

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performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (repealed)

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⁽¹⁾ 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⁽²⁾;
- 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 The following implementing measures may be taken in accordance with the procedure referred to in Article 62(3):

- 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.

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.

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";
- b EN 45002 on "General criteria for the assessment of testing laboratories";
- 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.

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.
- 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 in accordance with the procedure referred to in Article 62(3) or, in the absence of such conditions, with national rules.

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.

The rates in Annex IV, Section B and Annex V, Section B shall be updated at least every two years, in accordance with the procedure referred to in Article 62(3), in particular to take account of inflation.

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.

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 Without prejudice to requirements concerning official certification adopted for animal health or animal welfare purposes, requirements may be adopted, in accordance with the procedure referred to in Article 62(3), 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.

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.

*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 .../...⁺, 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 .../...⁽³⁾, Regulation (EC) No .../...⁽⁴⁾, 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).

- (1) [OJ L 281, 23.11.1995, p. 31](#). Directive as amended by Regulation (EC) No 1882/2003.
- (2) [OJ L 145, 31.5.2001, p. 43](#).
- (3) Note to OJ: Insert No of Regulation from footnote 1 on previous page.
- (4) Regulation (EC) No .../... of the European Parliament and of the Council of, laying down specific hygiene rules for food of animal origin intended for human consumption, and amending Directives 89/662/EEC and 91/67/EEC (OJ L ...).