

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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Economic and Social Committee ⁽²⁾,

Following consultation of the Committee of the Regions,

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

Whereas:

- (1) Livestock production occupies a very important place in the agriculture of the Community. Satisfactory results depend to a large extent on the use of safe and good-quality feedingstuffs.
- (2) The free movement of safe and wholesome food and feed is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.
- (3) A high level of protection of human life and health should be assured in the pursuit of Community policies.
- (4) In order to protect human health, animal health and the environment, feed additives should undergo a safety assessment through a Community procedure before being placed on the market, used or processed within the Community. Since pet food is not part of the human food chain and has no environmental impact on arable land, specific provisions for additives in pet food are appropriate.
- (5) It is a principle of the Community food law enshrined in Article 11 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ⁽⁴⁾ that food and feed imported for placing on the market within the Community must comply with the relevant requirements of Community legislation or with conditions recognised by the Community to be at least equivalent

thereto. It is therefore necessary to subject imports from third countries of additives for use in animal nutrition to requirements equivalent to those applying to additives produced in the Community.

- (6) Action by the Community relating to human health, animal health and the environment should be based on the precautionary principle.
- (7) In accordance with Article 153 of the Treaty, the Community is to contribute to promoting the right of consumers to information.
- (8) Experience with the application of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs ⁽⁵⁾ has shown that it is necessary to review all the rules on additives in order to take into account the need to ensure a greater degree of protection of animal and human health and of the environment. It is also necessary to take into account the fact that technological progress and scientific developments have made available new types of additives, such as those to be used on silage or in water.
- (9) This Regulation should also cover mixtures of additives sold to the end-user, and the marketing and use of those mixtures should comply with the conditions laid down in the authorisation of each single additive.
- (10) Premixtures should not be regarded as preparations covered by the definition of additives.
- (11) The basic principle in this field should be that only those additives approved under the procedure provided for in this Regulation may be placed on the market, used and processed in animal feeding under conditions set out in the authorisation.
- (12) Categories of feed additives should be defined in order to facilitate the assessment procedure with a view to authorisation. Amino acids, their salts and analogues, and urea and its derivatives, which are currently covered by Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition ⁽⁶⁾, should be included as a category of feed additives and therefore transferred from the scope of that Directive to this Regulation.

⁽¹⁾ OJ C 203 E, 27.8.2002, p. 10.

⁽²⁾ OJ C 61, 14.3.2003, p. 43.

⁽³⁾ Opinion of the European Parliament of 21 November 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 (OJ C 113 E, 13.5.2003, p. 1), Decision of the European Parliament of 19 June 2003 (not yet published in the Official Journal) and Council Decision of 22 July 2003.

⁽⁴⁾ OJ L 31, 1.2.2002, p. 1.

⁽⁵⁾ OJ L 270, 14.12.1970, p. 1. Directive as last amended by Regulation (EC) No 1756/2002 (OJ L 265, 3.10.2002, p. 1).

⁽⁶⁾ OJ L 213, 21.7.1982, p. 8. Directive as last amended by Directive 1999/20/EC (OJ L 80, 25.3.1999, p. 20).

- (13) Implementing rules concerning applications for authorisation of feed additives should take into account different documentation requirements for food-producing and other animals.
- (14) In order to ensure a harmonised scientific assessment of feed additives, such assessment should be carried out by the European Food Safety Authority, established by Regulation (EC) No 178/2002. Applications should be supplemented by residue studies in order to assess the establishment of Maximum Residues Limits (MRLs).
- (15) The Commission should establish guidelines for the authorisation of feed additives in cooperation with the European Food Safety Authority. In establishing these guidelines, attention should be paid to the possibility of extrapolating the results of the studies carried out on major species to minor species.
- (16) It is also necessary to provide for a simplified authorisation procedure for those additives which have successfully undergone the authorisation procedure for food use provided for in Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption ⁽¹⁾.
- (17) It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account, including societal, economic or environmental factors, feasibility of controls and the benefit for the animal or for the consumer of animal products. Therefore, the authorisation of an additive should be granted by the Commission.
- (18) In order to ensure the necessary level of protection for animal welfare and consumer safety, applicants should be encouraged to seek authorisation extensions for minor species by being granted one year's additional data protection in addition to the 10 years' data protection for all species for which the additive is authorised.
- (19) Competence for authorising feed additives and establishing conditions for their use and for maintaining and publishing a register of authorised feed additives should be conferred on the Commission in accordance with a procedure by which close collaboration between Member States and the Commission is guaranteed in the framework of the Standing Committee on the Food Chain and Animal Health.
- (20) It is necessary to introduce, where appropriate, an obligation for the holder of the authorisation to implement a post-market monitoring plan in order to trace and identify any direct or indirect, immediate, delayed, or unforeseen effect resulting from the use of feed additives on human or animal health or the environment using a product tracing framework similar to that which already exists in other sectors and in line with the traceability requirements laid down in food law.
- (21) In order to allow technological progress and scientific development to be taken into account, it is necessary to revise the authorisations of feed additives regularly. Time-limited authorisations should allow this review.
- (22) A register of authorised feed additives should be established, including product-specific information and detection methods. Non-confidential data should be made available to the public.
- (23) It is necessary to establish transitional rules to take into account additives which are already on the market and which were authorised under Directive 70/524/EEC, and amino acids, their salts and analogues, urea and its derivatives, currently authorised under Directive 82/471/EEC, and silage agents, as well as additives for which the authorisation procedure is in progress. In particular, it is appropriate to provide that such products can remain on the market only insofar as notification with a view to their evaluation has been submitted to the Commission within one year after the entry into force of this Regulation.
- (24) A number of silage additives are currently marketed and used in the Community without an authorisation granted pursuant to Directive 70/524/EEC. While it is indispensable to apply the provisions of this Regulation to such substances in view of their nature and use, it is appropriate to apply the same transitional arrangements. In this way it will be possible to obtain information on all the substances currently used and to establish a list of them, which would allow safeguard measures to be taken, where appropriate, for those substances that do not fulfil the authorisation criteria mentioned in Article 5 of this Regulation.
- (25) The Scientific Steering Committee stated in its opinion of 28 May 1999 that: 'regarding the use of antimicrobials as growth promoting agents, the use of agents from classes which are or may be used in human or veterinary medicine (i.e. where there is a risk of selecting for cross-resistance to drugs used to treat bacterial infections) should be phased out as soon as possible and ultimately abolished'. The second opinion of the Scientific Steering Committee on antimicrobial resistance adopted on 10 and 11 May 2001 confirmed the need to provide a sufficient time to replace those antimicrobials by alternative products: 'Thus, the phase-out process must be planned and coordinated since precipitous actions could have repercussions for animal health'.

⁽¹⁾ OJ L 40, 11.2.1989, p. 27. Directive amended by Directive 94/34/EC of the European Parliament and of the Council (OJ L 237, 10.9.1994, p. 1).

- (26) Therefore, it is necessary to set a date after which the use of the antibiotics still authorised for use as growth promoting agents will be forbidden, while allowing sufficient time for the development of alternative products to replace those antibiotics. Provision should also be made to forbid the authorisation of any further antibiotics for use as feed additives. Within the framework of the phasing out of antibiotics used as growth promoters and in order to ensure a high level of protection of animal health, the European Food Safety Authority will be asked to review the progress achieved in the development of alternative substances and alternative methods of management, feeding, hygiene, etc., before 2005.
- (27) Certain substances with coccidiostatic and histomono-static effects should be considered as feed additives for the purposes of this Regulation.
- (28) Detailed labelling of the product should be required since it enables the end-user to make a choice with full knowledge of the facts, creates fewer obstacles to trade and facilitates fairness of transactions. In this respect, it is generally appropriate for requirements applying to feed additives to mirror the ones applying to food additives. It is therefore appropriate to provide for simplified labelling requirements for flavouring compounds similar to the ones applied to food flavourings; this should however be without prejudice to the possibility to provide for specific labelling requirements in the authorisation of individual additives.
- (29) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed⁽¹⁾ provides for an authorisation procedure for the placing on the market of genetically modified food and feed, including feed additives consisting of, containing or produced from genetically modified organisms. Since the objectives of the said Regulation are different from those of this Regulation, feed additives should undergo an authorisation procedure in addition to the authorisation procedure provided for by that Regulation before they are placed on the market.
- (30) Articles 53 and 54 of Regulation (EC) No 178/2002 establish procedures for taking emergency measures in relation to feed of Community origin or imported from a third country. They allow such measures to be adopted in situations where feed is likely to constitute a serious risk to human health, animal health or the environment and where such risk cannot be contained satisfactorily by measures taken by the Member State(s) concerned.
- (31) 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⁽²⁾.
- (32) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.
- (33) Directive 70/524/EEC should be repealed. However labelling provisions applicable to compound feeding-stuffs incorporating additives should be maintained until a revision of Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs⁽³⁾ is completed.
- (34) Guidelines addressed to the Member States for the presentation of an application dossier are contained in Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition⁽⁴⁾. Verification of the conformity of dossiers is entrusted to the European Food Safety Authority. It is therefore necessary to repeal Directive 87/153/EEC. However, the Annex should remain in force until implementing rules are adopted.
- (35) A transitional period is needed to avoid disruptions in the use of feed additives. Therefore, until the rules of this Regulation are applicable, the substances already authorised should be permitted to remain on the market and be used under the conditions of the current legislation.

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

Scope

1. The purpose of this Regulation is to establish a Community procedure for authorising the placing on the market and use of feed additives and to lay down rules for the supervision and labelling of feed additives and premixtures in order to provide the basis for the assurance of a high level of protection of human health, animal health and welfare, environment and users' and consumers' interests in relation to feed additives, whilst ensuring the effective functioning of the internal market.

⁽²⁾ OJ L 184, 17.7.1999, p. 23.

⁽³⁾ OJ L 86, 6.4.1979, p. 30. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

⁽⁴⁾ OJ L 64, 7.3.1987, p. 19. Directive as last amended by Commission Directive 2001/79/EC (OJ L 267, 6.10.2001, p. 1).

⁽¹⁾ See page 1 of this Official Journal.

2. This Regulation shall not apply to:

- (a) processing aids;
- (b) veterinary medicinal products as defined in Directive 2001/82/EC ⁽¹⁾, with the exception of coccidiostats and histomonostats used as feed additives.

Article 2

Definitions

1. For the purpose of this Regulation, the definitions of 'feed', 'feedingstuff', 'feed business', 'feed business operator', 'placing on the market' and 'traceability' laid down in Regulation (EC) No 178/2002 shall apply.

2. The following definitions shall also apply:

- (a) 'feed additives' means substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3);
- (b) 'feed materials' means products as defined in Article 2(a) of Council Directive 96/25/EC of 29 April 1996 on the circulation of feed materials ⁽²⁾;
- (c) 'compound feedingstuffs' means products as defined in Article 2(b) of Directive 79/373/EEC;
- (d) 'complementary feedingstuffs' means products as defined in Article 2(e) of Directive 79/373/EEC;
- (e) 'premixtures' means mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals;
- (f) 'daily ration' means the average total quantity of feedingstuffs, calculated on a moisture content of 12 %, required daily by an animal of a given species, age category and yield, to satisfy all its needs;
- (g) 'complete feedingstuffs' means products as defined in Article 2(c) of Council Directive 1999/29/EC of 22 April 1999 on the undesirable substances and products in animal nutrition ⁽³⁾;
- (h) 'processing aids' means any substance not consumed as a feedingstuff by itself, intentionally used in the processing of feedingstuffs or feed materials to fulfil a technological purpose during treatment or processing which may result in the unintentional but technologically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not have an adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed;
- (i) 'antimicrobials' means substances produced either synthetically or naturally, used to kill or inhibit the growth of micro-organisms, including bacteria, viruses or fungi, or of parasites, in particular protozoa;

(j) 'antibiotic' means antimicrobials produced by, or derived from, a micro-organism, which destroys or inhibits the growth of other micro-organisms;

(k) 'coccidiostats' and 'histomonostats' means substances intended to kill or inhibit protozoa;

(l) 'maximum residue limit' means the maximum concentration of residue resulting from the use of an additive in animal nutrition which may be accepted by the Community as being legally permitted or recognised as acceptable in or on a food;

(m) 'micro-organism' means: colony-forming micro-organisms.

(n) 'first placing on the market' means the initial placing on the market of an additive after its manufacture, the import of an additive, or, where an additive has been incorporated into feed without being placed on the market, the first placing on the market of that feed.

3. Where necessary, it may be determined, in accordance with the procedure referred to in Article 22(2), whether a substance, micro-organism or preparation is a feed additive within the scope of this Regulation.

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 ⁽⁴⁾ 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.

⁽¹⁾ OJ L 311, 28.11.2001, p. 1.

⁽²⁾ OJ L 125, 23.5.1996, p. 35. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽³⁾ OJ L 115, 4.5.1999, p. 32. Directive as last amended by Regulation (EC) No 806/2003.

⁽⁴⁾ OJ L 126, 13.5.1983, p. 23.

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 ⁽¹⁾.

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).

⁽¹⁾ 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.

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 ⁽¹⁾.

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).

⁽¹⁾ 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. 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 ⁽²⁾.

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 ⁽³⁾ 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:

⁽²⁾ See page 24 of this Official Journal.

⁽³⁾ OJ L 125, 23.5.1996, p. 10.

- (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.

CHAPTER III

LABELLING AND PACKAGING

Article 16

Labelling and packaging of feed additives and premixtures

1. No person shall place on the market a feed additive or a premixture of additives unless its packaging or container is labelled under the responsibility of a producer, packer, importer, seller or distributor established within the Community and bears the following information, in a conspicuous, clearly legible and indelible manner, in at least the national language or languages of the Member State in which it is marketed, in relation to each additive contained in the material:

- (a) the specific name given to the additives upon authorisation, preceded by the name of the functional group as mentioned in the authorisation;
- (b) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this Article;
- (c) the net weight or, in the case of liquid additives and premixtures, either the net volume or the net weight;
- (d) where appropriate, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of Directive 95/69/EC or the registration number assigned to the establishment or the intermediary pursuant to Article 10 of that Directive;
- (e) directions for use, and any safety recommendations regarding the use and, where applicable, the specific requirements mentioned in the authorisation, including animal species and categories for which the additive or premixture of additives is intended;
- (f) the identification number;
- (g) the batch reference number and date of manufacture.

2. For flavouring compounds, the list of additives may be replaced by the words 'mixture of flavouring compounds'. This shall not apply to flavouring compounds subject to a quantitative limitation when used in feed and drinking water.

3. In addition to the information specified in paragraph 1, the packaging or container of an additive belonging to a functional group specified in Annex III must bear the information, presented in a conspicuous, clearly legible and indelible manner, indicated in that Annex.

4. Moreover, in the case of premixtures, the word 'Premixture' (in capital letters) must appear clearly on the label, and the carrier substance must be declared.

5. Additives and premixtures shall be marketed only in closed packages or closed containers which must be closed in such a way that the fastener is damaged on opening and cannot be re-used.

6. Amendments to Annex III to take technological progress and scientific development into account may be adopted in accordance with the procedure referred to in Article 22(2).

CHAPTER IV

GENERAL AND FINAL PROVISIONS

Article 17

Community Register of Feed Additives

1. The Commission shall establish and keep up to date a Community Register of Feed Additives.

2. The Register shall be made available to the public.

Article 18

Confidentiality

1. The applicant may indicate which information submitted under this Regulation he wishes to be treated as confidential on the ground that its disclosure might significantly harm his competitive position. Verifiable reasons must be given in such cases.

2. The Commission shall determine, after consultation with the applicant, which information other than that specified in paragraph 3 should be kept confidential and shall inform the applicant of its decision.

3. The following information shall not be considered confidential:

- (a) name and composition of the feed additive and, where appropriate, indication of the production strain;
- (b) physico-chemical and biological characteristics of the feed additive;
- (c) the conclusions of the study results on effects of the feed additive on human and animal health and on the environment;
- (d) the conclusions of the study results on effects of the feed additive on the characteristics of animal products and its nutritional properties;
- (e) methods for detection and identification of the feed additive and, where applicable, monitoring requirements and a summary of the results of the monitoring.

4. Notwithstanding paragraph 2, the Authority shall, on request, supply the Commission and Member States with all information in its possession, including any identified as confidential pursuant to paragraph 2.

5. The Authority shall apply the principles of 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 ⁽¹⁾ when handling applications for access to documents held by the Authority.

6. The Member States, the Commission and the Authority shall keep confidential all the information identified as confidential under paragraph 2 except where it is appropriate for such information to be made public in order to protect human health, animal health or the environment. Member States shall handle applications for access to documents received under this Regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.

7. If an applicant withdraws or has withdrawn an application, the Member States, the Commission and the Authority shall respect the confidentiality of commercial and industrial information, including research and development information, as well as information on which the Commission and the applicant disagree as to its confidentiality.

Article 19

Administrative review

Any decision taken under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned.

For that purpose, a request shall be submitted to the Commission within two months after the day on which the party concerned became aware of the act or omission in question.

The Commission shall take a decision within two months requiring, if appropriate, the Authority to withdraw its decision or to remedy its failure to act within a set time limit.

Article 20

Data protection

1. The scientific data and other information in the application dossier required under Article 7 may not be used for the benefit of another applicant for a period of 10 years from the date of authorisation, unless the other applicant has agreed with the previous applicant that such data and information may be used.

2. In order to stimulate efforts to obtain authorisations for minor species for additives whose use is authorised for other species, the 10-year data protection period shall be extended by one year for each minor species for which a use extension authorisation is granted.

⁽¹⁾ OJ L 145, 31.5.2001, p. 43.

3. The applicant and the previous applicant shall take all necessary steps to reach agreement on sharing the use of information, in order not to repeat toxicological tests on vertebrates. If, however, no such agreement is reached on sharing the information, the Commission may decide to disclose information necessary to avoid repeating toxicological tests on vertebrates, while ensuring a reasonable balance between the interests of the parties concerned.

4. On the expiry of the 10-year period, the findings of all or part of the evaluation conducted on the basis of the scientific data and information contained in the application dossier may be used by the Authority for the benefit of another applicant.

Article 21

Reference laboratories

The Community Reference Laboratory and its duties and tasks shall be those laid down in the Annex II.

Applicants for the authorisation of additives shall contribute to supporting the cost of the tasks of the Community Reference Laboratory and the consortium of National Reference Laboratories mentioned in Annex II.

Detailed rules for implementing Annex II and any amendments to that Annex shall be adopted in accordance with the procedure referred to in Article 22(2).

Article 22

Committee procedure

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

2. 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.

3. The Committee shall adopt its rules of procedure.

Article 23

Repeals

1. Directive 70/524/EEC shall be repealed with effect from the date of application of this Regulation. However, Article 16 of Directive 70/524/EEC shall remain in force until Directive 79/373/EEC has been revised to include rules concerning the labelling of feedingstuffs incorporating additives.

2. Points 2.1, 3 and 4 of the Annex to Directive 82/471/EEC shall be deleted with effect from the date of application of this Regulation.

3. Directive 87/153/EEC shall be repealed with effect from the date of application of this Regulation. However, the Annex to that Directive shall remain in force until the implementing rules provided for in Article 7(4) of this Regulation are adopted.

4. References to Directive 70/524/EEC shall be construed as references to this Regulation.

Article 24

Penalties

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.

Member States shall notify those rules and measures to the Commission at the latest 12 months after the date of publication of this Regulation and shall notify it without delay of any subsequent amendment affecting them.

Article 25

Transitional measures

1. Applications submitted under Article 4 of Directive 70/524/EEC before the date of application of this Regulation shall be treated as applications under Article 7 of this Regulation where the initial comments provided for under Article 4(4) of Directive 70/524/EEC have not yet been forwarded to the Commission. Any Member State selected as rapporteur in respect of any such application shall immediately forward the dossier submitted in support of that application to the Commission. Notwithstanding Article 23(1), such applications shall continue to be treated in accordance with Article 4 of Directive 70/524/EEC where the initial comments provided for under Article 4(4) of Directive 70/524/EEC have already been forwarded to the Commission.

2. The labelling requirements laid down in Chapter III shall not apply to products which have been lawfully manufactured and labelled in the Community or which have been lawfully imported into the Community and put into circulation, before the date of application of this Regulation.

Article 26

Entry into force

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

2. It shall apply from 12 months after the date of publication of this Regulation.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22 September 2003.

For the European Parliament

The President

P. COX

For the Council

The President

R. BUTTIGLIONE

ANNEX I

ADDITIVE GROUPS

1. In the category 'technological additives', the following functional groups are included:
 - (a) preservatives: substances or, when applicable, micro-organisms which protect feed against deterioration caused by micro-organisms or their metabolites;
 - (b) antioxidants: substances prolonging the storage life of feedingstuffs and feed materials by protecting them against deterioration caused by oxidation;
 - (c) emulsifiers: substances that make it possible to form or maintain a homogeneous mixture of two or more immiscible phases in feedingstuffs;
 - (d) stabilisers: substances which make it possible to maintain the physico-chemical state of feedingstuffs;
 - (e) thickeners: substances which increase the viscosity of feedingstuffs;
 - (f) gelling agents: substances which give a feedingstuff texture through the formation of a gel;
 - (g) binders: substances which increase the tendency of particles of feedingstuffs to adhere;
 - (h) substances for control of radionucleide contamination: substances that suppress absorption of radionucleides or promote their excretion;
 - (i) anticaking agents: substances that reduce the tendency of individual particles of a feedingstuff to adhere;
 - (j) acidity regulators: substances which adjust the pH of feedingstuffs;
 - (k) silage additives: substances, including enzymes or micro-organisms, intended to be incorporated into feed to improve the production of silage;
 - (l) denaturants: substances which, when used for the manufacture of processed feedingstuffs, allow the identification of the origin of specific food or feed materials.
 2. In the category 'sensory additives', the following functional groups are included:
 - (a) colourants:
 - (i) substances that add or restore colour in feedingstuffs;
 - (ii) substances which, when fed to animals, add colours to food of animal origin;
 - (iii) substances which favourably affect the colour of ornamental fish or birds;
 - (b) flavouring compounds: substances the inclusion of which in feedingstuffs increases feed smell or palatability.
 3. In the category 'nutritional additives', the following functional groups are included:
 - (a) vitamins, pro-vitamins and chemically well-defined substances having similar effect;
 - (b) compounds of trace elements;
 - (c) amino acids, their salts and analogues;
 - (d) urea and its derivatives.
 4. In the category 'zootechnical additives', the following functional groups are included:
 - (a) digestibility enhancers: substances which, when fed to animals, increase the digestibility of the diet, through action on target feed materials;
 - (b) gut flora stabilisers: micro-organisms or other chemically defined substances, which, when fed to animals, have a positive effect on the gut flora;
 - (c) substances which favourably affect the environment;
 - (d) other zootechnical additives.
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ANNEX II

DUTIES AND TASKS OF THE COMMUNITY REFERENCE LABORATORY

1. The Community reference laboratory referred to in Article 21 is the Joint Research Centre of the Commission (JRC).
2. For the tasks outlined in this Annex, the JRC may be assisted by a consortium of national reference laboratories.
The JRC shall be notably responsible for:
 - the reception, preparation, storage and maintenance of the reference samples;
 - the testing and evaluation or validation of the method for detection;
 - evaluating the data provided by the applicant for authorisation to place the feed additive on the market, for the purpose of testing and evaluation or validation of the method for detection;
 - submitting full evaluation reports to the Authority.
3. The Community reference laboratory shall play a role in dispute settlements between Member States concerning the results of the tasks outlined in this Annex.

ANNEX III

SPECIFIC LABELLING REQUIREMENTS FOR CERTAIN FEED ADDITIVES AND FOR PREMIXTURES

- (a) Zootechnical additives, coccidiostats and histomonostats:
 - the expiry date of the guarantee or the storage life from the date of manufacture,
 - the directions for use, and
 - the concentration;
- (b) Enzymes, in addition to the abovementioned indications:
 - the specific name of the active component or components in accordance with their enzyme activities, in conformity with the authorisation given,
 - the International Union of Biochemistry identification number, and
 - instead of concentration: units of activity (units of activity per gram or units of activity per millilitre);
- (c) Micro-organisms:
 - the expiry date of the guarantee or the storage life from the date of manufacture,
 - the directions for use,
 - the strain identification number, and
 - the number of colony-forming units per gram;
- (d) Nutritional additives:
 - the active-substance level, and
 - the expiry date of the guarantee of that level or storage life from the date of manufacture;
- (e) Technological and sensory additives with the exception of flavouring compounds:
 - the active substance level;
- (f) Flavouring compounds:
 - the incorporation rate in premixtures.

ANNEX IV

GENERAL CONDITIONS OF USE

1. The quantity of additives that also exists in the natural state in certain feed materials shall be calculated so that the total of the elements added and the elements present naturally does not exceed the maximum level provided for in the authorisation Regulation.
 2. Mixing of additives shall be permitted only in premixtures and feedingstuffs where there is physico-chemical and biological compatibility between the components of the mixture in relation to the effects desired.
 3. Supplementary feedingstuffs, diluted as specified, may not contain levels of the additives which exceed those fixed for complete feedingstuffs.
 4. In the case of premixtures containing silage additives the words 'of silage additives' must clearly be added on the label after 'PREMIXTURE'.
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