

## Draft paper on a proposal on official controls

### 1.1. Grounds for and objectives 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 'agro-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 for animal health and for plant health in general, and rules on the quality of seeds. 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, seed's quality). It also includes rules established to ensure the provision of information to consumers and to guarantee fair commercial practices in 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.

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 *aquis*. Its aim is therefore to modernise and integrate the system of official controls in a manner that also 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 medicines 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 medicines) 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 carried out 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 import controls system could be made more consistent by reviewing and consolidating the existing sectoral acts with regard to official controls. The report indicates that this improvement 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 carried out 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 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 carry out official controls is not being met throughout the EU with a subsequent impact on delivery of controls. It also pointed at 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 IA.

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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.

## **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 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 which 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 'agro-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 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 food chain legislation lies with the MS, whose authorities monitor and verify that the relevant requirements are effectively implemented, 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 controls for animal health purposes (both on domestic and imported goods) and controls on residues of veterinary medicines, 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 law, 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 medicines, 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.

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

The scope of the Regulation will be expanded to cover controls carried out 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 carried out 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. An empowerment will

allow the Commission to adopt delegated acts to lay down sector specific rules for such goods in order to take account of risk to public 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 AND TESTING.**

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 always, a documentary review of the sampling, analysis or testing 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 or test of 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, analysis and testing 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 cascade of methods will be clarified and extended so as to require that methods complying with internationally recognised rules or protocols shall meet state of the art scientific standards, 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 or testing 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 or testing 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 or testing 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 analysis or testing 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 or testing 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 or testing, and for certain laboratories only carrying out analysis or testing 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 carried out 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 carried out 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 carried out 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 carried out 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 BCP's, clarifying the steps that the competent authorities of such BCP's 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 carried out 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 carried out 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 carried out 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 carried out 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 carries out 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 (this would not apply to flat rate fees for controls at borders).

Existing provisions that prohibit the refund – direct or indirect - of mandatory fees will be retained (unless of course the fees were unduly collected). However, a new provision will provide Member States with the possibility to refund fully or partly (or to exempt from) fees collected from enterprises employing fewer than 10 persons and whose annual turnover and / or balance sheet does not exceed EUR 2 million (micro-businesses), on condition that such refunds are in compliance with Union legislation on State Aid.

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 and from 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 implementation 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 unambiguously defined.

Finally, the cases in which the Commission is required to coordinate administrative cooperation/assistance, 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 assist them in ensuring their own delivery of the 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 general and special conditions for the entry of certain categories of goods into the Union;
- 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 control, which will allow the integrate operation and ad update of all existing and future computerised system 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. The new provisions are largely due to the repeal of Directive 96/23/EC<sup>4</sup>.

A new provision dealing specifically with actions to be taken in case of suspicion of non-compliance will be inserted in the Regulation. This will require that the competent authority shall carry out an investigation in order to confirm or to eliminate the suspicion or doubt.

With regard to action in case of established non-compliance, the competent authorities shall be requested to carry out any further necessary investigation to determine the origin and the extent of the non-compliance and to establish operators' responsibilities, and take measures to ensure that those concerned remedy the situation and avoid further non-compliance .

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 potential 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.

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<sup>4</sup> Council Directive 96/23/EC 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.

...

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

**on official controls and other official activities performed to ensure the application of feed and food law, rules on animal health and welfare, plant health and plant reproductive material, plant protection products and pesticides, and amending Regulations ... ((Official controls Regulation))**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,  
HAVE ADOPTED THIS REGULATION:

# Title I

## Subject matter, scope and definitions

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

1. This Regulation lays down rules for:
  - (a) the performance of official controls and other official activities carried out 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 implementation of the rules referred to in paragraph 2;
  - (d) the performance of official controls by the Commission in Member States and third countries;
  - (e) the adoption of requirements 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 carried out for the verification of compliance with the following rules:
  - (a) governing food and food safety, at any stage of production, processing and distribution of food, including rules aimed at guaranteeing fair practices in trade and protecting consumer interests and information; the manufacture and use of materials and articles intended to come into contact with food;
  - (b) governing the deliberate release into the environment of genetically modified organisms;
  - (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 the requirements for placing on the market and the use of plant protection products and the sustainable use of pesticides;

whether established at Union level or by the Member States to implement Union legislation in those areas.

3. This Regulation shall also apply to official controls carried out for the verification of compliance of the requirements applicable to animals and goods:
  - (a) 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 the rules laid down in 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>5</sup>.
5. Articles 3, 4, 5, 7, 23, 24, 25, 26, 28(2) and (3), 31, 32, 35, 36, 37, 38, 39, 40, 75, Titles III and IV, Article 126, and 133 of this Regulation shall also apply to other official activities performed by the competent authorities according to this Regulation or to the rules referred to in paragraph 2.

## *Article 2* *Definitions*

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

1. 'official control' means any form of control that the Commission or 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 are assigned to competent authorities by:
  - (a) this Regulation;
  - (b) the rules referred to in Article 1(2) to ensure the correct application of these rules;

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<sup>5</sup> OJ L 299, 16.11.2007, p. 1.

3. 'competent authorities' means:
  - (a) the central authorities of a Member State responsible for the organisation of official controls and of other official activities, in accordance with this Regulation and the rules referred to in Article 1(2);
  - (b) any other authority to which that responsibility has been conferred;
  - (c) where appropriate, the corresponding authorities of a third country;
4. 'animals' means animals as defined in point (1) of Article 4 of Regulation (EU) No XXX/XXXX [on animal health law];
5. 'goods' means any good subject to one or more rules referred to in Article 1(2). This term does not include animals;
6. 'food' means food as defined in Article 2 of Regulation (EC) No 178/2002;
7. 'feed' means feed as defined in point (1) of Article 3 of Regulation (EC) No 178/2002;
8. 'animal by-products' means animal by-products as defined in point (1) of Article 3 of Regulation (EC) No 1069/2009;
9. 'derived products' means derived products as defined in point (2) of Article 3 of Regulation (EC) No 1069/2009;
10. 'pests' means harmful organisms as defined in Article 1(1) of Regulation (EU) No XXX/XXXX [on protective measures against pests of plants];
11. 'plant reproductive material' means plant reproductive material as defined in Article 3(2) of Regulation (EU) No XXX/XXXX of the European Parliament and of the Council of [date] on the marketing and production, with a view to marketing, of plant reproductive material, and repealing Council Directives 66/401/EC, 66/402/EEC, 68/193/EC, 1998/56/EC, 1999/105/EC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC;
12. 'plant protection products' means plant protection products as defined in Article 2(1) of Regulation (EC) No 1107/2009 [concerning the placing of plant protection products on the market];
13. 'pesticides' means pesticides as defined in point 10(a) of Article 3 of Directive 2009/128/EC [establishing a framework for Community action to achieve the sustainable use of pesticides];
14. 'food law' means food law as defined in point (4) of Article 3 of Regulation (EC) No 178/2002;
15. 'risk assessment' means risk assessment as defined in point (11) of Article 3 of Regulation (EC) No 178/2002;

16. 'feed law' means feed law as defined in point (g) of Article 3 of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 October 2003 laying down requirements for feed hygiene<sup>6</sup>;
17. 'products of animal origin' means products of animal origin as defined in point 8.3 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>7</sup>;
18. 'germinal products' means germinal products as defined in point (25) of Article 4 of Regulation (EU) No XXX/XXXX [on animal health law];
19. 'plants' means plants as defined in point (a) of Article 2 of Regulation (EU) No XXX/XXXX [on protective measures against pests of plants];
20. 'plant products' means plant products as defined in point (b) of Article 2 of Regulation (EU) No XXX/XXXX [on protective measures against pests of plants];
21. 'other objects' means other objects as defined in point (d) of Article 2 of Regulation (EU) No XXX/XXXX [on protective measures against pests of plants];
22. 'certifying officer' means:
  - (a) any official of the competent authorities authorised to sign official certificates by such authorities;
  - (b) in the cases 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 written 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 official control 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 Article 1(2), except for those entities in charge with official controls and other official activities;

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<sup>6</sup> OJ L 35, 8.2.2005, p. 1.

<sup>7</sup> OJ L 139, 30.4.2004, p. 55.

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) any aspect of animals and goods ;
  - (b) activities under the control of operators;
  - (c) location of the activities or operations;
  - (d) substances or materials which may influence feed or food safety, animal health or welfare, plant health or plant reproductive material identity and quality;
29. 'border control post' means any inspection post designated to carry out the official controls provided for in Article 44(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 implemented effectively and are suitable to achieve objectives;
31. 'official veterinarian' means a veterinarian appointed by the competent authorities and appropriately qualified to perform the official controls and other official activities attributed to the competent authorities by:
- (a) this Regulation;
  - (b) the rules referred to in Article 1(2);
32. 'hazard' means any agent or condition with the potential to cause adverse effect on human, animal or plant health or animal welfare;
33. '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;
34. 'delegated body' means a third party to which the competent authorities have delegated certain tasks;
35. 'control verification procedures' means the arrangements put in place and activities carried out by the competent authorities for the purpose of ensuring that official controls and other official activities are consistent and effective;
36. 'screening' means a form of official control carried out by conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with the rules referred to in Article 1(2);
37. 'targeted screening' means a form of official control involving observation of one or more operators or their activities;

38. 'control system' means a system comprising the competent authorities and the resources, structures, arrangements and procedures set up by a Member State to carry out official controls;
39. '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;
40. 'entry into the Union' means the act through which animals and goods are brought into one of the territories listed in Annex I;
41. 'documentary check' means the examination of the official certificates, official attestations and other document(s) including documents of a commercial nature, which shall accompany the consignment as provided for by the rules referred to in Article 1(2), Article 53(1), or by delegated acts adopted in accordance with Articles 74 or 121(2)(c), or by implementing acts adopted pursuant to Article 117(2)(b);
42. 'identity check' means a visual inspection to verify that the content and the labelling of a consignment, including the marks on animals, seals and means of transport, correspond with the information provided in the official certificates, official attestations and other documents accompanying it;
43. 'physical check' means a check on animals or goods and, as appropriate, checks on packaging, the means of transport, labelling and temperature, the sampling for analysis and laboratory testing and any other check necessary to verify compliance with the rules referred to in Article 1(2);
44. 'transshipment' means the movement of goods subject to the official controls provided for in Article 44(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;
45. 'transit' means movement from one third country to another third country passing under customs supervision through the territory of the Union or from one Member State to another Member State passing through the territory of a third country;
46. '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;
47. '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.
48. '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.

49. 'control plan' means a description established by the competent authorities containing information on the structure and organisation of its official control systems, and of their operation over a period of time;
50. 'journey log' means the document set out in Annex II to Council Regulation (EC) No 1/2005.

## **Title II**

# **Official controls and other official activities in Member States**

### **Chapter I**

## **Competent authorities**

#### *Article 3*

#### *Designation of competent authorities*

1. Member States shall designate the competent authorities responsible for the official controls and the other official activities.
2. When a Member State confers the competence to carry out official controls or other official activities on regional or local authorities or allows the competent authorities in charge with official controls or other official activities to attribute specific tasks to other public authorities, it shall 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.
3. For each of the areas governed by the rules referred to in Article 1(2), Member States shall designate a single authority responsible for the effective cooperation and contacts with the Commission and other Member States in relation to the official controls and other official activities carried out in such areas.
4. Member States shall inform the Commission and other Member States of the contact details of the authorities referred to in paragraph 3, and of any changes to those details.
5. This Article shall not prevent Member States from conferring to the competent authorities referred to in paragraph 1 the responsibility to carry out official controls for the verification of compliance with, or for the application of, rules other than those referred to in Article 1(2).

#### *Article 4*

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

1. The competent authorities shall:
  - (a) ensure the effectiveness and appropriateness of official controls and other official activities;
  - (b) ensure that staff carrying out official controls and other official activities are free from any conflict of interest;

- (c) have, or have access to, an adequate laboratory capacity for testing, analysis and diagnosis;
  - (d) have, or have access to, a sufficient number of suitably qualified and experienced staff so that official controls and other official activities can be carried out efficiently and effectively;
  - (e) have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls and other official activities efficiently and effectively;
  - (f) have the legal powers to carry out 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);
  - (g) have legal procedures in place in order to ensure that their staff have access to premises of and documents kept by operators so as to be able to accomplish their tasks properly;
  - (h) have contingency plans in place, and be prepared to operate such plans in the event of an emergency, where appropriate in accordance with the relevant Union rules referred to in Article 1(2).
2. Competent authorities shall ensure the impartiality, quality and consistency of official controls and other official activities at all levels.
  3. When, within the services of a competent authority, more than one unit is competent to carry out 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 external 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. 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 138(2).

## *Article 6*

### *Decisions of the competent authorities concerning natural and legal persons*

The decisions taken by the competent authorities in accordance with Articles 52, 63(3) and (5), 64, 132 and 133 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 ensure that members of their staff are required not to disclose information acquired when undertaking their official duties in the context of official controls and other official activities which by its nature is covered by professional secrecy.
2. Information covered by professional secrecy as referred to in paragraph 1 shall include:
  - (a) information whose disclosure would undermine the protection of the public interest as regards the matters referred to in Article 4(1) (a) of Regulation (EC) No 1049/2001;
  - (b) information whose disclosure would undermine the protection of privacy and of the integrity of the individual in accordance with union legislation regarding the protection of personal data.
3. 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.
4. This Article shall not prevent the competent authorities from publishing or making otherwise available to the public information about the results of official controls regarding individual operators, in accordance with national law.

## *Article 8*

### *General obligations of the competent authorities concerning official controls*

1. Competent authorities shall carry out official controls 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 or of processes, materials, substances that may influence feed or food safety, animal health or animal welfare, plant health or plant reproductive material identity and quality, or, in the case of plant protection products, may adversely impact on the environment;
  - (b) operators' past record as regards compliance with the rules referred to in Article 1(2);
  - (c) the reliability of any own controls that has already been carried out by operators;
  - (d) any information that might indicate non-compliance with the rules referred to in Article 1(2).
2. Official controls carried out prior to the placing on the market or of the movement of certain animal 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 condition for the placing on the market or the movement of the animals or goods shall be carried out in accordance with the rules referred to Article 1(2) and, as appropriate, with the delegated acts adopted by the Commission in accordance with Articles 10 to 17.
3. Official controls shall be carried out without prior warning, except where:
- (a) prior notification of the operator is necessary;
  - (b) the operator has requested such official controls.
4. Official controls shall be carried out as much as possible in a manner that minimises the burden on the operators.
5. Competent authorities shall carry out official controls with the same care to animals and goods:
- (a) available on the Union market;
  - (b) to be exported from the Union;
  - (c) from third countries.
6. The competent authorities of the Member State of destination may carry out official controls by means of non-discriminatory controls. To the extent strictly necessary for the organisation of the official controls, Member States 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 carry out official controls:

- (a) at all stages of production, processing and distribution of animals and goods, and of any substance, material or object which may influence their characteristics; and
- (b) on operators and the activities under their control, on their premises and processes, on storage and use of goods and keeping of animals, on any activity or operation including transport.

*Article 10*  
*Specific rules on official controls concerning*  
*products of animal origin intended for human consumption*

1. In order to take account of the risk for human health and animal health associated to products of animal origin intended for human consumption, the Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning specific rules for the performance of official controls on those products and on animals intended for the production of such products to verify compliance with the Union rules referred to in Article 1(2)(a)(c)(d)(e) applicable to them. Those delegated acts shall lay down rules on:
  - (a) additional responsibilities and tasks of the competent authorities;
  - (b) specific qualifications and skills of the staff of the competent authorities and specific training which such staff shall follow;
  - (c) the organisation of official controls and their frequency;
  - (d) the involvement of slaughterhouse staff in official controls and tests to assess its performance;
  - (e) specific measures to be taken by the competent authorities following official controls;
  - (f) specific requirements for meat inspections;
  - (g) cases and conditions where specific post-mortem inspection procedures are not required having regard to the level of risk;
  - (h) 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 ante-mortem and post-mortem inspection.

Where imperative grounds of urgency relating to human health and animal health so require, the procedure provided for in Article 137 shall apply to delegated acts adopted pursuant to this paragraph.

2. The Commission shall take into account the following elements, when adopting delegated acts as provided for in paragraph 1:
  - (a) the experience gained by food business operators on the hazard analysis and critical control points based systems;

- (b) technological developments and their practical consequences and consumer expectations with regard to food composition;
  - (c) new scientific developments;
  - (d) changes in patterns of consumption.
3. Provided that the objectives of the rules referred to in paragraph 1 are not affected, the Commission shall also take into account the following elements, when adopting delegated acts as provided for in paragraph 1:
- (a) the need to facilitate the application of the delegated acts as provided for in paragraph 1 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 11*  
*Specific rules on official controls on non-authorised substances and non-authorised use of authorised substances*

In order to ensure that, within the Union, a minimum level of official controls are performed to prevent the use of non-authorised substances or the non-authorised use of authorised substances to manufacture feed and food or to treat food producing animals, the Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning rules on official controls on feed, food or food producing animals to detect the presence of such substances or their respective residue levels in or on food and food producing animals set out in the rules referred to in Article 1(2)(a). Those delegated acts shall lay down rules on:

- (a) the organisation of official controls and their frequency;
- (b) the criteria according to which the multi-annual national control plan provided for in point (a) of Article 103 shall be prepared as far as non-~~authorised~~ substances or non-~~authorised use of authorised~~ substances to manufacture feed or food or to treat food producing animals are concerned;
- (c) specific measures to be taken by the competent authorities following official controls.

*Article 12*  
*Specific rules on official controls for animal health*

In order to take account of the risk for animal health related to animals, products of animal origin and germinal products, and human and animal health risks related to animal by-products and derived products, the Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning rules for the performance of official controls on those

animals and goods to verify compliance with the Union rules referred to in Article 1(2)(d)(e) applicable to them. Those delegated acts shall lay down rules on:

- (a) additional responsibilities and tasks of the competent authorities;
- (b) specific qualifications and skills of the staff of the competent authorities and specific training which such staff shall follow;
- (c) the organisation of official controls and their frequency;
- (d) specific measures to be taken by the competent authorities following official controls;
- (e) specific requirements for inspections on the goods referred to in the first paragraph.

### *Article 13*

#### *Specific rules on official controls for animal welfare*

In order to take into account the animal welfare risk related to the farming activities and transport, slaughter and killing activities where these concern animals, the Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning rules for the performance of official controls on animals to verify compliance with Union rules laying down animal welfare requirements referred to in Article 1(2)(f). Those delegated acts shall lay down rules on:

- (a) additional responsibilities and tasks of the competent authorities;
- (b) specific qualifications and skills of the staff of competent authorities and specific training which such staff shall follow;
- (c) the organisation of official controls and their frequency;
- (d) specific measures to be taken by the competent authorities following the official controls;
- (e) the verification of animal welfare requirements at exit points and the minimum requirements applicable to such exit points;
- (f) the design of specific animal welfare indicators to assist the competent authorities in carrying out official controls.

### *Article 14*

#### *Specific rules on official controls for plant health*

In order to take into account the plant health risk associated to plants, plant products and other objects in relation to specific pests of plants, the Commission shall be empowered to adopt delegated acts in accordance with Article 136 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 Article 1(2)(g) applicable to such goods. Those delegated acts shall lay down rules on:

- (a) additional responsibilities and tasks of the competent authorities;
- (b) specific qualifications and skills of the staff of the competent authorities and specific training which such a staff shall follow;
- (c) specific control requirements, including the frequency of official controls performed by the competent authorities with regard to the operators authorised to issue plant passports in accordance with Article 69 of Regulation (EU) No XXX/XXXX [on protective measures against pests of plants];
- (d) specific measures to be taken by the competent authorities following the official controls.

#### *Article 15*

##### *Specific rules on official controls for plant reproductive material*

For the purpose of ensuring the uniform application of Union rules on plant reproductive material referred to in Article 1(2)(h) applicable to the determination of the identity and quality of plant reproductive material, the Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning official controls on plant reproductive material carried out to verify compliance with the rules referred to in Article 1(2)(h). Those delegated acts shall lay down rules on:

- (a) additional responsibilities and tasks of the competent authorities;
- (b) specific qualifications and skills of the staff of the competent authorities and specific training which such a staff shall follow;
- (c) specific measures to be taken by the competent authorities following the official controls.

#### *Article 16*

##### *Specific rules on official controls on plant protection products and pesticides*

In order to take into account the risks that plant protection products and pesticides may represent for humans, animals and the environment, the Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning rules for the performance of official controls on plant protection products in order to verify compliance with Union rules referred to in Article 1(2)(i) applicable to such goods. Those delegated acts shall lay down rules on:

- (a) additional responsibilities and tasks of the competent authorities;
- (b) specific qualifications and skills of the staff of the competent authorities and specific training which such a staff shall follow;
- (c) the organisation of official controls and their frequency;
- (d) specific measures to be taken by the competent authorities following the official controls;

- (e) specific requirements for inspections on the goods referred to in the first paragraph, and for the frequency of the inspections of pesticide application equipment as defined in point (4) of Article 3 of Directive 2009/128/EC and their frequency;
- (f) the design of certificate systems to assist the competent authorities in the inspections of pesticide application equipment referred to in point (e);
- (g) the collection of information, monitoring and reporting on suspected poisonings;
- (h) the collection of information, the monitoring and reporting on counterfeited pesticides and illegal trade of pesticides.

#### *Article 17*

#### *Specific rules on official controls on organic products, products authorised as traditional specialties, geographical indications and protected designation of origin*

In order to take account of the specificities of the organic sector as well as of products authorised, by Union law, to use terms recognised as traditional specialties guaranteed, geographical indications and protected designation of origin, the Commission shall be empowered to adopt delegated acts, in accordance with Article 136 concerning amendments to this Regulation as regards official controls to verify compliance with:

- (a) Council Regulation (EC) No 834/2007 [on organic production and labelling of organic products];
- (b) Council Regulation (EC) No 509/2006 [on agricultural products and foodstuffs as traditional specialties guaranteed];
- (c) Council Regulation (EC) No 510/2006 [on the protection of geographical indications and designations of origin for agricultural products and foodstuffs].

#### *Article 18*

#### *Delegations by the competent authorities of specific official control tasks*

1. Competent authorities may delegate specific official control tasks related to one or more delegated bodies or natural persons in accordance with the conditions provided for in Articles 19 and 20 respectively.
2. Competent authorities shall not delegate the decision concerning the measures provided for in Article 132.
3. In addition to the task referred to in paragraph 2, the Commission shall be empowered to adopt delegated acts in accordance with Article 136 establishing specific official control tasks that may not be delegated.

#### *Article 19*

##### *Conditions for delegating specific official control tasks related to delegated bodies*

1. Competent authorities may delegate specific official control tasks to a delegated body subject to compliance with the following conditions:
  - (a) there is an accurate description of:
    - (i) the specific official control tasks that the delegated body may carry out;
    - (ii) the conditions under which it may carry them out;
  - (b) there is proof that the delegated body:
    - (i) has the expertise, equipment and infrastructure required to carry out the specific official control tasks delegated to it;
    - (ii) has a sufficient number of suitably qualified and experienced staff; and
    - (iii) is impartial and free from any conflict of interest as regards the exercise of the specific official control tasks delegated to it;
  - (c) the delegated body works and is accredited in accordance with standard EN ISO/IEC 17020 ‘General criteria for the operation of various types of bodies performing inspection’ and/or another standard if more relevant to the delegated tasks in question;
  - (d) there are arrangements in place ensuring efficient and effective coordination between the delegating competent authorities and the delegated body.

#### *Article 20*

##### *Conditions for delegating specific official control tasks to natural persons*

Competent authorities may delegate specific official control tasks to one or more natural persons subject to compliance with the following conditions:

- (a) the rules referred to in Article 1(2) so allow;
- (b) the conditions laid down in Article 19 are fulfilled with the exception of points (b)(ii) and (c).

#### *Article 21*

##### *Obligations of the delegated body and natural person to which specific official control tasks are delegated*

The delegated body or the natural person to which specific official control tasks are delegated shall:

- (a) communicate the results of the official controls carried out by it to the competent authorities on a regular basis and whenever the competent authorities so request;

- (b) immediately inform the delegating competent authorities whenever the results of the official controls indicate non-compliance or point to the likelihood of non-compliance.

#### *Article 22*

##### *Obligations of the competent authorities delegating specific official control tasks*

1. Competent authorities delegating specific official control tasks to delegated bodies or natural persons shall organise audits or inspections of such bodies or persons as necessary.
2. The delegating competent authorities shall withdraw the delegation without delay where:
  - (a) following an audit or an inspection, it appears that such delegated bodies or natural persons are failing to carry out properly the official control tasks delegated to them;
  - (b) the delegated body or the natural person fails to take appropriate and timely remedial action.

#### *Article 23*

##### *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 19 are fulfilled with the exception of paragraph (c).
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 19 are fulfilled with the exception of paragraphs (b)(ii) and (c).

#### *Article 24*

##### *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 which specific tasks related to other official activities are delegated shall:

- (a) communicate the results of the other official activities carried out by it to the competent authorities on a regular basis and whenever the competent authorities so request;
- (b) immediately inform the delegating competent authorities whenever the results of the other official activities indicate non-compliance or point to the likelihood of non-compliance.

#### *Article 25*

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

1. Competent authorities delegating specific tasks related to other official activities to delegated bodies or natural persons shall organise audits or inspections of such bodies or persons as necessary.
2. The delegating competent authorities shall withdraw the delegation without delay where:
  - (a) following an audit or an inspection, it appears that such delegated bodies or natural persons are failing to carry out properly the tasks related to other official activities delegated to them;
  - (b) the delegated body or the natural person fails to take appropriate and timely remedial action.

#### *Article 26*

#### *Staff performing official controls and other official activities*

1. Competent authorities shall ensure that its staff performing official controls and other official activities:
  - (a) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out 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 on the obligations of the competent authorities resulting from this Regulation.
2. For the purpose of ensuring that the staff of the competent authorities referred to in paragraph 1 have the necessary skills and the knowledge, the Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning rules for the specific qualification and training requirements of such staff.

*Article 27*  
*Transparency of official controls*

1. Competent authorities shall carry out official controls with a high level of transparency and ensure the regular and timely publication of information on the official control that they carry out. The following information shall be made available to the public:
  - (a) type, number and outcome of official controls;
  - (b) type and the number of non-compliances detected;
  - (c) the cases where measures were taken by the competent authorities in accordance with Articles 132;
  - (d) the cases where penalties were imposed in accordance with Article 133.
2. To ensure the uniform implementation of the rules provided for in paragraph 1, 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 138(2).

*Article 28*  
*Documented and control verification procedures*

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

These procedures shall contain the subject areas for control procedures set out in Chapter II of Annex II.
2. Competent authorities shall have internal procedures in place to verify the consistency and effectiveness of official controls and other official activities that they carry out.
3. Competent authorities shall:
  - (a) take corrective actions in all cases where the control verification 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 29*  
*Reports*

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

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. In the case of official controls which require the performance of continuous and/or regular inspections by the competent authorities, 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 shortcomings identified through the official controls.

#### *Article 30*

##### *Official controls - activities, methods and techniques*

1. Competent authorities shall carry out official controls using appropriate control methods and techniques such as screening, targeted screening, verification, inspection, audit, sampling, analysis, diagnosis and test.
2. Official controls shall include the following activities:
  - (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 and pesticides;
    - (v) labelling, presentation and advertising;

- (c) controls on the hygiene conditions in feed and food businesses;
- (d) an assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), good farming practices and 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) official controls carried out with the competent authorities' own instruments to verify measurements taken by operators;
- (i) any other activity required to ensure that the rules of this Regulation are met.

*Article 31*  
*Obligations of operators*

1. Where required by the competent authorities for the purposes of official controls or of other official activities, operators shall give the staff of the competent authorities access to their:
  - (a) premises;
  - (b) computerised information management systems;
  - (c) animals and goods;
  - (d) documents and any other relevant information.
2. During the official controls, operators shall assist the staff of the competent authorities in the accomplishment of their tasks.
3. The operator responsible for the consignment shall cooperate fully with competent authorities to ensure an efficient performance of official controls and make available all information on paper or electronically.

## **Chapter II**

### **Sampling, analysis and tests**

*Article 32*  
*Methods used for sampling, analysis and tests*

1. Methods used for sampling, analysis and tests referred to in Article 30(1) shall:
  - (a) comply with Union rules establishing those methods or the performance criteria for those methods; or,

- (b) in the absence of the Union rules referred to in point (a), comply with relevant internationally recognised rules or protocols, including those that the European Committee for Standardisation (CEN) has accepted, unless they would:
    - (i) be ineffective or inappropriate in view of the legitimate objective pursued; or,
    - (ii) not meet state of the art scientific standards; or,
  - (c) in the absence of the rules or protocols referred to in points (a) and (b), be the relevant methods validated by the European Union reference laboratories in accordance with internationally accepted scientific protocols; or,
  - (d) in the absence of the rules or protocols referred to in points (a) and (b) and the methods referred to in point (c), comply with relevant rules established at national level; or,
  - (e) in the absence of the rules or protocols referred to in points (a) and (b), the methods referred to in point (c) and the national rules referred to in point (d), be the relevant methods validated by national reference laboratories in accordance with internationally accepted scientific protocols; or,
  - (f) in the absence of the rules or protocols referred to in points (a) and (b) and the methods referred to in point (c), the national rules referred to in point (d) and the methods referred to in point (e), be the relevant methods validated in accordance with internationally accepted scientific protocols.
2. In the context of screening, targeted screening and of other official activities, any of the methods referred to in points (b) to (f) of paragraph 1 may be used in the absence of Union rules referred to in point (a) paragraph 1.
  3. Where analyses or tests are urgently needed and none of the methods referred to in paragraph 1 exists, the relevant national reference laboratory or, if no such national reference laboratory exists, any other laboratory designated in accordance with Article 35(1) may use methods others than those referred to in paragraph 1 until the validation of an appropriate method in accordance with internationally accepted scientific protocols.
  4. Wherever possible, methods of analysis shall be characterised by the appropriate criteria set out in Annex III.
  5. Samples shall be taken, handled and labelled in such a way as to guarantee their legal and scientific validity.
  6. The Commission may lay down by means of implementing acts rules for:
    - (a) the methods used for sampling, analysis and tests;
    - (b) performance criteria, analysis or test parameters, measurement uncertainty and procedures for the validation of the methods referred to in point (a); and
    - (c) the interpretation of analytical and testing results.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 138(2).

### *Article 33*

#### *Supplementary expert opinion*

1. The competent authorities shall establish adequate procedures in order to guarantee, in the context of an official control, the right of operators whose animals or goods are subject to sampling, analysis, diagnosis or test to apply for a supplementary expert opinion.
2. The right to apply for a supplementary expert opinion provided for in paragraph 1:
  - (a) shall always entitle the operator to request a documentary review of the sampling, analysis or test by another expert; and
  - (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, that right shall entitle the operator to request:
    - (i) that a sufficient number of other samples be taken for a supplementary expert opinion; or,
    - (ii) here it is not possible to take a sufficient number of samples as referred to in point (i), that an independent second analysis or test of the sample be carried out.
3. Notwithstanding paragraphs 1 and 2, competent authorities shall always give priority to their obligation to take prompt action to eliminate or contain the risks for human, animal and plant health, and animal welfare.
4. The Commission may lay down by means of implementing acts procedures for the uniform application of the rules provided for in paragraph 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 138(2).

### *Article 34*

#### *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 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 sample referred to in paragraph 1 is analysed or tested, are entitled to exercise the right to apply for a supplementary expert opinion provided for in Article 33(1).

*Article 35*  
*Designation of official laboratories*

1. The competent authorities shall designate official laboratories to carry out the , analyses and tests of samples taken during official controls and other official activities referred to in Article 30(1), in the Member State in whose territory those competent authorities operate or in another Member State.
2. The competent authorities may only designate a laboratory provided that:
  - (a) there is an accurate description of:
    - (i) the tasks that the laboratory shall carry out as official laboratory; and,
    - (ii) the conditions under which it shall carry out those tasks; and,
  - (b) there is efficient and effective coordination and collaboration between the laboratory and the competent authorities designating it; and,
  - (c) the laboratory:
    - (i) has the expertise, equipment and infrastructure required to carry out analyses or tests of samples; and,
    - (ii) has a sufficient number of suitably qualified, trained and experienced staff; and,
    - (iii) is impartial and free from any conflict of interest as regards the exercise of its tasks as official laboratory; and,
    - (iv) can deliver timely the results of the analysis or test of the samples taken during official controls and other official activities; and
    - (v) operates and is assessed and accredited in accordance with the standard EN ISO/IEC 17025 on ‘General requirements for the competence of testing and calibration laboratories’ by a national accreditation body, operating in accordance with:
      - (1) Regulation (EC) No 765/2008; and,
      - (2) the standard EN ISO/IEC 17011 on ‘General requirements for accreditation bodies accrediting conformity assessment bodies’,taking into account Union rules establishing the methods of analysis or test or the performance criteria for those methods.
3. The scope of the accreditation and assessment of an official laboratory referred to in paragraph 2(c)(v):

- (a) shall include all the methods of analysis or test required to be used by the laboratory for analysis or tests of samples when it operates as an official laboratory; and,
  - (b) may comprise one or more methods of analysis or test or a group of methods.
4. 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 analyses or tests, the competent authorities may request a laboratory or diagnostic centre which does not meet one or more of the requirements of this article to carry out those analysis and tests.

*Article 36*  
*Obligations of official laboratories*

- 1. Official laboratories shall immediately inform the competent authorities where the results of an analysis or test of 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, laboratories shall take part in inter-laboratory comparative tests organised for the analyses or tests they use as official laboratories.

*Article 37*  
*Audits and inspections of official laboratories*

- 1. The competent authorities having designated official laboratories shall organise audits or inspections of those laboratories:
  - (a) on a regular basis; and,
  - (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 partly, 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 that:
  - (a) it no longer complies with the conditions provided for in Article 35(2) and Article 35(3); or,
  - (b) it does not comply with the obligations provided for in Article 36; or,
  - (c) it is underperforming at inter-laboratory comparative tests referred to in Article 36(2).

*Article 38*

*Derogations from the condition for the mandatory assessment and accreditation of official laboratories*

Article 35(2)(c)(v) shall not apply to:

- (a) laboratories that:
  - (i) only carry out detection of *Trichinella* in meat; and,
  - (ii) only use for the detection of *Trichinella* the reference method or equivalent methods referred to in Article 6 of Commission Regulation (EC) No 2075/2005;  
  
provided that they carry out the detection under the supervision of:
    - (1) the competent authorities; or,
    - (2) an official laboratory designated in accordance with Article 35(1) 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);
- (b) laboratories carrying out analyses or tests to verify compliance with the rules on plant reproductive materials referred to in Article 1(2)(h);
- (c) laboratories which only carry out analyses or tests in the context of other official activities provided that they:
  - (i) only use the methods of analysis and test referred to in Article 32 (1) points (a) to (d); and,
  - (ii) carry out the analyses or tests under the supervision of:
    - (1) the competent authorities; or,
    - (2) the national reference laboratories for the methods they use referred to in point (c)(i); and,
  - (iii) participate regularly in the inter-laboratory comparative tests organised by the national reference laboratories for the methods they use referred to in point (c)(i); and,
  - (iv) have a quality assurance system in place to ensure sound and reliable results from the methods for analysis and test used.

Where the methods used by the laboratories referred to under point (c)(i) require confirmation of the result of the analysis or test, the confirmatory analysis or test shall be carried out by an official laboratory which meets the requirements of Article 35(2)(c)(v) and of Article 35(3).

#### *Article 39*

#### *Permanent derogations from the condition for the mandatory assessment and accreditation of official laboratories for all the methods of analysis and test*

The Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning the cases and the conditions where, by way of derogation from Article 35(2)(c)(v) and Article 35(3), laboratories are not required to be accredited for all the methods of analysis and test they use as official laboratories, provided that they comply with the following conditions:

- (a) they are accredited for the use of one or more methods which are similar to the other methods they use by the laboratories and representative of a number of methods;
- (b) they make significant use of those methods referred to in (a).

#### *Article 40*

#### *Temporary derogations from the condition for the mandatory assessment and accreditation of official laboratories for all the methods of analysis and test*

1. By way of derogation from Article 35 (2)(c)(v) and Article 35(3), the competent authorities may temporarily designate an official laboratory for the use of a method of analysis or test for which it has not been accredited:
  - (a) when the use of this method is newly required by Union rules; or,
  - (b) when changes to the method in use require a new accreditation or an extension of the scope of the accreditation obtained by the official laboratory; or,
  - (c) in emergency situations or in cases of emerging risks for human health, animal health and welfare and plant health, where the sudden analytical or testing needs of samples require the urgent use of a method for which the official laboratory has not been accredited.
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; and,
  - (b) a quality assurance system is in place in the official laboratory to ensure sound and reliable results from the use of that method; and,
  - (c) the analyses or tests of samples must be carried out under the supervision of:
    - (i) the competent authorities; or,
    - (ii) the national reference laboratory for that method.
3. The temporary designation provided for in paragraph 2 shall not exceed a period of one year, and may be renewed once for a period of one year.

4. The Commission may, by means of implementing acts, lay down modalities for the uniform application of paragraph 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 138(2).

## **Chapter III**

### **Official controls on animals and goods entering the Union**

#### **SECTION I**

##### **ANIMALS AND GOODS NOT SUBJECT TO SPECIFIC OFFICIAL CONTROLS AT BORDERS**

###### *Article 41*

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

1. Competent authorities shall carry out official controls regularly on animals and goods entering the Union to which the provisions of Article 44 do not apply. Those official controls shall be carried out at a rate dependent on the risk to human, plant or animal health or to animal welfare and with appropriate frequency, taking into account:
  - (a) the risks to human, plant or animal health or to animal welfare associated with different types of animals and goods and, as regards plant protection products, to the environment;
  - (b) the history of compliance with the requirements 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 carried out on the animals and goods concerned;
  - (d) the guarantees that the competent authorities of the third country of origin has given with regard to the 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.
2. The official controls provided for in paragraph 1 shall be carried out at an appropriate place, including:
  - (a) the point of entry into the Union;
  - (b) a border control post;
  - (c) the point of release for free circulation in the Union;

- (d) the warehouses and the premises of the operator responsible for the consignment;
  - (e) any other place within the customs territory of the Union.
3. Competent authorities at border control posts and other points of entry into the Union shall carry out official controls on the following whenever they have reason to believe that their entry into the Union may pose a risk to human, plant or animal health, or animal welfare:
- (a) means of transport, including where empty;
  - (b) packaging.
4. Competent authorities may also carry out official controls on goods that are placed under one of the customs procedures defined in Article 4(12)(a) and (b) of Regulation (EC) No 450/2008.

#### *Article 42*

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

1. The official controls referred to in Article 41(1) shall:
- (a) always include a documentary check;
  - (b) include identity and physical checks depending on the risk to human, plant or animal health or to animal welfare.
2. Competent authorities shall carry out the physical checks referred to in paragraph 1(b) 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 63 to 69 shall apply as appropriate.

#### *Article 43*

#### *Samples taken of goods not subject to specific official controls at borders*

1. Where samples of goods are taken, the competent authorities shall:
- (a) inform the customs services and the operators concerned;
  - (b) indicate whether or not the goods can be released before the results of the analysis, diagnosis or tests of the samples are available, provided that the traceability of the goods is ensured.
2. The Commission shall, by means of implementing acts, establish:
- (a) the mechanisms necessary to ensure the traceability of the goods;

- (b) identify the documents that should accompany the goods when samples have been taken.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 138(2).

## **SECTION II**

### **OFFICIAL CONTROLS AT BORDER CONTROL POSTS ON ANIMALS AND GOODS**

#### *Article 44*

#### *Animals and goods subject to controls at border control posts*

1. Competent authorities shall carry out official controls, at the border control post of first arrival to the Union, on each consignment of the following categories of animals and goods arriving 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 organisms that are harmful to plants as referred to in the lists adopted on the basis of Article 58(2) of Regulation XXX *[on measures against pests of plants]*;
  - (d) goods for which the Commission has decided, by means of implementing acts provided for in paragraph 2(b), that a temporary increase of official controls at their entry into the Union is necessary due to a known or emerging risk which may arise when such goods originate from certain third countries.
  - (e) goods which are subject to an emergency measure adopted by the Commission in accordance with Article 53 of Regulation (EC) No 178/2002, Article 247 of Regulation XXX/XXXX *[on animal health law]*, Article 27 of Regulation XXX/XXXX *[protective measures against pests of plants]* requiring consignments of those animals or goods to be subject to official controls at their entry into the Union;
  - (f) goods for which conditions for entry into the Union have been established in accordance with Article 121, with the rules referred to therein or with Article 123 and requiring that compliance with the conditions in question be ascertained at the entry of the animals or goods into the Union.

The official controls referred to in this paragraph shall aim to ascertain compliance with the rules referred to in Article 1(2).

2. The Commission shall, by means of implementing acts:
  - (a) establish lists detailing the animals and goods belonging to the categories referred to in paragraphs 1(a) and (b), indicating their codes from the Combined Nomenclature;
  - (b) establish the list of goods belonging to the category referred to in paragraph 1(d) and update it as necessary in relation to the risks referred thereto.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 138(2).

3. The provisions of this Article shall also apply to consignments of the categories of animals and goods referred to in paragraph 1(a), (b) and (c) when they are of a non-commercial nature.
4. Customs services shall not allow the entry or handling in free zones or customs warehouses of consignments of the categories of animals and goods referred to in paragraph 1(a), (b) and (c) without the agreement of the competent authorities.
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning amendments of the categories of consignments referred to in paragraph 1, to include other products which may give rise to risks for human, animal or plant health and, as regards plant protection products, to risks for the environment.

#### *Article 45*

##### *Animals and goods exempted from official controls at border control posts*

The Commission shall be empowered to adopt delegated acts in accordance with Article 136, concerning rules establishing the cases and conditions under which the following categories of animals and goods are exempted from the provisions of Article 44:

- (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 travellers' 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 5 of Regulation (EU) No XXX/XXXX *[on animal health law]*;
- (g) goods which have undergone heat treatment and do not exceed quantities to be defined in the 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 46*

##### *Official controls at border control posts*

1. The official controls provided for in Article 44(1) shall be carried out upon arrival of the consignment at the border control post and shall include documentary, identity and physical checks by the competent authorities.
2. All consignments of the categories of animals and goods referred to in Article 44(1) shall be subject to documentary and identity checks.
3. Physical checks shall be carried out on consignments of animals and goods referred to in Article 44(1) at a frequency dependent on the risk posed by each animal, good or category of animals or goods.
4. Physical checks to verify compliance with animal health and welfare requirements or with plant health requirements shall be carried out 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. Competent authorities at border control posts shall systematically carry out 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 controls on animals being transported and to reduce delays on such controls.
6. The Commission may, by means of implementing acts establish the maximum number of containers that can compose a consignment of the categories of goods referred to in Article 44(1) taking into account the need to guarantee their rapid and efficient handling and the controls to be performed. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 138(2).

#### *Article 47*

##### *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 44(1) shall be presented to, and kept by, the competent authorities of the border control post.
2. The competent authority of the border control post shall issue the operator responsible for the consignment with an authenticated paper or electronic copy or, if the consignment is split, with individually authenticated paper or electronic copies.

3. Consignments shall not be split until official controls have been performed and the Common Health Entry Document (CHED) referred to in Article 53 has been finalised in accordance with the requirements of Article 53(4) and 54(1).

#### *Article 48*

##### *Specific rules for official controls at border control posts*

The Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning rules to establish:

- (a) the cases and 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 44(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;
- (c) the cases and conditions under which identity and physical checks of transhipped consignments and animals arriving by air or sea and staying on the same means of transport for onward travel may be carried out at a border control post other than the one of first arrival into the Union;
- (d) the cases and conditions under which the transit of animals and goods can be authorised and the specific official controls to be carried out at border control posts on such animals and goods, including the conditions for their storage in specially approved free or customs warehouses where applicable.

#### *Article 49*

##### *Modalities of documentary, identity and physical checks*

For the purposes of ensuring the uniform implementation of the rules laid down in Articles 46, 47 and 48, the Commission shall by means of implementing acts, lay down the modalities concerning the tasks to be carried out during and after the documentary, identity and physical checks referred to in those rules. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 138(2).

#### *Article 50*

##### *Official controls not carried out at border control posts*

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning rules establishing the cases and conditions under which:
  - (a) identity and physical checks may be carried out by competent authorities at control points other than border control posts without adversely affecting the controls referred to in Article 46(1) and provided that those control points comply with the requirements provided for in Article 61(3) and 61(4);

- (b) 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 62(2);
  - (ii) passenger's personal luggage;
  - (iii) goods ordered by distance selling.
- 2. Articles 53(2)(b), 56, 57, 59, 60, 61(3) and 61(4), shall apply to the control points referred to in paragraph 1(a).

*Article 51*  
*Frequency of identity and physical checks*

- 1. The Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning rules establishing the categories of animals and goods and the conditions under which, taken account of the reduced risk, identity checks on consignments of animals and goods referred to in Article 44(1) shall be:
  - (a) carried out at a reduced frequency;
  - (b) limited to the verification of a consignment's official seal, where any such seal is present.
- 2. For the categories of animals and goods referred to in Article 44(1)(e) and (f) the frequency rate of physical checks shall be established by the Commission with the acts or measures referred thereto.

The frequency rate of physical checks for the categories of goods referred to in Article 44(1)(d) shall be determined by means of the implementing act provided for in Article 44(2)(b).

- 3. The Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning rules establishing:
  - (a) the criteria and the procedures for determining and modifying the frequency rates of physical checks to be carried out on consignments of animals and goods referred to in Article 44(1)(a), (b) and (c), and to adjust them to the level of the risk, having regard to:
    - (i) information collected by the Commission in accordance with Article 120(1);
    - (ii) the outcome of controls carried out by the Commission in accordance with Article 111(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 127;

- (v) scientific assessments; and
  - (vi) any other relevant information.
- (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.

#### *Article 52*

##### *Decisions on consignments*

1. A decision shall be taken on each consignment 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 53*

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

1. For each consignment of animals or goods of the categories referred to in Article 44(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 44(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, to:
    - (i) record the outcome of the official controls carried out and any decisions taken on that basis, including the decision to reject a consignment;
    - (ii) to communicate such information through the TRACES system.
3. Operators shall give prior notification in accordance with paragraph 2(a) 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 controls required by Article 46(1) have been carried out;
  - (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 52 and recorded on the CHED.

#### *Article 54*

##### *Use of the Common Health Entry Document by customs authorities*

1. The placing under one of the customs procedures referred to in Article 4(12)(a) and (b) of Regulation (EC) No 450/2008 of consignments of the categories of animals and goods referred to in Article 44(1) of this Regulation 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 compliance with the rules referred to in Article 1(2).

#### *Article 55*

##### *Time requirements, format and specific rules for the use of the Common Health Entry Document*

1. The Commission shall be empowered to adopt implementing acts establishing:
  - (a) the format of the CHED and the modalities for its use;
  - (b) the minimum time requirements for prior notification of consignments by operators as provided for in Article 53(2)(a) in order to enable the competent authorities of the border control post to carry out official controls in a timely and effective manner.

Those acts shall be adopted in accordance with the examination procedure referred to in Article 138(2).

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning rules establishing the cases and conditions under which the

CHED must accompany consignments of the categories of animals and goods referred to in Article 44(1) to the place of destination.

#### *Article 56*

##### *Designation of border control posts*

1. Member States shall designate border control posts for the purpose of carrying out official controls on one or more of the categories of animals and goods referred to in Article 44(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 61.
3. The Commission shall, within three months of receiving the notification referred to in paragraph 2, inform the Member State whether the designation of the proposed border control post is dependent upon the favourable outcome of a control carried out by Commission experts in accordance with Article 111 in order to verify compliance with the minimum requirements laid down in Article 61. The Commission shall indicate the date of such a control and 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 57*

##### *Listing of border control posts*

1. Each Member State shall make available through the Internet the updated 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/or goods referred to in Article 44(1) which are included in the scope of its designation;
  - (d) the equipment and premises available for carrying out 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/or goods referred to in Article 44(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 138(2).

#### *Article 58*

##### *Re-designation of existing border control entities*

1. Border inspection posts approved by the Commission in accordance with Article 6 of Directive 97/78/EC and Article 6 of Council Directive 91/496/EEC, designated points of entry designated by Member States in accordance with Article 5 of Regulation (EC) No 669/2009 and points of entry designated by Member States in accordance with Article 13c(4) of Directive 2000/29/EC shall cease to exist.
2. Member States may re-designate border inspection posts, designated points of entry and points of entry as border control posts in accordance with Article 56(1) provided that the minimum requirements referred to in Article 61 are complied with. Article 56(2) and 56(3) shall not apply.

#### *Article 59*

##### *Withdrawal of border control posts*

1. Where border control posts cease to comply with the requirements referred to in Article 61, the Member States shall:
  - (a) withdraw the designation provided for in Article 56(1);
  - (b) remove them from the lists referred to in Article 57(1), for all or for certain categories of animals and/or goods for which the designation was made.
2. Member States shall inform the Commission and the other Member States of the withdrawal of the designation of a border control post and of the reasons for such a withdrawal.
3. The concerned border control post can be re-listed following verification by the competent authorities that the requirements laid down in Article 61 are met.

#### *Article 60*

##### *Suspension 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/or goods for which the designation was made, in cases where such activities may result in a risk to human, plant or animal health or to animal welfare.
2. Member States shall inform the Commission and the other Member States of any suspension of a border control post and the reasons for such a suspension.
3. The suspension of a border control post shall be indicated in the list referred to in Article 57(1).
4. Member States shall remove the suspension provided for in paragraph 1 as soon as:

- (a) the competent authorities are satisfied that the border control post no longer presents a risk to human, plant or animal health, or animal welfare;
  - (b) they have communicated to the Commission and to the other Member States the information on the basis of which the competent authorities determined that the border control post no longer presents such a risk.
5. The Commission shall be empowered to adopt implementing acts establishing the procedures for the exchanges of information and communications referred to in paragraphs 2 and 4(b).

#### *Article 61*

##### *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 an area which is designated by Custom authorities in accordance with Article 92 of Regulation (EC) No 450/2008.
2. Upon request by the Member State concerned, the Commission shall be empowered to decide by implementing act adopted in accordance with Article 138(2) that a border control post can be situated at a certain distance from the point of entry into the Union given specific geographical constraints affecting the territory of the requesting Member State.
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 implement the measures taken in accordance with Articles 62 and 63 in cases of suspicion or non-compliant consignments;
  - (e) contingency arrangements to ensure the smooth operation of official controls and the effective implementation of the measures taken in accordance with Articles 62 and 63 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 computerized 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, diagnostic and testing results within appropriate deadlines and equipped with the information technology tools necessary to ensure the introduction of the results of analysis 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 and appropriate biosecurity requirements in relation to animals and goods referred to in Article 44(1) 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 the implementation of arrangements and measures on the different categories of animals and goods referred to in Article 44(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 138(2).

**SECTION III**  
**ACTION IN CASE OF SUSPICION OF NON-COMPLIANCE AND OF NON-COMPLIANCE**  
**OF ANIMALS AND GOODS**  
**FROM THIRD COUNTRIES**

*Article 62*  
*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 44(1) with the rules referred to in Article 1(2), the competent authorities shall carry out 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 44(1), shall be subject to official controls by 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 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 63(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 carry out 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 the specific rules for carrying out the uniform intensified official controls referred to in paragraphs (4) and (5) at Union level.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 138.

### *Article 63*

#### *Measures to be taken in cases of non-compliant consignments arriving from third countries*

1. The competent authorities shall place under official detention any consignment of animals or goods 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 a consignment 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 paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 138(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);
  - (b) re-dispatch the consignment outside the Union in accordance with Article 69;
  - (c) subject the consignment to special treatment in accordance with Article 68 to eliminate the risks resulting from non-compliance; or
  - (d) adopt any other appropriate measures to eliminate the risks resulting from non-compliance with the rules referred to in Article 1(2).
4. The competent authorities shall immediately notify any decision to refuse entry of a consignment as provided for in paragraph (1) and orders issued pursuant to Article 63(3) and 63(5) and Article 64 to:
  - (a) the Commission;
  - (b) the competent authorities of other Member States;

- (c) customs services;
- (d) 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 128.

5. If a consignment of the categories of animals or goods referred to in Article 44(1) is not presented for official controls, or is not presented in accordance with the requirements established in Article 44, the competent authorities shall order that it be retained, or recalled, and placed under official detention without delay.

Paragraphs 1 to 4 and Article 66 shall apply.

#### *Article 64*

##### *Official detention of animals or goods arriving from third countries presenting a risk*

Where official controls indicate that a consignment of animals or goods presents a risk for human, plant or animal health or animal welfare or for the environment in the case of plant protection products, the competent authorities shall retain the consignment in question under official detention pending its destruction and/or any other measure necessary to protect human, plant or animal health or animal welfare.

#### *Article 65*

##### *Follow up of decisions taken in relation to non-compliant consignments arriving from third countries*

1. Competent authorities shall:
  - (a) invalidate the official certificates and/or other documents accompanying consignments which have been subject to measures pursuant to Article 63(3) and 63(5) and Article 64.
  - (b) cooperate in accordance with Title IV to take any further measures necessary to ensure that it is not possible to reintroduce rejected consignments into the Union.
2. The competent authorities in the Member State where the official controls were carried out shall supervise the implementation of the measures ordered pursuant to Article 63(3) and 63(5) and Article 64 to ensure that the consignment does not give rise to adverse effects on human, plant or animal health or animal welfare, during or pending the implementation of the measures.

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

#### *Article 66*

##### *Failure by the operator to implement the measures ordered by the competent authorities*

The operator shall carry out all the measures ordered by the competent authority in accordance with Article 63 paragraph 3 without delay and, at the latest, within 60 days from the day on which the competent authorities notified him of their decision in accordance with Article 63(4).

If, after the expiry of the 60-day period no action has been taken by the operator, the consignment shall be destroyed in suitable facilities located as close as possible to the border control post.

This provision shall not affect the applicability of national rules detailing time limits for applying for supplementary expert opinions.

#### *Article 67*

##### *Consistency of application of Articles 63 to 64*

The Commission shall, by means of implementing acts, lay down rules to ensure the consistency of decisions taken by competent authorities within the framework of Articles 63 and 64.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 138(2).

#### *Article 68*

##### *Special treatment of consignments*

1. The special treatment of consignments provided for in Article 63(3)(c) may, as appropriate, include:
  - (a) treatment or processing to bring the consignment into line with the requirements of the rules referred to in Article 1(2), or with the requirements of a third country of re-dispatch, including decontamination, where appropriate, but excluding dilution;
  - (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 be:
  - (a) carried out effectively and ensure the elimination of any risk for human, plant, or animal health or animal welfare or for the environment in the case of plant protection products;
  - (b) documented and carried out under the control of the competent authorities.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning the requirements and the conditions in accordance to which the special treatment provided for in paragraph 1 shall take place. In the absence of

rules adopted by delegated act, special treatment shall take place in accordance with national rules.

*Article 69*  
*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) when 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.
2. The requirements of paragraph 1 (b) and (c) shall not apply to consignments of the categories of goods referred to in Article 44(1) (c).
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 138(2).

*Article 70*  
*Approval of pre-export controls carried out 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 apply only 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 138(2).
2. Without adversely affecting the application of Article 62, the approval provided for in paragraph 1 shall specify:
  - (a) the maximum frequency of official controls to be carried out by the competent authorities of Member States at the entry of the consignments into the Union;
  - (b) the official certificates that must accompany consignments entering the Union;

- (c) a model for such certificates.
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 carried out in accordance with Article 115 demonstrates that the system of official controls 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 carried out in the third country prior to dispatch to the Union are sufficiently effective to replace or reduce the documentary, identity and physical checks laid down in the rules referred to in Article 1(2).
4. The approval provided for in paragraph 1 shall specify:
- (a) the competent authorities of the third country under the responsibility of which pre-export controls must be performed;
  - (b) 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 18 to 25 or equivalent conditions.
5. 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 paragraph 2 accompany each consignment controlled.
6. The Commission shall by means of implementing acts establish detailed rules and criteria for approving pre-export controls carried out by third countries in accordance with paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 138 (2).

#### *Article 71*

#### *Non-compliance with, and withdrawal of, the approval of pre-export controls carried out by third countries*

When official controls on consignments subject to the conditions provided for in Article 70(2) reveal significant 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, they shall detain a reasonable number of samples under appropriate storage conditions.

The Commission shall withdraw the approval provided for in Article 70(1) where, following the official controls referred to in paragraph 1, it appears that the requirements laid down in Article 70(3) and 70(5) are no longer being met.

*Article 72*  
*Cooperation amongst authorities*

1. Competent authorities, customs authorities and other authorities of the Member States shall cooperate closely to ensure that the official controls carried out 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 relevant information;
  - (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 44(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 138(2).

*Article 73*  
*Cooperation amongst authorities in relation to consignments not subject to specific controls at borders*

In the case of consignments of animals and goods other than those subject to controls at entry into the Union as required by Article 44(1) and for which a customs declaration for release for free circulation has been made in accordance with Articles 4 and 104 to 116 of Regulation (EC) No 450/2008, customs authorities shall cooperate with competent authorities in accordance with the requirements laid down in Articles 27(3), (4) and (5), and Articles 28 and 29 of Regulation (EC) No 765/2008.

*Article 74*  
*Delegated powers for specific official controls*

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning rules for the performance of specific official controls and appropriate monitoring procedures, and for the adoption of actions 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 under Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, amending Regulations (EEC) No 2847/93, (EC) No 1936/2001 and (EC) No 601/2004 and repealing Regulations (EC) No 1093/94 and (EC) No 1447/1999 from a fishing vessel flying a third-country flag;
  - (b) consignments of unskinned, furred wild game;
  - (c) the categories of consignments of goods referred to in Article 44(1)(b) which are delivered, with or without storage in a specially approved free/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) the entry into the Union of animals and goods ordered by distance selling and delivered directly, 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 Article 44(1)(a) to (c) originating from, and returning to, the Union following a refusal of entry by a third country;
  - (i) goods arriving in bulk;
  - (j) consignments of goods referred to in Article 44(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 44 in accordance with Article 45.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 136 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.

## **Chapter IV**

### **Financing of official controls**

#### *Article 75*

##### *General principle*

1. Member States shall ensure that adequate financial resources are available to provide the staff and other resources necessary to the competent authorities to perform official controls and other official activities.
2. In addition to the fees collected in accordance with Article 76, Member States may collect fees to cover the costs occasioned by official controls other than those referred to in Article 76(1) and (2).
3. This Chapter also applies in the case of delegation of specific control tasks in accordance with Article 18.

#### *Article 76*

##### *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 fully the costs they incur in relation to:
  - (a) official controls carried out 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 registered and/or approved in accordance with Article 6 of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs;
    - (ii) feed business operators as defined in Article 3(6) of Regulation (EC) No 178/2002 registered and/or approved in accordance with Articles 9 and 10 of Regulation (EC) No 183/2005;
    - (iii) operators as defined in Article 2(8) of Regulation (EU) No XXX/XXXX *[on protective measures against pests of plants]*;
    - (iv) operators as defined in Article 3(4) of Regulation (EU) No XXX/XXXX *[on the marketing and production, with a view of marketing, of plant reproductive material]*;
  - (b) the official controls performed in view of the issuance of official certificates or to supervise the issuance of official labels, mark or other official attestations;

- (c) official controls performed to verify that the conditions are met:
    - (i) to obtain and maintain the approval referred to in point (a)(i) and (ii);
    - (ii) to obtain and maintain the authorisation referred to in Articles 68 and 77 of Regulation (EU) No XXX/XXXX *[on protective measures pests of plants]*;
    - (iii) to obtain and maintain the authorisation referred to in Article 22 Regulation (EU) No XXX/XXXX *[on the marketing and production, with a view of marketing, of plant reproductive material]*;
  - (d) official controls carried out by the competent authorities at the border control posts or at the control points referred to in Article 50(1)(a).
2. For the purposes of this Article, the official controls referred to in point (a) of paragraph 1 include official controls carried out to verify compliance with measures adopted by the Commission in accordance with Article 134, Article 53 of Regulation (EC) No 178/2002, Articles 27(2) and 42(1) of Regulation (EU) No XXX/XXXX *[on protective measures against pests of plants]*, Article 29 of Regulation (EU) No XXX/XXXX *[on the marketing and production, with a view of marketing, of plant reproductive material]* and Part VI of Regulation (EU) No XXX/XXXX *[on animal health law]*, unless the decision establishing the measures requires otherwise.
3. For the purposes of this Article, the official controls referred to in paragraph 1(a) shall not include official controls carried out to verify compliance with temporary restrictions, requirements or other disease control measures adopted by the competent authorities in accordance with Articles 57, 58, 62, 63, 64, 67 and 69(1) of Regulation (EU) No XXX/XXXX *[on animal health law]* and with Article 14 of Regulation (EU) No XXX/XXXX *[on protective measures against pests of plants]*.

#### *Article 77* *Costs*

1. Competent authorities shall collect fees in accordance with Article 76 to recover the following costs:
- (a) the salaries of the staff involved in official control activities, including support staff, and including 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, with the exclusion of the training necessary to obtain the qualification necessary to be employed by the competent authorities;
  - (e) the cost of travel and transportation, and associated subsistence costs;
  - (f) the cost of sampling and of laboratory analysis, diagnosis and testing.

2. If the competent authorities for which the fees are collected also carry out other activities, only the fraction of the cost elements referred to in paragraph 1 which results from the official control activities referred to in Article 76 shall be considered for the calculation of the fees.

*Article 78*  
*Calculation of fees*

1. Fees collected in accordance with Article 76 may be:
  - (a) established at a flat-rate on the basis of the overall costs borne by the competent authorities over a given period of time, and applied to all operators irrespective of whether any official control is carried out 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 control costs; 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. Where fees are established in accordance with paragraph 1(a), the rate of the fee to be applied to each operator shall be adjusted to take 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 non-compliant ones.

This paragraph shall not apply to the fees collected pursuant to Article 76(1)(d).

3. Travel and transportation costs as referred to in Article 77(e) shall be considered for the calculation of the fees referred to in Article 76 in a manner that does not discriminate operators on the basis of the distance of their premises from the location of the competent authorities.

*Article 79*  
*Application of fees*

1. Operators shall receive proof of the payment of fees provided for in Article 76.
2. Fees collected in accordance with Article 76(1)(b) shall be paid by the operator responsible for the consignment or its representative.

*Article 80*  
*Fees refunds*

1. Fees provided for in Article 76 shall not directly or indirectly be refunded, unless unduly collected.
2. However, Member States may:
  - (a) refund fully or partly fees provided for in Article 76 collected from enterprises employing fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million;
  - (b) exempt enterprises referred to in point (a) from the payment of the fees provided for in Article 76 provided that:
    - (i) all costs incurred by the competent authorities, including those related to the activities of the enterprises referred to in point (a), are calculated in accordance with Articles 76 and 77; and
    - (ii) the loss of revenue for the competent authorities which is the result of the exemption is compensated by the transfer to the competent authorities of an amount equivalent to the loss.
3. Union legislation applicable to State aid shall apply to the measures referred to in paragraphs (2) and (3).

*Article 81*  
*Transparency*

1. Competent authorities shall ensure the highest level of transparency of:
  - (a) the method and data used to establish the fees provided for in Article 76(1); and,
  - (b) the use of 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 of the competent authorities for which a fee is due in accordance with Article 76, indicating the breakdown of such costs per activity referred to in Article 76 and per cost element referred to in Article 77(1);
  - (b) the amount of the fees provided for in Article 76(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 76(1), including the data and estimates used for the establishment of the flat rate fees referred to in Article 77(3)(a);
  - (d) where Article 77(3)(a) applies, the method used to adjust the level of the fees in accordance with Article 77(5);

- (e) if a refund or an exemption is granted in accordance with Article 80(2), the categories of operators benefiting from it, and the overall amount of the refunds or exemptions granted.

#### *Article 82*

#### *Expenses arising from additional official controls and from enforcement measures*

1. Fees shall be applied to cover the additional costs incurred by the competent authorities:
  - (a) as a result of additional official controls:
    - (i) which have become necessary following the detection of a non-compliance during an official control carried out in accordance with this Regulation; and,
    - (ii) are carried out to assess the extent and the impact of the non-compliance or to verify that the non-compliance has been remedied;
  - (b) as a result of official controls performed at the request of the operator;
  - (c) as a result of 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 132 to remedy the established non-compliance.
2. The operator responsible for the consignment shall be liable for the costs incurred by the competent authorities as a result of official controls and action taken by the competent authorities in accordance with Articles 63 to 69 and of 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.

## **Chapter V**

### **Official certification**

#### *Article 83*

#### *General requirements concerning the 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 one or more tasks related to the official certification, such delegation shall comply with the provisions of Articles 18 to 22.

*Article 84*  
*Official certificates*

1. When the rules referred to in Article 1(2) require the issuance of an official certificate, the provisions of Articles 85, 86 and 87 shall apply.
2. Articles 85, 86, 87 shall also apply to official certificates which are necessary for the purposes of exporting consignments of animals and goods to third countries.

*Article 85*  
*Official certificates – Issuance and content*

1. 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.
2. Official certificates shall be issued and signed by the certifying officer on one of the following grounds:
  - (a) direct knowledge by the certifying officer of facts and data relevant for the certification, acquired 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, the knowledge of which was ascertained by another person so authorised by, and acting under the control of, the competent authorities, provided that the certifying officer can verify the accuracy of those facts and data;
  - (c) facts and data relevant for the certification which were obtained from the operators' self-control systems, complemented and confirmed by results from regular official controls carried out by the competent authorities, where the certifying officer is thus satisfied that the conditions for issuing the official certificate are met.
3. Official certificates shall be issued and signed by the certifying officer on the basis of point (a) of paragraph 2 when rules referred to in Article 1(2) so require.

*Article 86*  
*Official certificates – Guarantees of reliability*

1. Official certificate shall:

- (a) not be signed by the certifying officer where they are blank or incomplete;
  - (b) be drawn up in at least one of the official languages of the institutions of the Union that is understood by the certifying officer and, where relevant, in the one of the official language of the Member State of destination;
  - (c) be authentic and accurate;
  - (d) enable the identification of the person who signed it;
  - (e) where it relates to a consignment, allow the verification of the link between the certificate and the consignment.
2. The competent authorities shall take all measures necessary to prevent and penalise the issuing of false or misleading official certificates or the abuse of such official certificate. In particular, such measures may include:
- (a) the temporary suspension of the person issuing the certificate from its duty;
  - (b) the withdrawal of the authorisation to sign the official certificates;
  - (c) any other necessary measure to prevent that the offence referred to in the first subparagraph is repeated.

*Article 87*  
*Implementing powers for official certificates*

1. For the purposes of the uniform application of Articles 85 and 86 the Commission may adopt implementing acts concerning:
- (a) model official certificates and rules for the issuance of the certificates;
  - (b) the mechanisms and the legal and technical arrangements to ensure the issuance of accurate, truthful 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 copy certificates, including in cases where the consignment is split into smaller consignments or is mixed with other consignments;
  - (e) the format of documents that must accompany animals and goods after official controls have been carried out;
  - (f) rules by which certificates may be issued electronically, and those for the electronic signature of the certificates.
2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 138(2).

*Article 88*  
*Official labels, marks and other official attestations*

1. When the rules referred to in Article 1(2) require the issuance of official labels, marks or other 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 labels, marks and other official attestations shall be authentic and accurate.
3. Competent authorities shall ensure that the staff supervising the certification procedure:
  - (a) are impartial and free from any conflict of interest in relation to what is being attested by the official attestations;
  - (b) receives appropriate training on the rules:
    - (i) with which compliance is attested by the official attestations;
    - (ii) the rules laid down in this Regulation.

## **Title III**

### **Reference laboratories and centres**

*Article 89*  
*Designation of European Union reference laboratories*

1. The Commission shall designate European Union reference laboratories.
2. European Union reference laboratories shall operate and be assessed and accredited in accordance with the standard EN ISO/IEC 17025 on ‘General requirements for the competence of testing and calibration laboratories’ by a national accreditation body, operating in accordance with:
  - (a) Regulation (EC) No 765/2008; and,
  - (b) the standard EN ISO/IEC 17011 on ‘General requirements for accreditation bodies accrediting conformity assessment bodies’;taking into account Union rules establishing the methods of analysis or test or the performance criteria for those methods.
3. European Union reference laboratories shall:
  - (a) have suitably qualified staff with adequate training in diagnostic, analytical and testing techniques applied in their area of competence;
  - (b) possess the equipment and products needed to carry out the tasks assigned to them;
  - (c) have appropriate infrastructure;
  - (d) have appropriate administrative support;
  - (e) ensure that their staff respect the confidential nature of certain subjects, results or communications;
  - (f) have sufficient knowledge of international standards and practices;
  - (g) have available, if appropriate, an updated list of:
    - (i) available reference substances and reagents; and,
    - (ii) manufacturers and suppliers of such substances and reagents;
  - (h) take account of research activities at national, Union and international level;
  - (i) have trained personnel available for emergency situations occurring within the Union; and,
  - (j) where appropriate, respect necessary biosecurity standards.

*Article 90*  
*Responsibilities and tasks of European Union reference laboratories*

1. European Union reference laboratories shall contribute to the improvement and harmonisation of methods of analysis or test to be used by official laboratories designated in accordance with Article 35(1) and to the quality and uniformity of analytical and testing data generated by them.
2. They shall be responsible, in accordance with a work programme approved by the Commission, for:
  - (a) providing national reference laboratories with details of methods of analysis or test, 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, within their area of competence, practical arrangements needed to apply new methods of analysis or test 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 in the field within their mission;
  - (f) providing information on relevant Union, national and international research activities to national reference laboratories;
  - (g) collaborating, as regards methods of analysis or test falling within their competence, with laboratories in third countries and where relevant, with the European Food Safety Authority (EFSA), the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDPC);
  - (h) where relevant, assisting actively in the diagnosis of outbreaks of foodborne, zoonotic or animal diseases or of pests of plants in Member States by receiving pathogen isolates or harmful organism specimens for confirmatory diagnosis, characterisation and taxonomic or epizootic studies;
  - (i) where relevant, establishing and maintaining reference collections of pests of plants or reference strains of pathogenic agents;
  - (j) where relevant, coordinating and harmonising controls carried out as prescribed by Union rules to ensure the quality of reagents for the diagnosis of animal, zoonotic or foodborne diseases or carrying out such controls; and,

- (k) where relevant, establishing and maintaining reference collections of materials intended to come into contact with food used to calibrate analytical equipment and provide samples thereof to national reference laboratories.
3. European Union reference laboratories shall publish the list of the national reference laboratories designated by the Member States in accordance with Article 94(1).

#### *Article 91*

##### *European Union reference centres for plant reproductive material*

The Commission may designate European Union reference centres that shall support the Commission, the Member States and the Community Plant Variety Office (CVPO) in the field of production and marketing of plant reproductive material, in accordance with a work programme approved by the Commission by:

- (a) providing technical expertise, in the fields within their mission;
- (b) organising comparative tests and trials;
- (c) conducting training courses for the benefit of staff of the competent authorities and of experts from third countries;
- (d) contributing to the dissemination of research findings and technical innovations.

#### *Article 92*

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

The Commission may designate European Union animal welfare reference centres that shall support the Commission and the Member States in the field of animal welfare, in accordance with a work programme agreed with the Commission, by:

- (a) providing technical expertise, in the fields within their mission;
- (b) organising comparative tests and technical studies;
- (c) conducting training courses for the benefit of staff of the competent authorities and of experts from third countries;
- (d) contributing to the dissemination of research findings and technical innovations and coordinating research in collaboration with existing Union research bodies.

#### *Article 93*

##### *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 89;
  - (b) European Union reference centres for plant reproductive material provided for in Article 91;

- (c) European Union reference centres for animal welfare provided for in Article 92.
- 2. The Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning the establishment of responsibilities, tasks and requirements for the European Union reference laboratories, the European Union reference centres for plant reproductive material and the European Union reference centres for animal welfare in addition to those laid down in Article 89(2) and (3), Article 90, Article 91 and Article 92.
- 3. The Commission shall proceed to the designation of the European Union reference laboratories and of the European Union reference centres through public selection processes, and review them regularly.
- 4. European Union reference laboratories and European Union reference centres shall be subject to Commission controls to verify compliance with the requirements of Articles 89, Article 90, Article 91 and Article 92.
- 5. If these controls show non-compliance with the requirements laid down in Article 89, Article 90, Article 91 or Article 92, the Commission shall, after having received the comments of the laboratory or centre:
  - (a) withdraw the designation of the reference laboratory or centre; or,
  - (b) take any other appropriate measure.

*Article 94*  
*Designation of national reference laboratories*

- 1. Member States shall designate one or more national reference laboratories for each European Union reference laboratory referred to in Article 89.

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 in Article 35(2)(c)(v), Article 35(3), Article 37 and Article 40(1) and (2)(a)(b) and (3) shall apply to national reference laboratories.
- 3. National reference laboratories shall:
  - (a) have suitably qualified staff with adequate training in diagnostic, analytical and testing techniques in their area of competence;
  - (b) possess the equipment and products needed to carry out the tasks assigned to them;
  - (c) have appropriate infrastructure;

- (d) have appropriate administrative support;
  - (e) ensure that their staff respect the confidential nature of certain subjects, results or communications;
  - (f) have sufficient knowledge of international standards and practices;
  - (g) where appropriate, maintain an updated list of:
    - (i) available reference substances and reagents; and,
    - (ii) manufacturers and suppliers of such substances and reagents;
  - (h) take account of research activities at national, Union and international level in their area of competence;
  - (i) have trained personnel available for emergency situations occurring within the Member State or the Union;
  - (j) where appropriate, respect necessary 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 this information available to the public; and,
  - (c) update this 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 136 concerning the establishment of requirements for national reference laboratories in addition to those provided additional to the ones referred to in paragraphs 2 and 3 for national reference laboratories.

#### *Article 95*

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

1. National reference laboratories shall:
- (a) collaborate with the European Union reference laboratories in their area of competence, including by taking part in training courses and in inter-laboratory comparative tests organised by these laboratories;

- (b) coordinate, for their area of competence, the activities of official laboratories designated in accordance with Article 35(1), including by coordinating, harmonising and improving the methods of analysis or test and their use;
  - (c) where appropriate, organise inter-laboratory comparative tests between official laboratories, ensure an appropriate follow-up of such comparative testing and inform the competent authorities of the results of such testing 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 scientific and technical assistance to the competent authorities for the implementation of coordinated control plans adopted in accordance with Article 107.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 136 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 96* *General principles*

1. Competent authorities in the Member States concerned shall provide each other with administrative assistance in accordance with Articles 98, 99, 100 and 101, in view of enabling the correct implementation of the rules referred to in Article 1(2) in cases which have relevance in more than one Member State.
2. Administrative assistance may include, where appropriate, participation in on-the-spot official controls that the competent authorities of another Member State carry out.
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 98, 99, 100 and 101 shall be in writing.
5. In order to streamline and simplify communication exchanges, the Commission shall be empowered, by means of implementing acts, to establish a standard format for:
  - (a) the requests for assistance provided for in Article 98(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 138(2).

*Article 97*  
*Liaison bodies*

1. Each Member State shall designate one or more liaison bodies to assist and coordinate communication flows between competent authorities and to liaise with other Member States' liaison bodies in order to ensure a correct and efficient implementation of the rules provided for in this Title.
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 136 to establish the minimum requirements that liaison bodies 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 Article 59(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 3 on its website.
6. All requests for assistance pursuant to Article 98(1), and notifications and communications pursuant to Articles 99, 100 and 101 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 be empowered to adopt implementing acts to establish the specifications of the technical tools and the procedures for communication between liaison bodies.
8. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 138(2).

*Article 98*  
*Assistance on request*

1. Upon receiving a motivated and documented request for administrative assistance, the requested competent authorities shall:
  - (a) acknowledge receipt of the request without delay;
  - (b) indicate within 10 days from the date of receipt of the request, the time necessary to provide an informed response to the request;
  - (c) carry out official controls or other investigation activities necessary to provide the requesting competent authorities without delay with all necessary

information and documents that 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 on-the-spot official controls referred to in paragraph 1(c) carried out 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 99*

##### *Assistance without request*

1. When the competent authorities in a Member State become aware of non-compliance, and if such non-compliance may have implications for another Member State or States, they shall notify such information to the competent authorities of that other Member State(s) 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 10 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 100*

##### *Assistance in the event of non-compliance*

1. Where, during official controls carried out 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, plant or animal health or animal welfare or, for the environment in the case of plant protection products, or to constitute a serious infringement of those rules,

they shall, without delay, notify the competent authorities of the Member State of dispatch 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 it intends 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 carried out, of the decisions taken and of the reasons for such decisions.
3. If the notifying competent authorities have reason to believe that the investigations carried out or the measures taken by the notified competent authorities do not adequately address the non-compliance established, it shall request the notified competent authorities to complement the official controls carried out or the measures taken. In such cases:
  - (a) the competent authorities from the two Member States shall seek ways and means of finding an agreed approach with the aim of appropriately addressing the non-compliance, including through joint on-the-spot official controls carried out in accordance with Article 98(3);
  - (b) they shall inform the Commission without delay where they are not able to agree on appropriate measures.
4. When official controls carried out 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 101*

##### *Assistance by third countries*

1. When competent authorities receive information from a third country indicating non-compliance or a risk to human, plant or animal health or animal welfare, or to the environment in the case of plant protection products, 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 carried out 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 for 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 102*

#### *Coordinated assistance and follow-up by the Commission*

1. The Commission shall coordinate without delay the measures undertaken by competent authorities in accordance with this Title when, on the basis of the information available to the Commission, the conditions set out in points (a),(b) and (c) or in point (d) are met:
  - (a) it becomes aware of activities that are, or appear to be, non-compliant with the rules referred to in Article 1(2);
  - (b) such activities have, or might have, ramifications in more than one Member State; and
  - (c) it appears that similar activities have been carried out in more than one Member State;or
  - (d) 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 carry out an on-the-spot official control;
  - (b) request 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).

## **Title V**

### **Planning and reporting**

#### *Article 103*

##### *Multi-annual national control plans*

Member States shall:

- (a) ensure that official controls provided for in this Regulation are carried out by the competent authorities on the basis of a multi-annual national control plan, whose preparation and implementation are coordinated;
- (b) designate a single authority responsible for:
  - (i) coordinating the preparation of the plan referred to in point (a) of the first paragraph across all competent authorities responsible for the official controls;
  - (ii) ensuring that it is coherent.

#### *Article 104*

##### *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 risk based;
  - (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 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 concerned by the multi-annual control plan;
  - (c) the designation of competent authorities and their tasks at central, regional and local level, and on resources available to these authorities;
  - (d) the general organisation and management of official controls at national, regional and local level, including official controls in individual establishments;

- (e) control systems applied to different sectors and coordination between the different services of competent authorities responsible for official controls in these sectors;
- (f) where appropriate, the delegation of tasks to delegated bodies;
- (g) methods to ensure compliance with the obligations of the competent authorities provided for in Article 4(1);
- (h) the training of staff performing official controls referred to in Article 10;
- (i) the documented procedures provided for in Articles 12 and 13;
- (j) the organisation and operation of contingency plans in accordance with rules referred to Article 1(2);
- (k) the organisation of cooperation and mutual assistance amongst competent authorities in the Member States.

#### *Article 105*

##### *Preparation and implementation of multi-annual control plans*

1. Member States shall ensure that the multi-annual national control plan provided for in point (a) of Article 103 is made available to the public except where the disclosure of information whose disclosure 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 or animal welfare or to the environment in the case of plant protection products;
  - (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 carried out in accordance with Article 111(1);
  - (e) delegated acts adopted by the Commission in accordance with Article 106;
  - (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 106*  
*Delegated powers for multi-annual national control plans*

In order to promote a consistent, comprehensive and integrated approach to official controls, the Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning the multi-annual national control plans provided for in point (a) of Article 103.

Those delegated acts shall:

- (a) identify risk-based priorities and criteria for the risk categorisation of the official controls concerned and the most effective official control procedures;
- (b) identify other priorities for official controls and the most effective official control procedures;
- (c) indicate the main performance indicators to be applied in assessing multi-annual national control plans.

*Article 107*  
*Coordinated control plans and data collection*

With a view of 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 136 concerning

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

*Article 108*  
*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 plans to take account of the factors referred to in Article 105(2);
  - (b) the results of official controls carried out in the previous year under the provisions of the 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 by the competent authorities;
  - (d) actions to ensure the effective operation of multi-annual national control plans, including enforcement action and the results of such action.

2. In order to ensure the uniform presentation of the annual reports provided for in paragraph 1, the Commission shall, by means implementing acts, adopt and update as necessary standard model forms for the submission of the information and data referred to in paragraph 1.

The implementing acts provided for in the first subparagraph shall, whenever possible, allow the use of the standard model forms it adopts for the submission of other reports on official controls that the competent authorities are requested 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 138(2).

#### *Article 109* *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 108;
  - (b) the results of official controls carried out by the Commission in accordance with Article 111(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 and audit systems in Member States and specific control actions concerning sectors or activities.

#### *Article 110* *Contingency plans for feed and food by Member States*

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 feed and food setting out measures to be applied without delay when feed or food is found to pose a serious risk to human or animal health either directly or through the environment.
2. These contingency plans for feed and food 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 the relevant parties.
3. Member States shall review their contingency plans for feed and food as appropriate, particularly in the light of changes in the organisation of the competent authorities and of experience, including experience gained from simulation exercises.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning:
- (a) harmonised rules for contingency plans for feed and food provided for in paragraph 1 to the extent necessary to ensure that they are compatible with 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 for feed and food.

# **Title VI**

## **Union activities**

### **Chapter I**

#### **Commission official controls**

##### *Article 111*

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

1. Commission experts shall carry out controls in each Member State to:
  - (a) verify the overall 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 implementation practices;
    - (ii) on important or recurring implementation problems;
    - (iii) in relation to emergency situations, emerging problems or new developments in the Member States.
2. The official controls provided for in paragraph 1 shall be organised in cooperation with the competent authorities of the Member States and be carried out on a regular basis.
3. The official controls provided for in paragraph 1 may include on the spot verifications. The Commission experts may accompany the staff of the competent authorities carrying out official controls.
4. Experts from the Member States may assist the Commission experts. National experts accompanying Commission experts shall be given access to premises, documents and information as the Commission experts.

##### *Article 112*

##### *Reports by the Commission on official controls by its experts in Member States*

1. The Commission shall:
  - (a) prepare a report on the findings of official controls carried out in accordance with Article 111(1);

- (b) send to the Member States where those official controls were carried out 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 official controls carried out by its experts in the Member States as provided for in Article 111(1);
  - (d) make publically 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 required to address the specific or systemic shortcomings identified by its experts during official controls carried out in accordance with Article 111(1).

#### *Article 113*

##### *Annual control programme of the Commission in Member States*

1. The Commission shall:
- (a) establish an annual control programme for the official controls to be carried out by its experts in the Member States as provided for in Article 111(1);
  - (b) communicate to Member States the annual control programme referred to in point (a) by the end of the year preceding the commencement of such programme.
2. The Commission may amend its annual programme to take account of developments in the fields governed by the rules referred to in Article 1(2).

#### *Article 114*

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

Member States shall:

- (a) take appropriate follow-up action to remedy any specific or systemic shortcomings identified by the official controls by the Commission experts carried out in accordance to Article 71(1);
- (b) give all necessary assistance and provide all documentation and other technical support that Commission experts request to enable them to carry out official 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 115*  
*Commission controls in third countries*

1. Commission experts may carry out official 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, 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 conditions 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 official 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 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 carried out 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 official controls in a third country, the Commission may, in advance of carrying out such controls, request that the third country concerned provide:
  - (a) the information referred to in Article 120;
  - (b) where appropriate, the written records on the implementation of controls they carry out.

*Article 116*  
*Frequency of commission controls in third countries*

1. The frequency of Commission official 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 arriving from the third country concerned;
  - (d) the results of official controls already carried out by the Commission services or other inspection bodies have already carried out;
  - (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 carried out;
  - (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 (WHO);
    - (ii) the Codex Alimentarius Commission;
    - (iii) the World Organisation for Animal Health (OIE);
    - (iv) European and Mediterranean Plant Protection Organisation (EPPO);
    - (v) International Plant Protection Convention (IPPC);
    - (vi) Organisation for Economic Co-operation and Development (OECD);
    - (vii) United Nations Economic Commission for Europe (UN-ECE);
    - (viii) from other sources;
  - (h) evidence of emerging disease situations or other circumstances that might result in animals and goods arriving from a third country presenting health or environmental risks;
  - (i) the need to investigate or respond to emergency situations in individual third countries.

*Article 117*

*Reports by the Commission on official controls by its experts in third countries*

The Commission shall report on the findings of each official control carried out in accordance with Articles 115 and 116.

Its report shall, if appropriate, contain recommendations.

The Commission shall make its reports publicly available.

*Article 118*

*Annual control programme of the Commission controls in third countries*

1. The Commission shall communicate its programme of official controls in third countries to Member States in advance and report on the results.

It may amend that programme to take account of developments in the fields governed by the rules referred to in Article 1(2) of feed and food safety, animal health and welfare, plant health and plant reproductive material.

2. The Commission may appoint experts from Member States to assist its own experts during the official controls provided for in Article 115.

*Article 119*

*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:

- (a) the competent authorities of Member States where those controls are being carried out; and/or
- (b) the competent authorities of the third country carrying out those controls.

The participation by Commission experts and the final planning 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.

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 carried out by the competent authorities of the third country;
- (c) ensure uniformity with regard to controls carried out by the competent authorities of third countries.

## **Chapter II**

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

#### *Article 120*

##### *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, 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 117;
  - (f) where relevant, results of official controls carried out 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 117.
2. The information referred to in paragraph 1 shall be proportionate to the nature of the animals and goods to be exported to the Union, taking account of the specific situation and structure of the third country.

#### *Article 121*

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

1. To the extent that the conditions to be respected when animals and goods enter the Union from third countries are not provided for by the rules referred to in

Article 1(2), the Commission shall be empowered to adopt delegated acts, in accordance with Article 136 laying down such conditions, where necessary to ensure that animals and goods comply with the requirements established by those rules or with requirements recognised to be at least equivalent.

2. The conditions referred to in paragraph 1 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 relevant Union requirements or with requirements recognised to be at least equivalent;
  - (c) the requirement that consignments of certain animals and goods be accompanied by specific guarantees, including in the form of an official certificate, label, mark or other official attestation, or by any other evidence that the consignment complies with requirements established by Union legislation or with requirements recognised to be at least equivalent; the establishment of such conditions may be accompanied by the obligation to provide the guarantees or evidence required in accordance with a specific format;
  - (d) any other condition necessary to ensure that certain animals and goods offer a level of protection of human, animal and plant health and, as regards plant protection products, of the environment equivalent to the one ensured by the rules referred to in Article 1(2).
3. Where imperative grounds of urgency relating to human health and animal health or, as regards plant protection products, to the protection of the environment, so require, the procedure provided for in Article 137 shall apply to delegated acts adopted pursuant to paragraph 1.

#### *Article 122*

##### *Inclusion in the list of third countries referred to in Article 121(2)(a)*

1. The inclusion of a third country or region thereof in the list referred to in Article 121(2)(a) shall be made following the approval by the Commission, by means of implementing acts, of the request transmitted for that purpose by the third country concerned, accompanied by appropriate guarantees as regards compliance or equivalence with relevant Union legislation. Those implementing acts shall be adopted and updated in accordance with the examination procedure referred to in Article 138(2).
2. The Commission shall grant the approval referred to in paragraph 1 when the information and data available provide evidence that the animals or goods to be exported to the Union comply with the requirements established by Union legislation or with requirements at least equivalent thereto, 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 implementation of adequate official controls and other activities carried out to assess the presence of hazards for human, animal or plant health or for animal welfare;
- (d) the regularity and rapidity of information supplied by the third country on the presence of hazards for human, animal or plant health or for animal welfare;
- (e) the guarantees given by a third country that:
  - (i) conditions applied to the establishments from which animals or goods to be exported to the Union are equivalent to the requirements in Union law;
  - (ii) a list of the establishments referred to in (i) is drawn up and kept up to date;
  - (iii) the list of establishments referred to in (i) and its updated versions are communicated to the Commission without delay;
  - (iv) the establishments referred to in (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 the one afforded by the requirements laid down in the rules referred to in Article 1(2) enter into the Union.

#### *Article 123*

#### *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 247 of Regulation (EU) No XXX/XXXX [*on animal health law*] and in Articles 27(2) and 42(1) of Regulation (EU) No XXX/XXXX [*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, plant health or, as regards plant protection products, the environment, the Commission shall adopt, by means of implementing acts, the measures necessary to contain such risk. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 138(2).
2. The measures referred to in paragraph 1 may include:

- (a) the prohibition to allow the 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 the animals and goods referred to in paragraph 1 originating or dispatched from certain third countries or regions thereof, be accompanied by specific guarantees, including in the form of an official certificate, label, mark or attestation, or by any other evidence that the consignment complies with requirements established by relevant Union legislation or with requirements recognised to be at least equivalent; the establishment of such conditions may be accompanied by the obligation to provide the guarantees or evidence required in accordance with a specific format;
  - (e) 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 74;
  - (b) any other information that the third countries concerned have provided;
  - (c) where necessary, the results of Commission controls provided for in Article 115.
4. Where imperative grounds of urgency relating to human health and animal health or, as regards plant protection products, to the protection of the environment, so require, the procedure provided for in Article 138(3) shall apply to implementing acts adopted pursuant to paragraph 1.

*Article 124*  
*Equivalence*

1. The Commission may, by means of implementing acts, recognise that measures that a third country or regions thereof apply in one of the areas referred to in Article 1(2) offer guarantees equivalent to those applied in the Union, on the basis of:
- (a) a thorough examination of information and data provided by the third country concerned pursuant to Article 120;
  - (b) where appropriate, the satisfactory outcome of a control carried out in accordance with Article 115;

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 138(2).

2. The implementing acts referred to in paragraph 1 shall set out the conditions governing the entry of animals and goods into the Union from that third country or region.

Those conditions 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 carried out at entry;
  - (c) where necessary, procedures for drawing up and amending lists of regions or establishments in the third country 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 138(2).

#### *Article 125* *Support for developing countries*

1. The Commission shall be empowered to adopt delegated acts in accordance with the procedure referred to in Article 136 concerning support to developing countries in the form of:
  - (a) a phased introduction of the requirements provided for in Articles 120, 121 and 123 for goods exported to the Union. Progress in meeting these requirements shall be evaluated by the Commission and taken into account in determining the need for specified time-limited exemptions in whole or in part from the requirements. The phased introduction shall also take into account the progress in building the institutional capacity referred to in paragraph 2 of this Article;
  - (b) assistance with providing the information referred to in Article 120, if necessary by Commission experts;
  - (c) the promotion of joint projects between developing third countries and Member States;
  - (d) the assistance of experts provided by the Commission with the organisation of official controls.
2. In the context of the Union's development cooperation policy, the Commission shall promote support to developing third countries with the aim of strengthening their

institutional capacity to meet requirements equivalent to those laid down in this Regulation and to ensure compliance with the requirements laid down in the rules referred to in Article 1(2) and in this Regulation in relation to goods from third countries.

## **Chapter III**

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

#### *Article 126*

#### *Training and exchange of staff between Member States*

1. The Commission may organise training activities for the staff of the competent authorities of Member States.
2. Those training activities shall serve to develop a harmonised approach to official controls and other official activities in Member States. They may include training on:
  - (a) this Regulation and the rules referred to in Article 1(2);
  - (b) control methods and techniques, such as the auditing of systems that operators design to comply with rules referred to in Article 1(2);
  - (c) controls to be carried out on goods and animals from third countries;
  - (d) 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 in the training courses referred to in paragraph 1 is disseminated as necessary and appropriately used in the staff training activities referred to in Article 26.
5. The Commission may organise the training activities referred to in paragraph 1 in cooperation with Member States.
6. The Commission may organise in cooperation with the Member States programmes for the exchange of control staff between two or more Member States, to be implemented through the temporary secondment of staff tasked with control duties from one Member State to the other or through the exchange of such staff between the relevant competent authorities.

The Commission shall be empowered to adopt implementing acts concerning the training activities referred to in paragraph 1 and the organisation of the programmes referred to in the first subparagraph. Those acts shall be adopted in accordance with the examination procedure referred to in Article 138(2).

## **Chapter IV**

### **Information management systems**

#### *Article 127*

##### *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 (hereafter 'the IMSOC').
2. The information system referred to in paragraph 1 shall:
  - (a) integrate fully and provide the necessary updates to the TRACES system as established by Commission 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 for human, animal health and welfare, and plant health, as established by Article 50 of Regulation (EC) No 178/2002, Article 22 of Regulation (EU) XXX/XXXX [*on animal health law*] and Article 80 of Regulation (EU) XXX/XXXX [*on protective measures against pests of plants*]; provide appropriate linkages between the TRACES system and those systems to allow, as necessary, the efficient exchange and update of data between those systems.

#### *Article 128*

##### *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 recording 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 10 to 17 provide for the exchange among competent authorities, between the competent authorities and the Commission, and where appropriate with 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 official certificates and of the common health entry document referred to in Article 54.

### *Article 129*

#### *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 tasked with 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 controls carried out.

This paragraph shall not apply to goods subject to the rules referred to in Article 1(2)(g) and (h). The Commission shall be empowered to adopt delegated acts in accordance with the procedure laid down in Article 136 establishing when and the extent to which this paragraph shall apply to such goods.

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 allow the competent authorities of the place of dispatch and other competent authorities tasked with official controls to exchange in real time data, information and documents concerning such animals and goods and the result of controls carried out;
3. In case of animals or goods subject to the controls referred to in Title II, Chapter III, Section II, the IMSOC shall:
  - (a) enable the competent authorities at the border control posts and other competent authorities tasked with official controls on those animals or goods to exchange in real time data, information and documents concerning those animals and goods and on controls carried out 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 tasked with controls on animals or goods arriving from third countries, and with operators involved in entry procedures, in accordance with the rules adopted pursuant to Article 72(2) and with other relevant Union rules;
  - (c) support and operate the mechanisms referred to in Article 51(3)(a) and in Article 62(6).

### *Article 130*

#### *Empowerment for the adoption of rules for the functioning of the IMSOC*

1. The Commission shall be empowered to adopt delegated acts in accordance with the procedure laid down in Article 136 to establish:
  - (a) the technical specifications and the 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 and 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 and conditions under which exemptions to 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.

# **Title VII**

## **Enforcement action**

### **Chapter I**

#### **Action by the competent authorities and sanctions**

##### *Article 131*

###### *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 for human health, animal health and welfare and plant health.
2. In case of suspicion of non-compliance, the competent authorities shall carry out an investigation in order to confirm or to eliminate that suspicion.
3. Where necessary for its purposes, that investigation shall include:
  - (a) the performance of increased 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 132*

###### *Investigations and measures in case of established non-compliance*

1. Where the non-compliance is established, the competent authorities shall:
  - (a) carry out any further investigation necessary to determine the origin and the extent of the non-compliance and to establish the operators' 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 appropriate treatments on animals and goods, quarantine periods, the postponement of the slaughter of animals, the alteration of labels and/or corrective information to be provided to consumers, or any other action deemed necessary to ensure compliance with the rules referred to in Article 1(2);

- (b) 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;
  - (c) order that the operator increases the frequency of own controls;
  - (d) order the recall, withdrawal, removal and/or destruction of goods, authorising where appropriate, the use of the goods for purposes other than those for which they were originally intended;
  - (e) order the isolation or closure, for an appropriate period of time, of all or part of the business of the concerned operator, or its establishments, holdings or other premises;
  - (f) order the cessation for an appropriate period of time of all or part of the activities of the concerned operator and, where relevant, of the Internet sites it operates or employs;
  - (g) order the suspension or withdrawal of the approval of the establishment, plant or holding;
  - (h) order the slaughter or killing of animals provided that this is the most appropriate measure to safeguard human health and animal health and welfare;
  - (i) any other measure the competent authorities deem appropriate.
3. The competent authorities shall provide the operator concerned, or a representative, with:
- (a) written notification of its decision concerning the action or measure to be taken in accordance with paragraphs 1 and 2, together with the reasons for the 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 133*  
*Penalties*

1. Member States shall lay down the rules on sanctions applicable to infringements of the provisions of this Regulation and take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.
2. Member States shall ensure that financial penalties applicable to intentional infringements of the provisions of this Regulation and of the rules referred to in Article 1(2) offset the potential economic advantage sought through the infringement.

3. Member States shall ensure that appropriate 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 certification;
  - (c) fraudulent production or use of official certificates, official labels, marks and other official attestations.

## **Chapter II**

### **Union enforcement measures**

#### *Article 134*

#### *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 for human health, animal health, animal welfare, or plant health, either directly or through the environment, or result in a widespread infringement of the rules referred to in Article 1(2), it shall be empowered to adopt without delay, in accordance with the procedure in Article 138(2) one or more of the following measures, to be implemented 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 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 control system or the withdrawal of such border control posts or other control points;
  - (d) other appropriate temporary measures necessary to contain the risk referred to in paragraph 1 until the failure in the control system is eliminated.
2. Such measures 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. Where imperative grounds of urgency relating to human health and animal health or, as regards plant protection products, to the protection of the environment, so require, the procedure provided for in Article 138(3) shall apply to implementing acts adopted pursuant to paragraph 1.

# Title VIII

## Common provisions

### Chapter I

#### Procedural provisions

##### *Article 135*

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

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 136 concerning amendments to Annexes II and III to this Regulation, in order to take into account administrative changes, technical progress and scientific developments.
2. In order to keep the references to the European standards referred to in Articles 19(1)(c), 35(2)(c)(v) and 89(2) up-to-date, the Commission may, by means of implementing acts, amend those references in the event that CEN amends them.

##### *Article 136*

##### *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 *[list Articles]* 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 *[list Articles]* 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 *[list Articles]* shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 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 2 months at the initiative of the European Parliament or the Council.

*Article 137*  
*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 136(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 138*  
*Committee*

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed instituted 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, Articles 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 decide or 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 139*  
*Repeals*

1. Regulation (EC) No 882/2004, and Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC, 97/78/EC, and Council Decision 92/438/EEC are repealed as from [*the date of application*].
2. References to the repealed acts shall be construed as references to this Regulation and shall be read in accordance to the correlation table in Annex IV.

#### *Article 140*

##### *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 group 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 136 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 11 and 121 of this Regulation.

#### *Article 141*

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

1. Directives 91/496/EEC and 97/78/EC 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 136 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 44(2), 45, points (b), (c) and (d) of Article 48(1), 50(1)(a), 51(1) and (3), 55(1)(a) of this Regulation.

#### *Article 142*

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

Article 21 of 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 is deleted.

#### *Article 143*

##### *Amendments to Regulation (EC) No 178/2002*

Regulation (EC) No 178/2002 is amended as follows:

1. In Article 58 paragraph 1 is replaced by the following:
  - '1. The Commission shall be assisted by a Standing Committee on Plants, Animals, Food and Feed, hereinafter referred to as the 'Committee', composed of representatives of the Member States and chaired by the representative of

the Commission. The Committee shall be organised in sections to deal with all relevant matters.'

2. In Article 62, paragraph 2 s replaced by the following:

'Every reference in Union legislation to the Standing Committee on Foodstuffs, the Standing Committee for Feedingstuffs, the Standing Veterinary Committee, the Standing Committee on Plant Health in Community legislation based upon and including Directives 76/895/EEC, 86/362/EEC, 86/363/EEC, 90/642/EEC and 91/414/EEC relating to plant protection products and the setting of maximum residue levels, and the Standing Committee on the Food Chain and the Animal Health shall be replaced by a reference to the Standing Committee on Plants, Animals, Food and Feed.'

*Article 144*  
*Amendments to Regulation (EC) No 1069/2009*

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

1. Article 3 is amended as follows:

(a) points 10 and 15 are deleted;

(b) the following second subparagraph is added:

'The definition of 'competent authorities' and 'transit' laid down in points 3 and 45 of Article of Regulation (EU) No XXX/XXXX [*this Regulation*] shall also apply'.

2. Articles 45, 49 and 50 are deleted.

*Article 145*  
*Amendments to Regulation (EC) No 183/2005*

Article 3 of Regulation (EC) No 183/2005 is amended as follows:

1. point (e) is deleted;

2. the following point (g) is added:

'(g) '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.'

3. the following second subparagraph is added:

'The definition of 'competent authorities' laid down in point (3) of Article 2 of Regulation (EU) No XXX/XXXX [*this Regulation*] shall also apply'.

#### *Article 146*

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

1. Articles 26, 27 and 30 of Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC are deleted.
2. In Article 28, paragraphs 1 and 2 are deleted.
3. The first subparagraph 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 and the Authority and the Member States by 30 June each year:'
4. 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 4.
5. The Commission shall be empowered to adopt delegated acts in accordance to Article 136 concerning the date on which Articles 26, 27(1) and 30 referred to in paragraph 3 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 11 of this Regulation.

#### *Article 147*

##### *Amendments to Directive 98/58/EC*

1. Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes 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 (3) of Article 2 of Regulation (EU) No XXX/XXXX [*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 Standing Veterinary Committee.'

(iii) point (a) of paragraph 3 is deleted.

(c) Article 7 is deleted.

*Article 148*  
*Amendments to Council Directive 1999/74/EC*

1. Council Directive 1999/74/EC of 19 July 1999 laying down minimum standards for the protection of laying hens 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 Standing Veterinary Committee.'

(iii) point (a) of paragraph 3 is deleted.

(b) Article 9 is deleted.

*Article 149*  
*Amendments to Council Directive 2008/120/EC and related transitional measures*

1. Council Directive 2008/120/EC of 18 December 2008 laying down minimum standards for the protection of pigs 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 (3) of Article 2 of Regulation (EU) No XXX/XXXX [*this Regulation*] shall also apply'.

- (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 Standing Veterinary Committee.'

- (c) Article 10 is deleted.
2. Article 8(1) of Directive 2008/120/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 136 concerning the date on which Article 8(1) 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 13 of this Regulation.

#### *Article 150*

#### *Amendments to Council Directive 2008/119/EC and related transitional measures*

1. Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves 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 (3) of Article 2 of Regulation (EU) No XXX/XXXX [*this Regulation*] shall also apply'.
  - (b) Article 7 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 Standing Veterinary Committee.'

- (c) Article 9 is deleted.
- 2. Article 7(1) of Directive 2008/119/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 136 concerning the date on which Article 8(1) 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 13 of this Regulation.

#### *Article 151*

#### *Amendments to Council Directive 2007/43/EC and related transitional measures*

- 1. Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production 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 (3) and (31) of Article 2 of Regulation (EU) No XXX/XXXX [*this Regulation*] shall also apply'.
  - (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 Standing Veterinary Committee.'
- 2. Article 7(1) of Directive 2007/43/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 136 concerning the date on which Article 7(1) 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 13 of this Regulation.

*Article 152*  
*Amendments to Council Regulation (EC) No 1099/2009 and*  
*related transitional measures*

1. Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing is amended as follows:
  - (a) Article 2 is amended as follows:
    - (i) in the first paragraph:
      - point (q) is deleted;
      - the following second subparagraph is added:

'In addition to definitions referred to in the first subparagraph, the definition of 'competent authorities' laid down in point (3) of Article 2 of Regulation (EU) No XXX/XXXX [*this Regulation*] shall also apply'.
    - (b) Article 22 is deleted.
2. Article 22 of Regulation (EC) No 1099/2009 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 136 concerning the date on which Article 22 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 13 of this Regulation.

*Article 153*  
*Amendments to Council Regulation (EC) No 1/2005 and*  
*related transitional measures*

1. Regulation (EC) No 1/2005 is amended as follows:
  - (a) Article 2 is amended as follows:
    - (i) in the first paragraph:
      - points (d), (f), (i) and (p) are deleted;
      - the following second subparagraph is added:

'The definitions of 'competent authorities', 'official veterinarian', 'border control post' and 'exit point' laid down in points (3), (31), (29) and (33) of Article 2 of Regulation (EU) No XXX/XXXX [*this Regulation*] shall also apply'.

(b) Articles 14, 15, 16, 21, 23, 24, 26 and 28 are deleted.

(c) In Article 22, paragraph 2 is deleted.

(d) 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.'

2. Articles 14, 15, 16, 21, 22(2), 23, 24, 26 and 27(1) of Regulation (EC) No 1/2005 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 136 concerning the date on which Articles 14, 15, 16, 21, 22(2), 23, 24, 26 and 27(1) 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 13 of this Regulation.

#### *Article 154*

#### *Amendments to Regulation (EC) No 1107/2009*

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 is amended as follows:

(a) Recital 46 is deleted;

(b) Article 68 is amended as follows:

(i) paragraph 1 is replaced by the following:

'Member States shall finalise and transmit to the Commission a report on the scope and the results of the official controls carried out in order to verify compliance with this Regulation by 30 June each year';

(ii) paragraph 2 and 3 are deleted.

*Article 155*  
*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, paragraphs 3, 4, 6 and 7 are deleted.
  - (b) Annex II is deleted.
2. Article 8(1), second subparagraph of paragraph 2, (3), (4) and (6) 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 136 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 16 of this Regulation.

*Article 156*  
*Entry into force*

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

It shall apply [*Office of Publications please insert date counting 36 months from the entry into force*], with the following exceptions:

- (a) Article 32(1) and (2) shall apply from [*entry into force + 5 years*] as regards official controls and other official activities performed for the implementation of the rules referred to in Article 1(2)(g) and (h);
- (b) Article 35(2)(c)(v) and (3) shall apply from [*entry into force + 5 years*] as regards official controls and other official activities performed for the implementation of the rules referred to in Article 1(2)(g);
- (c) Articles 76, 77, 78, 79, 80 and 81 shall apply from [*entry into force + 3 years*]; prior to this date Articles 27 and 29, and Annexes IV and V to Regulation (EC) No 882/2004 shall continue to apply.

...

## ANNEX I

### TERRITORIES REFERRED TO IN POINT (t) 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 the Republic 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 Article 1(2)(f), the territories listed in Annex I to Regulation (EU) No XXX/XXXX *[on protective measures against pests of plants]* shall be considered not to belong to the territories of the Union.

## **ANNEX II**

### **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 for human health, and where appropriate for the health of animals and plants, for the welfare of animals, for the environment, and for the 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 conditions for entry into the Union of animals and goods arriving from third countries.
14. Any other area necessary to ensure that official controls are carried out 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 carry out official controls or other official activities
2. The relationship between competent authorities and delegated bodies 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, diagnosis and test, 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 or departments that may have relevant responsibilities
10. Verification of the appropriateness of methods of sampling, analysis and test
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 should be characterised by the following criteria:
  - (a) accuracy;
  - (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 the IUPAC International Harmonised Protocol) 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' or IUPAC). 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 e.g. IUPAC Harmonised 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 89(2)**

1. Regulation (EC) No 882/2004

Regulation (EC) No 882/2004	This Regulation
Article 1	Article 1
Article 2	Article 2
Article 3	Article 6
Article 4	Articles 3 and 4
Article 5	Article 8
Article 6	Article 10
Article 7	Articles 5 and 11
Article 8	Article 12
Article 9	Article 13
Article 10	Article 14

2. Directive 96/23/EC

Directive 96/23/EC	This Regulation

3. Directives 89/662/EEC and 90/425/EC

Directive 89/662/EEC	This Regulation
Directive 90/425/EC	This Regulation

4. Directives 97/78/EC and 91/496

Directive 97/78/EC	This Regulation
Article 1	-
Article 2	Article 2 (some definitions no longer needed)
Article 3	Articles 23 and 29
Article 4	Articles 25 and 27
Article 5	Article 29
Article 6	Articles 30, 31 and 32
Article 7	Articles 25 and 29
Article 8	Article 41 (para 1 no longer relevant, substituted by CHED)
Article 9	Article 25
Article 10	Article 27(3) (Article 77 for para 3?)
Article 11	Article 25
Article 12	Articles 24 and 41
Article 13	Article 41
Article 14	- (TAXUD to confirm)
Article 15	Article 41
Article 16	Articles 24 and 41
Article 17	Articles 33, 34, 36 and 38 (costs)
Article 18	Article 32
Article 19	Articles 32 and 41
Article 20	Article 33

Article 22	Articles 35 and 36 (correspond to para of Article 21 - Safeguard measures remain outside)
Article 24	Article 33 (Article 77 for para 3?)
Article 25	Articles 4, 58, 59, 60, 61, 62, 63 and 64
Article 26	Article 79
Article 27	Article 79
Article 28	-
Article 29	-
Article 30	-
Article 31	-
Article 32	-
Article 33	-
Article 34	-
Article 35	-
Article 36	-
Annex I	Annex I
Annex II	Article 32
Annex III	Article 25
Directive 91/496	This Regulation
Article 1	-
Article 2	Article 2
Article 3	Articles 23, 29 and 34 (costs issues)
Article 4	Articles 23, 25 and 32 (costs issues)
Article 5	Article 25
Article 6	Articles 30 and 32
Article 7	Articles 21, 22, 25, 29 and 80
Article 8	Articles
Article 9	Article 25
Article 10	Article 34
Article 11	Article 33

Article 12	Article 34, 36 and 38 (costs issues)
Article 13	Article 32
Article 14	-
Article 15	Article 43
Article 16	Articles 27
Article 17	Article 4
Article 17a	-
Article 18	Articles 35 and 36 (correspond to paras 2 and 3 of Article 18 - Safeguard measures remain outside)
Article 19	Article 71
Article 20	Articles 58, 59, 60, 61, 62, 63 and 64
Article 21	Article 79
Article 22	-
Article 23	-
Article 24	-
Article 25	-
Article 26	-
Article 27	-
Article 28	-
Article 29	-
Article 30	-
Article 31	-
Annex A	Article 32
Annex B	Article 34

5. Directive 96/93/EC

Directive 96/93/EC	This Regulation

6. Directive 89/608/EC

Directive 89/608/EC	This Regulation