Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (Text with EEA relevance)

CHAPTER II

AUTHORISATION, USE, MONITORING AND TRANSITIONAL MEASURES APPLICABLE FOR FEED ADDITIVES

Article 3

Placing on the market, processing and use

1 No person shall place on the market, process or use a feed additive unless:

a it is covered by an authorisation granted in accordance with this Regulation;

b the conditions for use set out in this Regulation, including the general conditions set out in Annex IV, unless otherwise provided for in the authorisation, and in the authorisation of the substance are met; and

c the conditions on labelling set out in this Regulation are met.

2 For experiments for scientific purposes, Member States may authorise the use, as additives, of substances which are not authorised at Community level, with the exception of antibiotics, provided that the experiments are carried out in accordance with the principles and conditions laid down in Directive 87/153/EEC, Directive 83/228/EEC[(1)] or the guidelines set out in Article 7(4) of this Regulation and provided that there is adequate official supervision. The animals concerned may be used for food production only if the authorities establish that this will have no adverse effect on animal health, human health or the environment.

3 In the case of additives belonging to categories (d) and (e) of Article 6(1) and of those additives falling within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from genetically modified organisms (GMOs), no person other than the holder of the authorisation named in the authorisation Regulation referred to in Article 9, his legal successor or successors, or a person acting under his written authority, shall first place the product on the market.

4 Unless otherwise specified, the mixing of additives to be sold directly to the end-user shall be allowed, subject to compliance with the conditions for use laid down in the authorisation for each single additive. Consequently, the mixing of authorised additives shall not be subject to specific authorisations other than the requirements laid down in Directive 95/69/EC[(2)].

5 Where necessary as a result of technological progress or scientific development, the general conditions set out in Annex IV may be adapted in accordance with the procedure referred to in Article 22(2).

Article 4

Authorisation

1 Any person seeking an authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

2 An authorisation shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds and under the procedures set out in this Regulation, or in accordance with Articles 53 and 54 of Regulation (EC) No 178/2002.

3 The applicant for an authorisation or his representative shall be established in the Community.

Article 5

Conditions for authorisation

1 No feed additive shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated in accordance with the implementing measures referred to in Article 7 that, when used in accordance with conditions to be set out in the Regulation authorising the use of the additive, it satisfies the requirements of paragraph 2, and has at least one of the characteristics set out in paragraph 3.

2 The feed additive shall not:

a have an adverse effect on animal health, human health or the environment,

b be presented in a manner which may mislead the user,

c harm the consumer by impairing the distinctive features of animal products or mislead the consumer with regard to the distinctive features of animal products.

3 The feed additive shall:

a favourably affect the characteristics of feed,

b favourably affect the characteristics of animal products,

c favourably affect the colour of ornamental fish and birds,

d satisfy the nutritional needs of animals,

e favourably affect the environmental consequences of animal production,

f favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs, or

g have a coccidiostatic or histomonostatic effect.

4 Antibiotics, other than coccidiostats or histomonostats, shall not be authorised as feed additives.

Article 6

Categories of feed additives

1 A feed additive shall be allocated to one or more of the following categories, depending on its functions and properties, in accordance with the procedure set out at Articles 7, 8 and 9:

a technological additives: any substance added to feed for a technological purpose;

b sensory additives: any substance, the addition of which to feed improves or changes the organoleptic properties of the feed, or the visual characteristics of the food derived from animals;

c nutritional additives;

d zootechnical additives: any additive used to affect favourably the performance of animals in good health or used to affect favourably the environment;

e coccidiostats and histomonostats.

2 Within the categories referred to in paragraph 1, feed additives shall further be allocated within one or more of the functional groups mentioned in Annex I, according to their principal function or functions, in accordance with the procedure specified in Articles 7, 8 and 9.

3 Where necessary as a result of technological progress or scientific development, additional feed additive categories and functional groups may be established in accordance with the procedure referred to in Article 22(2).

Article 7

Application for authorisation

1 An application for an authorisation as provided for in Article 4 shall be sent to the Commission. The Commission shall without delay inform the Member States and forward the application to the European Food Safety Authority (hereinafter referred to as the Authority).

2 The Authority shall:

a acknowledge receipt of the application, including the particulars and documents referred to in paragraph 3, in writing, to the applicant within 15 days of its receipt, stating the date of receipt;

b make any information supplied by the applicant available to the Member States and the Commission;

c make the summary of the dossier mentioned in paragraph 3(h) available to the public, subject to the confidentiality requirements laid down in Article 18(2).

3 At the time of application, the applicant shall send the following particulars and documents directly to the Authority:

a his name and address;

b the identification of the feed additive, a proposal for its classification by category and functional group under Article 6, and its specifications, including, where applicable, purity criteria;

c a description of the method of production, manufacturing and intended uses of the feed additive, of the method of analysis of the additive in feed according to its intended use and, where appropriate, of the method of analysis for the determination of the level of residues of the feed additive, or its metabolites, in food;

d a copy of the studies which have been carried out and any other material which is available to demonstrate that the feed additive satisfies the criteria laid down in Article 5(2) and (3);

e proposed conditions for placing the feed additive on the market, including labelling requirements and, where appropriate, specific conditions for use and handling (including known incompatibilities), use levels in complementary feedingstuffs and animal species and categories for which the feed additive is intended;

f a written statement that three samples of the feed additive have been sent by the applicant directly to the Community reference laboratory referred to in Article 21, in accordance with the requirements set out in Annex II;

g for additives which, according to the proposal under point (b), do not belong to either category (a) or category (b) referred to in Article 6(1), and for additives falling within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from GMOs, a proposal for post-market monitoring;

h a summary containing the information provided under points (a) to (g);

i for additives falling within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from GMOs, details of any authorisation granted in accordance with the applicable legislation.

4 The Commission, having first consulted the Authority, shall establish, in accordance with the procedure laid down in Article 22(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.

Until such implementing rules are adopted, the application shall be made in accordance with the Annex to Directive 87/153/EEC.

5 After the Authority has been consulted, specific guidelines for the authorisation of additives shall be established, where necessary for each category of additive referred to in Article 6(1) in accordance with the procedure laid down in Article 22(2). These guidelines shall take account of the possibility of extrapolating the results of the studies carried out on major species to minor species.

After the Authority has been consulted, further rules for the implementation of this Article may be established in accordance with the procedure referred to in Article 22(2). These rules should, where appropriate, differentiate between requirements for feed additives in respect of food-producing animals and requirements in respect of other animals, in particular pets. The implementing rules shall include provisions which allow for simplified procedures for the authorisation of additives which have been authorised for use in food.

6 The Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of its application.

Article 8

Opinion of the Authority

1 The Authority shall give an opinion within six months of receipt of a valid application. This time limit shall be extended whenever the Authority seeks supplementary information from the applicant under paragraph 2.

2 The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a time limit specified by the Authority after consultation with the applicant.

3 In order to prepare its opinion, the Authority:

a shall verify that the particulars and documents submitted by the applicant are in accordance with Article 7 and undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5;

b shall verify the report of the Community Reference Laboratory.

4 In the event of an opinion in favour of authorising the feed additive, the opinion shall also include the following elements:

a the name and address of the applicant;

b the designation of the feed additive including its categorisation and allocation within functional groups provided for in Article 6, its specification, including, where applicable, purity criteria and method of analysis;

c depending on the outcome of the assessment, specific conditions or restrictions in relation to handling, post-market monitoring requirements and use, including animal species and categories of animal species for which the additive is to be used;

d specific additional requirements for the labelling of the feed additive necessary as a result of conditions and restrictions imposed under (c);

e a proposal for the establishment of Maximum Residues Limits (MRLs) in the relevant foodstuffs of animal origin, unless the opinion of the Authority concludes that the establishment of MRLs is not necessary for the protection of consumers or MRLs have already been established in Annex I or III to Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin[(3)].

5 The Authority shall without delay forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the feed additive and stating the reasons for its conclusion.

6 The Authority shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 18(2).

Article 9

Authorisation by the Community

1 Within three months of receipt of the opinion of the Authority, the Commission shall prepare a draft Regulation to grant authorisation or to deny authorisation. This draft shall take into account the requirements of Article 5(2) and (3), Community law and other legitimate factors relevant to the matter under consideration and in particular benefits for animal health and welfare and for the consumer of animal products.

Where the draft is not in accordance with the opinion of the Authority, it shall provide an explanation of the reasons for the differences.

In exceptionally complex cases, the three-month deadline may be extended.

2 The draft shall be adopted in accordance with the procedure referred to in Article 22(2).

3 Rules for the implementation of this Article and in particular concerning an identification number for authorised additives may be established in accordance with the procedure referred to in Article 22(2).

4 The Commission shall without delay inform the applicant of the Regulation adopted in accordance with paragraph 2.

5 A Regulation granting the authorisation shall include the elements mentioned in Article 8(4)(b), (c), (d) and (e) and an identification number.

6 A Regulation granting authorisation for additives belonging to categories (d) and (e) referred to in Article 6(1) and also for additives consisting of, containing or produced from GMOs, shall include the name of the holder of the authorisation, and, where appropriate, the unique identifier attributed to the GMO as referred to in Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC[(4)].

7 Where the levels of residues of an additive in food from animals fed with that additive might have a detrimental effect on human health, the Regulation shall include MRLs for the active substance or for its metabolites in the relevant foodstuffs of animal origin. In this case the active substance shall be considered for the purposes of Council Directive 96/23/EC[(5)] as falling under Annex I to that Directive. Where an MRL for the substance concerned has already been established in Community rules, that MRL shall also apply to residues of the active substance or its metabolites originating from the use of the substance as a feed additive.

8 The authorisation granted in accordance with the procedure laid down in this Regulation shall be valid throughout the Community for 10 years and shall be renewable in accordance with Article 14. The authorised feed additive shall be entered in the Register referred to in Article 17 (hereinafter referred to as the Register). Each entry in the Register shall state the date of authorisation and shall include the particulars referred to in paragraphs 5, 6 and 7.

9 The granting of authorisation shall be without prejudice to the general civil and criminal liability of any feed operator in respect of the feed additive concerned.

Article 10

Status of existing products

1 By way of derogation from Article 3, a feed additive which has been placed on the market pursuant to Directive 70/524/EEC and urea and derivatives, an amino acid, salt of an amino acid or analogous substance, which was listed in points 2.1, 3 and 4 of the Annex to Directive 82/471/EEC, may be placed on the market and used in accordance with the conditions specified in Directives 70/524/EEC or 82/471/EEC and their implementing measures, including in particular specific labelling provisions concerning compound feed and feed materials, provided that the following conditions are met:

a within one year of the entry into force of this Regulation, persons first placing the feed additive on the market or any other interested parties shall notify this fact to the Commission. At the same time, the particulars mentioned in Article 7(3)(a), (b) and (c) shall be directly sent to the Authority;

b within one year of the notification mentioned under (a), the Authority shall, after verification that all the information required has been submitted, notify the Commission that it has received the information required under this Article. The products concerned shall be entered in the Register. Each entry in the Register shall mention the date on which the product concerned was first entered in the Register and, where applicable, the expiry date of the existing authorisation.

2 An application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of seven years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC. A detailed calendar listing in order of priority the different classes of additives to be re-evaluated may be adopted in accordance with the procedure referred to in Article 22(2). The Authority shall be consulted in drawing up the list.

3 Products entered in the Register shall be subject to the provisions of this Regulation, in particular Articles 8, 9, 12, 13, 14 and 16, which without prejudice to specific conditions concerning the labelling, placing on the market and use of each substance pursuant to paragraph 1, shall apply to such products as if they had been authorised pursuant to Article 9.

4 In the case of authorisations not issued to a specific holder, any person who imports or manufactures the products referred to in this Article or any other interested party may submit

the information as referred to in paragraph 1 or the application as referred to in paragraph 2 to the Commission.

5 Where the notification and accompanying particulars referred to in paragraph 1(a) are not supplied within the period specified or are found to be incorrect, or where an application is not submitted as required by paragraph 2 within the period specified, a Regulation shall be adopted, in accordance with the procedure referred to in Article 22(2), requiring the additives concerned to be withdrawn from the market. Such a measure may provide for a limited period of time within which existing stocks of the product may be used up.

6 Where, for reasons beyond the control of the applicant, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until the Commission takes a decision. The Commission shall inform the applicant of this extension of the authorisation.

7 By way of derogation from Article 3, substances, micro-organisms and preparations used in the Community as silage additives at the date referred to in Article 26(2), may be placed on the market and used provided that points (a) and (b) of paragraph 1 and paragraph 2 are complied with. Paragraphs 3 and 4 shall apply accordingly. For these substances, the deadline for application as referred to in paragraph 2 shall be seven years after the entry into force of this Regulation.

Article 11

Phasing out

1 With a view to a decision on the phasing out of the use of coccidiostats and histomonostats as feed additives by 31 December 2012, the Commission shall submit to the European Parliament and the Council before 1 January 2008 a report on the use of these substances as feed additives and available alternatives, accompanied, where appropriate, by legislative proposals.

2 By way of derogation from Article 10 and without prejudice to Article 13, antibiotics, other than coccidiostats and histomonostats, may be marketed and used as feed additives only until 31 December 2005; as from 1 January 2006, those substances shall be deleted from the Register.

Article 12

Supervision

1 After an additive has been authorised in accordance with this Regulation, any person using or placing on the market that substance, or a feedingstuff into which it has been incorporated, or any other interested party shall ensure that any conditions or restrictions which have been imposed on the placing on the market, use and handling of the additive or feedingstuffs containing it are respected.

2 Where monitoring requirements, as referred to in Article 8(4)(c), have been imposed, the holder of the authorisation shall ensure that monitoring is carried out and shall submit reports to the Commission in accordance with the authorisation. The holder of the authorisation shall forthwith communicate to the Commission any new information that might influence the evaluation of the safety in use of the feed additive, in particular health sensitivities of specific categories of consumers. The holder of the authorisation shall forthwith inform the Commission

of any prohibition or restriction imposed by the competent authority of any third country in which the feed additive is placed on the market.

Article 13

Modification, suspension and revocation of authorisations

1 On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation still meets the conditions set out by this Regulation. It shall forthwith transmit this opinion to the Commission, to the Member States and, where applicable, to the holder of the authorisation. The opinion shall be made public.

2 The Commission shall examine the opinion of the Authority without delay. Any appropriate measures shall be taken in accordance with Articles 53 and 54 of Regulation (EC) No 178/2002. A decision on the modification, suspension or revocation of an authorisation shall be taken in accordance with the procedure referred to in Article 22(2) of this Regulation.

3 If the holder of the authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States. The Commission shall examine the opinion of the Authority without delay and decide in accordance with the procedure referred to in Article 22(2).

4 The Commission shall without delay inform the applicant of the decision taken. The Register shall be amended where appropriate.

5 Articles 7(1) and (2), 8 and 9 shall apply accordingly.

Article 14

Renewal of authorisations

1 Authorisations under this Regulation shall be renewable for 10-year periods. An application for renewal shall be sent to the Commission at the latest one year before the expiry date of the authorisation.

In the case of authorisations not issued to a specific holder, any person who first places the additive on the market or any other interested party may submit the application to the Commission and shall be considered as the applicant.

In the case of authorisations issued to a specific holder, the holder of the authorisation or his legal successor or successors may submit the application to the Commission and shall be deemed to be the applicant.

2 At the time of application, the applicant shall send the following particulars and documents directly to the Authority:

a a copy of the authorisation for placing the feed additive on the market;

b a report on the results of the post-market monitoring, if such monitoring requirements are included in the authorisation;

c any other new information which has become available with regard to the evaluation of the safety in use of the feed additive and the risks of the feed additive to animals, humans or the environment;

d where appropriate, a proposal for amending or supplementing the conditions of the original authorisation, *inter alia*, the conditions concerning future monitoring.

3 Articles 7(1), (2), (4) and (5), 8 and 9 shall apply accordingly.

4 Where, for reasons beyond the control of the applicant, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until the Commission takes a decision. Information on this extension of the authorisation shall be made available to the public in the Register referred to in Article 17.

Article 15

Urgent authorisation

In specific cases where urgent authorisation is needed to ensure the protection of animal welfare, the Commission may, in accordance with the procedure referred to in Article 22(2), provisionally authorise the use of an additive for a maximum period of five years.

(**1**) OJ L 126, 13.5.1983, p. 23.

(**2**) 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 and amending Directives 70/524/EEC, 74/63/EEC, 79/373/EEC and 82/471/EEC (OJ L 332, 30.12.1995, p. 15). Directive as last amended by Regulation (EC) No 806/2003.

(**3**) OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1490/2003 (OJ L 214, 26.8.2003, p. 3).

(**4**) See page 24 of this Official Journal.

(**5**) OJ L 125, 23.5.1996, p. 10.

Status:
Point in time view as at 22/09/2003.

Changes to legislation:
There are outstanding changes not yet made to Regulation (EC) No 1831/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.