



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 18.12.2002
COM(2002) 771 final

2002/0073 (COD)

Amended proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

ON ADDITIVES FOR USE IN ANIMAL NUTRITION

(presented by the Commission pursuant to Article 250 (2) of the EC Treaty)

EXPLANATORY MEMORANDUM

1. BACKGROUND

- Adoption of the proposal by the Commission on 22 March 2002 and transmission to the Parliament and the Council on 22 March 2002 (COM (2002) 153 final – 2002/0073(COD)), on the basis of Articles 37, and 152 (4) (b) of the EC-Treaty.
- Opinion of the European Economic and Social Committee adopted on 18 September 2002.
- Opinion of the European Parliament at first reading adopted on 21 November 2002.

2. OBJECTIVE OF THE COMMISSION PROPOSAL

The objectives of this proposal are:

1. to distinguish clearly between the risk evaluation (EFSA) and the risk management (Commission and Member States),
2. to simplify the existing rules regarding the authorisation procedure of additives in feedingstuffs,
3. to lay down provisions for the phasing out of antibiotics used as growth promoters,
4. to maintain the use of coccidiostats as feed additives and to consolidate EU provisions on additives for use in animal nutrition.

3. COMMISSION POSITION ON THE 57 AMENDMENTS ADOPTED BY THE PARLIAMENT

3.1. Amendments accepted by the Commission

The Commission can accept 24 amendments entirely 1, 3, 4, 5, 6, 8, 12, 16, 17, 18, 19, 21, 24, 25, 26, 29, 31, 34, 38, 41, 43, 44, 45 and 47, as these amendments improve or bring more clarification to the Commission's initial proposal.

- **Status of coccidiostats - Inclusion of histomonostats- Report of use of coccidiostats**

Amendment n° 17 concerning Article 3(2) and 24 on Article 7(1) propose to treat histomonostats in the same way as of coccidiostats, thus maintaining these two groups within the framework of the feed additives legislation. The Commission can accept this amendment. In this case, this inclusion brought clarification of the concept of coccidiostats. Amendment n° 31 concerning Article 11(2) asks the Commission to present a report on the use of coccidiostats and histomonostats before 1 January 2008. The Commission can accept this amendment, and the report will contain valuable information, concerning the use of coccidiostats, in view of a decision on the final fate of

these substances as additives or as veterinary drugs. The Commission considers that this report will be an important element for taking a decision to keep or to delete the coccidiostats from the register.

- **Flexibility of the authorisation procedure**

Some amendments n°4, 5, 8 aim to ensure more flexibility in the authorisation procedure, in particular the extension to minor species and the extension to further categories of animals and have been included in the new recitals 9a, 10a or in recital 15.

Specific conditions for data protection when applying for authorisations for minor species are included in amendment n° 44 (Article 9(2)).

Amendments 45 and 47 include other additive groups in the technological (45) and zootechnical (47) categories, these additional groups are acceptable and have been included in Annex I (points 1 and 4).

- **Clarification of the authorisation procedure**

Several amendments n° 12, 16, 19, 21, 34, 38 aim to clarify the Commission proposal regarding the authorisation procedure, in particular concerning the steps and delays to be followed by the applicant, the Commission and the EFSA. In general, the Commission can accept these amendments. These amendments have been incorporated respectively in Article 2(1), Article 3f, Article 4(2b), Article 6(2 b and c), Article 11(5b) and Article 15(2) c.

- **Improvement of transparency and traceability**

Amendment n° 29, which is included in Article 9(3 d), amendment 41 in Article 16 (1b) and amendment 43 in Article 16(1f) improve the traceability of additives and facilitate communication during the authorisation procedure.

- **Specific requirements for pets**

Amendment n° 1 included in recital 3 and amendment 26 in Article 8 (4) 1st indent indicates that specific provisions for additives in pet food are appropriate. Taking into account that pets do not enter the human food chain, such exclusive rules may be adopted for pets.

- **Mixtures of feedingstuffs to be sold directly to the final user**

Amendment n°3, included in Recital 6a, covers mixtures of nutritional additives, which can be sold to the end user under the condition that the marketing and the use of those mixtures follow the requirements laid down in the authorisation of each single additive. Nutritional additives can be sold to the end user on condition that the provisions of use laid down in the authorisation Regulation allow it.

3.2. Amendments accepted in principle, in part and/or subject to re-wording

The Commission can accept 2 amendments in part only (33 and 35) and 5 amendments subject to re-wording (13, 20, 28, 32 and 36).

- **Extension to other substances**

Amendment n°33, which is incorporated in Article 11(5b) foresees in its first part, an extension for silage agents. This extension can be accepted because the scope of Directive 70/524/EEC is vague and therefore there is no uniform application in the MS concerning silage agents.

Furthermore, amendment n°13 concerning Article 2(1) includes substances of animal or vegetable origin in the scope of this proposal and clarifies the Commission's text.

- **Phasing out of antibiotics used as growth promoters**

Amendment n°35 (1) second part is incorporated in Article 12 and indicates that the antibiotics used as growth promoters still authorised on the date of entry into force of the Regulation shall be deleted from the Register from that date. This amendment is totally in line with the Commission's strategy of banning the last remaining antibiotics.

- **Improvement of transparency**

Amendment n° 28 (Article 9(2)) improves the transparency of the procedure. It is important that the applicant is involved in all decisions concerning his application and particularly concerning the time frame of the risk assessment and the provision of new information. The Commission accepted the spirit of this amendment but prefers a more appropriate wording.

Amendment n° 36 is incorporated in Article 14 (1) and improves also the communication to the public. The Commission accepted this amendment taking into account that the confidentiality precautions laid down also apply.

3.3. Amendments not accepted by the Commission

The Commission cannot accept the following amendments: 2, 7, 9, 10, 11, 15, 22, 27, 30, 35 (1) - first part, 37, 39, 40, 42, 46, 48, 51, 53, 54, 55, 56 and 57.

The Commission considers that many of these amendments would undermine the aim to sustain the overall Community legislation as more transparent, less complex and efficient.

4. TECHNICAL AMENDMENTS

Certain technical changes have been made to the text to ensure its conformity with the Interinstitutional Agreement of 22 December 1998 on common guidelines for the quality of drafting of Community legislation (OJ C 73, 17.3.1999, p. 1), drawn up pursuant to Declaration No 39 annexed to the Final Act of Amsterdam on the quality of the drafting of Community legislation. In accordance with points (b) and (g) of that Agreement, the text has been revised to take account of the common guidelines and the Joint Practical Guide drawn up under point (a) thereof.

Amended proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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 Commission¹,

Having regard to the opinion of the European Economic and Social Committee²,

Having regard to the opinion of the Committee of the Regions³,

Acting in accordance with the procedure laid down in Article 251 of the Treaty

Whereas:

- (1) 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.
- (2) A high level of protection of human life and health should be assured in the pursuit of Community policies.
- (3) 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****
- (4) Action by the Community relating to human health, animal health and the environment should be based on the precautionary principle.
- (5) In accordance with Article 153 of the Treaty, the Community is to contribute to promoting the right of consumers to information.
- (6) Experience with the application of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs⁴ has shown that it is necessary to review all

¹ OJ C [...], [...], p. [...].

² OJ C [...], [...], p. [...].

³ OJ C [...], [...], p. [...].

the rules on additives 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 has made available new types of additives, such as those to be used on silage or in drinking water.

- (6a) **The measures provided for by this Regulation should also cover mixtures of nutritional additives sold to the end user and the marketing and use of those mixtures should comply with the conditions laid down on the authorisation of each single additive.**
- (7) The basic principle in this field should be that only those additives approved under the procedure set out in this Regulation may be placed on the market, used and processed in animal feeding under conditions foreseen by the authorisation.
- (8) Categories of feed additives should be defined in order to facilitate the assessment procedure in view of the authorisation. Amino acids which are currently covered by Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition⁵ should be included as a category of feed additives, and therefore transferred from the scope of that Directive to this Regulation.
- (9) In order to ensure a harmonised scientific assessment of feed additives such assessment should be carried out by the European Food Safety Authority. The applications should be supplemented by residue studies in order to assess the establishment of Maximum Residues Limits (MRL's).
- (9a) **The guidelines for the authorisation of feed additives should be established by the Commission in co-operation with the EFSA. In establishing these guidelines, attention should be paid to the possibility to extrapolate the results of the studies carried out on major species to minor species.**
- (10) 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.
- (10a) **The effort required in order to obtain authorisation for an additive is, in certain cases, so prohibitive as to deter applicants from generating scientific data for "minor species". 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.**
- (11) 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 according to the procedure by which a close

⁴ OJ L 270, 14.12.1970, p. 1.

⁵ OJ L 213, 21.7.1982, p. 8.

collaboration between Member States and the Commission is guaranteed in the framework of Standing Committee on the Food Chain and Animal Health.

- (12) It is necessary to introduce, where appropriate, an obligation 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.**
- (13) In order to allow technical and scientific progress to be taken into account it is necessary to revise regularly the authorisations of feed additives. Time limited authorisations will allow this review.
- (14) A register of authorised feed additives should be established, including product specific information and sampling and detection methods. Non-confidential data should be made available to the public.
- (15) It is necessary to establish rules to take into account additives which are already on the market and which were authorised under Directive 70/524/EEC, and amino acids currently authorised under Directive 82/471/EEC, as well as for additives for which the authorisation procedure is in progress. 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 consumption⁶.**
- (16) 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 anti-microbial resistance adopted on 10-11 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 co-ordinated since precipitous actions could have repercussions for animal health”. 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.
- (17) Certain substances with coccidiostatic effects should be considered as feed additives for the purpose of this Regulation.
- (18) 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

⁶ OJ L 40, 11.2.1989, p. 27. Directive as amended by Directive 94/34/EC of the European Parliament and of the Council (OJ L 237, 10.9.1994, p. 1).

Safety Authority will be asked to review the progress in the development of alternative substances and alternative rearing methods before 2005.

- (19) Detailed labelling of the product should be required since it enables the final user to make a choice in full knowledge of the facts and creates fewest obstacles to trade and facilitates fairness of transactions.
- (20) Regulation (EC) No .../... of the European Parliament and of the Council on genetically modified food and feed⁷ 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 Regulation (EC) No.../...of the European Parliament and of the Council on genetically modified food and feed are different from those of this Regulation, feed additives should undergo an authorisation procedure in addition to the authorisation procedure provided for by this Regulation prior to their placing on the market.
- (21) Fees could be charged for the consideration of dossiers by the European Food Safety Authority, subject to the outcome of the report provided for in Article 45 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety⁸.
- (22) 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 the Commission to adopt such measures 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 or States concerned.
- (23) Technological progress and scientific developments should be taken into account when implementing this Regulation.
- (24) Since the measures necessary for the implementation of this Regulation are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁹, they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision.
- (25) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.
- (26) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs should be repealed. However labelling provisions applicable to compound feedingstuffs incorporating additives should be maintained until a revision of Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound

⁷ OJ L [...], [...], p. [...].

⁸ OJ L 31, 28.1.2002, p. 1.

⁹ OJ L 184, 17.7.1999, p. 23.

feedingstuffs¹⁰ is completed. Points 3 and 4 of the Annex of Directive 82/471/EEC should be deleted in order to enable the transfer of amino acids and their salts to this Regulation.

- (27) Since the task of verification of the conformity of dossiers is conferred to the European Food Safety Authority, it is necessary to repeal Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition¹¹. Certain provisions of that Directive should be kept in place, until implementing rules have been adopted.
- (28) 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

SUBJECT-MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter

1. The purpose of this Regulation is to establish a Community procedure for authorisation and supervision of feed additives **and premixtures** and to lay down rules to ensure 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' interests in relation to feed additives, whilst ensuring the effective functioning of the internal market.

Article 2

Scope

1. This Regulation shall apply to chemically defined **or described** substances or micro-organisms not normally used as feed materials which are intentionally added to feedingstuffs or drinking water, hereinafter referred to as "feed additives".
2. This Regulation shall not apply to:
 - (a) processing aids, nor to technological but unavoidable residues of processing aids in the final product;

¹⁰ OJ L 86, 6.4.1979, p. 30.

¹¹ 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).

- (b) veterinary medicinal products as defined in Directive 2001/82/EC of the European Parliament and of the Council¹².
3. Where necessary, it may be determined, in accordance with the procedure referred to in Article 21 (2), whether a substance or a microorganism is a feed additive within the scope of this Regulation.

Article 3
Definitions

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

The following definitions shall also apply:

- (a) “feed materials” means products as defined in Article 2(a) of Council Directive 96/25/EC¹³ ;
- (b) “complementary feedingstuffs” means products as defined in Article 2(e) of Directive 79/373/EEC;
- (c) “premixtures of feed additives” means mixtures of feed additives or mixtures of one or more feed additives with feed materials used as carriers, not intended to direct feeding of animals but intended for distribution to establishments registered or approved according to Council Directive 95/69/EC¹⁴;
- (d) “compound feedingstuffs” means products as defined in Article 2 (b) of Directive 79/373/EEC ;
- (e) “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;
- (f) “processing aids” means any substances not consumed as feedingstuffs by themselves, intentionally used in the processing of feedingstuffs or feed materials to fulfil a technological purpose during treatment or processing ~~and which do not remain in the final product;~~ **which may result in the unintentional but technically unavoidable presence of residues of the substances or their derivatives in the final product, provided that those residues do not present any health risk and do not have any technological effect on the finished feed;**
- (g) “antimicrobial agents” means substances produced either synthetically or naturally by bacteria, fungi or plants, used to kill or inhibit the growth of micro-organisms including bacteria, viruses and fungi, and of parasites, in particular protozoa;

¹² OJ L311, 28.11.2001,p. 1.

¹³ OJ L 125, 13.5.1996, p. 35; Directive as last amended by Directive 2001/46/EC of the European Parliament and of the Council (OJ L 234, 1.9.2001, p. 55).

¹⁴ OJ L 332, 30.12.1995, p. 15; Directive as last amended by Directive 1999/20/EC (OJ L 80, 25.3.1999, p. 20).

- (h) “antibiotic” means antimicrobial produced by or derived from a micro-organism, which destroys or inhibits the growth of other micro-organisms;
- (i) “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 to be legally permitted or recognised as acceptable in or on a food;
- (j) “growth promoter” means a chemically defined substance which, when fed to animals, improves production performance parameters,
- (ja) **‘coccidiostats and histomonostats’ means substances with a coccidiostatic or histomonal effect.**

CHAPTER II

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

Article 4

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 and in the authorisation of the substance are met; and
 - c) the conditions on labelling set out in this Regulation are met.
2.
 - (a) **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 the experiments are carried out in accordance with the principles and conditions laid down in Directive 87/153/EEC, Council Directive 83/228/EEC¹⁵ or the guidelines in Article 8(4) and provided that there is adequate official supervision. The animals concerned may only be used for food production if the authorities establish that no health risk exists.**
 - (b) **Unless otherwise specified, the mixing of nutritional additives to be sold directly to the end user will be allowed, when respecting 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 provided under Council Directive 95/69/EEC¹⁶.**

¹⁵ OJ L 126, 13.5.1983, p.23.

¹⁶ OJ L 332, 30.12.1995, p. 15; Directive as last amended by Directive 1999/20/EC (OJ L 80, 25.3.1999, p. 20).

- (c) In the case of additives belonging to categories (d) and (e) as provided for in Article 7(1) and of additives consisting of, containing or produced from genetically modified organisms (GMOs), no person shall place the product on the market other than the authorisation holder named in the [authorisation] Regulation granting authorisation pursuant to Article 10 of this Regulation, or a person acting under his written authority.

Article 5
Authorisation

1. Any person seeking an authorisation for a feed additive shall submit an application in accordance with Article 8.
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 shall be established in the Community.

Article 6
Conditions for authorisation

1. No feed additive shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated, **according to guidelines provided for in Article 8(4)**, 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 of this Article, and has at least one of the characteristics set out in paragraph 3.
2. The feed additive must not:
 - (a) present a risk to 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 must :
 - (a) favourably affect the characteristics of feed,
 - (b) favourably affect the characteristics of animal products,
 - (c) satisfy the nutritional needs of animals,
 - (d) favourably affect the environmental consequences of animal production.
4. Antibiotics shall not be authorised as feed additives.

5. By derogation from paragraph 4, coccidiostats presented for continuous use mixed in feed or drinking water are considered as feed additives for the purpose of this Regulation.

Article 7
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 8 to 10:
 - (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: any substance used for nutritional purposes;
 - (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, in accordance with the procedure specified in Articles 8 to 10.
3. Where necessary, as a result of scientific progress or technological development, additional feed additive categories and functional groups may be established in accordance with the procedure referred to in Article 21 (2).

Article 8
Application for authorisation

1. An application for an authorisation as provided for in Article 5 shall be submitted to the European Food Safety Authority, hereinafter referred to as “the Authority”.
2. The Authority shall acknowledge receipt of the application, in writing, to the applicant within 15 days of its receipt. The acknowledgement shall state the date of receipt of the application.
3. The application shall be accompanied by the following particulars and documents:
 - (a) the name and the address of the applicant;
 - (b) the designation of the feed additive, including a proposal for its classification by category and functional group under Article 7, and its specifications, including purity criteria, **where appropriate;**

- (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 and, where appropriate, of the analytical method for the determination of residues of the feed additive 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 6(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, use levels in complementary feedingstuffs and animals species 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 20 for the purpose of validation of the method of analysis, in accordance with the requirements set out in Annex II;
- (g) for additives proposed in paragraph b) as not belonging to category a) and b) referred to in Article 7 (1), and in the case of additives consisting of, containing or produced from GMOs, a proposal for post-market monitoring;
- (h) a summary of the dossier;
- (i) for additives consisting of, containing or produced from GMOs, details of the Community authorisation according to Regulation (EC) No [.../...].

4. **After consultation of the Authority, specific guidelines for the authorisation of additives shall be established for each category of additive referred to in Article 7 (1) in accordance with the procedure referred to in Article 21(2). Those guidelines shall take account of the possibility of extrapolating the results of the studies carried out on major species to minor species.**

After consultation of the Authority, **further** rules for the implementation of this Article may be established in accordance with the procedure referred to in Article 21(2). **Those implementing rules shall, where appropriate, differentiate between standards for feed additives in respect of animals for food production and standards 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.**

Until the adoption of these implementing rules the application shall be made in accordance with the Annex to Directive 87/153/EEC

5. The Authority shall publish detailed guidance concerning the preparation, presentation, and validation of the applications, not later than one year after the entry into force of this Regulation.

Article 9
Opinion of the Authority

1. The Authority shall give an opinion within six months of the receipt of a valid application.
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**. Where the Authority requests supplementary information, the time limit laid down in paragraph 1 shall be suspended until such time that the information has been provided. Likewise, the applicant may at the request of the Authority, or on his own initiative prepare oral or written explanations within a specified time limit.
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 8, and shall undertake a risk assessment in order to determine whether the feed additive complies with the criteria laid down in Article 6(2) and (3);
 - (b) shall verify the report of the Community Reference Laboratory.
 - (c) shall make the application and any supplementary information supplied by the applicant available to Member States and to the Commission;
 - (d) shall make the summary of the dossier mentioned in Article 8 (3) (h) available to the public, **without prejudice to the confidentiality requirements laid down in Article 18(2)**
 - (e) may ask any official scientific body of the Member States working in the field of animal nutrition to contribute to the assessment of the feed additive.
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 7, its specification, including purity criteria and method of analysis;
 - (c) depending on the results of the risk assessment, specific conditions or restrictions in relation to handling, use levels, the proportion of incorporation when used in feed or drinking water, and animal species and categories of animal species for which the additive is to be used, and post-market monitoring requirements;
 - (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 the consumers or MRLs have already been established in Annex I or III to Council Regulation (EC) No 2377/90¹⁷.

5. The Authority shall forward its opinion to the Commission, the Member States and the applicant, including 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 10
Authorisation by the Community

1. Within three months of receipt of the opinion of the Authority, the Commission shall prepare a draft of the Regulation to be adopted in respect of the application, taking into account the requirements of Article 6(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 Regulation is not in accordance with the opinion of the Authority, the Commission shall provide an explanation of the reasons for the differences.

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

2. In the event of a draft Regulation which envisages the granting of authorisation, the draft Regulation shall include the elements mentioned in Article 9(4)(b), (c) and (d).
3. In the event of a draft Regulation which envisages the granting of authorisation for additives belonging to categories d) and e) referred to in Article 7(1) and also for additives consisting of, containing or produced from GMOs, the draft Regulation shall include the name of the authorisation holder, and, where appropriate, the unique code attributed to the GMO as referred to in the Regulation (EC) No .../... [of the European Parliament and of the Council 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]¹⁸.
4. Where the Commission considers that levels of residues of an additive in food obtained from animals fed with that additive might have a detrimental effect on human health, it shall include in the draft Regulation Maximum Residues Limits (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/EC¹⁹ 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 feed additive.

¹⁷ OJ L 224, 18.8.1990, p. 1. Regulation last amended by Commission Regulation (EC) No 1937/2002 (OJ L 297, 31.10.2002, p. 3).

¹⁸ OJ L,

¹⁹ OJ L 125, 23.5.1993, p. 10.

5. The Regulation concerning the application for authorisation of a feed additive shall be adopted in accordance with the procedure referred to in Article 21 (2).
6. The Commission shall without delay inform the applicant of the decision taken.
7. The authorisation granted in accordance with the procedure laid down in this Regulation shall be valid throughout the Community for ten years and shall be renewable in accordance with Article 15. 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 2 and 3.
8. 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 11
Status of existing products

1. By way of derogation from Article 4, a feed additive which has been placed on the market pursuant to Directive 70/524/EEC and an amino acid, salt of an amino acid, and analogous substance which was listed in points 3 and 4 of the Annex to Directive 82/471/EEC before the date referred to in the second paragraph of Article 25 of this Regulation, may be placed on the market and used in accordance with the conditions specified in the entries in the annexes to Directives 70/524/EEC or 82/471/EEC relating to that substance, provided that the following conditions are met:
 - (a) within one year of the entry into force of this Regulation, each person who places the feed additive on the market shall notify this fact to the Authority. This notification shall be accompanied by the particulars mentioned in Article 8(3)(a), (b) and (c);
 - (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 concerned products shall be entered in the Register. Each entry in the Register shall mention the date on which the concerned product 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 8, at the latest one year before the expiry date of the authorisation given pursuant with 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. ~~For the substances belonging to the category of coccidiostats, an application shall be submitted within a maximum of four years after the entry into force of this Regulation.~~ A detailed calendar listing the priority order for the re-evaluation of the different classes of additives may be adopted in accordance with the procedure referred to in Article 21 (2). **For the substances belonging to the category of coccidiostats and histomonostats, an application shall be submitted within a maximum of four years after the entry into force of this Regulation.**

Before 1 January 2008, the Commission shall submit a report on the use of these substances as feed additives.

For additives authorised without a time limit, a list of those additives which require re-evaluation and their priority order for re-evaluation shall be adopted in accordance with the procedure referred to Article 21 (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 13, 14, 15, 16 and 21, which shall apply to such products as if they had been authorised pursuant to Article 10.
4. In case of authorisations not issued to a specific holder, any person who imports or manufactures the products referred to in this Article shall submit the information **that is to accompany notification pursuant to paragraph 1** or the application **referred to in paragraph 2** to the Authority ~~or the application to the Authority.~~
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 21(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,
- 5a **Paragraphs 2 to 5 shall also apply to chemically defined substances, enzymes and micro-organisms used as silage agents. 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.**
- 5b **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**

*Article 12
Phasing out*

By derogation from Article 5 and Article 11, from 1 January 2006 the placing on the market and use **of** antibiotic growth promoters ~~of the following substances mentioned in Annex B under A of Chapters I and II of Directive 70/524/EEC: sodium monensin, sodium salinomycin, flavophospholipol and avilamyacin,~~ shall be prohibited and **any antibiotic growth promoters which are still authorised when this Regulation enters into force** and, ~~from that date, those substances shall be deleted from the Register.~~

*Article 13
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 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. Where monitoring requirements, as referred to in Article 9(4)(c) have been imposed, the authorisation holder shall ensure that it is carried out and shall submit reports to the Authority in accordance with the authorisation.

2. The authorisation holder shall forthwith communicate to the Authority 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 authorisation holder shall forthwith inform the Authority 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 14

Modification, suspension and revocation of authorisations

1. ~~Where, on its own initiative or following a request from a Member State or from the Commission, the Authority concludes that an authorisation granted in accordance with this Regulation should be modified, suspended or revoked, it shall forthwith transmit this opinion to the Commission.~~ **The Authority shall on its own initiative or following a request from a Member State or the Commission, deliver an opinion on compliance with the conditions laid down in this Regulation. It shall forward this opinion to the Commission, the authorisation holder and the Member States. The opinion shall be made public, in accordance with the confidentiality requirements laid down in Article 18(2)**
2. If the authorisation holder proposes to modify the terms of the authorisation, he shall submit an application to the Authority, which includes the relevant data supporting the request for the change. The Authority shall give an opinion on the proposal.
3. The Commission shall examine the opinion of the Authority without delay, and a final decision on the modification, suspension or revocation of an authorisation shall be adopted in accordance with the procedure referred to in Article 21(2).
4. The Commission shall without delay inform the applicant of the decision taken. The Register shall be amended as appropriate.

Article 15

Renewal of authorisations

1. Authorisations under this Regulation shall be renewable for ten-year periods, on application to the Authority by the applicant at the latest one year before the expiry date of the authorisation.

In case of authorisations not issued to a specific holder, any person who imports or produces the products referred to in this Article may submit the information or the application to the Authority and shall be considered as the applicant.

The Authority shall acknowledge receipt of the application, in writing, to the applicant within 15 days of its receipt. The acknowledgement shall state the date of receipt of the application.

2. The application shall be accompanied by the following particulars and documents:
 - (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 ~~and the efficacy~~ 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 complementing the conditions of the original authorisation, inter alia the conditions concerning future monitoring.
3. The applicant shall also send to the Commission at the same time as he submits an application to the Authority the particulars and documents referred to in paragraph 2.
4. The procedure set out in Articles 9 and 10 shall apply in a like manner.
5. 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.
6. The implementing rules for the application of this Article shall be established after consultation of the Authority, in accordance with the procedure referred to in Article 21 (2).
7. The Authority shall publish detailed guidance concerning the preparation and the presentation of the application.

Chapter III

LABELLING

Article 16 Labelling of feed additives

1. No person shall place on the market a feed additive, a mixture of feed additives or a premixture of additives, unless its packaging or container bears the following information, in a conspicuous, clearly legible and indelible manner, 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 **in the Community** of the person responsible for the particulars referred to in this paragraph;
 - (c) the net weight or in the case of liquid additives, 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, additive mixture or premixture of additives is intended;
 - (f) the batch reference number and the date of manufacture.**
2. 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.
 3. In the case of premixtures, the word “PREMIXTURE ” must clearly appear on the label.
 4. Amendments to Annex III to take technical and scientific development into account may be adopted in accordance with the procedure referred to in Article 21 (2).

Chapter IV

GENERAL PROVISIONS

Article 17

Community Register of Feed additives

1. The Commission shall establish and maintain a *Community Register of Feed additives*.
2. The Register shall be made available to the public.
3. The Register shall be consolidated at least once a year.

Article 18
Confidentiality

1. The applicant may indicate which information submitted under this Regulation he wishes to be treated as confidential because its disclosure may significantly harm his competitive position. Verifiable justification must be given in such cases.
2. The Authority 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. Information relating to the following shall not be considered confidential:
 - (a) name and composition of the feed additive and, where appropriate, indication of the substrate and the production strain;
 - (b) physico-chemical and biological characteristics of the feed additive;
 - (c) effects of the feed additive on human and animal health and on the environment;
 - (d) effects of the feed additive on the characteristics of animal products and its nutritional properties;
 - (e) methods for sampling, detection and identification of the feed additive and, where applicable, monitoring requirements and a summary of the results of the monitoring;
 - (f) information on waste treatment and emergency response.
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 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.
6. If an applicant withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Authority and the applicant disagree as to its confidentiality.

Article 19
Data Protection

1. The scientific data and other information in the application dossier required under Article 8 may not be used for the benefit of another applicant for a period of ten years from the date of authorisation, unless the other applicant has agreed with the previous applicant that such data and information may be used. On expiry of the ten-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.

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

In specific cases where urgent approval is needed to ensure the protection of animal welfare, the Commission may, by special derogation, provisionally authorise the use of an additive for a maximum period of 5 years, with the possible extension of authorisation subject to a satisfactory outcome of the post-approval monitoring programme.

Article 20

Reference laboratories

The Community reference laboratory and its duties and tasks shall be those laid down in Annex II.

National reference laboratories may be established in accordance with the procedure referred to in Article 21 (2).

Detailed rules for implementing Annex II and any amendments to that Annex shall be adopted in accordance with the procedure referred to in Article 21(2).

Article 21

Committee

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, established by Regulation (EC) No 178/2002.
2. When reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.
3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 22

Repeals

1. Directive 70/524/EEC is 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 compound feedingstuffs incorporating additives.
2. Points 3 and 4 of the Annex of Directive 82/471/EEC are deleted with effect from the date of application of this Regulation.

3. Directive 87/153/EEC is repealed with effect from the date of application of this Regulation. However, the Annex to that Directive shall remain in force until the adoption of the implementing rules provided for in Article 8 (4) of this Regulation.
4. References to Directive 70/524/EEC shall be construed as references to this Regulation.

Article 23
Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the provisions 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 rules and measures to the Commission at the latest six months after the date of publication of this Regulation and shall notify it without delay of any subsequent amendment affecting them.

Article 24
Transitional measures

1. Applications submitted under Article 4 of Directive 70/524/EEC before the entry into force of this Regulation shall be treated as applications under Article 8 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 States selected as rapporteur in respect of such an application shall immediately transmit the dossier submitted pursuant to that application to the Authority.
2. The labelling requirements laid down in Chapter III of this Regulation 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 free circulation, before the date of application of this Regulation.

Article 25
Entry into force

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

It shall apply from [*1 year 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,

For the European Parliament
The President

For the Council
The President

ANNEX I

ADDITIVE GROUPS

1. In the category “technological additives”, the following functional groups are included:
 - a) Preservatives: substances, including silage agents or, when applicable, microorganisms which prolong the storage life of feedingstuffs and feed materials by protecting them against deterioration caused by micro-organisms.
 - b) Antioxidants: substances which prolong 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) Anticaking agents: substances that reduce the tendency of individual particles of a feedingstuff to adhere to one another.
 - h) Acidity regulators: substances which adjust the pH of feedingstuffs.
 - i) Binders: substances, which increase the tendency of particles of feedingstuffs to adhere.**
 - j) Coagulants: substances, which increase the viscosity of liquid feedingstuffs.**

2. In the category ‘sensory additives’, the following functional groups are included:
 - a) Colorants:
 - i) Substances that add or restore colour in feedingstuffs, including natural constituents of feed materials and natural sources which are normally not consumed as feed materials;
 - ii) Substances which, when fed to animals, add or restore colours to food of animal origin;
 - iii) Denaturants: substances which, when used for the manufacture of processed feedingstuffs, allow the identification of the origin of specific food or feed materials;

- b) Flavouring and appetising compounds: natural products obtained by appropriate physical, chemical, enzymatic or microbiological processes from materials of vegetable or animal origin, or chemically defined substances, the inclusion of which in feedingstuffs increases feed palatability.
3. In the category ‘nutritional additives’, the following functional groups are included:
- a) Vitamins;
 - b) Trace elements;
 - c) Amino acids;
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 improvers: micro-organisms forming colonies or other chemically defined substances, which, when fed to animals, have a positive effect on the gut flora.
 - c) Growth promoters: chemically defined substances which, when fed to animals, improve production performance parameters.
 - d) substances which have a positive effect on the environmental impact of animal production.**

ANNEX II

DUTIES AND TASKS OF THE COMMUNITY REFERENCE LABORATORY

1. The Community reference laboratory referred to in Article 20 is the Joint Research Centre of the Commission (JRC).
2. For the tasks outlined in this Annex, the Commission's Joint Research Centre shall be assisted by a consortium of national reference laboratories.

The JRC shall be notably responsible for:

- reception, preparation, storage and maintenance of the control samples;
 - testing and validation of the method for sampling and detection;
 - evaluating the data provided by the applicant for authorisation for placing the feed additive on the market, for the purpose of testing and validation of the method for sampling and 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: the expiry date of the guarantee or the storage life from the date of manufacture, the batch reference number and the date of manufacture, the directions for use and, where appropriate, a safety recommendation regarding the use in the case of additives which are the subject of special provisions upon authorisation;
- b) Enzymes, in addition of the above mentioned 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 (IUB number);
- c) Micro-organisms, in addition to the above mentioned indications: the strain identification number of colony forming units (CFU 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: the active-substance level.