method to be used by the official laboratory will be clarified and extended so as to require that methods meet state-of-the-art scientific standards, and satisfy the analytical, testing and diagnostic need of the laboratory concerned and to incorporate methods validated by European or national reference laboratories. In the context of screening, targeted screening and other official activities and in the absence of Union rules on methods or performance criteria on methods, it will be furthermore possible to use any of the methods prescribed by the cascade.

The accreditation according to EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories' will remain a mandatory condition for the designation of official laboratories. In this regard, it will be clarified that the scope of the accreditation shall include all the methods used by the laboratory for analysis, testing or diagnosis when operating as an official laboratory (with the exception of cases to be specifically identified by secondary legislation – for instance in the plant health sector - where the scope of accreditation could be limited to the analytical, testing or diagnostic methods which are the most significant and representative). The inclusion of plant health under the

scope of the Regulation will imply that official laboratories carrying out analysis, testing or diagnosis in this sector will have to be accredited according to EN ISO/IEC 17025. A five years transitional period will be thus foreseen for these laboratories.

The temporary designation of an official laboratory for the use of a method required for laboratory analysis, testing or diagnosis not included in its scope of accreditation will be possible (for a period of one year renewable once) when the use of the method is newly required by Union legislation, where changes of the method in use require a new accreditation or an extension of the scope of the accreditation already obtained by the laboratory, and in emergency situations or in cases of emerging risks where the sudden increase of analytical, testing or diagnostic needs requires the urgent use by official laboratories of a method which is not included in their scope of accreditation.

Derogations from the accreditation requirement will be introduced for laboratories which only carry out detection of *Trichinella* in meat and use only the methods prescribed by Union rules, for laboratories performing analyses or tests on plant reproductive materials other than plant health analysis, testing or diagnosis, and for certain laboratories only carrying out analysis, testing or diagnosis in the context of other official activities.

### **CHAPTER III: OFFICIAL CONTROLS ON ANIMALS AND GOODS ENTERING THE UNION**

Chapter V of Regulation (EC) No 882/2004 will be redrafted in order to create a common set of rules applicable to all controls performed on animals and goods entering the Union. An integrated approach will increase efficiency savings and should help in prioritising controls on the basis of risk. As noted below the Chapter is likely to be substantially altered.

Firstly, provisions largely mirroring the current Articles 15 and 16 of Regulation (EC) No 882/2004 (to be deleted) will be inserted. Some adjustments will be made to align the said provisions to the modernised customs code and to guarantee that sectoral specificities are accounted for.

Secondly, a specific section will consolidate current legislation and lay down the categories of animals and goods arriving from third countries that require controls at entry into the Union. Empowerments will allow the Commission to modify the abovementioned categories and to establish a list detailing which specific animals and goods (including their respective CN codes) should be controlled. The Commission will also be given the power to define the cases and conditions under which animals and goods can be exempted from said controls.

Border Control Posts (BCPs) will replace the different entities currently tasked with border control duties. Common requirements for BCPs shall be established with the possibility for the Commission to further refine such requirements to take account of specific features related to the different categories of animals and goods being controlled. Harmonised rules for the designation, listing, withdrawal and suspension of BCPs will also be laid down.

A Common Health Entry Document (CHED) will be established and governed by rules based on current practices. The CHED will be used by operators for the mandatory prior notification of arrival of consignments of animals and goods and by competent authorities to record controls on such consignments and any decisions taken. The Commission shall be empowered to establish the format of the CHED, the modalities for its use, and the minimum time requirements for the prior notification of consignments to Border Control Posts.

A common set of rules for controls on consignments (including those of a non-commercial nature) of animals and goods subject to controls at borders will also be laid down. Controls will, in principle, be performed by the BCP authorities to whom the consignment is first presented although the Commission will be allowed to establish exceptions to this rule in certain cases. All consignments shall be subject to documentary and identity checks whilst physical checks will be performed at a frequency depending on the risk posed by each specific animal/good or category of animals/goods. Empowerments will, inter alia, allow the Commission to detail how documentary, identity and physical checks should be performed and to establish reduced frequencies for identity and physical checks.

Thirdly, the provisions detailing the actions to be taken in case of suspicion and in case of non-compliant consignments will be amended. Changes will aim to increase efficiency by simplifying the decision-making of BCPs, clarifying the steps that the competent authorities of such BCPs should take and by ensuring that the specificities of the sectors being brought under the Regulation are fully taken into account. Such rules will also be applicable to official controls performed on animals and goods arriving from third countries which are not subject to specific controls at borders.

Finally, a new provision will be introduced to require close cooperation between competent authorities, customs authorities and other authorities involved in the handling of animals and goods arriving from third countries. Moreover, an empowerment will allow the Commission to establish the modalities of cooperation between the said authorities with a view to ensuring the timely and proper access to information, the synchronisation of relevant data sets, and the rapid communication of decisions taken.

#### **CHAPTER IV: FINANCING OF OFFICIAL CONTROLS**

The general principle of the existing Regulation will be retained. MS will continue to be required to ensure that adequate financial resources are available to provide the staff and other resources necessary to the competent authorities to perform official controls and the other activities referred to in the Regulation.

As it is the case under the current rules, Member States will decide at what level (local, regional, national) the fees are established and collected, depending on the organisation of their competent authorities.

Under new provisions, mandatory fees will be collected to cover the costs occasioned by:

- official control activities performed on food and feed businesses registered and or approved under either or both of Regulation (EC) No 852/2004 (food hygiene) and Regulation (EC) No 1831/2003 (feed hygiene), on operators defined in the future Plant Health Regulation and on those defined in the future Regulation on Plant Reproductive Material, in order to verify compliance with Union 'agri-food chain' rules (feed and food law, animal health and animal welfare, plant health and plant reproductive material rules);
- controls performed in view of issuing an official certificate or to supervise the issuance of an official attestation of compliance;
- official control activities performed to verify that the conditions to obtain or maintain approval are met;

- official control activities performed with respect to border controls (including cost of controls with regard to plant health requirements, which will be transferred to the new official controls regulation);
- official control activities performed to verify compliance with emergency measures adopted by the Commission in accordance with so called 'safeguard' provisions, where the decision establishing the measures so requires.

Mandatory fee levels shall be calculated so as to enable the competent authorities performing the official control activities to fully recover costs resulting from official controls (if the competent authority for which the fees are collected also performs other activities, then only the fraction of the relevant cost elements which results from official control activities should be considered for the calculation of fees).

A new provision will ensure that operators charged a flat-rate fee will benefit from recognition of good performance by requiring that the rate of fee applied to each operator shall be adjusted to take account of the operator's record of compliance as ascertained through official controls. As a rule, fees applied to consistently compliant operators should be lower than those applied to non-compliant ones.

Existing provisions that prohibit the refund – direct or indirect - of mandatory fees will be retained (unless of course the fees were unduly collected).

Enterprises employing fewer than 10 persons and whose annual turnover or balance sheet does not exceed EUR 2 million (micro-businesses) will be exempted from the payment of mandatory fees.

Underpinning the provisions on the financing of official controls will be the requirement that competent authorities shall ensure the highest level of transparency of the method and data used to establish fees, and of the use of resources collected through such fees.

The current provisions with regard to expenses arising from additional official controls due to non-compliance with enforcement measures (Article 28 of the Regulation) will be made clearer in order to ensure effective use by Member States.

## **CHAPTER V: OFFICIAL CERTIFICATION**

The definition of 'official certification' and the relevant provisions will be amended to ensure that the Regulation is the general framework for official certification as regards all sectors covered by the Regulation.

### **TITLE III: REFERENCE LABORATORIES AND CENTRES**

As a consequence of the extension of scope of the Regulation to new sectors (measures against pests of plants; rules governing the production, with a view of placing on the market, of plant reproductive material; animal by-products rules), it will be possible for the Commission to establish European Union reference laboratories (EURLs) in those sectors. The obligations for Member States to designate national reference laboratories (NRLs) for each EURL designated by the Commission will follow accordingly.

It will also be possible for the Commission to designate European Union reference centres for the production and marketing of plant reproductive material and for animal welfare. These centres will in particular provide technical expertise, conduct training courses and contribute to the dissemination of research findings and technical innovations.

## **TITLE IV: ADMINISTRATIVE ASSISTANCE AND COOPERATION**

The administrative assistance and cooperation provisions of the Regulation will be re-enforced and clarified so as to increase their usability and effectiveness as a tool for tackling cross-border non-compliances. Several changes are envisaged in this respect.

First of all, competent authorities will be required to provide each other with administrative assistance where necessary to ensure the correct application of Union rules. The requirement for all communications to be in writing will also be introduced. Moreover, the Commission will be empowered to establish a standard format for requests for assistance and for communication exchanges.

Secondly, the role of liaison bodies will be clarified and the need for administrative assistance/cooperation to be 'channelled' through such bodies will be made explicit. The Commission will be required to publish and update the list of liaison bodies on its website. An empowerment will also allow it to establish minimum requirements for liaison bodies.

Thirdly, the modalities for requesting administrative assistance and for activating cooperation procedures will be simplified (where necessary) and the actions that competent authorities must take following requests for assistance shall be defined.

Finally, the cases in which the Commission is required to coordinate administrative assistance and cooperation, and the actions that it can take in such circumstances, will be clarified.

## **TITLE V: PLANNING AND REPORTING**

The Multi-annual national control plan (MANCP) will remain a document produced and owned by the MS which they will use to assist the competent authorities in ensuring the delivery of official controls in compliance with Union law.

A new provision requiring Member States to designate the single competent authority responsible for coordinating the preparation of the MANCP and ensuring the coherence of such plan will be created.

With regard to annual reports a revised Article 44 will provide for an empowerment for the Commission to progressively adopt standardised templates taking duly into account, where appropriate, existing reporting requirements.

## **TITLE VI: UNION ACTIVITIES**

This title will continue to govern a number of activities at Union level:

- controls by the Commission's Food and Veterinary Office (FVO) in Member States and in third countries;
- the procedures (clarified and streamlined) for the establishment of requirements for the entry of certain categories of goods from third countries into the Union, and of measures regarding certain goods from certain specific third countries in cases where there is evidence that the entry into the Union of those goods may pose a risk 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 rules might be taking place;

- the organisation by the Commission of training for the staff of the competent authorities in the Member States and in third countries (the current programme Better Training for Safer Food), and of programmes for the exchange of staff between Member States (new activity, to be organised in cooperation with Member States).

This title will also include the creation of an integrated information management system for official controls, which will allow the integrated operation and update of all existing and future computerised systems through which information, data and documents regarding official controls are exchanged among competent authorities, and with the Commission (and operators where appropriate).

## **TITLE VII: ENFORCEMENT MEASURES**

Provisions governing national enforcement measures will be applicable to all the sectors of the scope of the Regulation.

A new provision dealing specifically with actions to be taken in case of suspicion of non-compliance will be included, requiring competent authority to carry out investigations in order to confirm or to eliminate the suspicion or doubt.

The list of possible measures in case of established non-compliance will furthermore be completed: restriction or prohibition of movements of animals, imposition of quarantine periods, slaughter or killing of animals, postponement of slaughter of animals, isolation or closure of establishments, closure of websites will for instance be added to the list.

A new provision in former Article 55 (on sanctions for non-compliance) will require MS to ensure that financial penalties applicable to intentional infringements offset the economic advantage sought by the perpetrator of the violation. Member States will also be required to ensure the application of appropriate criminal and/or administrative penalties to operators who fail to cooperate during an official control.

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [...] /2013 [Office of Publications, please insert number of 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], and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation)**

(Text with EEA relevance)

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), 114 and 168(4)(b) thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee<sup>8</sup>,

Having regard to the opinion of the Committee of the Regions<sup>9</sup>,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) The 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 performed in accordance with specific requirements. Union rules exist also to ensure a high level of human, animal and plant health and animal welfare

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<sup>8</sup> OJ C , , p. .

<sup>9</sup> OJ C , , p. .



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 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.

- (4) The basic Union rules with regard to food and feed law are laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and setting out procedures in matters of food safety<sup>10</sup>. 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 genetically modified organisms (GMOs).
- (5) Union legislation on animal health aims to ensure high standards of human and animal health in the Union, the rational development of the agriculture and aquaculture sectors and to increase productivity. That legislation is necessary to contribute to the completion of the internal market 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.
- (6) 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 them unnecessary pain and suffering. Such rules are based on scientific evidence and may indirectly improve the quality and safety of food and feed.
- (7) 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.
- (8) 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.
- (9) 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

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<sup>10</sup> OJ L 31, 1.2.2002, p. 1.

the protection of natural resources, biodiversity and animal welfare, and the development of rural areas.

- (10) 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.
- (11) 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.
- (12) 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.
- (13) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with food and feed law, animal health and animal welfare rules<sup>11</sup> has established a single legislative framework for the organisation of official controls. That framework has significantly improved the efficiency of official controls, the enforcement of Union agri-food chain legislation and the level of protection against risks to human, animal and plant health and animal welfare in the Union and the level of protection of the environment from risks that might arise from GMOs and plant protection products. It has also provided a consolidated legal framework to support an integrated approach towards the performance of official controls along the agri-food chain.
- (14) 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<sup>12</sup>. Plant health also largely falls outside the scope of Regulation (EC) No 882/2004 with certain rules on official controls being laid down in Council Directive 2000/29/EC 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<sup>13</sup>.
- (15) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC<sup>14</sup> also provides for a very detailed set of rules that establish among other things minimum frequencies of official controls and specific enforcement measures to be adopted in cases of non-compliance.

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<sup>11</sup> OJ L 165, 30.4.2004, p. 1.

<sup>12</sup> OJ L 300, 14.11.2009, p. 1.

<sup>13</sup> OJ L 169, 10.7.2000, p. 1.

<sup>14</sup> OJ L 125, 23.5.1996, p. 10.

- (16) In order to rationalise and simplify the overall legislative framework, whilst simultaneously pursuing the objective of better regulation, the rules applicable to official controls in specific areas should be integrated into a single legislative framework for official controls. For that purpose, Regulation (EC) No 882/2004 and other acts currently governing official controls in specific areas should be repealed and replaced by this Regulation.
- (17) 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.
- (18) For the verification of compliance with the rules on the common organisation of the markets of agricultural products (arable crops, wine, olive oil, fruit and vegetables, hops, milk and milk products, beef and veal, sheepmeat and goatmeat and honey), a well-established and specific control system is already in place. This Regulation should therefore not apply to the verification of compliance with the provisions of Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation)<sup>15</sup>.
- (19) 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.
- (20) Union agri-food chain legislation entrusts the competent authorities of the Member States with specialised tasks to be carried out for the protection of animal health, plant health and animal welfare, 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 must 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.
- (21) 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.
- (22) 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.

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<sup>15</sup> OJ L 299, 16.11.2007, p. 1.

- (23) For the performance of official controls aimed at verifying the correct application of Union agri-food chain legislation, and of the other official activities entrusted to Member State authorities by Union agri-food chain legislation, Member States should designate competent authorities which act in the public interest, are appropriately resourced and equipped, and offer guarantees of impartiality and professionalism. Competent authorities should ensure the quality, consistency and effectiveness of official controls.
- (24) 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 is regularly trained on the applicable legislation, according to their area of competence, as well as on the obligations resulting from this Regulation.
- (25) Operators should have a right to appeal against the decisions taken by the competent authorities, and be informed of such a right.
- (26) The competent authorities should ensure that staff responsible for official controls does not disclose information acquired during the performance of such controls which is covered by professional secrecy. Unless there is an overriding interest justifying disclosure, professional secrecy should include information which would undermine the purpose of inspections, investigations or audits, the protection of commercial interests and the protection of court proceedings and legal advice. However, professional secrecy should not prevent competent authorities from disclosing factual information on the outcome of official controls regarding individual operators when the operator concerned has been allowed to comment upon it prior to the disclosure and such comments have been taken into account, or released alongside the information being divulged by the competent authorities. The need to respect professional secrecy is also without prejudice to the obligation to inform the general public where there are reasonable grounds to suspect that food or feed may present a risk for health in accordance with Article 10 of Regulation (EC) No 178/2002. The obligation for competent authorities to inform the general public in cases where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, in accordance with Article 10 of Regulation (EC) No 178/2002, and the right of individuals to the protection of their personal data as provided for in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>16</sup> should not be affected by this Regulation.
- (27) 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.

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<sup>16</sup> OJ L 281, 23.11.1995, p. 31.

- (28) 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 notably the case of audit activities).
- (29) 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.
- (30) 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.
- (31) 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.
- (32) The competent authorities act in the interest of operators and of the general public ensuring that the high standards of protection established by Union agri-food chain legislation are consistently preserved and protected through appropriate enforcement action, and that compliance with such 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.
- (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-compliances and streamline the taking of corrective action by the operator concerned, the outcome of official controls should be

recorded in a report, a copy of which should 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.

- (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 such 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.

- (39) 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.
- (40) For the purposes of performing official controls on trade which takes 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.
- (41) 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 of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93<sup>17</sup>.
- (42) 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.
- (43) 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.

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<sup>17</sup> OJ L 218, 13.8.2008, p. 30.

- (44) 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 might 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.
- (45) Given the risks to human, animal or plant health, animal welfare or to the environment that certain animals or goods may pose, they should be subject to specific official controls to be performed upon them 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 phytosanitary 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 of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries<sup>18</sup>, Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC<sup>19</sup>, Council Directive 2000/29 and Commission Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 of the European Parliament and the Council as regards the increased level of official controls on imports of certain food and feed of non-animal origin and amending Decision 2006/504/EC<sup>20</sup>, should be provided for in this Regulation.
- (46) 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, must be controlled at their entry into the Union.
- (47) 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.
- (48) 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

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<sup>18</sup> OJ L 24, 30.1.1998, p. 9.

<sup>19</sup> OJ L 268, 24.9.1991, p. 56.

<sup>20</sup> OJ L 194, 25.7.2009, p. 11.



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.

- (49) 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.
- (50) 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 they accompany. The same document should be used by the operator to obtain clearance by customs authorities once all official controls have been performed.
- (51) 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.
- (52) 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 might pose a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment.
- (53) 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.
- (54) 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 collect fees 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 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.

- (55) 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 States will chose 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.
- (56) 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.
- (57) 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.
- (58) 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.
- (59) 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 must 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.
- (60) 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.

- (61) 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.
- (62) 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 Article 50 of Regulation (EC) No 178/2002 already enables competent authorities to rapidly exchange and disseminate information on serious direct or indirect risks to human health in relation to food or feed, or serious risks to human or animal health or to the environment in relation to feed, for the purpose of enabling rapid measures to be taken to counter those 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 non-compliances 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.
- (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 Article 11 of Regulation (EC) No 178/2002, which requires that food and feed imported into the Union must 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 of 30 December 2002 concerning the development of an integrated computerised veterinary system and currently used for the management of data and information on animals and products of animal origin and official controls thereon<sup>21</sup>. That system should be upgraded 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. Article 50 of Regulation (EC) No 178/2002 establishes the RASFF, Article 20 of Regulation (EU) XXX/XXXX [*Office of Publications, please insert number, date, title and, in a footnote, the OJ reference for the Regulation on animal health*] a system for the notification and reporting on the measures on listed diseases, and Article 97 of Regulation (EU) XXX/XXXX [*Office of Publications, please insert number, date, title and, in a footnote, the OJ reference for the Regulation on protective measures against*

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<sup>21</sup> OJ L 8, 14.1.2003, p. 44.

*pests of plants*] 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.

- (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 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 of 13 December 1999 on a Community framework for electronic signatures<sup>22</sup> should be foreseen, in line with the Digital Agenda for Europe.
- (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 the economic advantage sought by the perpetrator through the violation. Member States should also be required to apply appropriate criminal and/or administrative penalties in cases where operators fail to cooperate during an official control.
- (78) This Regulation covers areas that are already covered in certain acts currently in force. To avoid duplications and to establish a coherent legislative framework, the following acts should be repealed and replaced by the rules of this Regulation: Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the

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<sup>22</sup> OJ L 13, 19.1.2000, p. 12.

Commission to ensure the correct application of legislation on veterinary and zootechnical matters<sup>23</sup>; Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market<sup>24</sup>; Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market<sup>25</sup>; Council Directive 91/496/EEC; Council Decision 92/438/EEC of 13 July 1992 on computerization of veterinary import procedures (Shift project), amending Directives 90/675/EEC, 91/496/EEC, 91/628/EEC and Decision 90/424/EEC, and repealing Decision 88/192/EEC<sup>26</sup>; Council Directive 96/23/EC; Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products<sup>27</sup>; Council Directive 97/78/EC; Regulation (EC) No 882/2004; and Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption<sup>28</sup>.

- (79) In order to ensure consistency, amendments should also be effected to the following acts: Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies<sup>29</sup>; Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97<sup>30</sup>; Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum levels of pesticides in or on food and feed of plant of animal origin and amending Council Directive 91/414/EEC<sup>31</sup>; Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) 2092/91<sup>32</sup>; Regulation (EC) No 1069/2009; Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing<sup>33</sup>; Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC<sup>34</sup>; Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs<sup>35</sup>; Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes<sup>36</sup>; Council Directive 1999/74/EC of 19 July 1999 laying down minimum standards for the protection of laying hens<sup>37</sup>; Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003

<sup>23</sup> OJ L 351, 21.12.1989, p. 34.

<sup>24</sup> OJ L395, 30.12.1989, p. 13.

<sup>25</sup> OJ L 224, 18.8.1990, p. 29.

<sup>26</sup> OJ L 243, 25.8.1992 p. 27.

<sup>27</sup> OJ L 13, 16.1.1997, p. 28.

<sup>28</sup> OJ L 139, 30.4.2004, p. 206.

<sup>29</sup> OJ L 147, 31.5.2001, p. 1.

<sup>30</sup> OJ L 3, 5.1.2005, p. 1.

<sup>31</sup> OJ L 70, 16.3.2005, p.1.

<sup>32</sup> OJ L 189, 20.7.2007, p. 1.

<sup>33</sup> OJ L 303, 18.11.2009, p.1.

<sup>34</sup> OJ L 309, 24.11.2009, p. 1.

<sup>35</sup> OJ L 343, 14.12.2012, p.1.

<sup>36</sup> OJ L 221, 8.8.1998, p. 23.

<sup>37</sup> OJ L 203, 3.8.1999 p. 53.

on genetically modified food and feed<sup>38</sup>; Regulation (EC) No 1831/2003 of the European Parliament and the Council of 22 September 2003 on additives for use in animal nutrition<sup>39</sup>; Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production<sup>40</sup>; Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves<sup>41</sup>; Council Directive 2008/120/EC of 18 December 2008 laying down minimum standards for the protection of pigs<sup>42</sup>; Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the Community action to achieve the sustainable use of pesticides<sup>43</sup>

- (80) Regulation (EU) No [...] /2013 [Office of Publications, please insert number, date, title and, in a 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] 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 [...] /2013 [Office of Publications, please insert 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] 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 Article 55(1) of Regulation (EC) No 178/2002, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union 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.

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<sup>38</sup> OJ L 268, 18.10.2003, p. 1.

<sup>39</sup> OJ L 268, 18.10.2003, p. 29.

<sup>40</sup> OJ L 812, 12.7.2007, p. 19.

<sup>41</sup> OJ L 10, 15.1.2009, p. 7.

<sup>42</sup> OJ L 47, 18.2.2009, p. 5.

<sup>43</sup> OJ L 309, 24.11.2009, p. 71.



- (82) In order to ensure uniform conditions for the implementation of this Regulation regarding the designation of European Union reference laboratories and of the European Union reference centres for plant reproductive material and for animal welfare, the adoption of the programme of the Commission controls in the Member States, and the performance of increased official controls in the event of violations of agri-food chain rules which require coordinated assistance and follow-up by the Commission, implementing powers should be conferred on the Commission.
- (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 of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers<sup>44</sup>.
- (84) 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 and 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:

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<sup>44</sup> OJ L 55, 28.2.2011, p. 13.

# Title I

## Subject matter, scope and definitions

### *Article 1* *Subject matter and scope*

1. This Regulation lays down rules for:
  - (a) the performance of official controls and other official activities 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, 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 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;
  - (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 specialities guaranteed.
3. This Regulation shall also apply to official controls performed for the verification of compliance with requirements laid down in the rules referred to in paragraph 2 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) the rules laid down in Regulation (EC) No 1234/2007;
    - (b) the rules laid down in Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes<sup>45</sup>.
  5. Articles 3, 4, 5, 7, 11(2) and (3), 14, 30 to 33, 36 to 41, 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 shall apply:

1. 'official control' means any form of control that the competent authorities perform for the verification of compliance with:
  - (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) to ensure the application of those rules;
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 official controls and of other official activities, in accordance with this Regulation and the rules referred to in Article 1(2);
  - (b) any other authority to which that responsibility has been conferred;

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<sup>45</sup> OJ L 276, 20.10.2010, p. 33.

- (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 XXX/XXXX [*Office of Publications, please insert number of the Regulation on animal health*];
  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 XXX/XXXX [*Office of Publications, please insert number of the Regulation on protective measures against pests of plants*];
  13. 'plants' means plants as defined in point (1) of Article 2 of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of the Regulation on protective measures against pests of plants*];
  14. 'plant reproductive material' means plant reproductive material as defined in point (2) of Article 3 of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert 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*];
  15. 'plant protection products' means plant protection products as referred to in Article 2(1) of Regulation (EC) No 1107/2009;
  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;
  17. 'products of animal origin' means products of animal origin as defined in point 8.1 of Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin<sup>46</sup>;
  18. 'germinal products' means germinal products as defined in point (25) of Article 4(1) of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of the Regulation on animal health*];
  19. 'plant products' means plant products as defined in point (2) of Article 2 of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of the Regulation on protective measures against pests of plants*];

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<sup>46</sup> OJ L 139, 30.4.2004, p. 55.

20. 'other objects' means other objects as defined in point (4) of Article 2 of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of the Regulation on protective measures against pests of plants*];
21. 'risk assessment' means risk assessment as defined in point (11) of Article 3 of Regulation (EC) No 178/2002;
22. '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;
23. '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);
24. 'non-compliance' means non-compliance with:
  - (a) this Regulation;
  - (b) rules referred to in Article 1(2);
25. '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);
26. '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;
27. '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;
28. '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 used to perform those activities;
  - (c) places where operators perform their activities;
29. 'border control post' means a place, and the facilities belonging to it, designated by a Member State to perform the official controls provided for in Article 45(1);
30. 'audit' means a systematic and independent examination to determine whether activities and the related results of such activities comply with planned arrangements and whether these arrangements are applied effectively and are suitable to achieve objectives;
31. 'rating' means a classification of operators based on an assessment of their conformity with rating criteria;

32. 'official veterinarian' means a veterinarian appointed by the competent authorities and appropriately qualified to perform the official controls and other official activities in accordance with:
  - (a) this Regulation;
  - (b) the rules referred to in Article 1(2);
33. '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;
34. 'specified risk material' means tissues as defined in point (g) of Article 3(1) of Regulation (EC) No 999/2001;
35. 'long journey' means a journey as defined in point (m) of Article 2 of Regulation (EC) No 1/2005;
36. '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;
37. 'pesticide application equipment' means any apparatus as defined in point (4) of Article 3 of Directive 2009/128/EC;
38. 'delegated body' means a third party, to which the competent authorities have delegated specific official control tasks;
39. 'control authority for organic products' means a public administrative organisation of a Member State to which the competent authorities have conferred, in whole or in part, their competences in relation to the application of Regulation (EC) No 834/2007, including, where appropriate, the corresponding authority of a third country or operating in a third country;
40. '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;
41. '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);
42. 'targeted screening' means a form of official control involving observation of one or more operators or their activities;
43. '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;
44. 'equivalence' or 'equivalent' means:
  - (a) the capability of different systems or measures to meet the same objectives;
  - (b) different systems or measures capable of meeting the same objectives;
45. 'entry into the Union' means the action of bringing animals and goods into one of the territories listed in Annex I;
46. 'documentary check' means the examination of the official certificates, official attestations and other document(s) 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);

47. '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;
48. '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);
49. 'transshipment' means the movement of goods 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;
50. '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;
51. 'supervision by the customs authorities' means action as defined in Article 4(13) of Regulation (EEC) No 2913/92<sup>47</sup>;
52. 'control by the customs authorities' means customs controls as defined in Article 4(14) of Regulation (EEC) No 2913/92;
53. '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 under the control of the competent authorities;
54. 'additional official controls' means those controls which were not originally planned and which were decided on the basis of the findings of previous official controls, or other official activities;
55. '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;
56. '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;
57. 'journey log' means the document set out in points 1 to 5 of Annex II to Council Regulation (EC) No 1/2005.

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<sup>47</sup> OJ L 302, 19.10.1992, p. 1.

## **Title II**

# **Official 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 the competent authority or authorities on which they confer the responsibility to perform official controls and other official activities.
2. Where, for the same area, a Member State confers the responsibility to perform official controls or other official activities on more than one competent authority, at national, regional or local level, or where the competent authorities designated in accordance with paragraph 1 are allowed by that designation to transfer specific responsibilities for official controls or other official activities to other public authorities, the Member State shall:
  - (a) put in place procedures to ensure efficient and effective coordination between all authorities involved, and the consistency and effectiveness of official controls or other official activities across its territory;
  - (b) designate 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.
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. In such cases, they shall attribute a code number to each of them.
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).



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).

#### *Article 4*

##### *General obligations of the competent authorities*

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

3. For the purpose of ensuring that the staff of the competent authorities referred to in point (e) 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 139 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 a competent authority, more than one unit is competent to perform official controls or other official activities, efficient and effective coordination and cooperation shall be ensured between the different units.

#### *Article 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 request.
  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 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, 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 court proceedings and legal advice.
3. 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 together with such comments.

## **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:
- (a) identified risks associated with:
    - (i) animals and goods;
    - (ii) the activities under the control of operators;
    - (iii) the location of the activities or operations of operators;
    - (iv) the use of products, processes, materials or substances that may influence food or 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;
  - (b) operators' past record as regards the results of official controls performed on them and their compliance with the rules referred to in Article 1(2);
  - (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);
  - (d) any information that might indicate non-compliance with the rules referred to in Article 1(2).
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), 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.
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;
  - (b) the operator has requested such official controls.
5. Official controls shall be performed as much as possible in a manner that minimises the burden on the operators.
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.

#### *Article 9*

##### *Persons, processes and activities subject to official controls*

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 and distribution;
- (b) on substances, materials or objects which may influence the characteristics of animals and goods, at all stages of production, processing and distribution;
- (c) on operators and the activities and operations under their control, on their premises and processes, on the storage, transport, and the use of goods and the keeping of animals.

#### *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 and timely publication of information on the following:

- (a) the type, number and outcome of official controls;
- (b) the type and the number of non-compliances detected;

- (c) the cases where measures were taken by the competent authorities in accordance with Article 135;
  - (d) the cases where the penalties referred to in Article 136 were imposed.
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).
  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 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.

#### *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*

##### *Reports on official controls*

1. Competent authorities shall draw up reports on every official control that they perform.

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.

### *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:
  - (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;
    - (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 and other records which may be relevant to the assessment of compliance with the rules referred to in Article 1(2);
  - (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-compliances.

*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 access to:
  - (a) their premises;
  - (b) their computerised information management systems;
  - (c) their animals and goods;
  - (d) their documents and any other relevant information.
2. During official controls and other official activities, operators shall assist the staff of the competent authorities in the accomplishment of their tasks.
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 all information concerning the consignment on paper or electronically.
4. The Commission may, by means of implementing acts, lay down rules:
  - (a) establishing the modalities for access by the competent authorities to the computerised information management systems referred to in paragraph 1(b);
  - (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 on 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;
  - (b) official controls, by or under the responsibility of an official veterinarian, in slaughterhouses, cutting 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.

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 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 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, and the design and application of tests to assess their performance;
  - (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) criteria to determine when, on the basis of a risk analysis, the official veterinarian is not required to be present in slaughterhouses and game handling establishments during the official controls referred to in paragraph 1.

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 food business operators on the application of the procedures referred to in Article 5 of Regulation (EC) 852/2004 of the European Parliament and of the Council<sup>48</sup>;
  - (b) scientific and technological developments;
  - (c) consumer expectations with regard to food composition and changes in patterns of consumption of food;
  - (d) risks to human health and animal health associated with meat and other products of animal origin intended for human consumption.
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

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<sup>48</sup> OJ L 139, 30.4.2004, p. 1.



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 in small businesses;
- (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 delegated acts in accordance with Article 139 concerning rules on official controls 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. Those 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 the rules referred to in 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-authorized substances and to the non-authorized use of authorized 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, germinal products, animal by-products and derived products*

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 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. Those delegated acts 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 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, 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 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 18*

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

1. Official controls to verify compliance with the rules laying down welfare requirements for animals in case of their transport shall include:
  - (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;
    - (ii) official controls to verify that transporters comply with applicable international agreements and have valid transporter authorisations and certificates of competence for drivers and attendants;
    - (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.
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 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 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 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 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, 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 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.

#### *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 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:

- (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 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 XXX/XXXX [*Office of Publications, please insert number of the Regulation on protective measures against pests of plants*] 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 XXX/XXXX [*Office of Publications, please insert number of the Regulation on protective measures against pests of plants*] 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.

#### *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 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 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) 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 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 of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC<sup>49</sup> 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) 1829/2003;
  - (iii) the contained use of genetically modified microorganisms;
- (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 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 concerning rules for the performance of official controls to verify compliance with the rules referred to in Article 1(2)(i).

Those delegated acts 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:

- (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 and uniform minimum frequency of such official controls, concerning the manufacture, placing on the market, entry into the Union, labelling, packaging, transport, storage 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;
- (c) uniform specific requirements for inspections on pesticide application equipment and uniform minimum frequency of such controls;
- (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.

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<sup>49</sup> OJ L 106, 17.4.2001, p. 1.

### Article 23

*Specific rules on official controls and on action to be taken by the competent authorities in relation to organic products and to 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 rules referred to in point (j) of Article 1(2), the delegated acts referred to in paragraph 1 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 to 13, 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;
  - (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 Articles 13 and 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);
  - (e) 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);
  - (f) 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 32 for the delegation of official control tasks;
  - (g) 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;
  - (h) specific criteria and conditions for the activation of the mechanisms of administrative assistance provided for in Title IV.
3. 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:

- (a) 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;
  - (b) 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;
  - (c) 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;
  - (d) specific criteria and conditions for the activation of the mechanisms of administrative assistance provided for in Title IV;
  - (e) 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.
4. 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.

#### *Article 24*

##### *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*

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 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:
- (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 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.

## **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.
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 (e) of Article 23(2) following official controls performed to verify compliance with the rules referred to in point (j) of Article 1(2).
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*

1. 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 them;
  - (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 and free from any conflict of interest as regards the exercise of the specific official control tasks delegated to it;
    - (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;



- (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(1) 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 audits or inspections of such bodies or persons as necessary;
- (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).

#### *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(1) 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(1) 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;
- (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, official laboratories shall use state-of-the-art methods for their specific analytical, testing and diagnostic needs, taking into account:
  - (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; or,
  - (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; or,
  - (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; or,
  - (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. 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.
4. Where laboratory analyses, tests or diagnoses are urgently needed 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.
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.
7. The Commission may, by means of implementing acts, 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.

Such right:

- (a) shall always entitle the operator to request a documentary review of the sampling, analysis, test or diagnosis by another expert;
  - (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:
    - (i) that a sufficient number of other samples be taken for a second expert opinion; or,
    - (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.
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 shall take all steps to ensure that the operators from whom the samples are ordered in accordance with paragraph 1:
  - (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 compliance with 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 impartial and free from any conflict of interest as regards the exercise of its tasks as official laboratory;
  - (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.
5. The scope of the assessment and accreditation of an official laboratory referred to in point (e) of paragraph 4:
  - (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*

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 laying down specific rules on official controls for *Trichinella* in meat<sup>50</sup>;
    - (iii) that carry out the detection of *Trichinella* under the supervision of the competent authorities or of an official laboratory designated in accordance with Article 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;
  - (b) laboratories carrying out analyses or tests to verify compliance with the rules on plant reproductive material referred to in point (h) of Article 1(2);
  - (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*

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:

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<sup>50</sup> OJ L 338, 22.12.2005, p. 60.

- (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*

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; or,
  - (b) when changes to a method in use require a new accreditation or an extension of the scope of the accreditation obtained by the official laboratory; or,
  - (c) in cases where the need for the use of the method results from an emergency situation or an emerging risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment.
2. The temporary designation referred to in paragraph 1 shall be subject to the following conditions:
  - (a) the official laboratory is already accredited in accordance with the standard EN ISO/IEC 17025 for the use of a method which is similar to the one not included within the scope of its accreditation;
  - (b) a quality assurance system is in place in the official laboratory to ensure sound and reliable results 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.



# 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;
  - (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;
    - (ii) of the exporter;
    - (iii) of the operator responsible for the consignment;
  - (c) the controls that have already been performed on the animals and goods concerned;
  - (d) the guarantees that the competent authorities of the third country of origin has given with regard to compliance of the animals and goods with the requirements established by the rules referred to in Article 1(2) or with requirements recognised to be at least equivalent thereto.
2. 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.
3. The competent authorities at border control posts and other points of entry into the Union shall perform official controls on the following whenever they have reason to believe that their entry into the Union may pose a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment:
  - (a) means of transport, including where empty;

- (b) packaging.
- 4. 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 Council Regulation (EEC) No 2913/92.

*Article 43*

*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), Articles 64(1), (3), (4) and (5), 65, 66, 67, 69(1) and (2) and 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.

*Article 44*

*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, germinal products and animal by-products;
  - (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 XXX/XXXX [*Office of Publications, please insert number of the Regulation on protective measures against pests of plants*];
  - (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 XXX/XXXX [*Office of Publications, please insert number of the Regulation on animal health*], or Articles 27(1), 29(1), 40(2), 41(2), 47(1), 49(2) and 50(2) of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of the Regulation on protective measures against pests of plants*] 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;

- (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 the provisions of 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;
- (b) animals and goods intended for scientific purposes;
- (c) goods on board means of transport operating internationally which are not unloaded and are intended for consumption by the crew and passengers;
- (d) goods which form part of passengers personal luggage and are intended for personal consumption;
- (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 [*Office of Publications, please insert number of the Regulation on animal health*];
- (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 they shall be carried out by an official veterinarian or under his supervision.

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. 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);
  - (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 distance selling.
- 2. Point (b) of Article 54(2), point (a) of Article 55(2) and Articles 57, 58, 60, 61, 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 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 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 frequency of physical checks for the categories of goods referred to in point (d) of Article 45(1);
  - (b) the 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 shall be taken by an official veterinarian or under his supervision.

*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 the TRACES system.
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 as soon as:
  - (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.

#### *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 must accompany consignments of the categories of animals and goods referred to in Article 45(1) to the place of destination.

*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*

1. The approval of border inspection posts in accordance with Article 6 of Council Directive 97/78/EC and Article 6 of Council Directive 91/496/EEC and the designation of points of entry in accordance with Article 5 of Regulation (EC) No 669/2009 and with Article 13(c)(4) of Council Directive 2000/29/EC shall be withdrawn.
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 the provisions of 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, to the environment.
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 suitably equipped to be designated by the customs authorities in accordance with Article 38(1) of Regulation (EEC) No 2913/92.
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 in order to confirm or to eliminate that suspicion.
2. Consignments of animals and goods which are not declared by operators to consist of the categories of animals and goods referred to in Article 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.
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) and refuse entry into the Union to it.

As appropriate, any such consignment shall be isolated or quarantined and animals belonging to it shall be kept and treated under appropriate conditions pending any further decision.

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, without delay, order that the operator:

- (a) destroy the consignment in compliance, where appropriate, with the rules referred to in Article 1(2); or
- (b) re-dispatch the consignment outside the Union in accordance with Article 70(1) and (2); or
- (c) subject the consignment 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.

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 computerised 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), 54(1), (2) and

(3), or with the rules adopted pursuant to Articles 46, 47(6), 49, 51(1) and 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 from third countries presenting a risk*

Where official controls indicate that a consignment of animals or goods presents a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, 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 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, 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, within

60 days from the day on which the competent authorities notified the operator of their decision in accordance with Article 64(4).

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).

#### *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 in addition to seeking administrative assistance in accordance with the procedures established in Title IV;
  - (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.
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 Articles 4(17) and 59 to 83 of Regulation (EC) 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 XXX/XXXX [*Office of Publications, please insert number of this Regulation*];
  - (b) no other customs procedure shall be permitted without the consent of the competent authorities;
  - (c) Articles 64(1), (3), (4) and (5), 65, 66, 67, 69(1) and (2) and 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.

#### *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 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, amending Regulations (EEC) 2847/93, (EC) No 1936/2001 and (EC) No

601/2004 and repealing Regulations (EC) No 1093/94 and (EC) No 1447/1999<sup>51</sup> from a fishing vessel flying a third country flag;

- (b) consignments of unskinned, furred wild game;
  - (c) consignments of the categories of goods referred to in point (b) of Article 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;
  - (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).

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<sup>51</sup> OJ L 286, 29.10.2008, p. 1.

## **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.
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 provided for in Article 77.

#### *Article 77* *Mandatory fees*

1. For the purpose of ensuring that competent authorities are provided with adequate resources for the performance of official controls, the competent authorities shall collect fees to recover 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 laying down requirements for feed hygiene<sup>52</sup>;
    - (iii) professional operators as defined in point (7) of Article 2 of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of the Regulation on protective measures against pests of plants*];
    - (iv) professional operators as defined in point (6) of Article 3 of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert 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:

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<sup>52</sup> OJ L 35, 8.2.2005, p. 1.

- (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 XXX/XXXX [*Office of Publications, please insert number of the Regulation on protective measures against pests of plants*];
  - (iii) to obtain and maintain the authorisation referred to in Article 25 of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of the Regulation on the production and making available on the market of plant reproductive material*];
  - (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 XXX/XXXX [*Office of Publications, please insert number of the Regulation on protective measures against pests of plants*], Articles 41 and 144 of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of the Regulation on the production and making available on the market of plant reproductive material*] and Part VI of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of the Regulation on animal health*], 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 Articles 55(1), 56, 61, 62, 64, 65, 68(1) and 69, and rules adopted pursuant to Articles 55(2), 63, 67 and 68(2) of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of the Regulation on animal health*] and Article 16 of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of the Regulation on protective measures against pests of plants*];
  - (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 in accordance with Article 77 to recover the following costs:
- (a) the salaries of the staff, including support staff, involved in the performance of official controls, their social security, pension and insurance costs;

- (b) the cost of facilities and equipment, including maintenance and insurance costs;
  - (c) the cost of consumables, services and tools;
  - (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 referred to in point (a), and associated subsistence costs;
  - (f) the cost of sampling and of laboratory analysis, testing and diagnosis.
2. If the competent authorities collecting fees 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 fees.

*Article 79*  
*Calculation of fees*

1. Fees 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 operators, the competent authorities shall take into consideration the impact that the type and the size of the activity concerned and the relevant risk factors have on the distribution of the overall costs of those official controls; or,
  - (b) 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 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 fees are calculated in accordance with point (a) of paragraph 1, the fees 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.

*Article 80*  
*Reduction of fees for consistently compliant operators*

Where fees 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 applied to consistently compliant operators are lower than those applied to other operators.

*Article 81*  
*Application of fees*

1. Operators shall receive proof of the payment of fees provided for in Article 77(1).
2. Fees collected in accordance with point (d) of Article 77(1) shall be paid by the operator responsible for the consignment or its representative.

*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.

*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 provided for in Article 77(1);
  - (b) the use of resources collected through such fees;
  - (c) the arrangements in place to ensure an efficient and thrifty use of the resources collected through such fees.
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 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 provided for in Article 77(1), including the data and estimates used for the establishment of the flat rate fees 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 in accordance with Article 80;
  - (e) the overall amount of fees corresponding to the exemption referred to in Article 82(2).

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

Competent authorities shall charge fees to cover the additional costs they have incurred as a result of:

- (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 Articles 64(3) and (5), 65 and 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.
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 the provisions of 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, the provisions of Articles 87, 88 and 89 shall apply.
2. Articles 87, 88 and 89 shall also apply to official certificates which are necessary for the purposes of exporting consignments of animals and goods to third countries.

*Article 87*  
*Signature and issuance of official certificates*

1. Official certificates shall be issued by the competent authorities.
2. Competent authorities shall designate the certifying officers who are authorised to sign official certificates. Certifying officers shall:
  - (a) be free from conflict of interest in relation to what is being certified and act impartially;
  - (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;
  - (e) allow the verification of the link between the certificate and the consignment, lot or individual animal or good covered by the certificate.
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;
  - (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 impartial and free from any conflict of interest in relation to what is being certified by the official attestations;
  - (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:
  - (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.
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 impartial and free of conflict of interests as regards the exercise of its tasks as European Union reference laboratories;
  - (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.

#### *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;
  - (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;
  - (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 for the benefit of staff from national reference laboratories and, if needed, from other official laboratories, as well as of experts from third countries;
  - (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;
  - (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:
    - (i) reference collections of pests of plants or reference strains of pathogenic agents;
    - (ii) reference collections of materials intended to come into contact with food used to calibrate analytical equipment and provide samples thereof to national reference laboratories;
    - (iii) up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents.
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 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 (EPVA) in relation to the application of the rules referred to in point (h) of Article 1(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.

### *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.



### *Article 95*

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

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 in relation to the application of the rules referred to in point (f) of Article 1(2).
2. The designations provided for in paragraph 1 shall:
  - (a) follow a public selection process;
  - (b) be reviewed regularly.
3. European Union reference centres for animal welfare shall:
  - (a) possess 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;
  - (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;
  - (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);
- (c) developing or coordinating the development of methods for the assessment of the level of welfare of animals and of methods for the improvement of the welfare of animals;
- (d) carrying out scientific and technical studies on the welfare of animals used for commercial or scientific purposes;
- (e) conducting training courses for 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 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;
  - (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 Articles 91(3), 92, 93(3), 95(3) and 96.
3. European Union reference laboratories and European Union reference centres shall be subject to Commission controls to verify compliance with the requirements of Articles 91(3), 92, 93(3), 95(3) and 96.
4. If the Commission controls referred to in paragraph 3 show non-compliance with the requirements laid down in Articles 91(3), 92, 93(3), 95(3) and 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), Articles 36(5), 38 and 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 impartial and free of conflict of interests as regards the exercise of its tasks as national reference laboratories;

- (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; and,
  - (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.

#### *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.
- 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.

## **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.
- 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).

#### *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 the list of liaison bodies communicated to it by the Member States in accordance with paragraph 4 on its website.
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 specifications 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).

*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 ten days from the date of receipt of the request, the time necessary to provide an informed response to the request;
  - (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 ten days from the date of receipt of the notification:
    - (i) what investigations they intend to carry out; or,
    - (ii) the reasons why they consider that no investigations are necessary;
  - (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.
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.
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 authority 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, 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.
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, animal or plant health, animal welfare or, in the case of GMOs and plant protection products, to the environment;
  - (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) delegated acts adopted by the Commission in accordance with Article 110;
  - (f) scientific findings;
  - (g) 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 plans 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.

### *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 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);
- (b) the organisation, on an ad hoc basis, of the collection of data and information in relation to the application of a specific set of the rules referred to in Article 1(2) or regarding the prevalence of certain hazards.

### *Article 112*

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

1. By 30<sup>th</sup> 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;
  - (d) measures taken to ensure the effective operation of its multi-annual national control plan, including enforcement action and the results of such measures.
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 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;
  - (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, include recommendations on possible improvements to official control systems in Member States and specific official controls in certain areas.

#### *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.

#### *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;
  - (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 Commission controls 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;
- (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 the requirements referred to in paragraph 1.
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 Article 125(2)(a)*

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 125(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;
  - (c) the performance by the competent authorities of the third country of adequate official controls and other activities to assess the presence of hazards for human, animal or plant health, for animal welfare or 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 XXX/XXXX [*Office of Publications, please insert number of the Regulation on animal health*] and in Articles 27(1), 29(1), 40(2), 41(2), 47(1), 49(2) and 50(2) of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of the Regulation on*

*protective measures against pests of plants*], 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, 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 acts, the measures necessary to contain such risk or put an end to the identified non-compliance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

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;
  - (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).

### **Chapter III**

#### **Training of staff of the competent authorities**

##### *Article 129*

##### *Training and exchange of staff of the competent authorities*

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

The Commission may organise those activities in cooperation with Member States.

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 managed and handled ('the IMSOC').
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) XXX/XXXX [*Office of Publications, please insert number of the Regulation on animal health*] and Article 97 of Regulation (EU) XXX/XXXX [*Office of Publications, please insert number of the Regulation on protective measures against pests of plants*];
  - (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.

*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 the provisions of 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.

*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.
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;
  - (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.

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;
  - (b) order the unloading, transfer to another means of transport, holding and care of animals, quarantine periods, the postponement of the slaughter of animals;
  - (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;
  - (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;
  - (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 the provisions 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 provisions 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.
2. Member States shall ensure that financial penalties applicable to intentional violations of the provisions of this Regulation and of the rules referred to in Article 1(2) at least offset the economic advantage sought through the violation.
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;
- (c) fraudulent production or use of official certificates, official labels, official marks and other official attestations.

## **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 the references to the European standards referred to in point (b)(iv) of Article 26(1), point (e) of Article 36(4) and point (a) of Article 91(3) up-to-date, 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 Articles 4(3), 15(2), 16, 17, 18(3), 19, 20, 21, 22, 23(1), 24(1), 25(3), 26(2), 40, 43(4), 45(3), 46, 49, 51(1), 52(1) and (2), 56(2), 60(3), 62(2), 69(3), 75(1) and (2), 97(2), 98(6), 99(2), 101(3), 106(3), 110, 111, 114(4) and 125(1), the third subparagraph of Article 132(1), Articles 133, 138(1) and (2), 143(2), 144(3), 151(3), 153(3) and 159(3) shall be conferred for an indeterminate period of time from the date of entry into force of this Regulation.
3. The delegation of powers referred to in Articles 4(3), 15(2), 16, 17, 18(3), 19, 20, 21, 22, 23(1), 24(1), 25(3), 26(2), 40, 43(4), 45(3), 46, 49, 51(1), 52(1) and (2), 56(2), 60(3), 62(2), 69(3), 75(1) and (2), 97(2), 98(6), 99(2), 101(3), 106(3), 110, 111, 114(4) and 125(1), the third subparagraph of Article 132(1), Articles 133, 138(1) and (2), 143(2), 144(3), 151(3), 153(3) and 159(3) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Articles 4(3), 15(2), 16, 17, 18(3), 19, 20, 21, 22, 23(1), 24(1), 25(3), 26(2), 40, 43(4), 45(3), 46, 49, 51(1), 52(1) and (2), 56(2), 60(3), 62(2), 69(3), 75(1) and (2), 97(2), 98(6), 99(2), 101(3), 106(3), 110, 111, 114(4) and 125(1), the third subparagraph of Article 132(1), Articles 133, 138(1) and (2), 143(2), 144(3), 151(3), 153(3) and 159(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.

*Article 140*  
*Urgency procedure*

1. 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.
2. 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.

*Article 141*  
*Committee*

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002. That Committee is a Committee in the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the 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 [*Office of Publications, please insert date of entry into force of this Regulation + 1 year*].

However, Articles 14 to 17 and 26 to 29 of Regulation (EC) No 882/2004 shall continue to apply until [*Office of Publications, please insert date of entry into force of this Regulation + 3 years*].

2. Regulation (EC) No 854/2004 and Directives 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC and 97/78/EC are repealed as from [*Office of Publications, please insert date of entry into force of this Regulation + 3 years*].
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 Articles 45(2), 46, points (b), (c) and (d) of Article 49, 51(1)(a), 52(1) and (2), 56(1)(a) 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 to 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 Articles 45(2), 46, points (b), (c) and (d) of Article 49, 51(1)(a), 52(1) and (2), 56(1)(a) of this Regulation.

#### *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 Annex II, III and IV to this 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 to Article 139 concerning the date on which the competent authorities shall cease to perform official controls in accordance with the provisions referred to in 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 Article 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 XXX/XXXX [*Office of Publications, please insert number of this Regulation*] 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-compliances 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) 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-compliances 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.';
  - (iii) point (a) of paragraph 3 is deleted;
- (b) Article 9 is deleted.

*Article 147*  
*Amendments to Council 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 [*Office of Publications, please insert 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.

*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 laboratory and the national reference laboratories designated in accordance with Articles 91(1) and 98(1) of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of this Regulation*] for that area.'
- (c) Annex II is deleted.

*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 XXX/XXXX [*Office of Publications, please insert number of this Regulation*]\* shall also apply.'

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\* OJ L ..., ..., p. ...';

- (b) Articles 14, 15, 16, 21, 22(2), 23, 24 and 26 are deleted;



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

#### *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;
  - (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 XXX/XXXX [*Office of Publications, please insert number of this Regulation*]\* shall also apply.

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\* OJ L ..., ..., p. ...';

(b) Article 7 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-compliances 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 XXX/XXXX [*Office of Publications, please insert number of this Regulation*]\*.

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\* 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 XXX/XXXX [*Office of Publications, please insert number of this Regulation*]';

(b) in point (a) of Article 24(1), 'Article 27(10)' is replaced by 'Articles 3(3) and 25(4) of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of this Regulation*]';

(c) Article 27 is amended as follows:

(i) paragraph 1 is replaced by the following:

'Official controls to verify compliance with this Regulation shall be performed in accordance with Regulation (EC) No 882/2004';

(ii) paragraphs 2 to 14 are deleted;

(d) in Article 29(1), 'Article 27(4)' is replaced by 'Articles 3(3) and 25(4) of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of this Regulation*]';

(e) in Article 30, paragraph 2 is deleted.

2. Articles 27 and 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.

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 XXX/XXXX [*Office of Publications, please insert number of this Regulation*]\* shall also apply.

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\* 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-compliances 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 XXX/XXXX [*Office of Publications, please insert number of this Regulation*]\* shall also apply.

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\* 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-compliances 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 XXX/XXXX [*Office of Publications, please insert number of this Regulation*]\* shall also apply.
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- \* 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 XXX/XXXX [*Office of Publications, please insert number of this Regulation*]\* 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 to be adopted in accordance with paragraph 3.
3. The Commission shall be empowered to adopt delegated acts in accordance to 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 22 of this Regulation.

*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 XXX/XXXX [*Office of Publications, please insert number of this Regulation*]\* shall cover:

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\* 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 XXX/XXXX [*Office of Publications, please insert number of this Regulation*]; or,
    - (b) delegated bodies within the meaning of point 38 of Article 2 of Regulation (EU) No XXX/XXXX [*Office of Publications, please insert number of this Regulation*].';
  - (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 [*Office of Publications, please insert 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*] 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 XXX/XXXX [*Office of Publications, please insert number of this Regulation*]\*;
      - (b) the European Union reference centres for plant reproductive material referred to in Article 93 of that Regulation;
      - (c) the European Union reference centres for animal welfare referred to in Article 95 of that Regulation.

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\* 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 XXX/XXXX [*Office of Publications, please insert number of this Regulation*] 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.
2. Grants may be awarded to a single national reference laboratory in each Member State for each European Union reference laboratory for plant health, up to three years after the designation of that European Union reference laboratory.'

*Article 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 [*Office of Publications, please insert date of entry into force of this Regulation + 1 year*].
2. In the area covered by the rules referred to in point (g) of Article 1(2), this Regulation, shall apply from [*Office of Publications, please insert date of application of the Regulation on protective measures against pests of plants*], with the following exceptions:
  - (a) Articles 91 and 92 and 97, 98 and 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 [*Office of Publications, please insert date of entry into force of this Regulation + 5 years*].
3. In the area covered by the rules referred to in point (h) of Article 1(2), this Regulation, shall apply from [*Office of Publications, please insert 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 [*Office of Publications, please insert date of entry into force of this Regulation + 5 years*].
4. Articles 15(1), 18(1), 45 to 62 and 76 to 84, point (b) of Article 150, point (b)(i) of Article 152, point (b)(i) of Article 154, point (b)(i) of Article 155 and point (b) of Article 156 shall apply from [*Office of Publications, please insert date of entry into force this Regulation + 3 years*].
5. Article 161 shall apply from [*Office of Publications, please insert date of entry into force of this Regulation*].

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

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*



**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 XXX/XXXX [*Office of Publications, please insert number of the Regulation on protective measures against pests of plants*], and references to the Union territory shall be read as references to the Union territory without the territories listed in that Annex.

**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
6. The different stages of production, processing and distribution, and the possible risks to human health, and where appropriate to the health of animals and plants, to the welfare of animals, to the environment, and to the identity and quality of plant reproductive material.
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 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 1(e) shall either be obtained from a collaborative trial which has been conducted in accordance with an internationally recognised protocol on collaborative trials (e.g. ISO 5725 'Accuracy (trueness and precision) of measurement methods and results') or, where performance criteria for analytical methods have been established, be based on criteria compliance tests. The repeatability and reproducibility values shall be expressed in an internationally recognised form (e.g. the 95 % confidence intervals as defined by ISO 5725 'Accuracy (trueness and precision) of measurement methods and results'). The results from the collaborative trial shall be published or freely available.
3. Methods of analysis which are applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities.
4. In situations where methods of analysis can only be validated within a single laboratory, 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)**

1. Regulation (EC) No 882/2004

Regulation (EC) No 882/2004	This Regulation
Article 1(1) first subparagraph	Article 1(1)
Article 1(1) second subparagraph	Article 1(2)
Article 1(2)	Article 1(4)
Article 1(3)	-
Article 1(4)	-
Article 2	Article 2
Article 3(1)	Article 8(1)
Article 3(2)	Article 8(4)
Article 3(3)	Article 9
Article 3(4)	Article 8(6)
Article 3(5)	Article 8(6)
Article 3(6)	Article 8(7)
Article 3(7)	-
Article 4(1)	Article 3(1)
Article 4(2)	Article 4(1)(a), (c), (d), (e), (f), (g) and (i)
Article 4(3)	Article 3(2)
Article 4(4)	Article 4(1)(b)
Article 4(5)	Article 4(4)
Article 4(6)	Article 5(1)
Article 4(7)	Article 5(3)
Article 5(1) first subparagraph	Article 25(1)
Article 5(1) second subparagraph	Article 25(3)
Article 5(1) third subparagraph	Article 25(2) first subparagraph
Article 5(2)(a), (b), (c) and (f)	Article 26(1)
Article 5(2)(d)	-
Article 5(2)(e)	Article 28
Article 5(3)	Article 29
Article 5(4)	-
Article 6	Article 4(2) and (3)
Article 7(1), first subparagraph	Article 10(1), first subparagraph
Article 7(1), second subparagraph, point (a)	Article 10(1), second subparagraph
Article 7(1), second subparagraph, point (b)	-
Article 7(2), first sentence	Article 7(1)
Article 7(2), second sentence	-

Article 7(2), third sentence	-
Article 7(3)	Article 7(2), and (3)
Article 8(1)	Article 11(1)
Article 8(2)	Article 4(1)(h)
Article 8(3)(a)	Article 11(2)
Article 8(3)(b)	Article 11(3)
Article 8(4)	-
Article 9(1)	Article 12(1) first subparagraph
Article 9(2)	Article 12(1) second subparagraph
Article 9(3)	Article 11(2)
Article 10	Article 13
Article 11(1)	Article 33(1) and (2)
Article 11(2)	-
Article 11(3)	Article 33(5)
Article 11(4)	Article 33(7)
Article 11(5)	Article 34(1) first subparagraph and (2)
Article 11(6)	Article 34(1)(b)(i)
Article 11(7)	Article 33(6)
Article 12(1)	Article 36(1)
Article 12(2)	Article 36(4)(e)
Article 12(3)	Article 36(5)(c)
Article 12(4)	Article 38(2)
Article 13	Article 114
Article 14(1)	-
Article 14(2)	Article 43(3)
Article 14(3)	-
Article 15(1)	Article 42(1) first sentence
Article 15(2)	Article 42(2) and (4)
Article 15(3)	Article 42(2) and (4)
Article 15(4)	-
Article 15(5)	Article 45(1)(d), 45(2)(b) and 52(3), first sentence
Article 16(1)	Article 43(1)
Article 16(2)	Article 42(1) second sentence
Article 16(3) first sentence	Article 43(2)
Article 16(3) second sentence	Article 33(6)
Article 17(1) first indent	Article 57(1)
Article 17(1) second indent	Article 54(1),(2)(a), (3) and Article 56(1)

Article 17(2)	-
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