Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)

TITLE III

OFFICIAL CONTROLS AND FINAL PROVISIONS

CHAPTER I

Official controls

Article 44

Procedure for approval

1 The competent authority shall approve establishments or plants only where an on site visit, prior to start-up of any activity, has demonstrated that they meet the relevant requirements laid down in accordance with Article 27.

2 The competent authority may grant conditional approval if it appears, from the on site visit, that the establishment or plant meets all the infrastructure and equipment requirements with a view to ensuring the application of the operational procedures in compliance with this Regulation. It shall grant full approval only if it appears, from another on site visit carried out within three months of granting conditional approval, that the establishment or plant meets the other requirements referred to in paragraph 1. If clear progress has been made, but the establishment or plant still does not meet all of these requirements, the competent authority may extend conditional approval. However, conditional approval shall not exceed a total of six months.

3 Operators shall ensure that an establishment or plant ceases to operate if the competent authority withdraws its approval or in the case of conditional approval fails to extend it or to grant full approval.

Article 45

Official controls

1 Without prejudice to Article 5, the competent authority shall at regular intervals carry out official controls and supervision of the handling of animal by-products and derived products falling within the scope of this Regulation.

2 Articles 41 and 42 of Regulation (EC) No 882/2004 shall apply mutatis mutandis to official controls carried out to verify compliance with this Regulation.

3 The competent authority may take into account adherence to guides to good practice, when carrying out its official controls.

4 Detailed arrangements for implementing this Article, including rules concerning the reference methods for microbiological analyses, may be laid down.

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 52(4).

Article 46

Suspensions, withdrawals and prohibitions on operations

1 If the official controls and supervision carried out by the competent authority reveal that one or more of the requirements of this Regulation are not met, it shall take appropriate action.

The competent authority shall in particular, as appropriate to the nature and to the gravity of the deficiencies and to the potential risks for public and animal health:

a suspend approvals of establishments or plants approved pursuant to this Regulation, if:

(i) the conditions for approving or operating the establishment or plant are no longer fulfilled;

(ii) the operator can be expected to remedy the deficiencies within a reasonable period of time; and

(iii) the potential risks to public and animal health do not require action in accordance with point (b);

b withdraw approvals of establishments or plants approved pursuant to this Regulation, if:

(i) the conditions for approving or operating the establishment or plant are no longer fulfilled; and

(ii) the operator cannot be expected to remedy the deficiencies within a reasonable period of time:

— for reasons relating to the infrastructure of the establishment or plant,

— for reasons relating to the personal capacity of the operator or the staff under his supervision, or

— because of serious risks to public and animal health requiring major adjustments to the operation of the establishment or plant before the operator may apply for re-approval;

c impose specific conditions on establishments or plants in order to rectify existing deficiencies.

2 The competent authority shall, as appropriate to the nature and to the gravity of the deficiencies and to the potential risks for public and animal health, temporarily or permanently prohibit operators referred to in Articles 23(1) and (3) and Article 24(1) from carrying out operations under this Regulation, as appropriate, following receipt of information indicating:

a that the requirements of Community legislation are not met; and

b potential risks to public or animal health arising from such operations.

Article 47

Lists

1 Each Member State shall draw up a list of establishments, plants and operators which have been approved or registered in accordance with this Regulation within its territory.

It shall assign an official number to each approved or registered establishment, plant or operator, which identifies the establishment, plant or operator with respect to the nature of its activities.

Member States shall indicate, if applicable, an official number which has been assigned to the establishment, plant or operator under other Community legislation.

Member States shall make the lists of approved or registered establishments, plants and operators available to the Commission and other Member States.

Member States shall keep up-to-date the lists of approved or registered establishments, plants and operators and make them available to other Member States and to the public.

2 Measures for the implementation of this Article may be laid down in accordance with the regulatory procedure referred to in Article 52(3), in particular on:

a the format for the lists referred to in paragraph 1; and

b the procedure for making the lists referred to in paragraph 1 available.

Article 48

Controls for dispatch to other Member States

1 Where an operator intends to dispatch Category 1 material, Category 2 material and meat-and-bone meal or animal fat derived from Category 1 and Category 2 materials to another Member State, it shall inform the competent authority of the Member State of origin and the competent authority of the Member State of destination.

The competent authority of the Member State of destination shall decide upon application by the operator, within a specified time period:

a to refuse receipt of the consignment;

b to accept the consignment unconditionally; or

c to make receipt of the consignment subject to the following conditions:

(i) if the derived products have not undergone pressure sterilisation, it must undergo such treatment; or

(ii) the animal by-products or derived products must comply with any conditions for the dispatch of the consignment which are justified for the protection of public and animal health in order to ensure that animal by-products and derived products are handled in accordance with this Regulation.

2 Formats for applications by operators referred to in paragraph 1 may be adopted in accordance with the regulatory procedure referred to in Article 52(3).

3 The competent authority of the Member State of origin shall inform the competent authority of the Member State of destination, by means of the Traces system in accordance

with Decision 2004/292/EC, of the dispatch of each consignment sent to the Member State of destination, of

a animal by-products or derived products referred to in paragraph 1;

b processed animal protein derived from Category 3 material.

When informed of the dispatch, the competent authority of the Member State of destination shall inform the competent authority of the Member State of origin of the arrival of each consignment by means of the Traces system.

4 Category 1 and Category 2 materials, meat-and-bone meal and animal fat referred to in paragraph 1 shall be transported directly to the establishment or plant of destination, which must have been registered or approved in accordance with Articles 23, 24 and 44 or, in the case of manure, to the farm of destination.

5 When animal by-products or derived products are sent to other Member States via the territory of a third country, they shall be sent in consignments which have been sealed in the Member State of origin and shall be accompanied by a health certificate.

The sealed consignments shall re-enter the Community only via a border inspection post, in accordance with Article 6 of Directive 89/662/EEC.

6 By way of derogation from paragraphs 1 to 5, animal by-products or derived products referred to therein which have been mixed or contaminated with any waste listed as hazardous in Decision 2000/532/EC shall be sent to other Member States only subject to the requirements of Regulation (EC) No 1013/2006.

7 Measures for the implementation of this Article may be adopted relating to the following:

a a specified time period for the decision of the competent authority as referred to in paragraph 1;

b supplementary conditions for the dispatch of animal by-products or derived products referred to in paragraph 4;

c models for the health certificates which have to accompany consignments sent in accordance with paragraph 5; and

d conditions under which animal by-products or derived products intended to be used for exhibitions, artistic activities, for diagnostic, educational or research purposes may be sent to other Member States, by way of derogation from paragraph 1 to 5 of this Article.

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 52(4).

8 Measures for the implementation of this Article may specify the conditions subject to which, by way of derogation from paragraphs 1 to 4, the competent authorities may allow:

a the dispatch of manure transported between two points located on the same farm or between farms located in the border regions of Member States sharing a common border;

b the dispatch of other animal by-products transported between establishments or plants located in the border regions of Member States sharing a common border; and

c the transport of a dead pet animal for incineration to an establishment or plant located in the border region of another Member State sharing a common border.

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 52(4).

Article 49

Community controls in Member States

1 Experts from the Commission may make on-the-spot checks, in cooperation with the competent authorities of Member States, in so far as is necessary for the uniform application of this Regulation.

The Member State on whose territory the checks are made shall provide the experts with all the assistance necessary for carrying out their duties.

The Commission shall inform the competent authority of the results of the checks made.

2 Measures for the implementation of this Article may be adopted in accordance with the regulatory procedure referred to in Article 52(3), in particular on the procedure for the cooperation with national authorities.

Article 50

Application of Regulation (EC) No 882/2004 for the purposes of certain controls

1 Article 46 of Regulation (EC) No 882/2004 shall apply mutatis mutandis to Community controls in third countries carried out to verify compliance with this Regulation.

2 Article 50(1)(a) of Regulation (EC) No 882/2004 shall apply mutatis mutandis to the phased introduction of the requirements of Article 41(3) of this Regulation.

3 Article 52 of Regulation (EC) No 882/2004 shall apply mutatis mutandis to third-country controls in Member States related to operations under this Regulation.

CHAPTER II

Final provisions

Article 51

National provisions

Member States shall communicate to the Commission the text of the provisions of national law they adopt in areas under their competence which directly concern the proper implementation of this Regulation.

Article 52

Committee procedure

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58(1) of Regulation (EC) No 178/2002.

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 set at three months.

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.

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

The time limits laid down in Article 5a(3)(c), (4)(b) and (4)(e) of Decision 1999/468/EC shall be two months, one month and two months respectively.

6 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 53

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 4 June 2011 and shall notify it without delay of any subsequent amendment affecting them.

Article 54

Repeal

Regulation (EC) No 1774/2002 shall be repealed with effect from 4 March 2011.

References to Regulation (EC) No 1774/2002 shall be construed as references to this Regulation and shall be read in accordance with the correlation table laid down in the Annex.

Article 55

Transitional measure

Establishments, plants and users approved or registered in accordance with Regulation (EC) No 1774/2002 before 4 March 2011 shall be deemed to be approved or registered, as required, in accordance with this Regulation.

Article 56

Entry into force

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

It shall apply from 4 March 2011.