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performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (repealed)

[X1REGULATION (EC) No 882/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 29 April 2004

on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules] (repealed)

[X1THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37, 95 and 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee(1),

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

Acting in accordance with the procedure laid down in Article 251 of the Treaty(3),

Whereas:

(1) Feed and food should be safe and wholesome. Community legislation comprises a set of rules to ensure that this objective is attained. These rules extend to the production and the placing on the market of both feed and food.

(2) The basic rules with regard to feed and food law are laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(4).

(3) In addition to those basic rules, more specific feed and food law covers different areas such as animal nutrition including medicated feedingstuffs, feed and food hygiene, zoonoses, animal by-products, residues and contaminants, control and eradication of animal diseases with a public health impact, feed and food labelling, pesticides, feed and food additives, vitamins, mineral salts, trace elements and other additives, materials in contact with food, quality and compositional requirements, drinking water, ionisation, novel foods and genetically modified organisms (GMOs).

(4) Community feed and food law is based on the principle that feed and food business operators at all stages of production, processing and distribution within the businesses under their control are responsible for ensuring that feed and food satisfy the requirements of feed and food law which are relevant to their activities.

(5) Animal health and animal welfare are important factors that contribute to the quality and safety of food, to the prevention of the spreading of animal diseases and to a humane

treatment of animals. The rules covering these matters are laid down in several acts. These acts specify the obligations of natural and legal persons with regard to animal health and animal welfare as well as the duties of the competent authorities.

(6) The Member States should enforce feed and food law, animal heath and animal welfare rules and monitor and verify that the relevant requirements thereof are fulfilled by business operators at all stages of production, processing and distribution. Official controls should be organised for that purpose.

(7) It is therefore appropriate to establish at Community level a harmonised framework of general rules for the organisation of such controls. It is appropriate to assess in the light of experience whether such a general framework functions properly, in particular in the area of animal health and welfare. It is therefore appropriate for the Commission to present a report together with any necessary proposal.

(8) As a general rule this Community framework should not include official controls with regard to organisms harmful to plants and plant products since these controls are already adequately covered by Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community[(5)]. Certain aspects of this Regulation should however also apply to the plant health sector and in particular those concerning the establishment of multiannual national control plans and Community inspections within the Member States and in third countries. It is therefore appropriate to amend Directive 2000/29/EC accordingly.

(9) Council Regulations (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs[(6)], (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs[(7)], and (EEC) No 2082/92 of 14 July 1992 on certificates of specific character for agricultural products and foodstuffs[(8)] contain specific measures for the verification of compliance with the requirements contained therein. The requirements of this Regulation should be flexible enough so as to take account of the specificity of these areas.

(10) For the verification of compliance with the rules on the common organisation of the markets of agricultural products (arable crops, wine, olive oil, fruit and vegetables, hops, milk and milk products, beef and veal, sheepmeat and goatmeat and honey) a well established and specific control system is already in place. This Regulation should therefore not apply to these areas, all the more since the objectives of this Regulation differ from the objectives pursued by the control mechanisms for the common organisation of the markets of agricultural products.

(11) The competent authorities for performing official controls should meet a number of operational criteria so as to ensure their impartiality and effectiveness. They should have a sufficient number of suitably qualified and experienced staff and possess adequate facilities and equipment to carry out their duties properly.

(12) The official controls should be carried out using appropriate techniques developed for that purpose, including routine surveillance checks and more intensive controls

such as inspections, verifications, audits, sampling and the testing of samples. The correct implementation of those techniques requires appropriate training of the staff performing official controls. Training is also required in order to ensure that the competent authorities take decisions in a uniform way, in particular with regard to the implementation of the hazard analysis and critical control points (HACCP) principles.

(13) The frequency of official controls should be regular and proportionate to the risk, taking into account the results of the checks carried out by feed and food business operators under HACCP based control programmes or quality assurance programmes, where such programmes are designed to meet requirements of feed and food law, animal health and animal welfare rules. Ad hoc controls should be carried out in case of suspicion of non-compliance. Additionally ad hoc controls could be carried out at any time, even where there is no suspicion of non-compliance.

(14) Official controls should take place on the basis of documented procedures so as to ensure that these controls are carried out uniformly and are of a consistently high quality.

(15) The competent authorities should ensure that where different control units are involved in carrying out official controls, appropriate coordination procedures are in place and effectively implemented.

(16) The competent authorities should also ensure that, where the competence to carry out official controls has been delegated from the central level to a regional or local level, there is effective and efficient coordination between the central level and that regional or local level.

(17) Laboratories involved in the analysis of official samples should work in accordance with internationally approved procedures or criteria-based performance standards and use methods of analysis that have, as far as possible, been validated. Such laboratories should in particular have equipment that enables the correct determination of standards such as maximum residue levels fixed by Community law.

(18) The designation of Community and national reference laboratories should contribute to a high quality and uniformity of analytical results. This objective can be achieved by activities such as the application of validated analytical methods, ensuring that reference materials are available, the organisation of comparative testing and the training of staff from laboratories.

(19) The activities of reference laboratories should cover all the areas of feed and food law and animal health, in particular those areas where there is a need for precise analytical and diagnostic results.

(20) For a number of activities related to official controls, the European Committee for Standardisation (CEN) has developed European standards (EN standards) appropriate for the purpose of this Regulation. These EN standards relate in particular to the operation and assessment of testing laboratories and to the operation and accreditation of control bodies. International standards have also been drawn up by the International Organisation for Standardisation (ISO) and the International Union of Pure and Applied Chemistry (IUPAC). These standards might, in certain well defined cases, be appropriate for the purposes of this Regulation, taking into account that performance

criteria are laid down in feed and food law in order to ensure flexibility and cost effectiveness.

(21) Provision should be made for delegating competence for performing specific control tasks from the competent authority to a control body, and for the conditions under which such delegation can take place.

(22) Appropriate procedures should be available for the cooperation of the competent authorities in and between the Member States, in particular when official controls reveal that feed and food problems extend to more than one Member State. In order to facilitate such cooperation, Member States should designate one or more liaison bodies with the role of coordinating the transmission and reception of requests for assistance.

(23) In accordance with Article 50 of Regulation (EC) No 178/2002, the Member States shall inform the Commission where information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed is available.

(24) It is important to create uniform procedures for the control of feed and food from third countries introduced into the territory of the Community, taking into account that harmonised import procedures have already been established for food of animal origin by virtue of Council Directive 97/78/EC[(9)], and for live animals by virtue of Council Directive 91/496/EEC[(10)].
These existing procedures function properly and should be maintained.

(25) The checks on feed and food from third countries referred to in Directive 97/78/EC are limited to veterinary aspects. It is necessary to supplement these checks with official controls on aspects that are not covered by veterinary checks, such as those on additives, labelling, traceability, irradiation of food and materials in contact with food.

(26) Community legislation also provides for procedures for the control of imported feed by virtue of Council Directive 95/53/EC of 25 October 1995 fixing the principles governing the organisation of official inspections in the field of animal nutrition[(11)]. That Directive contains principles and procedures that must be applied by the Member States when releasing imported feed for free circulation.

(27) It is appropriate to establish Community rules in order to ensure that feed and food from third countries is submitted to official controls before release for free circulation in the Community. Special attention should be paid to import controls of feed and food for which there may be an increased risk of contamination.

(28) Provision should also be made for the organisation of official controls of feed and food that is introduced into the territory of the Community under customs procedures other than free circulation, and in particular those introduced under the customs procedures referred to in points (b) to (f) of Article 4(16) of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code[(12)], as well as their entry into a free zone or free warehouse. This includes the introduction of feed and food from third countries by passengers of international means of transport and through parcels sent by mail.

(29) For the purpose of official controls on feed and food, it is necessary to define the territory of the Community in which the rules apply in order to ensure that feed and food that is introduced into this territory is submitted to the controls laid down by this Regulation. This territory is not necessarily the same as provided for in Article 299 of the Treaty, or as defined in Article 3 of Regulation (EEC) No 2913/92.

(30) In order to ensure a more efficient organisation of the official controls on feed and food from third countries and in order to facilitate commercial flows, it may be necessary to designate specific points of entry for feed and food from third countries into the territory of the Community. Likewise, it may be necessary to require prior notification of the arrival of goods at the territory of the Community. It should be ensured that each designated point of entry has access to the appropriate facilities to operate controls within reasonable time limits.

(31) In establishing rules on the official controls of feed and food from third countries, it should be ensured that the competent authorities and the customs services work together, taking into account the fact that rules to that effect already exist in Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries[(13)].

(32) Adequate financial resources should be available for organising official controls. Hence, the competent authorities of the Member States should be able to levy the fees or charges to cover the costs incurred through official controls. In the process, the competent authorities of the Member States will be at liberty to establish the fees and charges as flat-rate amounts based on the costs incurred and taking the specific situation of the establishments into account. Where fees are imposed on operators, common principles should apply. It is appropriate therefore to lay down the criteria for setting the level of inspection fees. With regard to fees applicable for import controls, it is appropriate to establish directly the rates for main import items with a view to ensuring their uniform application and to avoiding trade distortions.

(33) Community feed and food law provides for the registration or approval of certain feed and food businesses by the competent authority. This is particularly the case in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[(14)], 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[(14)], Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector[(15)] and the future regulation on feed hygiene.
Procedures should be put in place in order to ensure that registration and approval of feed and food businesses are carried out in an effective and transparent way.

(34) In order to have a global and uniform approach with regard to official controls, Member States should establish and implement multiannual national control plans in accordance with broad guidelines drawn up at Community level. These guidelines should promote coherent national strategies, and identify risk-based priorities and the most effective control procedures. A Community strategy should take a comprehensive, integrated

approach to the operation of controls. In view of the non-binding character of certain technical guidelines to be established it is appropriate to establish them by means of a consultative Committee procedure.

(35) The multiannual national control plans should cover feed and food law, and the legislation on animal health and animal welfare.

(36) The multiannual national control plans should establish a solid basis for the Commission inspection services to carry out controls in the Member States. The control plans should enable the Commission inspection services to verify whether the official controls in the Member States are organised in accordance with the criteria laid down in this Regulation. Where appropriate and, in particular, where the audit of the Member States against the multiannual national control plans shows weaknesses or failures, detailed inspections and audits should be carried out.

(37) Member States should be required to present an annual report to the Commission with information on the implementation of the multiannual national control plans. This report should provide the results of the official controls and audits carried out during the previous year and, where necessary, an update of the initial control plan in response to these results.

(38) Community controls in the Member States should allow the Commission control services to verify whether feed and food law and the legislation on animal health and animal welfare are implemented in a uniform and correct way throughout the Community.

(39) Community controls in third countries are required in order to verify compliance or equivalence with Community feed and food law as well as with the legislation on animal health and, where appropriate, welfare. Third countries may also be requested to provide information on their control systems. This information, which should be established on the basis of Community guidelines, should form the basis for subsequent Commission controls, which should be carried out within a multidisciplinary framework covering the main sectors exporting to the Community. This evolution should allow a simplification of the current regime, enhance effective control cooperation, and consequently facilitate trade flows.

(40) In order to ensure that imported goods comply with or are equivalent to Community feed and food law, it is necessary to establish procedures that allow the definition of import conditions and certification requirements as appropriate.

(41) Breaches of feed and food law and of animal health and animal welfare rules may constitute a threat to human health, animal health, and animal welfare. Such breaches should therefore be subject to effective, dissuasive and proportionate measures at national level throughout the Community.

(42) Such measures should include administrative action by the competent authorities in the Member States who should have procedures in place for that purpose. The advantage of such procedures is that quick action can be undertaken in order to restore the situation.

(43) Operators should have a right to appeal against the decisions taken by the competent authority as a result of the official controls, and be informed of such a right.

(44) It is appropriate to take account of the special needs of developing countries, and in particular of the least-developed countries, and to introduce measures to that effect. The Commission should be committed to support developing countries with regard to feed and food safety, which is an important element of human health and trade development. Such support should be organised in the context of the Community's development cooperation policy.

(45) The rules contained in this Regulation underpin the integrated and horizontal approach necessary to implement a coherent control policy on feed and food safety, animal health and animal welfare. There should be room however to develop specific control rules where required, for example with regard to the setting of maximum residue levels for certain contaminants at Community level. Likewise, more specific rules existing in the area of feed and food and animal health and animal welfare controls should be kept in place.
These include in particular the following acts: Directive 96/22/EC Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in[16], Directive 96/23/EC[17], Regulation (EC) No 854/2004[18], Regulation (EC) No 999/2001[19], Regulation (EC) No 2160/2003[20], Directive 86/362/EEC[21], Directive 90/642/EEC[22] and the implementing rules resulting therefrom, Directive 92/1/EEC[23], Directive 92/2/EEC[24], and acts on the control of animal diseases such as foot-and-mouth disease, swine fever etc., as well as requirements on the official controls on the welfare of animals.

(46) This Regulation covers areas that are already covered in certain acts in force at present. It is appropriate therefore to repeal in particular the following acts on feed and food controls and to replace them by the rules of this Regulation: Directive 70/373/EEC[25]; Directive 85/591/EEC[26]; Directive 89/397/EEC[27]; Directive 93/99/EEC[28]; Decision 93/383/EEC[29]; Directive 95/53/EC; Directive 96/43/EC[30]; Decision 98/728/EC[31]; and Decision 1999/313/EC[32].

(47) In the light of this Regulation, Directives 96/23/EC, 97/78/EC and 2000/29/EC should be amended.

(48) Since the objective of this Regulation, namely to ensure a harmonised approach with regard to official controls, cannot be sufficiently achieved by the Member States and can therefore, by reason of its complexity, its trans-border character and, with regard to feed and food imports, its international character, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(49) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[33],

HAVE ADOPTED THIS REGULATION:

Editorial Information

X1 Substituted by Corrigendum to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (Official Journal of the European Union L 165 of 30 April 2004).

TITLE I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1 This Regulation lays down general rules for the performance of official controls to verify compliance with rules aiming, in particular, at:

a preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment;

and

b guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information.

2 This Regulation shall not apply to official controls for the verification of compliance with the rules on common market organisations of agricultural products.

3 This Regulation shall be without prejudice to specific Community provisions concerning official controls.

4 The performance of official controls pursuant to this Regulation shall be without prejudice to feed and food business operators' primary legal responsibility for ensuring feed and food safety, as laid down in Regulation (EC) No 178/2002, and any civil or criminal liability arising from the breach of their obligations.

Article 2

Definitions

For the purposes of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 shall apply.

The following definitions shall also apply:

1. ‘official control’ means any form of control that the competent authority or the Community performs for the verification of compliance with feed and food law, animal health and animal welfare rules;

2. ‘verification’ means checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled;

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

4. ‘competent authority’ means the central authority of a Member State competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country;

5. ‘control body’ means an independent third party to which the competent authority has delegated certain control tasks;

6. ‘audit’ means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives;

7. ‘inspection’ means the examination of any aspect of feed, food, animal health and animal welfare in order to verify that such aspect(s) comply with the legal requirements of feed and food law and animal health and animal welfare rules;

8. ‘monitoring’ means conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with feed or food law, animal health and animal welfare rules;

9. ‘surveillance’ means a careful observation of one or more feed or food businesses, feed or food business operators or their activities;

10. ‘non-compliance’ means non-compliance with feed or food law, and with the rules for the protection of animal health and welfare;

11. ‘sampling for analysis’ means taking feed or food or any other substance (including from the environment) relevant to the production, processing and distribution of feed or food or to the health of animals, in order to verify through analysis compliance with feed or food law or animal health rules;

12. ‘official certification’ means the procedure by which the competent authority or control bodies, authorised to act in such a capacity, provide written, electronic or equivalent assurance concerning compliance;

13. ‘official detention’ means the procedure by which the competent authority ensures that feed or food is not moved or tampered with pending a decision on its destination; it includes storage by feed and food business operators in accordance with instructions from the competent authority;

14. ‘equivalence’ means the capability of different systems or measures to meet the same objectives; and ‘equivalent’ means different systems or measures capable of meeting the same objectives;

15. ‘import’ means the release for free circulation of feed or food or the intention to release feed or food for free circulation within the meaning of Article 79 of Regulation (EEC) No 2913/92 in one of the territories referred to in Annex I;

16. ‘introduction’ means import as defined in point 15 above, and the placing of goods under the customs procedures referred to in points (b) to (f) of Article 4(16) of Regulation (EEC) No 2913/92, as well as their entry into a free zone or free warehouse;

17. ‘documentary check’ means the examination of commercial documents and, where appropriate, of documents required under feed or food law that are accompanying the consignment;

18. ‘identity check’ means a visual inspection to ensure that certificates or other documents accompanying the consignment tally with the labelling and the content of the consignment;

19. ‘physical check’ means a check on the feed or food itself which may include checks on the means of transport, on the packaging, labelling and temperature, the sampling for analysis and laboratory testing and any other check necessary to verify compliance with feed or food law;

20. ‘control plan’ means a description established by the competent authority containing general information on the structure and organisation of its official control systems.

TITLE II

OFFICIAL CONTROLS BY MEMBER STATES

CHAPTER I

GENERAL OBLIGATIONS

Article 3

General obligations with regard to the organisation of official controls

1 Member States shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of this Regulation taking account of:

a identified risks associated with animals, feed or food, feed or food businesses, the use of feed or food or any process, material, substance, activity or operation that may influence feed or food safety, animal health or animal welfare;

b feed or food business operators' past record as regards compliance with feed or food law or with animal health and animal welfare rules;

c the reliability of any own checks that have already been carried out;

and

d any information that might indicate non-compliance.

2 Official controls shall be carried out without prior warning, except in cases such as audits where prior notification of the feed or food business operator is necessary. Official controls may also be carried out on an ad hoc basis.

3 Official controls shall be carried out at any of the stages of production, processing and distribution of feed or food and of animals and animal products. They shall include controls on feed and food businesses, on the use of feed and food, on the storage of feed and food, on any process, material, substance, activity or operation including transport applied to feed or food and on live animals, required to achieve the objectives of this Regulation.

4 Official controls shall be applied, with the same care, to exports outside the Community, to the placing on the market within the Community and to introductions from third countries into the territories referred to in Annex I.

5 Member States shall take all necessary measures to ensure that products intended for dispatch to another Member State are controlled with the same care as those intended to be placed on the market in their own territory.

6 The competent authority of the Member State of destination may check compliance of feed and food with feed and food law by means of non-discriminatory checks. To the extent strictly necessary for the organisation of the official controls, Member States may ask operators who have goods delivered to them from another Member State to report the arrival of such goods.

7 If, during a check carried out at the place of destination or during storage or transport, a Member State establishes non-compliance, it shall take the appropriate measures, which may include re-dispatch to the Member State of origin.

CHAPTER II

COMPETENT AUTHORITIES

Article 4

Designation of competent authorities and operational criteria

1 Member States shall designate the competent authorities responsible for the purposes and official controls set out in this Regulation.

2 The competent authorities shall ensure:

a the effectiveness and appropriateness of official controls on live animals, feed and food at all stages of production, processing and distribution, and on the use of feed;

b that staff carrying out official controls are free from any conflict of interest;

c that they have, or have access to, an adequate laboratory capacity for testing and a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively;

d that they have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls efficiently and effectively;

e that they have the legal powers to carry out official controls and to take the measures provided for in this Regulation;

f that they have contingency plans in place, and are prepared to operate such plans in the event of an emergency;

g that the feed and food business operators are obliged to undergo any inspection carried out in accordance with this Regulation and to assist staff of the competent authority in the accomplishment of their tasks.

3 When a Member State confers the competence to carry out official controls on an authority or authorities other than a central competent authority, in particular those at regional or local level, efficient and effective coordination shall be ensured between all the competent authorities involved, including where appropriate in the field of environmental and health protection.

4 Competent authorities shall ensure the impartiality, quality and consistency of official controls at all levels. The criteria listed in paragraph 2 must be fully respected by every authority on which the competence to carry out official controls is conferred.

5 When, within a competent authority, more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

6 Competent authorities shall carry out internal audits or may have external audits carried out, and shall take appropriate measures in the light of their results, to ensure that they are achieving the objectives of this Regulation. These audits shall be subject to independent scrutiny and shall be carried out in a transparent manner.

7 Detailed rules for the implementation of this Article may be adopted in accordance with the procedure referred to in Article 62(3).

Article 5

Delegation of specific tasks related to official controls

1 The competent authority may delegate specific tasks related to official controls to one or more control bodies in accordance with paragraphs 2 to 4.

A list of tasks that may or may not be delegated may be established in accordance with the procedure referred to in Article 62(3).

However, the activities referred to in Article 54 shall not be the subject of such a delegation.

2 The competent authority may delegate specific tasks to a particular control body only if:

a there is an accurate description of the tasks that the control body may carry out and of the conditions under which it may carry them out;

b there is proof that the control body:

(i) has the expertise, equipment and infrastructure required to carry out the 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 tasks delegated to it;

c the control body works and is accredited in accordance with European Standard EN 45004 ‘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 laboratories operate in accordance with the standards referred to in Article 12(2);

e the control body communicates the results of the controls carried out to the competent authority on a regular basis and whenever the competent authority so requests. If the results of the controls indicate non-compliance or point to the likelihood of non-compliance, the control body shall immediately inform the competent authority;

f there is efficient and effective coordination between the delegating competent authority and the control body.

3 Competent authorities delegating specific tasks to control bodies shall organise audits or inspections of control bodies as necessary. If, as a result of an audit or an inspection, it appears that such bodies are failing to carry out properly the tasks delegated to them, the delegating competent authority may withdraw the delegation. It shall withdraw it without delay if the control body fails to take appropriate and timely remedial action.

4 Any Member State wishing to delegate a specific control task to a control body shall notify the Commission. This notification shall provide a detailed description of:

a the competent authority that would delegate the task;

b the task that it would delegate;

and

c the control body to which it would delegate the task.

Article 6

Staff performing official controls

The competent authority shall ensure that all of its staff performing official controls:

(a) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner. This training shall cover as appropriate the areas referred to in Annex II, Chapter I;

(b) keep up to date in their area of competence and receive regular additional training as necessary;

and

(c) have aptitude for multidisciplinary cooperation.

Article 7

Transparency and confidentiality

1 The competent authorities shall ensure that they carry out their activities with a high level of transparency. For that purpose, relevant information held by them shall be made available to the public as soon as possible.

In general, the public shall have access to:

a information on the control activities of the competent authorities and their effectiveness;

and

b information pursuant to Article 10 of Regulation (EC) No 178/2002.

2 The competent authority shall take steps to ensure that members of their staff are required not to disclose information acquired when undertaking their official control duties which by its nature is covered by professional secrecy in duly justified cases. Protection of professional secrecy shall not prevent the dissemination by the competent authorities of information referred to in paragraph 1(b). The rules of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[(34)] remain unaffected.

3 Information covered by professional secrecy includes in particular:

— the confidentiality of preliminary investigation proceedings or of current legal proceedings,
— personal data,
— the documents covered by an exception in Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents[35],
— information protected by national and Community legislation concerning in particular professional secrecy, the confidentiality of deliberations, international relations and national defence.

Article 8

Control and verification procedures

1 Competent authorities shall carry out official controls in accordance with documented procedures. These procedures shall contain information and instructions for staff performing official controls including, *inter alia*, the areas referred to in Annex II, Chapter II.

2 Member States shall ensure that they have legal procedures in place in order to ensure that staff of the competent authorities have access to premises of and documentation kept by feed and food business operators so as to be able to accomplish their tasks properly.

3 Competent authorities shall have procedures in place:

a to verify the effectiveness of official controls that they carry out;

and

b to ensure that corrective action is taken when needed and that the documentation referred to in paragraph 1 is updated as appropriate.

4 The Commission may establish guidelines for official controls in accordance with the procedure referred to in Article 62(2).

The guidelines may, in particular, contain recommendations concerning official controls on:

a the implementation of HACCP principles;
b management systems that feed or food business operators operate with a view to meeting the requirements of feed or food law;
c the microbiological, physical and chemical safety of feed and food.

Article 9

Reports

1 The competent authority shall draw up reports on the official controls that it has carried out.

2 These reports shall include a description of the purpose of the official controls, the control methods applied, the results of the official controls and, where appropriate, action that the business operator concerned is to take.

3 The competent authority shall provide the business operator concerned with a copy of the report referred to in paragraph 2, at least in case of non-compliance.

Article 10

Control activities, methods and techniques

1 Tasks related to official controls shall, in general, be carried out using appropriate control methods and techniques such as monitoring, surveillance, verification, audit, inspection, sampling and analysis.

2 Official controls on feed and food shall include, *inter alia*, the following activities:

a examination of any control systems that feed and food business operators have put in place and the results obtained;

b inspection of:

(i) primary producers' installations, feed and food businesses, including their surroundings, premises, offices, equipment, installations and machinery, transport, as well as of feed and food;

(ii) raw materials, ingredients, processing aids and other products used for the preparation and production of feed and food;

(iii) semi-finished products;

(iv) materials and articles intended to come into contact with food;

(v) cleaning and maintenance products and processes, and pesticides;

(vi) labelling, presentation and advertising;

c checks on the hygiene conditions in feed and food businesses;

d assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), good farming practices and HACCP, taking into account the use of guides established in accordance with Community legislation;

e examination of written material and other records which may be relevant to the assessment of compliance with feed or food law;

f interviews with feed and food business operators and with their staff;

g the reading of values recorded by feed or food business measuring instruments;

h controls carried out with the competent authority's own instruments to verify measurements taken by feed and food business operators;

i any other activity required to ensure that the objectives of this Regulation are met.

CHAPTER III

SAMPLING AND ANALYSIS

Article 11

Methods of sampling and analysis

1 Sampling and analysis methods used in the context of official controls shall comply with relevant Community rules or,

a if no such rules exist, with internationally recognised rules or protocols, for example those that the European Committee for Standardisation (CEN) has accepted or those agreed in national legislation;

or,

b in the absence of the above, with other methods fit for the intended purpose or developed in accordance with scientific protocols.

2 Where paragraph 1 does not apply, validation of methods of analysis may take place within a single laboratory according to an internationally accepted protocol.

3 Wherever possible, methods of analysis shall be characterised by the appropriate criteria set out in Annex III.

4 **[**[F1]The following implementing measures may be taken by the Commission:**]**

a methods of sampling and analysis, including the confirmatory or reference methods to be used in the event of a dispute;

b performance criteria, analysis parameters, measurement uncertainty and procedures for the validation of the methods referred to in (a);

and

c rules on the interpretation of results.

[[F2]Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).**]**

5 The competent authorities shall establish adequate procedures in order to guarantee the right of feed and food business operators whose products are subject to sampling and analysis to apply for a supplementary expert opinion, without prejudice to the obligation of competent authorities to take prompt action in case of emergency.

6 In particular, they shall ensure that feed and food business operators can obtain sufficient numbers of samples for a supplementary expert opinion, unless impossible in case of highly perishable products or very low quantity of available substrate.

7 Samples must be handled and labelled in such a way as to guarantee both their legal and analytical validity.

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

F2 Inserted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 12

Official laboratories

1 The competent authority shall designate laboratories that may carry out the analysis of samples taken during official controls.

2 However, competent authorities may only designate laboratories that operate and are assessed and accredited in accordance with the following European standards:

a EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';

[[F3]b EN ISO/IEC 17011 on 'General requirements for accreditation bodies accrediting conformity assessment bodies';**]**

[[F4]c EN 45003 on 'Calibration and testing laboratory accreditation system — General requirements for operation and recognition',**]**

taking into account criteria for different testing methods laid down in Community feed and food law.

3 The accreditation and assessment of testing laboratories referred to in paragraph 2 may relate to individual tests or groups of tests.

4 The competent authority may cancel the designation referred to in paragraph 1 when the conditions referred to in paragraph 2 are no longer fulfilled.

Textual Amendments

F3 Substituted by Commission Regulation (EC) No 1029/2008 of 20 October 2008 amending Regulation (EC) No 882/2004 of the European Parliament and of the Council to update a reference to certain European standards (Text with EEA relevance).

F4 Deleted by Commission Regulation (EC) No 1029/2008 of 20 October 2008 amending Regulation (EC) No 882/2004 of the European Parliament and of the Council to update a reference to certain European standards (Text with EEA relevance).

CHAPTER IV

CRISIS MANAGEMENT

Article 13

Contingency plans for feed and food

1 For the implementation of the general plan for crisis management referred to in Article 55 of Regulation (EC) No 178/2002, Member States shall draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to pose a serious risk to humans or animals either directly or through the environment.

2 These contingency plans shall specify:

a the administrative authorities to be engaged;

b their powers and responsibilities;

and

c channels and procedures for sharing information between the relevant parties.

3 Member States shall review these contingency plans as appropriate, particularly in the light of changes in the organisation of the competent authority and of experience, including experience gained from simulation exercises.

4 Where necessary, implementing measures may be adopted in accordance with the procedure referred to in Article 62(3). Such measures shall establish harmonised rules for contingency plans to the extent necessary to ensure that such plans are compatible with the general plan for crisis management referred to in Article 55 of Regulation (EC) No 178/2002. They shall also indicate the role of stakeholders in the establishment and operation of contingency plans.

CHAPTER V

OFFICIAL CONTROLS ON THE INTRODUCTION OF FEED AND FOOD FROM THIRD COUNTRIES

Article 14

Official controls on feed and food of animal origin

1 This Regulation shall not affect the requirements for veterinary checks on feed and food of animal origin provided for in Directive 97/78/EC. However, the competent authority designated in accordance with Directive 97/78/EC shall, in addition, carry out official controls to verify compliance with aspects of feed or food law that that Directive does not cover, as appropriate, including those aspects referred to in Title VI, Chapter II of this Regulation.

2 The general rules of Articles 18 to 25 of this Regulation shall also apply to official controls on all feed and food, including feed and food of animal origin.

3 Satisfactory results of checks on goods that are:

a placed under one of the customs procedures referred to in points (b) to (f) of Article 4(16) of Regulation (EEC) No 2913/92;

or

b to be handled in free zones or free warehouses, as defined in Article 4(15)(b) of Regulation (EEC) No 2913/92,

shall neither affect the duty of feed and food business operators to ensure that feed and food comply with feed and food law from the moment of release for free circulation nor prevent further official controls on the feed or food concerned from being carried out.

Article 15

Official controls on feed and food of non-animal origin

1 The competent authority shall carry out regular official controls on feed and food of non-animal origin not included in the scope of Directive 97/78/EC, imported into the territories referred to in Annex I. It shall organise these controls on the basis of the multi-annual national

control plan drawn up in accordance with Articles 41 to 43 and in the light of potential risks. The controls shall cover all aspects of feed and food law.

2 These controls shall be carried out at an appropriate place, including the point of entry of the goods into one of the territories referred to in Annex I, the point of release for free circulation, warehouses, the premises of the importing feed and food business operator, or other points of the feed and food chain.

3 These controls may also be carried out on goods that are:

a placed under one of the customs procedures referred to in points (b) to (f) of Article 4(16) of Regulation (EEC) No 2913/92;

or

b to enter free zones or free warehouses, as defined in Article 4(15)(b) of Regulation (EEC) No 2913/92.

4 Satisfactory results of checks referred to in paragraph 3 shall neither affect the duty of feed and food business operators to ensure that feed and food comply with feed and food law from the moment of release for free circulation nor prevent further official controls on the feed or food concerned from being carried out.

5 A list of feed and food of non-animal origin that is, on the basis of known or emerging risk, to be subject to an increased level of official controls at the point of entry into territories referred to in Annex I shall be drawn up and updated, in accordance with the procedure referred to in Article 62(3). The frequency and nature of these controls shall be laid down in accordance with the same procedure. At the same time, the fees related to such controls may be established in accordance with the same procedure.

Article 16

Types of checks on feed and food of non-animal origin

1 The official controls referred to in Article 15(1) shall include at least a systematic documentary check, a random identity check and, as appropriate, a physical check.

2 Physical checks shall be carried out at a frequency depending on:

a the risks associated with different types of feed and food;

b the history of compliance with the requirements for the product concerned of the third country and establishment of origin and of the feed or food business operators importing and exporting the product;

c the controls that the feed or food business operator importing the product has carried out;

d the guarantees that the competent authority of the third country of origin has given.

3 The Member States shall ensure that physical checks are carried out under appropriate conditions and at a place with access to appropriate control facilities allowing investigations to be conducted properly, a number of samples adapted to the risk management to be taken, and the feed and food to be handled hygienically. Samples must be handled in such a way as to guarantee both their legal and analytical validity. Member States shall ensure that the equipment and methodology are adequate for measuring the limit values laid down under Community or national legislation.

Article 17

Points of entry and prior notification

1 Member States shall, for the organisation of the official controls referred to in Article 15(5):

— designate particular points of entry in their territory which have access to the appropriate control facilities for different types of feed and food;

and

— require feed and food business operators responsible for consignments to give prior notification of their arrival and nature.

Member States may apply the same rules for other feed of non-animal origin.

2 Member States shall inform the Commission and other Member States of any measures that they take in accordance with paragraph 1.

They shall design those measures in such a way as to avoid unnecessary disruption of trade.

Article 18

Action in case of suspicion

In case of suspicion of non-compliance or if there is doubt as to the identity or the actual destination of the consignment, or as to the correspondence between the consignment and the certified guarantees, the competent authority shall carry out official controls in order to confirm or to eliminate the suspicion or doubt. The competent authority shall place the consignment concerned under official detention until it obtains the results of such official controls.

Article 19

Action following official controls on feed and food from third countries

1 The competent authority shall place under official detention feed or food from third countries that does not comply with feed or food law and, having heard the feed or food business operators responsible for the consignment, it shall take the following measures in respect of such feed or food:

a order that such feed or food be destroyed, subjected to a special treatment in accordance with Article 20 or re-dispatched outside the Community in accordance with Article 21; other appropriate measures such as the use of feed or food for purposes other than those for which they were originally intended may also be taken;

b if the feed or food has already been placed on the market, monitor or, if necessary, order its recall or withdrawal before taking one of the measures referred to above;

c verify that feed and food does not give rise to any adverse effects on human or animal health, either directly or through the environment, during or pending the implementation of any of the measures referred to in subparagraphs (a) and (b).

2 If, however:

a the official controls provided for in Articles 14 and 15 indicate that a consignment is injurious to human or animal health or unsafe, the competent authority shall place the consignment in question under official detention pending its destruction or any other appropriate measure necessary to protect human and animal health;

b feed or food of non-animal origin for which an increased level of controls has been laid down in accordance with Article 15(5) is not presented for official controls, or is not presented in accordance with any specific requirements established in accordance with Article 17, the competent authority shall order that it be recalled and placed under official detention without delay and that it be then either destroyed or re-dispatched in accordance with Article 21.

3 When it does not permit the introduction of feed or food, the competent authority shall notify the Commission and other Member States of its findings and of the identification of the products concerned in accordance with the procedure provided for in Article 50(3) of Regulation (EC) No 178/2002 and shall notify its decisions to the customs services, together with information as regards the final destination of the consignment.

4 Decisions on consignments shall be subject to the right of appeal referred to in Article 54(3).

Article 20

Special treatment

1 The special treatment referred to in Article 19 may include:

a treatment or processing to bring the feed or food into line with the requirements of Community law, or with the requirements of a third country of re-dispatch, including decontamination, where appropriate, but excluding dilution;

b processing in any other suitable manner for purposes other than animal or human consumption.

[[F1]2 The competent authority shall ensure that special treatment takes place in establishments under its control, or under the control of another Member State, and in accordance with conditions laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4). In the absence of such conditions, the special treatment shall take place in accordance with national rules.**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 21

Re-dispatch of consignments

1 The competent authority shall allow re-dispatch of consignments only if:

a the destination has been agreed with the feed or food business operator responsible for the consignment; and

b the feed and food business operator has first informed the competent authority of the third country of origin or third country of destination, if different, of the reasons and circumstances preventing the placing on the market of the feed or food concerned within the Community;

and

c when the third country of destination is not the third country of origin, the competent authority of the third country of destination has notified the competent authority of its preparedness to accept the consignment.

2 Without prejudice to the national rules applicable with respect to the time limits for applying for a supplementary expert opinion, and where the results of official controls do not preclude it, re-dispatch shall, as a general rule, take place no more than 60 days after the day on which the competent authority decided on the destination of the consignment, unless legal action has been undertaken. If, after the expiry of the 60-day period, re-dispatch does not take place, the consignment shall be destroyed, unless a delay is justified.

3 Pending re-dispatch of consignments or confirmation of the reasons for rejection, the competent authority shall place consignments under official detention.

4 The competent authority shall notify the Commission and other Member States in accordance with the procedure provided for in Article 50(3) of Regulation (EC) No 178/2002 and shall notify its decisions to the customs services. Competent authorities shall cooperate in accordance with Title IV to take any further measures necessary to ensure that it is not possible to reintroduce the rejected consignments into the Community.

Article 22

Costs

The feed or food business operator responsible for the consignment or its representative shall be liable for the costs incurred by competent authorities for the activities referred to in Articles 18, 19, 20 and 21.

Article 23

Approval of pre-export checks by third countries

1 Specific pre-export checks that a third country carries out on feed and food immediately prior to export to the Community with a view to verifying that the exported products satisfy Community requirements may be approved in accordance with the procedure referred to in Article 62(3). The approval may apply only to feed and food originating in the third country concerned and may be granted for one or more products.

2 Where such approval has been granted, the frequency of import controls for feed or food may be reduced as a consequence. However, Member States shall carry out official controls on feed and food imported in accordance with the approval referred to in paragraph 1 so as to ensure that the pre-export checks carried out in the third country remain effective.

3 The approval referred to in paragraph 1 may only be granted to a third country if:

a a Community audit has shown that feed or food exported to the Community meets Community requirements, or equivalent requirements;

b the controls carried out in the third country prior to dispatch are considered sufficiently effective and efficient as to replace or reduce the documentary, identity and physical checks laid down in Community law.

4 The approval referred to in paragraph 1 shall specify the competent authority of the third country under the responsibility of which the pre-export checks are performed and, if appropriate, any control body to which that competent authority may delegate certain tasks. Such delegation may be approved only if it meets the criteria of Article 5 or equivalent conditions.

5 The competent authority and any control body specified in the approval shall be responsible for contacts with the Community.

6 The competent authority or control body of the third country shall ensure the official certification of each consignment checked prior to its entry into one of the territories referred to in Annex I. The approval referred to in paragraph 1 shall specify a model for such certificates.

7 Without prejudice to Article 50(3) of Regulation (EC) No 178/2002, when official controls on imports subject to the procedure referred to in paragraph 2 reveal significant non-compliance, Member States shall immediately notify the Commission and other Member States and the operators concerned in accordance with the procedure provided for in Title IV of this Regulation; Member States shall increase the number of consignments checked and, where necessary to allow a proper analytical examination of the situation, keep an appropriate number of samples under appropriate storage conditions.

8 If it is found that, in a significant number of consignments, the goods do not correspond to the information in the certificates that the competent authority or control body of the third country has issued, the reduced frequency referred to in paragraph 2 shall no longer apply.

Article 24

Competent authorities and customs services

1 For the organisation of the official controls referred to in this Chapter, the competent authorities and the customs services shall cooperate closely.

2 With regard to consignments of feed and food of animal origin and of feed and food referred to in Article 15(5), customs services shall not allow their entry or handling in free zones or free warehouses without the agreement of the competent authority.

3 Where samples are taken, the competent authority shall inform the customs services and the operators concerned and indicate whether or not the goods can be released before the results of the analysis of the samples are available, provided the traceability of the consignment is ensured.

4 In the case of release for free circulation, competent authorities and customs services shall work together in accordance with the requirements laid down in Articles 2 to 6 of Regulation (EEC) No 339/93.

Article 25

Implementing measures

1 Measures necessary to ensure the uniform implementation of official controls on the introduction of feed and food shall be laid down in accordance with the procedure referred to in Article 62(3).

2 In particular, detailed rules may be laid down for:

a feed and food imported or placed under one of the customs procedures referred to in Article 4(16)(b) to (f) of Regulation (EEC) No 2913/92 or that are to be handled in free zones or free warehouses, as defined in Article 4(15)(b) of Regulation (EEC) No 2913/92;

b food for the supply of the crew and passengers of international means of transport;

c feed and food ordered remotely (for example, by mail, by telephone or via the internet) and delivered to the consumer;

d feed intended for pets or horses and food carried by passengers and crew of international means of transport;

e specific conditions or exemptions concerning certain territories referred to in Article 3 of Regulation (EEC) No 2913/92, so as to take account of the natural constraints specific to those territories;

f the purpose of ensuring the consistency of decisions by competent authorities concerning feed and food from third countries within the framework of Article 19;

g consignments of Community origin that are returned from a third country;

h documents that must accompany consignments when samples have been taken.

CHAPTER VI

FINANCING OF OFFICIAL CONTROLS

Article 26

General principle

Member States shall ensure that adequate financial resources are available to provide the necessary staff and other resources for official controls by whatever means considered appropriate, including through general taxation or by establishing fees or charges.

Article 27

Fees or charges

1 Member States may collect fees or charges to cover the costs occasioned by official controls.

2 However, as regards the activities referred to in Annex IV, section A, and Annex V, section A, Member States shall ensure the collection of a fee.

3 Without prejudice to paragraphs 4 and 6, fees collected as regards the specific activities mentioned in Annex IV, section A and Annex V, section A shall not be lower than the minimum rates specified in Annex IV, section B and Annex V, section B. However, for a transitional period until 1 January 2008, as regards the activities referred to in Annex IV, section A, Member States may continue to use the rates currently applied pursuant to Directive 85/73/EEC.

[[F1]The rates in Annex IV, Section B and Annex V, Section B shall be updated by the Commission at least every two years, in particular to take account of inflation. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).**]**

4 Fees collected for the purposes of official controls in accordance with paragraph 1 or 2:

a shall not be higher than the costs borne by the responsible competent authorities in relation to the items listed in Annex VI;

and

b may be fixed at a flat-rate on the basis of the costs borne by the competent authorities over a given period of time or, where applicable, at the amounts fixed in Annex IV, section B or in Annex V, section B.

5 In setting the fees Member States shall take into consideration:

a the type of business concerned and relevant risk factors;

b the interests of businesses with a low throughput;

c traditional methods used for production, processing and distribution;

d the needs of businesses located in regions subject to particular geographical constraints.

6 When, in view of own-check and tracing systems implemented by the feed or food business as well as of the level of compliance found during official controls, for a certain type of feed or food or activities, official controls are carried out with a reduced frequency or to take account of the criteria referred to in paragraph 5(b) to (d), Member States may set the official control fee below the minimum rates referred to in paragraph 4(b), provided that the Member State concerned provides the Commission with a report specifying:

a the type of feed or food or activity concerned;

b the controls performed in the feed and food business concerned;

and

c the method for calculating the reduction of the fee.

7 When the competent authority carries out several official controls at the same time in a single establishment, it shall consider these controls as a single activity and charge a single fee.

8 Fees relating to import controls are to be paid by the operator or his representative to the competent authority in charge of import controls.

9 Fees shall not directly or indirectly be refunded, unless unduly collected.

10 Without prejudice to the costs deriving from the expenses referred to in Article 28, Member States shall not collect any fees other than those referred to in this Article for the implementation of this Regulation.

11 Operators or other relevant businesses or their representatives shall receive proof of their payment of fees.

12 The Member States shall make public the method of calculation of fees and communicate it to the Commission. The Commission shall examine whether the fees comply with the requirements of this Regulation.

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 28

Expenses arising from additional official controls

When the detection of non-compliance leads to official controls that exceed the competent authority's normal control activities, the competent authority shall charge the operators responsible for the non-compliance, or may charge the operator owning or keeping the goods at the time when the additional official controls are carried out, for the expenses arising from the additional official controls. Normal control activities are the routine control activities required under Community or national law and, in particular, those described in the plan provided for in Article 41. Activities that exceed normal control activities include the taking and analysis of samples as well as other controls that are required to check the extent of a problem, to verify whether corrective action has been taken, or to detect and/or substantiate non-compliance.

Article 29

Level of expenses

When setting the level of expenses referred to in Article 28, account shall be taken of the principles laid down in Article 27.

CHAPTER VII

OTHER PROVISIONS

Article 30

Official certification

1 **[**[F1]Without prejudice to requirements concerning official certification adopted for animal health or animal welfare purposes, requirements may be adopted by the Commission concerning:**]**

a the circumstances in which official certification is required;

b model certificates;

c qualifications of the certifying staff;

d the principles to be respected to ensure reliable certification, including electronic certification;

e the procedures to be followed in case of withdrawal of certificates and for replacement certificates;

f consignments that are split into smaller consignments or that are mixed with other consignments;

g documents that must follow goods after official controls have been carried out.

[[F2]The measures referred to in point (a), designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).

The measures referred to in points (b) to (g) shall be adopted in accordance with the regulatory procedure referred to in Article 62(3).**]**

2 Where official certification is required, it shall be ensured that:

a a link exists between the certificate and the consignment;

b the information in the certificate is accurate and authentic.

3 A single model certificate shall, where appropriate, combine requirements concerning the official certification of feed and food and other requirements for official certification.

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

F2 Inserted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 31

Registration/approval of feed and food business establishments

1

a Competent authorities shall establish procedures for feed and food business operators to follow when applying for the registration of their establishments in accordance with Regulation (EC) No 852/2004, Directive 95/69/EC or with the future regulation on feed hygiene;

b They shall draw up and keep up to date a list of feed and food business operators which have been registered. Where such a list already exists for other purposes, it may also be used for the purposes of this Regulation.

2

a Competent authorities shall establish procedures for feed and food business operators to follow when applying for the approval of their establishments in accordance with Regulation (EC) No 852/2004, Regulation (EC) No 854/2004, Directive 95/69/EC or with the future regulation on feed hygiene.

b Upon receipt of an application for approval from a feed or food business operator, the competent authority shall make an on-site visit.

c It shall approve an establishment for the activities concerned only if the feed or food business operator has demonstrated that it complies with the relevant requirements of feed or food law.

d The competent authority may grant conditional approval if it appears that the establishment meets all the infrastructure and equipment requirements. It shall grant full approval only if it appears from a new official control of the establishment, carried out within three months of granting conditional approval, that the establishment meets the other relevant requirements of feed or food law. If clear progress has been made but the establishment still does not meet all of the relevant requirements, the competent authority may prolong conditional approval. However, conditional approval shall not exceed a total of six months.

e The competent authority shall keep the approval of establishments under review when carrying out official controls. If the competent authority identifies serious deficiencies or has to stop production at an establishment repeatedly and the feed or food business operator is not able to provide adequate guarantees regarding future production, the competent authority shall initiate procedures to withdraw the establishment's approval. However, the competent authority may suspend an establishment's approval if the feed or food business operator can guarantee that it will resolve deficiencies within a reasonable time;

f The competent authorities shall maintain up-to--date lists of approved establishments and make them available to other Member States and to the public in a manner that may be specified in accordance with the procedure referred to in Article 62(3).

TITLE III

REFERENCE LABORATORIES

Article 32

Community reference laboratories

1 The Community reference laboratories for feed and food referred to in Annex VII shall be responsible for:

a providing national reference laboratories with details of analytical methods, including reference methods;

b coordinating application by the national reference laboratories of the methods referred to in (a), in particular by organising comparative testing and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols, when available;

c coordinating, within their area of competence, practical arrangements needed to apply new analytical methods and informing national reference laboratories of advances in this field;

d conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries;

e providing scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses;

f collaborating with laboratories responsible for analysing feed and food in third countries.

2 The Community reference laboratories in the animal health sector shall be responsible for:

a coordinating the methods employed in the Member States for diagnosing diseases;

b assisting actively in the diagnosis of disease outbreaks in Member States by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies;

c facilitating the initial or further training of experts in laboratory diagnosis with a view to the harmonisation of diagnostic techniques throughout the Community;

d collaborating, as regards methods of diagnosing animal diseases falling within their competence, with the competent laboratories in third countries where those diseases are prevalent:

e conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries;

3 Article 12(2) and (3) shall apply to Community reference laboratories.

4 Community reference laboratories shall fulfil the following requirements. They must:

a have suitably qualified staff with adequate training in diagnostic and analytical techniques applied in their area of competence;

b possess the equipment and products needed to carry out the tasks assigned to them;

c have an appropriate administrative infrastructure;

d ensure that their staff respect the confidential nature of certain subjects, results or communications;

e have sufficient knowledge of international standards and practices;

f have available, if appropriate, an updated list of available reference substances and reagents and an updated list of manufacturers and suppliers of such substances and reagents;

g take account of research activities at national and Community level;

h have trained personnel available for emergency situations occurring within the Community.

[[F1]5 Other Community reference laboratories relevant to the areas referred to in Article 1 may be included in Annex VII by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4). In accordance with the same procedure, Annex VII may be updated.**]**

[[F1]6 Additional responsibilities and tasks for Community reference laboratories may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).**]**

7 Community reference laboratories may be granted a Community financial contribution in accordance with Article 28 of Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field[(36)].

8 Community reference laboratories may be subject to Community controls to verify compliance with the requirements of this Regulation. If these controls find that a laboratory is not complying with those requirements or tasks for which they have been designated, necessary measures may be taken in accordance with the procedure referred to in Article 62(3).

9 Paragraphs 1 to 7 shall apply without prejudice to more specific rules, and in particular Chapter VI of Regulation (EC) No 999/2001 and Article 14 of Directive 96/23/EC.

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 33

National reference laboratories

1 Member States shall arrange for the designation of one or more national reference laboratories for each Community reference laboratory referred to in Article 32. A Member State may designate a laboratory situated in another Member State or European Free Trade Association (EFTA) Member and a single laboratory may be the national reference laboratory for more than one Member State.

2 These national reference laboratories shall:

a collaborate with the Community reference laboratory in their area of competence;

b coordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples in accordance with Article 11;

c where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing;

d ensure the dissemination to the competent authority and official national laboratories of information that the Community reference laboratory supplies;

e provide scientific and technical assistance to the competent authority for the implementation of coordinated control plans adopted in accordance with Article 53;

f be responsible for carrying out other specific duties provided for in accordance with the procedure referred to in Article 62(3), without prejudice to existing additional national duties.

3 Article 12(2) and (3) shall apply to national reference laboratories.

4 Member States shall communicate the name and address of each national reference laboratory to the Commission, the relevant Community reference laboratory and other Member States.

5 Member States that have more than one national reference laboratory for a Community reference laboratory must ensure that these laboratories work closely together, so as to ensure efficient coordination between them, with other national laboratories and with the Community reference laboratory.

[[F1]6 Additional responsibilities and tasks for national reference laboratories may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).**]**

7 Paragraphs 1 to 5 shall apply without prejudice to more specific rules and in particular Chapter VI of Regulation (EC) No 999/2001 and Article 14 of Directive 96/23/EC.

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

TITLE IV

ADMINISTRATIVE ASSISTANCE AND COOPERATION IN THE AREAS OF FEED AND FOOD

Article 34

General principles

1 Where the outcome of official controls on feed and food requires action in more than one Member State, competent authorities in the Member States concerned shall provide each other with administrative assistance.

2 Competent authorities shall provide administrative assistance upon request, or spontaneously when the course of investigations so requires. Administrative assistance may include, where appropriate, participation in on-the-spot controls that the competent authority of another Member State carries out.

3 Articles 35 to 40 shall not prejudice national rules applicable to the release of documents that are the object of, or are related to, court proceedings, or rules aimed at the protection of natural or legal persons' commercial interests.

Article 35

Liaison bodies

1 Each Member State shall designate one or more liaison bodies to liaise as appropriate with other Member States' liaison bodies. The role of liaison bodies shall be to assist and coordinate communication between competent authorities and, in particular, the transmission and reception of requests for assistance.

2 Member States shall inform the Commission and other Member States of all the relevant details of their designated liaison bodies, and of any modification of these details.

3 Without prejudice to paragraph 1, 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.

4 The competent authorities to which Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure correct application of the legislation on veterinary and zootechnical matters[37] applies, shall liaise as appropriate with the authorities operating under this title.

Article 36

Assistance on request

1 Upon receiving a reasoned request, the requested competent authority shall ensure that the requesting competent authority is provided with all necessary information and documents enabling the latter to verify compliance with feed and food law within its jurisdiction. For that purpose, the requested competent authority shall arrange for the conduct of any administrative enquiries necessary to obtain such information and documents.

2 Information and documents provided pursuant to paragraph 1 shall be forwarded without undue delay. Documents may be transmitted in their original form or copies may be provided.

3 By agreement between the requesting authority and the requested authority, staff designated by the requesting authority may be present during administrative enquiries.

Such enquiries shall always be carried out by staff of the requested authority.

The requesting authority's staff may not, on their own initiative, exercise the powers of enquiry conferred on officials of the requested authority. They shall, however, have access to the same premises and documents as the latter, through their intermediary, and for the sole purpose of the administrative enquiry being carried out.

4 Staff of the requesting authority present in another Member State in accordance with paragraph 3 shall at all times be able to produce written authority stating their identity and their official capacity.

Article 37

Assistance without request

1 When a competent authority becomes aware of non-compliance, and if such non-compliance may have implications for another Member State or States, it shall pass such information to the other Member State(s) without prior request and without delay.

2 Member States receiving such information shall investigate the matter and inform the Member State that provided the information of the results of this investigation and, where appropriate, of any measures taken.

Article 38

Assistance in the event of non-compliance

1 If, during an official control carried out at the place of destination of the goods, or during their transport, the competent authority of the Member State of destination establishes that the goods do not comply with feed or food law in such a way as to create a risk to human or animal health or to constitute a serious infringement of feed or food law, it shall contact the competent authority of the Member State of dispatch without delay.

2 The competent authority of the Member State of dispatch shall investigate the matter, take all necessary measures and notify the competent authority of the Member State of

destination of the nature of the investigations and official controls carried out, the decisions taken and the reasons for such decisions.

3 If the competent authority of the Member State of destination has reason to believe that such measures are inadequate, the two Member States' competent authorities shall together seek ways and means of remedying the situation including, if appropriate, a joint on-the-spot inspection carried out in accordance with Article 36(3) and (4). They shall inform the Commission if they are not able to agree on appropriate measures.

Article 39

Relations with third countries

1 When a competent authority receives information from a third country indicating non-compliance and/or a risk to human or animal health, that authority shall pass that information on to competent authorities in other Member States if it considers that they might be interested in it or if they request it. It shall also communicate such information to the Commission whenever it is of relevance at Community level.

2 If the third country has given a legal undertaking to provide the assistance required to gather evidence of the irregular nature of transactions that are or appear to be contrary to the relevant feed and food law, information obtained under this Regulation may be communicated to that third country, with the consent of the competent authorities that supplied the information, in accordance with laws applying to the communication of personal data to third countries.

Article 40

Coordinated assistance and follow-up by the Commission

1 The Commission shall coordinate without delay the action undertaken by Member States when it, further to information received from Member States or from other sources, becomes aware of activities that are, or appear to be, contrary to feed or food law and are of particular interest at Community level, and in particular when:

a such activities have, or might have, ramifications in several Member States;

b it appears that similar activities have been carried out in several Member States;

or

c Member States are unable to agree on appropriate action to address non-compliance.

2 When official controls at destination show repeated non-compliance or other risks to humans, plants or animals from feed or food, either directly or through the environment, the competent authority of the Member State of destination shall inform the Commission and the competent authorities of the other Member States without delay.

3 The Commission may:

a in collaboration with the Member State concerned, send an inspection team to carry out an official control on the spot;

b request that the competent authority of the Member State of dispatch intensify relevant official controls and report on the action and measures taken.

4 Where the measures provided for in paragraphs 2 and 3 are taken to deal with repeated non-compliance by a feed or food business, the competent authority shall charge any expenses arising from such measures to the business in question.

TITLE V

CONTROL PLANS

Article 41

Multi-annual national control plans

In order to ensure the effective implementation of Article 17(2) of Regulation (EC) No 178/2002, of animal health and animal welfare rules and of Article 45 of this Regulation, each Member State shall prepare a single integrated multi-annual national control plan.

Article 42

Principles for the preparation of multi-annual national control plans

1 Member States shall:

a implement the plan referred to in Article 41 for the first time no later than 1 January 2007;

and

b regularly update it in the light of developments;

and

c provide the Commission with the latest version of the plan on request.

2 Each multi-annual national control plan shall contain general information on the structure and organisation of the systems of feed and food control, and of animal health and animal welfare control in the Member State concerned, in particular on:

a the strategic objectives of the plan and on how the prioritisation of controls and allocation of resources reflect these objectives;

b the risk categorisation of the activities concerned;

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 control bodies;

g methods to ensure compliance with the operational criteria of Article 4(2);

h the training of staff performing official controls referred to in Article 6;

i the documented procedures referred to in Articles 8 and 9;

j the organisation and operation of contingency plans for animal or food-borne disease emergencies, feed and food contamination incidents and other human health risks;

k the organisation of cooperation and mutual assistance.

3 Multi-annual national control plans may be adjusted during their implementation. Amendments may be made in the light of, or in order to take account of, factors including:

a new legislation;

b the emergence of new diseases or other health risks;

c significant changes to the structure, management or operation of the competent national authorities;

d the results of Member States' official controls;

e the results of Community controls carried out in accordance with Article 45;

f any amendment of the guidelines referred to in Article 43;

g scientific findings;

h the outcome of audits performed by a third country in a Member State.

Article 43

Guidelines for multi-annual national control plans

1 The multi-annual national control plans referred to in Article 41 shall take account of guidelines to be drawn up by the Commission in accordance with the procedure referred to in Article 62(2). These guidelines shall in particular:

a promote a consistent, comprehensive and integrated approach to official controls of feed and food, animal health and animal welfare legislation, and embrace all sectors and all stages of the feed and food chain, including import and introduction;

b identify risk-based priorities and criteria for the risk categorisation of the activities concerned and the most effective control procedures;

c identify other priorities and the most effective control procedures;

d identify the stages of production, processing and distribution of feed and food, including the use of feed, which will provide the most reliable and indicative information about compliance with feed and food law;

e encourage the adoption of best practices at all levels of the control system;

f encourage the development of effective controls on traceability systems;

g provide advice on the development of systems to record the performance and results of control actions;

h reflect relevant international bodies' standards and recommendations regarding the organisation and operation of official services;

i lay down criteria for the conduct of the audits referred to in Article 4(6);

j lay down the structure of, and information to be included in, the annual reports required in Article 44;

k indicate the main performance indicators to be applied in assessing multi-annual national control plans.

2 Where necessary, the guidelines shall be adapted in the light of the analysis of annual reports that Member States submit in accordance with Article 44 or Community controls carried out in accordance with Article 45.

Article 44

Annual reports

1 One year after starting the implementation of multi-annual national control plans, and subsequently every year, Member States shall submit to the Commission a report indicating:

a any amendments made to multi-annual national control plans to take account of the factors referred to in Article 42(3);

b the results of controls and audits conducted in the previous year under the provisions of the multi-annual national control plan;

c the type and number of cases of non-compliance identified;

d actions to ensure the effective operation of multi-annual national control plans, including enforcement action and its results.

2 In order to promote the consistent presentation of this report and in particular of the results of official controls, the information referred to in paragraph 1 shall take account of guidelines to be drawn up by the Commission in accordance with the procedure referred to in Article 62(2).

3 Member States shall finalise their reports and transmit them to the Commission, within six months of the end of the year to which the reports relate.

4 In the light of the reports referred to in paragraph 1, the outcome of Community controls carried out in accordance with Article 45 and any other relevant information, the Commission shall establish an annual report on the overall operation of official controls in Member States. This report may, where appropriate, include recommendations on:

a possible improvements to official control and audit systems in Member States, including their scope, management and implementation;

b specific control actions concerning sectors or activities, regardless of whether these are covered by multi-annual national control plans;

c coordinated plans aiming at addressing issues of particular interest.

5 Multi-annual national control plans and the related guidelines shall, where appropriate, be adapted on the basis of the conclusions and recommendations contained in the Commission's report.

6 The Commission shall submit its report to the European Parliament and the Council and make it available to the public.

TITLE VI

COMMUNITY ACTIVITIES

CHAPTER I

COMMUNITY CONTROLS

Article 45

Community controls in Member States

1 Commission experts shall carry out general and specific audits in Member States. The Commission may appoint experts from Member States to assist its own experts. General and specific audits shall be organised in cooperation with Member States' competent authorities. Audits shall be carried out on a regular basis. Their main purpose shall be to verify that, overall, official controls take place in Member States in accordance with the multi-annual national control plans referred to in Article 41 and in compliance with Community law. For this purpose, and in order to facilitate the efficiency and effectiveness of the audits, the Commission may, in

advance of carrying out such audits, request that the Member States provide, as soon as possible, up-to-date copies of national control plans.

2 Specific audits and inspections in one or more specific areas may supplement general audits. These specific audits and inspections shall in particular serve to:

a verify the implementation of the multi-annual national control plan, feed and food law and animal health and animal welfare legislation and may include, as appropriate, on-the-spot inspections of official services and of facilities associated with the sector being audited;

b verify the functioning and organisation of competent authorities;

c investigate important or recurring problems in Member States;

d investigate emergency situations, emerging problems or new developments in Member States.

3 The Commission shall report on the findings of each control carried out. Its report shall, if appropriate, contain recommendations for Member States on the improvement of compliance with feed and food law and animal health and animal welfare rules. The Commission shall make its reports publicly available. In the case of reports on controls carried out in a Member State, the Commission shall provide the relevant competent authority with a draft report for comments, take those comments into consideration in preparing the final report and publish the competent authority's comments together with the final report.

4 The Commission shall establish an annual control programme, communicate it to Member States in advance, and report on its results. The Commission may amend the programme to take account of developments in the fields of feed and food safety, animal health, animal welfare and plant health.

5 Member States shall:

a take appropriate follow-up action in the light of the recommendations resulting from Community controls;

b give all necessary assistance and provide all documentation and other technical support that Commission experts request to enable them to carry out controls efficiently and effectively;

c ensure that Commission experts have access to all premises or parts of premises and to information, including computing systems, relevant to the execution of their duties.

6 Detailed rules concerning Community controls in Member States may be drawn up or amended in accordance with the procedure referred to in Article 62(3).

Article 46

Community controls in third countries

1 Commission experts may carry out official controls in third countries in order to verify, on the basis of the information referred to in Article 47(1), the compliance or equivalence of third-country legislation and systems with Community feed and food law and Community animal health legislation. The Commission may appoint experts from Member States to assist its own experts. Such official controls 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 and plant diseases;

g the extent and operation of official controls on imports of animals, plants and their products;

h the assurances which the third country can give regarding compliance with, or equivalence to, Community requirements.

2 In order to facilitate the efficiency and effectiveness of the controls in a third country, the Commission may, in advance of carrying out such controls, request that the third country concerned provide the information referred to in Article 47(1) and, where appropriate, the written records on the implementation of such controls.

3 The frequency of Community controls in third countries shall be determined on the basis of:

a a risk assessment of the products exported to the Community;

b the provisions of Community legislation;

c the volume and nature of imports from the country concerned;

d the results of controls that the Commission services or other inspection bodies have already carried out;

e the results of import controls and of any other 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 the World Health Organisation (WHO), the Codex Alimentarius Commission and the World Organisation for Animal Health (OIE), or from other sources;

h evidence of emerging disease situations or other circumstances that might result in live animals, live plants or feed or food imported from a third country presenting health risks;

i the need to investigate or respond to emergency situations in individual third countries.

[[F1]The criteria for determining risk for the purpose of the risk assessment referred to in point (a) shall be decided by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).**]**

4 The procedure and detailed rules for controls in third countries may be determined or amended in accordance with the procedure referred to in Article 62(3).

They shall include, in particular, procedures for and detailed rules on:

a controls in third countries in the context of a bilateral agreement;

b controls in other third countries.

According to the same procedure, charges for the abovementioned controls may be established on a reciprocal basis.

5 If, during a Community control, a serious risk to human or animal health is identified, the Commission shall immediately take any necessary emergency measures in accordance

with Article 53 of Regulation (EC) No 178/2002 or safeguard provisions in other relevant Community legislation.

6 The Commission shall report on the findings of each Community control carried out. Its report shall, if appropriate, contain recommendations. The Commission shall make its reports publicly available.

7 The Commission shall communicate its programme of controls in third countries to Member States in advance and report on the results. It may amend the programme to take account of developments in the fields of feed and food safety, animal health and plant health.

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

CHAPTER II

IMPORT CONDITIONS

Article 47

General import conditions

1 The Commission shall be responsible for requesting third countries intending to export goods to the Community to provide the following accurate and up-to-date information on the general organisation and management of sanitary control systems:

a any sanitary or phytosanitary regulations adopted or proposed within its territory;

b any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures operated within its territory;

c risk-assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;

d where appropriate, the follow-up given to the recommendations made pursuant to controls referred to in Article 46.

2 The information referred to in paragraph 1 shall be proportionate to the nature of the goods and may take account of the specific situation and structure of the third country and the nature of the products exported to the Community. Its scope shall cover at least the goods intended to be exported to the Community.

3 The information referred to in paragraphs 1 and 2 may also relate to:

a results of the national controls carried out on goods intended to be exported to the Community;

b important changes which have been made to the structure and functioning of the relevant control systems, in particular to meet Community requirements or recommendations.

4 Where a third country does not provide such information or where such information is inadequate, specific import conditions may be fixed in accordance with the procedure referred

to in Article 62(3) on a case by case and strictly temporary basis following consultations with the third country concerned.

5 Guidelines, specifying how the information referred to in paragraphs 1, 2 and 3 shall be drawn up and presented to the Commission, as well as transitional measures allowing time for third countries to prepare this information shall be established in accordance with the procedure referred to in Article 62(2).

Article 48

Specific import conditions

[[F1]1 To the extent that the conditions and detailed procedures to be respected when importing goods from third countries or their regions are not provided for by Community law and in particular by Regulation (EC) No 854/2004, they shall, if necessary, be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).**]**

2 The conditions and detailed procedures referred to in paragraph 1 may include:

a the establishment of a list of third countries from which specific products may be imported into one of the territories referred to in Annex I;

b the establishment of models of certificates accompanying consignments;

c special import conditions, depending on the type of product or animal and the possible risks associated therewith.

3 Third countries shall appear on the lists referred to in paragraph 2(a) only if their competent authorities provide appropriate guarantees as regards compliance or equivalence with Community feed and food law and animal health rules.

4 When drawing up or updating lists, particular account shall be taken of the following criteria:

a the third country's legislation in the sector concerned;

b the structure and organisation of the competent authority of the third country and its control services, as well as the powers available to it/them and the guarantees that can be provided with regard to the implementation of the legislation concerned;

c the existence of adequate official controls;

d the regularity and rapidity of information supplied by the third country on the presence of hazards in feed and food, and in live animals;

e the guarantees given by a third country that:

(i) conditions applied to the establishments from which feed and food may be imported in the Community comply with or are equivalent to the requirements in Community feed and food law;

(ii) a list of such establishments is drawn up and kept up to date;

(iii) the list of establishments and its updated versions are communicated to the Commission without delay;

(iv) the establishments are the subject of regular and effective controls by the competent authority of the third country.

5 When adopting the special import conditions referred to in paragraph 2(c), account shall be taken of information that the third countries concerned have provided and, where necessary, the results of Community controls carried out in such third countries. Special import conditions may be established for a single product or for a group of products. They may apply to a single third country, to regions of a third country, or to a group of third countries.

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 49

Equivalence

1 Following the implementation of an equivalence agreement, or a satisfactory audit, a decision may be taken, in accordance with the procedure referred to in Article 62(3), recognising that measures that third countries or their regions apply in specific areas offer guarantees equivalent to those applied in the Community, if the third countries supply objective proof in this respect.

2 The decision referred to in paragraph 1 shall set out the conditions governing the imports from that third country or region of a third country.

The conditions may include:

a the nature and content of the certificates that must accompany the products;

b specific requirements applicable to importation into the Community;

c where necessary, procedures for drawing up and amending lists of regions or establishments from which imports are permitted.

3 The decision referred to in paragraph 1 shall be repealed in accordance with the same procedure and without delay where any of the conditions for recognition of equivalence established at the time of its adoption cease to be fulfilled.

Article 50

Support for developing countries

1 In accordance with the procedure referred to in Article 62(3) the following measures may be adopted and maintained so long as they have a demonstrable effect in ensuring that developing countries are able to comply with the provisions of this Regulation:

a a phased introduction of the requirements referred to in Articles 47 and 48 for products exported to the Community. Progress in meeting these requirements shall be evaluated 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;

b assistance with providing the information referred to in Article 47, if necessary by Community experts;

c the promotion of joint projects between developing countries and Member States;

d the development of guidelines to assist developing countries in organising official controls on products exported to the Community;

e sending Community experts to developing countries so as to assist in the organisation of official controls;

f the participation of control staff from developing countries in the training courses referred to in Article 51.

2 In the context of the Community's development cooperation policy, the Commission shall promote support to developing countries with regard to feed and food safety in general and compliance with feed and food standards in particular, in order to build the institutional capacity required to meet the requirements referred to in Articles 5, 12, 47 and 48.

CHAPTER III

TRAINING OF CONTROL STAFF

Article 51

Training of control staff

1 The Commission may organise training courses for the staff of the competent authorities of Member States responsible for the official controls referred to in this Regulation. These training courses shall serve to develop a harmonised approach to official controls in Member States. They may include in particular training on:

a Community feed and food law and animal health and animal welfare rules;

b control methods and techniques, such as the auditing of systems that operators design to comply with feed and food law, animal health and animal welfare rules;

c controls to be carried out on goods imported into the Community;

d feed and food production, processing and marketing methods and techniques.

2 The training courses referred to in paragraph 1 may be open to participants from third countries, in particular developing countries.

3 Detailed rules for the organisation of training courses may be laid down in accordance with the procedure referred to in Article 62(3).

CHAPTER IV

OTHER COMMUNITY ACTIVITIES

Article 52

Third-country controls in Member States

1 Commission experts may, at the request of and in cooperation with the competent authorities of Member States, assist Member States during controls that third countries carry out.

2 In such cases, Member States in whose territory a third country is to carry out a control shall inform the Commission about the planning, scope, documentation and any other relevant information enabling the Commission to take part effectively in the control.

3 The Commission's assistance shall serve in particular to:

a clarify Community feed and food law and animal health and animal welfare rules;

b provide information and data available at Community level that may be useful for the control carried out by the third country;

c ensure uniformity with regard to controls carried out by third countries.

Article 53

Coordinated control plans

The Commission may recommend coordinated plans in accordance with the procedure referred to in Article 62(2). These plans shall be:

(a) organised annually in accordance with a programme;

and

(b) where considered necessary, organised on an ad hoc basis, in particular with a view to establishing the prevalence of hazards in feed, food or animals.

TITLE VII

ENFORCEMENT MEASURES

CHAPTER I

NATIONAL ENFORCEMENT MEASURES

Article 54

Action in case of non-compliance

1 When the competent authority identifies non-compliance, it shall take action to ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and that operator's past record with regard to non-compliance.

2 Such action shall include, where appropriate, the following measures:

a the imposition of sanitation procedures or any other action deemed necessary to ensure the safety of feed or food or compliance with feed or food law, animal health or animal welfare rules;

b the restriction or prohibition of the placing on the market, import or export of feed, food or animals;

c monitoring and, if necessary, ordering the recall, withdrawal and/or destruction of feed or food;

d the authorisation to use feed or food for purposes other than those for which they were originally intended;

e the suspension of operation or closure of all or part of the business concerned for an appropriate period of time;

f the suspension or withdrawal of the establishment's approval;

g the measures referred to in Article 19 on consignments from third countries;

h any other measure the competent authority deems appropriate.

3 The competent authority shall provide the operator concerned, or a representative, with:

a written notification of its decision concerning the action to be taken in accordance with paragraph 1, 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 Where appropriate, the competent authority shall also notify the competent authority of the Member State of dispatch of its decision.

5 All expenditure incurred pursuant to this Article shall be borne by the responsible feed and food business operator.

Article 55

Sanctions

1 Member States shall lay down the rules on sanctions applicable to infringements of feed and food law and other Community provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

2 Member States shall notify the provisions applicable to infringements of feed and food law and any subsequent amendment to the Commission without delay.

CHAPTER II

COMMUNITY ENFORCEMENT MEASURES

Article 56

Safeguard measures

1 Measures shall be taken under the procedures provided for in Article 53 of Regulation (EC) No 178/2002 if:

a the Commission has evidence of a serious failure in a Member State's control systems;

and

b such failure may constitute a possible and widespread risk for human health, animal health or animal welfare, either directly or through the environment.

2 Such measures shall be adopted only after:

a Community controls have shown and reported non-compliance with Community legislation;

and

b the Member State concerned has failed to correct the situation upon request and within the time limit set by the Commission.

TITLE VIII

ADAPTATION OF COMMUNITY LEGISLATION

Article 57

Amendment of Directive 96/23/EC

Directive 96/23/EC is hereby amended as follows:

1. Article 14(2) is replaced by the following:

2. The Community reference laboratories shall be those referred to in the relevant part of Annex VII of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[38].

2. In Article 30, the part of paragraph 1 beginning 'Where such additional checks demonstrate…' and ending '…or to use it for other purposes authorised by Community legislation, without indemnity or compensation', is replaced by the following:

   Where checks demonstrate the presence of unauthorised substances or products or when maximum limits have been exceeded, the provisions of Articles 19 to 22 of Regulation (EC) No 882/2004 shall apply.

3. Annex V is deleted.

Article 58

Amendment of Directive 97/78/EC

Directive 97/78/EC is hereby amended as follows:

1. Article 1 is replaced by the following:

   Veterinary checks on products from third countries introduced into one of the territories listed in Annex I shall be carried out by Member States in accordance with this Directive and with Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[39].

2. Article 2(2)(a) is replaced by the following:

   (a) "products" means the products of animal origin referred to in Directives 89/662/EEC and 90/425/EEC, in Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption[40], in Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing,

distribution and introduction of products of animal origin for human consumption[41] and in Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption[42]; it also includes the plant products referred to in Article 19.

3. In Article 7(3), 'inspection fees referred to in Council Directive 85/73/EEC of 29 January 1985 on the financing of veterinary inspections and controls covered by Directives 89/662/EEC, 90/425/EEC, 90/675/EEC and 91/496/EEC (amended and consolidated)' is replaced by the following:

inspection fees referred to in Regulation (EC) No 882/2004.

4. In Article 10(1)(b), the following phrase is deleted: 'or, in the case of establishments approved in accordance with Council Decision 95/408/EC of 22 June 1995 on the conditions for drawing up, for an interim period, provisional lists of third-country establishments from which Member States are authorised to import certain products of animal origin, fishery products or live bivalve molluscs, from an establishment which has undergone either a Community or a national inspection.'

5. Article 12(9) is deleted.

6. Article 15(5) is deleted.

7. In Article 16, the following paragraph is inserted:

4. Detailed rules for the introduction of products of animal origin for the supply of the crew and passengers of international means of transport, and for products of animal origin ordered remotely (for example, by mail, by telephone or via the internet) and delivered to the consumer, shall be laid down in accordance with Article 25 of Regulation (EC) No 882/2004.

8. Article 21 is deleted.

9. Article 23 is deleted.

10. In Article 24(1), second indent, 'in accordance with Article 17(2)(a) and (b)' is replaced by 'in accordance with Article 17'.

Article 59

Amendment of Directive 2000/29/EC

The following Article is inserted in Directive 2000/29/EC:

Article 27a

For the purpose of this Directive and without prejudice to Article 21 thereof, Articles 41 to 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[43] shall apply, as appropriate.

Article 60

Amendment of Regulation (EC) No 854/2004

Regulation (EC) No 854/2004 is hereby amended as follows:

1. In Article 1, the following paragraph is added:

1a. This Regulation shall apply in addition to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[(44)].

2. In Article 2:

(a) in paragraph 1, subparagraphs (a), (b), (d) and (e) are deleted;

and

(b) the following subparagraph is added to paragraph 2:

(b)(a) Regulation (EC) No 882/2004.

3. In Article 3:

(a) paragraph 1 is replaced by the following:

1. The competent authorities shall approve establishments when, and in the manner, specified in Article 31(2) of Regulation (EC) No 882/2004;

and

(b) paragraphs 4(a) and (b) and paragraph 6 are deleted.

4. Article 9 is deleted.

5. Article 10 is replaced with the following:

Article 10

To ensure the uniform application of the principles and conditions laid down in Article 11 of Regulation (EC) No 178/2002 and Title VI, Chapter II, of Regulation (EC) No 882/2004 the procedures laid down in this Chapter shall apply.

6. In Article 11:

(a) paragraph 2 is replaced by the following:

2. A third country shall appear on such lists only if a Community control in that country has taken place and demonstrates that the competent authority provides appropriate guarantees as specified in Article 48(3) of Regulation (EC) No 882/2004. However, a third country may appear on such lists without a Community control having taken place if:

a the risk determined in accordance with Article 46(3)(a) of Regulation (EC) No 882/2004 does not warrant it;

and

b it is determined, when deciding to add a particular third country to a list in accordance with paragraph 1, that other information indicates that the competent authority provides the necessary guarantees.

(b) in paragraph 4, the introduction is replaced by the following:

4. When drawing up or updating lists, particular account shall be taken of the criteria listed in Articles 46 and 48(3) of Regulation (EC) No 882/2004. Regard shall also be had to.;

and

(c) subparagraphs (b) to (h) of paragraph 4 are deleted.

7. Article 14(2)(b) is replaced by the following:

(b) any specific import conditions established in accordance with Article 48 of Regulation (EC) No 882/2004.

8. Article 18(17) to (20) are deleted.

Article 61

Repeal of Community acts

1 Directives 70/373/EEC, 85/591/EEC, 89/397/EEC, 93/99/EEC and 95/53/EC and Decisions 93/383/EEC, 98/728/EC and 1999/313/EC are hereby repealed with effect from 1 January 2006. Directive 85/73/EEC is hereby repealed with effect from 1 January 2008.

2 However, the implementing rules adopted on the basis of those acts, in particular those referred to in Annex VIII, shall remain in force in so far as they are not in contradiction with this Regulation, pending the adoption of the necessary provisions on the basis of this Regulation.

3 Reference to the repealed acts shall be construed as references to this Regulation.

TITLE IX

GENERAL PROVISIONS

Article 62

Committee procedure

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 of Regulation (EC) No 178/2002 or, where dealing with matters mainly relating to plant health, by the Standing Committee on plant health set up by Council Decision 76/894/EEC[45].

2 Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be three months.

[[F1]4 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

[[F1]*Article 63*

Implementing and transitional measures

1 Transitional measures of general scope, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it with new non-essential elements, in particular

— any modification of the standards referred to in Article 12(2),

— a definition of what feed is to be regarded as feed of animal origin for the purpose of this Regulation,

and further specifications of the requirements laid down in the provisions of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).

Other transitional and implementing measures necessary in order to ensure the uniform application of this Regulation may be laid down in accordance with the regulatory procedure referred to in Article 62(3). This applies in particular to:

— the delegation of control tasks to control bodies referred to in Article 5, where those control bodies were already in operation before the entry into force of this Regulation,

— non-compliance as referred to in Article 28 which gives rise to expense arising from additional official controls,

— expenditure incurred pursuant to Article 54,

— rules on microbiological, physical and/or chemical analysis in official controls, in particular in cases involving a suspicion of risk and including the surveillance of the safety of products imported from third countries.

2 In order to take account of the specificity of Regulations (EEC) No 2092/91, (EEC) No 2081/92 and (EEC) No 2082/92, specific measures to be adopted by the Commission may provide for the necessary derogations from, and adjustments to, the rules laid down in this Regulation. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

[F1 Article 64

Amendment of Annexes and references to European standards

The following measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4):

(1) the Annexes to this Regulation may be updated, except for Annex I, Annex IV and Annex V, without prejudice to Article 27(3), in particular in order to take account of administrative changes and scientific and/or technological progress;

(2) the references to the European standards mentioned in this Regulation may be updated in the event that CEN amends those references.**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 65

Report to the European Parliament and the Council

1 The Commission shall, not later than 20 May 2007, submit a report to the European Parliament and the Council.

2 The report shall, in particular, review the experience gained from the application of this Regulation and consider in particular the following issues:

a re-evaluating the scope, in relation to animal health and animal welfare;

b ensuring that other sectors contribute to the financing of official controls by extending the list of activities referred to in Annex IV, section A and in Annex V, section A, and taking into account in particular the impact of the Community feed and food hygiene legislation after its adoption;

c setting updated minimum rates for fees referred to in Annex IV, section B and in Annex V, section B, taking into account in particular risk factors.

3 The Commission shall, if appropriate, accompany the report with relevant proposals.

[F5 Article 66

[F5 Community financial support]

. . . . . .

Textual Amendments

F5 Deleted by Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC.

TITLE X

FINAL PROVISION

Article 67

Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2006.

However, Articles 27 and 28 shall apply from 1 January 2007.

[F6 ANNEX I

TERRITORIES REFERRED TO IN ARTICLE 2(15)

Textual Amendments

F6 Substituted by Council Regulation (EU) No 517/2013 of 13 May 2013 adapting certain regulations and decisions in the fields of free movement of goods, freedom of movement for persons, company law, competition policy, agriculture, food safety, veterinary and phytosanitary policy, transport policy, energy, taxation, statistics, trans-European networks, judiciary and fundamental rights, justice, freedom and security, environment, customs union, external relations, foreign, security and defence policy and institutions, by reason of the accession of the Republic of Croatia.

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 Faeroe Islands and Greenland
5. The territory of the Federal Republic of Germany
6. The territory of the Republic of Estonia
7. The territory of Ireland
8. The territory of the Hellenic Republic
9. The territory of the Kingdom of Spain with the exception of Ceuta and Melilla
10. The territory of the French Republic
11. The territory of the Republic of Croatia
12. The territory of the Italian Republic
13. The territory of the Republic of Cyprus
14. The territory of the Republic of Latvia
15. The territory of the Republic of Lithuania
16. The territory of the Grand Duchy of Luxembourg
17. The territory of Hungary
18. The territory of Malta
19. The territory of the Kingdom of the Netherlands in Europe
20. The territory of the Republic of Austria
21. The territory of the Republic of Poland
22. The territory of the Portuguese Republic
23. The territory of Romania

24. The territory of the Republic of Slovenia

25. The territory of the Slovak Republic

26. The territory of the Republic of Finland

27. The territory of the Kingdom of Sweden

28. The territory of the United Kingdom of Great Britain and Northern Ireland.**]**

ANNEX II

COMPETENT AUTHORITIES

CHAPTER I: SUBJECT MATTER FOR THE TRAINING OF STAFF PERFORMING OFFICIAL CONTROLS

1. Different control techniques, such as auditing, sampling and inspection

2. Control procedures

3. Feed and food law

4. 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 and for the environment

5. Assessment of non-compliance with feed and food law

6. Hazards in animal feed and food production

7. The evaluation of the application of HACCP procedures

8. Management systems such as quality assurance programmes that feed and food businesses operate and their assessment in so far as these are relevant for feed or food law requirements

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 proficiency testing, accreditation and risk assessment, which may be relevant to the assessment of compliance with feed or food law; this may include financial and commercial aspects

13. Any other area, including animal health and animal welfare, 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 authority and the relationship between central competent authorities and authorities to which they have delegated tasks to carry out official controls
2. The relationship between competent authorities and control bodies to which they have delegated tasks related to official controls
3. A statement on the objectives to be achieved
4. Tasks, responsibilities and duties of staff
5. Sampling procedures, control methods and techniques, interpretation of results and consequent decisions
6. Monitoring and surveillance 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, methods of analysis and detection tests
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 determination;
   - (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 5725:1994 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 5725:1994 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

ACTIVITIES AND MINIMUM RATES FOR FEES OR CHARGES RELATED TO OFFICIAL CONTROLS IN RELATION TO COMMUNITY ESTABLISHMENTS

SECTION A: ACTIVITIES

1. The activities covered by Directives 89/662/EEC, 90/425/EEC, 93/119/EC and 96/23/EC for which Member States are currently collecting fees pursuant to Directive 85/73/EEC

2. The approval of feed establishments

SECTION B: MINIMUM RATES

Member States shall collect for controls relating to the following list of products, at least the corresponding minimum rates for fees or charges.

CHAPTER I

Minimum rates for fees or charges applicable to slaughter inspection

(a)beef meat	
— adult bovine animals:	5 EUR/animal
— young bovine animals:	2 EUR/animal

(b) solipeds and equidae:	3 EUR/animal
(c)pigmeat: animals of a carcase weight	
— of less than 25 kg:	0,5 EUR/animal
— equal to or greater than 25 kg:	1 EUR/animal
(d)sheepmeat and goatmeat: animals of a carcase weight	
— of less than 12 kg:	0,15 EUR/animal
— equal to or greater than 12 kg:	0,25 EUR/animal
(e)poultrymeat	
— poultry of genus Gallus and guinea fowl:	0,005 EUR/animal
— ducks and geese:	0,01 EUR/animal
— turkeys:	0,025 EUR/animal
— farmed rabbit meat:	0,005 EUR/animal.

CHAPTER II

Minimum rates for fees or charges applicable to cutting plants controls

Per tonne of meat:

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

CHAPTER III

Minimum rates for fees or charges applicable to game processing houses

(a) small game birds:	0,005 EUR/animal
(b) small ground game:	0,01 EUR/animal
(c) ratites:	0,5 EUR/animal
(d)land mammals:	
— boar:	1,5 EUR/animal

— ruminants:	0,5 EUR/animal

CHAPTER IV

Minimum rates for fees or charges applicable to milk production

— EUR 1 per 30 tonnes

and

— EUR 0,5 per tonne, thereafter.

CHAPTER V

Minimum rates for fees or charges applicable to the producing and placing on the market of fishery products and aquaculture products

(a) first placing on the market of fishery and aquaculture products:
- — 1 EUR/tonne for the first 50 tonnes in the month;
- — 0,5 EUR/tonne thereafter.

(b) first sale in fish market
- — 0,5 EUR/tonne for the first 50 tonnes in the month;
- — 0,25 EUR/tonne thereafter.

(c) first sale in case of lack of or insufficient gradation for freshness and/or size in accordance with Regulations (EEC) No 103/76 and (EEC) No 104/76:
- — 1 EUR/tonne for the first 50 tonnes in the month;
- — 0,5 EUR/tonne thereafter.

The fees collected on the species referred to in Annex II to Commission Regulation (EEC) No 3703/85 must not exceed EUR 50 per consignment.

Member States will collect 0,5 EUR/tonne for the processing of fishery and aquaculture products.

ANNEX V

ACTIVITIES AND MINIMUM RATES FOR FEES OR CHARGES RELATED TO THE OFFICIAL CONTROLS OF GOODS AND LIVE ANIMALS INTRODUCED INTO THE COMMUNITY

SECTION A: ACTIVITIES OR CONTROLS

The activities covered by Directives 97/78/EC and 91/496/EEC for which Member States are currently collecting fees pursuant to Directive 85/73/EEC.

SECTION B: FEES OR CHARGES

CHAPTER I

Fees applicable to imported meat

The minimum fee rates for the official control on the import of a consignment of meat are fixed at:

— EUR 55 per consignment, up to six tonnes,

and

— EUR 9 per tonne, up to 46 tonnes, thereafter,

or

— EUR 420 per consignment, over 46 tonnes.

CHAPTER II

Fees applicable to imported fishery products

1. The minimum fee for the official control on the import of a consignment of fishery products is fixed at:
   — EUR 55 per consignment, up to six tonnes,

   and

   — EUR 9 per tonne, up to 46 tonnes, thereafter,

   or

   — EUR 420 per consignment, over 46 tonnes.

2. The above amount for the official control on the import of a consignment of fishery products, transported as break bulk shipment, shall be:
   — EUR 600 per vessel, with a cargo of fishery products up to 500 tonnes,
   — EUR 1 200 per vessel, with a cargo of fishery products up to 1 000 tonnes,
   — EUR 2 400 per vessel, with a cargo of fishery products up to 2 000 tonnes,
   — EUR 3 600 per vessel, with a cargo of fishery products of more than 2 000 tonnes.

3. In the case of fishery products caught in their natural environment directly landed by a fishing vessel flying the flag of a third country, the provisions laid down in Annex IV, Section B, Chapter V, point (a) shall apply.

CHAPTER III

Fees or charges applicable to meat products, poultrymeat, wild game meat, rabbit meat, farmed game meat, by-products and feed of animal origin

1. The minimum fee for the official control on the import of a consignment of products of animal origin other than those mentioned in Chapters I and II or a consignment of by-products of animal origin or a consignment of feed, is fixed at:
   — EUR 55 per consignment, up to six tonnes,

and

— EUR 9 per tonne, up to 46 tonnes, thereafter,

or

— EUR 420 per consignment, over 46 tonnes.

2. The above amount for the official control on the import of a consignment of products of animal origin other than those mentioned in Chapters I and II, a consignment of by-products of animal origin or a consignment of feed transported as break bulk shipment, shall be:

— EUR 600 per vessel, with a cargo of products up to 500 tonnes,

— EUR 1 200 per vessel, with a cargo of products up to 1 000 tonnes,

— EUR 2 400 per vessel, with a cargo of products up to 2 000 tonnes,

— EUR 3 600 per vessel, with a cargo products of more than 2 000 tonnes.

CHAPTER IV

Fees applicable to transit trought the community of goods and live animals

The amount of fees or charges for the official control on the transit of goods and live animals through the Community is fixed at a minimum level of EUR 30, increased by EUR 20 per quarter of an hour for every member of staff involved in the controls.

CHAPTER V

Fees applicable to imported live animals

1. The fee for the official control on the import of a consignment of live animals is fixed:

(a) for bovine animals, equidae, pigs, sheep, goats, poultry, rabbits and small game birds or ground game and the following land mammals: wild boar and ruminants, at:

— EUR 55 per consignment, up to six tonnes,

and

— EUR 9 per tonne, up to 46 tonnes, thereafter,

or

— EUR 420 per consignment, over 46 tonnes,

(b) for animals of other species at the actual cost of inspection expressed either per animal or per tonne imported, at:

— EUR 55 per consignment, up to 46 tonnes,

or

— EUR 420 per consignment, over 46 tonnes,

it being understood that this minimum does not apply to imports of species referred to in Commission Decision 92/432/EEC.

2. At the request of a Member State, accompanied by appropriate supporting documents and in accordance with the procedure laid down in Article 18 of Directive 89/662/EEC, a lower level of fees may be applied to imports from certain third countries.

ANNEX VI

CRITERIA TO BE TAKEN INTO CONSIDERATION FOR THE CALCULATION OF FEES

1. The salaries of the staff involved in the official controls

2. The costs for the staff involved in the official controls, including facilities, tools, equipment, training, travel and associated costs

3. The laboratory analysis and sampling costs

[F7ANNEX VII

EUROPEAN UNION (EU) REFERENCE LABORATORIES (Previously referred to as 'COMMUNITY REFERENCE LABORATORIES')

Textual Amendments

F7 Substituted by Commission Regulation (EU) No 208/2011 of 2 March 2011 amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council and Commission Regulations (EC) No 180/2008 and (EC) No 737/2008 as regards lists and names of EU reference laboratories (Text with EEA relevance).

I.EU REFERENCE LABORATORIES FOR FEED AND FOOD

F8 1. **EU reference laboratory for milk and milk products**

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Textual Amendments

F8 Deleted by Commission Regulation (EU) 2017/2460 of 30 October 2017 amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, as regards the list of Union reference laboratories (Text with EEA relevance).

2. **EU reference laboratories for the analysis and testing of zoonoses (*salmonella*)**

Rijksinstituut voor Volksgezondheid en Milieu (RIVM)

Bilthoven

The Netherlands

3. **EU reference laboratory for the monitoring of marine biotoxins**

Agencia Española de Seguridad Alimentaria (AESA)

Vigo

Spain

[F9]4. EU reference laboratory for monitoring the viral and bacteriological contamination of bivalve molluscs

. . . . . .

Textual Amendments

F9 Deleted by Commission Regulation (EU) 2018/222 of 15 February 2018 amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the European Union reference laboratory for monitoring the viral and bacteriological contamination of bivalve molluscs (Text with EEA relevance).

5. **EU reference laboratory for *Listeria monocytogenes***

ANSES — Laboratoire de sécurité des aliments

Maisons-Alfort

France

6. **EU reference laboratory for Coagulase positive *Staphylococci*, including *Staphylococccus aureus***

ANSES — Laboratoire de sécurité des aliments

Maisons-Alfort

France

7. **EU reference laboratory for *Escherichia coli*, including Verotoxigenic *E. coli* (VTEC)**

Istituto Superiore di Sanità (ISS)

Roma

Italy

8. **EU reference laboratory for *Campylobacter***

Statens Veterinärmedicinska Anstalt (SVA)

Uppsala

Sweden

9. **EU reference laboratory for parasites (in particular *Trichinella, Echinococcus* and *Anisakis*)**

Istituto Superiore di Sanità (ISS)

Roma

Italy

10. **EU reference laboratory for antimicrobial resistance**

Fødevareinstituttet

Danmarks Tekniske Universitet

København

Denmark

11. **EU reference laboratory for animal proteins in feedingstuffs**

Centre wallon de recherches agronomiques (CRA-W)

Gembloux

Belgium

12. **EU reference laboratories for residues of veterinary medicines and contaminants in food of animal origin**

[F10(a) For the residues listed in Annex I, Group A (1), (2), (3) and (4), Group B (2)(d) and Group B (3)(d) to Directive 96/23/EC

RIKILT – Institute for Food Safety, part of Wageningen UR

Wageningen

The Netherlands**]**

Textual Amendments

F10 Substituted by Commission Regulation (EU) No 563/2012 of 27 June 2012 amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the list of EU reference laboratories (Text with EEA relevance).

(b) For the residues listed in Annex I, Group B (1) and B (3)(e) to Directive 96/23/EC and carbadox and olaquindox

ANSES – Laboratoire de Fougères

France

(c) For the residues listed in Annex I, Group A (5) and Group B (2)(a), (b), (e) to Directive 96/23/EC

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)

Berlin

Germany

F11(d) For the residues listed in Annex I, Group B(3)(c) to Directive 96/23/EC

. . . . . .

Textual Amendments

F11 Deleted by Commission Implementing Regulation (EU) 2018/1587 of 22 October 2018 revoking the designation of the Istituto Superiore di Sanità, Rome, Italy, as a European Reference Laboratory for the residues listed in Annex I, Group B(3)(c) to Council Directive 96/23/EC (Text with EEA relevance).

[F1213. **EU reference laboratory for transmissible spongiform encephalopathies (TSEs)**

The laboratory referred to in point 1 of Chapter B of Annex X to Regulation (EC) No 999/2001**]**

Textual Amendments

F12 Substituted by Commission Regulation (EU) 2018/221 of 15 February 2018 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the European Union reference laboratory for transmissible spongiform encephalopathies (Text with EEA relevance).

14. **EU reference laboratory for additives for use in animal nutrition**

The laboratory referred to in Annex II of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(46)]:

The Joint Research Centre of the European Commission

Geel

Belgium

15. **EU reference laboratory for genetically modified organisms (GMOs)**

The laboratory referred to in the Annex to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[(47)]:

The Joint Research Centre of the European Commission

Ispra

Italy

16. **EU reference laboratory for material intended to come into contact with foodstuffs**

The Joint Research Centre of the European Commission

Ispra

Italy

17. **EU reference laboratories for residues of pesticides**

(a) Cereals and feedingstuffs

Fødevareinstituttet

Danmarks Tekniske Universitet

København

Denmark

(b) Food of animal origin and commodities with high fat content

Chemisches und Veterinäruntersuchungsamt (CVUA) Freiburg

Freiburg

Germany

(c) Fruits and vegetables, including commodities with high water and high acid content

Laboratorio Agrario de la Generalitat Valenciana (LAGV)

Burjassot-Valencia

Spain

Grupo de Residuos de Plaguicidas de la Universidad de Almería (PRRG)

Almería

Spain

(d) Single residue methods

Chemisches und Veterinäruntersuchungsamt (CVUA) Stuttgart

Fellbach

Germany

[F13 18. EU reference laboratory for metals and nitrogenous compounds in feed and food

National Food Institute, Technical University of Denmark

Copenhagen

Denmark

Textual Amendments

F13 Substituted by Commission Regulation (EU) 2018/192 of 8 February 2018 amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the EU reference laboratories in the field of contaminants in feed and food.

19. **EU reference laboratory for mycotoxins and plant toxins in feed and food**

RIKILT (Stichting Wageningen Research)

Wageningen

The Netherlands

20. **EU reference laboratory for processing contaminants**

National Food Institute, Technical University of Denmark

Copenhagen

Denmark

21. **EU reference laboratory for halogenated persistent organic pollutants (POPs) in feed and food**

Chemisches und Veterinäruntersuchungsamt (CVUA) Freiburg

Freiburg

Germany**]**

[F14 22. **EU reference laboratory for foodborne viruses**

Livsmedelsverket

Uppsala

Sweden**]**

Textual Amendments

F14 Inserted by Commission Regulation (EU) 2017/1389 of 26 July 2017 amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the designation of the EU reference laboratory for foodborne viruses (Text with EEA relevance).

II. EU REFERENCE LABORATORIES FOR ANIMAL HEALTH AND LIVE ANIMALS

1. **EU reference laboratory for classical swine fever**

The laboratory referred to in Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever[48].

F15 2. **EU reference laboratory for African horse sickness**

. . . . . .

Textual Amendments

F15 Deleted by Commission Regulation (EU) 2018/415 of 16 March 2018 laying down additional responsibilities and tasks for the European Union reference laboratory for African horse sickness and amending Annex II to Council Directive 92/35/EEC, Annex II to Council Directive 2000/75/EC and Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council (Text with EEA relevance).

3. **EU reference laboratory for avian influenza**

The laboratory referred to in Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC[49].

4. **EU reference laboratory for Newcastle disease**

The laboratory referred to in Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease[50].

5. **EU reference laboratory for swine vesicular disease**

The laboratory referred to in Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease[51].

[F16 6. EU reference laboratory for fish and crustacean diseases

Danmarks Tekniske Universitet

Veterinærinstituttet

Afdeling for Diagnostik og Beredskab — Fiskesygdomme, Kemitorvet, Bygning 202

2800 Kgs. Lyngby

Denmark**]**

Textual Amendments

F16 Substituted by Commission Regulation (EU) 2018/455 of 16 March 2018 laying down additional responsibilities and tasks for the European Union reference laboratory for fish and crustacean diseases and amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council (Text with EEA relevance).

7. EU reference laboratory for mollusc diseases

Ifremer — Institut français de recherche pour l'exploitation de la mer

La Tremblade

France

8. EU reference laboratory for monitoring the effectiveness of rabies vaccination

The laboratory referred to in Council Decision 2000/258/EC of 20 March 2000 designating a specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines[52].

F15 9. EU reference laboratory for bluetongue

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10. EU reference laboratory for African swine fever

The laboratory referred to in Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever[53].

11. EU reference laboratory for zootechnics

The laboratory referred to in Council Decision 96/463/EC of 23 July 1996 designating the reference body responsible for collaborating in rendering uniform the testing methods and the assessment of the results for pure-bred breeding animals of the bovine species[54].

12. EU reference laboratory for foot-and-mouth disease

The laboratory referred to in Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC[55].

13. **EU reference laboratory for brucellosis**

ANSES — Laboratoire de santé animale

Maisons-Alfort

France

14. **EU reference laboratory for equine diseases other than African horse sickness**

ANSES — Laboratoire de santé animale/Laboratoire de pathologie équine

Maisons-Alfort

France

[F17]15. **EU reference laboratory for crustacean diseases**

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Textual Amendments

F17 Deleted by Commission Regulation (EU) 2018/455 of 16 March 2018 laying down additional responsibilities and tasks for the European Union reference laboratory for fish and crustacean diseases and amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council (Text with EEA relevance).

16. **EU reference laboratory for rabies**

ANSES — Laboratoire de la rage et de la faune sauvage de Nancy

Malzeville

France

17. **EU reference laboratory for bovine tuberculosis**

VISAVET — Laboratorio de vigilancia veterinaria, Facultad de Veterinaria, Universidad Complutense de Madrid

Madrid

Spain

[[F18]18. **EU reference laboratory for bee health**

ANSES — Sophia-Antipolis Laboratory

Sophia-Antipolis

France**]**

Textual Amendments

F18 Inserted by Commission Regulation (EU) No 880/2011 of 2 September 2011 correcting Regulation (EU) No 208/2011 amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of

the Council and Commission Regulations (EC) No 180/2008 and (EC) No 737/2008 as regards lists and names of EU reference laboratories (Text with EEA relevance).

[F19 19. EU reference laboratory for diseases caused by capripox viruses (lumpy skin disease and sheep and goat pox)

Veterinary and Agrochemical Research Centre — CODA-CERVA

Operational Directorate Viral Diseases

Unit Vesicular and Exotic Diseases

Groeselenberg 99

1180 Brussels

Belgium**]**

Textual Amendments

F19 Inserted by Commission Regulation (EU) 2017/140 of 26 January 2017 designating the EU reference laboratory for diseases caused by capripox viruses (lumpy skin disease and sheep and goat pox), laying down additional responsibilities and tasks for this laboratory and amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council (Text with EEA relevance).

[F20 20. EU reference laboratory for peste des petits ruminants

‘Centre de coopération internationale en recherche agronomique pour le développement (CIRAD)’

TA A-15/G,

Campus International de Baillarguet

34398 Montpellier Cedex

France**]**

Textual Amendments

F20 Inserted by Commission Regulation (EU) 2017/212 of 7 February 2017 designating the EU reference laboratory for peste des petits ruminants, laying down additional responsibilities and tasks for this laboratory and amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council (Text with EEA relevance).

[F21 21. EU reference laboratory for African horse sickness and bluetongue

Laboratorio Central de Veterinaria — Área de Sanidad Animal

Ctra. M-106, P.K. 1,4

28110 Algete (Madrid)

ESPAÑA**]]**

Textual Amendments

F21 Inserted by Commission Regulation (EU) 2018/415 of 16 March 2018 laying down additional responsibilities and tasks for the European Union reference laboratory for African horse sickness and amending Annex II to Council Directive 92/35/EEC, Annex II to Council Directive 2000/75/EC and Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council (Text with EEA relevance).

ANNEX VIII

IMPLEMENTING RULES THAT REMAIN IN FORCE PURSUANT TO ARTICLE 61

1. Implementing rules based on Directive 70/373/EEC on the introduction of Community methods of sampling and analysis for the official control of feedingstuffs

   (a) First Commission Directive 71/250/EEC of 15 June 1971 establishing Community methods of analysis for the official control of feedingstuffs[(56)]

   (b) Second Commission Directive 71/393/EEC of 18 November 1971 establishing Community methods of analysis for the official control of feedingstuffs[(57)]

   (c) Third Commission Directive 72/199/EEC of 27 April 1972 establishing Community methods of analysis for the official control of feedingstuffs[(58)]

   (d) Fourth Commission Directive 73/46/EEC of 5 December 1972 establishing Community methods of analysis for the official control of feedingstuffs[(59)]

   (e) First Commission Directive 76/371/EEC of 1 March 1976 establishing Community methods of sampling for the official control of feedingstuffs[(60)]

   (f) Seventh Commission Directive 76/372/EEC of 1 March 1976 establishing Community methods of analysis for the official control of feedingstuffs[(61)]

   (g) Eighth Commission Directive 78/633/EEC of 15 June 1978 establishing Community methods of analysis for the official control of feedingstuffs[(62)]

   (h) Ninth Commission Directive 81/715/EEC of 31 July 1981 establishing Community methods of analysis for the official control of feedingstuffs[(63)]

   (i) Tenth Commission Directive 84/425/EEC of 25 July 1984 establishing Community methods of analysis for the official control of feedingstuffs[(64)]

   (j) Eleventh Commission Directive 93/70/EEC of 28 July 1993 establishing Community methods of analysis for the official control of feedingstuffs[(65)]

   (k) Twelfth Commission Directive 93/117/EC of 17 December 1993 establishing Community methods of analysis for the official control of feedingstuffs[(66)]

(l) Commission Directive 98/64/EC of 3 September 1998 establishing Community methods of analysis for the determination of amino acids, crude oils and fats, and olaquindox in feedingstuffs[(67)]

(m) Commission Directive 2003/126/EC of 23 December 2003 on the analytical method for the determination of constituents of animal origin for the official control of foodstuffs[(68)]

(n) Commission Directive 1999/27/EC of 20 April 1999 establishing Community methods of analysis for the determination of amprolium, diclazuril and carbadox in feedingstuffs[(69)]

(o) Commission Directive 1999/76/EC of 23 July 1999 establishing a Community method of analysis for the determination of lasalocid sodium in feedingstuffs[(70)]

(p) Commission Directive 2000/45/EC of 6 July 2000 establishing Community methods of analysis for the determination of vitamin A, vitamin E and tryptophan in feedingstuffs[(71)]

(q) Directive 2002/70/EC of 26 July 2002 establishing requirements for the determination of levels of dioxins and dioxin-like PCBs in feedingstuffs[(72)]

2. Implementing rules based on Directive 95/53/EC of 25 October 1995 fixing the principles governing the organisation of official inspections in the field of animal nutrition

Commission Directive 98/68/EC of 10 September 1998 laying down the standard document referred to in Article 9(1) of Council Directive 95/53/EC and certain rules for checks at the introduction into the Community of feedingstuffs from third countries[(73)].**]**

(**1**) [X1OJ C 234, 30.9.2003, p. 25.

(**2**) OJ C 23, 27.1.2004, p. 14.

(**3**) Opinion of the European Parliament of 9 March 2004 (not yet published in the Official Journal) and Council Decision of 26 April 2004.

(**4**) OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

(**5**) OJ L 169, 10.7.2000, p. 1. Directive as last amended by Commission Directive 2004/31/EC (OJ L 85, 23.3.2004, p. 18).

(**6**) OJ L 198, 22.7.1991, p. 1. Regulation as last amended by Regulation (EC) No 392/2004 (OJ L 65, 3.3.2004, p. 1).

(**7**) OJ L 208, 24.7.1992, p. 1. Regulation as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

(**8**) OJ L 208, 24.7.1992, p. 9. Regulation as last amended by Regulation (EC) No 806/2003.

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

(**10**) Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries (OJ L 268, 24.9.1991, p. 56). Directive as last amended by Directive 96/43/EC (OJ L 162, 1.7.1996, p. 1).

(**11**) OJ L 265, 8.11.1995, p. 17. Directive as last amended by Directive 2001/46/EC of the European Parliament and of the Council (OJ L 234, 1.9.2001, p. 55).

(**12**) OJ L 302, 19.10.1992, p. 1. Regulation as last amended by Regulation (EC) No 2700/2000 of the European Parliament and of the Council (OJ L 311, 12.12.2000, p. 17).

(**13**) OJ L 40, 17.2.1993, p. 1. Regulation as last amended by Regulation (EC) No 806/2003.

(**14**) OJ L 139, 30.4.2004, p. 55.

(**15**) OJ L 332, 30.12.1995, p. 15. Directive as last amended by Regulation (EC) No 806/2003.

(**16**) stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, (OJ L 125, 23.5.1996, p. 3). Directive as last amended by Directive 2003/74/EC of the European Parliament and of the Council (OJ L 262, 14.10.2003, p. 17).

(**17**) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products (OJ L 125, 23.5.1996, p. 10). Directive as last amended by Regulation (EC) No 806/2003.

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

(**19**) Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1). Regulation as last amended by Commission Regulation (EC) No 2245/2003 (OJ L 333, 20.12.2003, p. 28).

(**20**) Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other food-borne zoonotic agents (OJ L 325, 12.12.2003, p. 1).

(**21**) Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals (OJ L 221, 7.8.1986, p. 37). Directive as last amended by Commission Directive 2004/2/EC (OJ L 14, 21.1.2004, p. 10).

(**22**) Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables (OJ L 350, 14.12.1990, p. 71). Directive as last amended by Commission Directive 2004/2/EC.

(**23**) Commission Directive 92/1/EEC of 13 January 1992 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption (OJ L 34, 11.2.1992, p. 28).

(**24**) Commission Directive 92/2/EEC of 13 January 1992 laying down the sampling procedure and the Community method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption (OJ L 34, 11.2.1992, p. 30).

(**25**) Council Directive 70/373/EEC of 20 July 1970 on the introduction of Community methods of sampling and analysis for the official control of feedingstuffs (OJ L 170, 3.8.1970, p. 2). Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

(**26**) Council Directive 85/591/EEC of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption (OJ L 372, 31.12.1985, p. 50). Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1)

(**27**) Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (OJ L 186, 30.6.1989, p. 23)

(**28**) Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs (OJ L 290, 24.11.1993, p. 14). Directive as amended by Regulation (EC) No 1882/2003.

(**29**) Council Decision 93/383/EEC of 14 June 1993 of reference laboratories for the monitoring of marine biotoxins (OJ L 166, 8.7.1993, p. 31). Decision as amended by Decision 1999/312/EC (OJ L 120, 8.5.1999, p. 37).

(**30**) Council Directive 96/43/EC of 26 June 1996 amending and consolidating Directive 85/73/EEC in order to ensure financing of veterinary inspections and controls on live animals and certain animal products (OJ L 162, 1.7.1996, p. 1).

(**31**) Council Decision 98/728/EC of 14 December 1998 concerning a Community system for fees in the animal feed sector (OJ L 346, 22.12.1998, p. 51).

(**32**) Council Decision 1999/313/EC of 29 April 1999 on reference laboratories for monitoring bacteriological and viral contamination of bivalve molluscs (OJ L 120, 8.5.1999, p. 40).

(**33**) OJ L 184, 17.7.1999, p. 23.

(**34**) OJ L 281, 23.11.1995, p. 31. Directive as amended by Regulation (EC) No 1882/2003.

(**35**) OJ L 145, 31.5.2001, p. 43.

(**36**) OJ L 224, 18.8.1990, p. 19. Decision as last amended by Regulation (EC) No 806/2003.

(**37**) OJ L 351, 2.12.1989, p. 34.

(**38**) OJ L 165, 30.4.2004, p. 1'.

(**39**) OJ L 165, 30.4.2004, p. 1.'

(**40**) OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 808/2003 (OJ L 117, 13.5.2003, p. 1).

(**41**) OJ L 18, 23.1.2003, p. 11.

(**42**) OJ L 139, 30.4.2004'.

(**43**) OJ L 165, 30.4.2004, p. 1'.

(**44**) OJ L 165, 30.4.2004, p. 1'.

(**45**) OJ L 340, 9.12.1976, p. 25.

(**46**) [F7OJ L 268, 18.10.2003, p. 29.

(**47**) OJ L 268, 18.10.2003, p. 1.

(**48**) OJ L 316, 1.12.2001, p. 5.

(**49**) OJ L 10, 14.1.2006, p. 16.

(**50**) OJ L 260, 5.9.1992, p. 1.

(**51**) OJ L 62, 15.3.1993, p. 69.

(**52**) OJ L 79, 30.3.2000, p. 40.

(**53**) OJ L 192, 20.7.2002, p. 27.

(**54**) OJ L 192, 2.8.1996, p. 19.

(**55**) OJ L 306, 22.11.2003, p. 1.**]**

(**56**) OJ L 155, 12.7.1971, p. 13. Directive as last amended by Commission Directive 1999/27/EC (OJ L 118, 6.5.1999, p. 36).

(**57**) OJ L 279, 20.12.1971, p. 7. Directive as last amended by Commission Directive 98/64/EC (OJ L 257, 19.9.1998, p. 14).

(**58**) OJ L 123, 29.5.1972, p. 6. Directive as last amended by Commission Directive 1999/79/EC (OJ L 209, 7.8.1999, p. 23).

(**59**) OJ L 83, 30.3.1973, p. 21. Directive as last amended by Commission Directive 1999/27/EC.

(**60**) OJ L 102, 15.4.1976, p. 1.

(**61**) OJ L 102, 15.4.1976, p. 8. Directive as last amended by Commission Directive 94/14/EC (OJ L 94, 13.4.1994, p. 30).

(**62**) OJ L 206, 29.7.1978, p. 43. Directive as last amended by Commission Directive 84/4/EEC (OJ L 15, 18.1.1984, p. 28).

(**63**) OJ L 257, 10.9.1981, p. 38.

(**64**) OJ L 238, 6.9.1984, p. 34.

(**65**) OJ L 234, 17.9.1993, p. 17.

(**66**) OJ L 329, 30.12.1993, p. 54.

(**67**) OJ L 257, 19.9.1998, p. 14.

(**68**) OJ L 339, 24.12.2003, p. 78.

(**69**) OJ L 118, 6.5.1999, p. 36.

(**70**) OJ L 207, 6.8.1999, p. 13.

(**71**) OJ L 174, 13.7.2000, p. 32.

(**72**) OJ L 209, 6.8.2002, p. 15.

(**73**) OJ L 261, 24.9.1998, p. 32.**]**

Editorial Information

X1 Substituted by Corrigendum to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (Official Journal of the European Union L 165 of 30 April 2004).

Textual Amendments

F7 Substituted by Commission Regulation (EU) No 208/2011 of 2 March 2011 amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council and Commission Regulations (EC) No 180/2008 and (EC) No 737/2008 as regards lists and names of EU reference laboratories (Text with EEA relevance).

Status:
Point in time view as at 01/01/2019.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 882/2004 of the European Parliament and of the Council (repealed).