Council Directive 96/51/EC of 23 July 1996 amending Directive 70/524/EEC concerning additives in feedingstuffs
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COUNCIL DIRECTIVE 96/51/EC of 23 July 1996 amending Directive 70/524/EEC concerning additives in feedingstuffs

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 43 thereof,

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

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

(1) Whereas application of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (4) has shown that certain basic concepts must be revised to take account of the need to ensure a greater degree of protection of animal and human health and of the environment;

(2) Whereas experience has shown that the current rules on the use of additives in feedingstuffs do not provide all the necessary assurances as to safety, particularly because of the circulation in the Community of poor copies of zootechnical additives; whereas it is therefore essential to link the authorization of such additives to the person responsible for putting the additive authorized by the Community into circulation;

(3) Whereas a distinction should be made between additives which are widely used and present no particular dangers for the manufacture of feedingstuffs and high technology additives with a very specific composition for which the person responsible for putting them into circulation must receive authorization, in order to avoid copies which might not be in conformity and might therefore be unsafe;

(4) Whereas there should be drawn up in the form of an Annex to this Directive, first a list of additives for which authorization to put them into circulation is granted to persons responsible who alone are entitled to put the additives in question into circulation, second, a list of other additives which may be put into circulation by any person provided that they are additives which meet the specifications in the dossiers on the basis of which they have been authorized;

(5) Whereas, to facilitate application of Directive 70/524/EEC, the list of definitions should be supplemented and certain definitions should be amended; whereas, in particular, the concept of additives should be defined so as also to take account of their possible effects on feed materials, animal products, animal welfare or the environment; whereas processing aids should be excluded from the scope of this Directive insofar as these substances are used in the processing of feed materials or of feedingstuffs and no longer have any effect in the finished product;

(6) Whereas micro-organisms authorized as such in group 0 for improving animal production and in particular influencing gastro-intestinal flora must form colonies;

(7) Whereas, where in particular vitamins, trace elements or colouring matter are present in certain raw materials in their natural state, they must not be considered as additives unless products specially enriched with such a substance corresponding to an additive are concerned which cannot therefore be considered as raw materials naturally containing the substances concerned;

(8) Whereas the premixtures referred to in this Directive may under no circumstances be regarded as preparations covered by the definition of additive;

(9) Whereas experience has shown that the authorization of additives by means of directives causes considerable delays; whereas such delays in the transposition of directives have sometimes resulted in distortions of competition and even created barriers to trade; whereas, to remedy this situation, additives should be authorized by means of regulations;

(10) Whereas fees may be charged for the examination of dossiers by the Member State acting as rapporteur; whereas the levels of such fees should be harmonized in order to obviate distortion of competition; whereas such harmonization will fall within the general framework of future Community rules on fees or charges to be levied in the animal feed sector; whereas it will then be necessary to examine whether the levels of fees to be charged should not vary depending on the type of authorization sought or the additive group concerned; whereas it would be fair to charge higher fees, for example for examining dossiers concerning growth promoters than for examining dossiers concerning vitamins; whereas it would be fair not to charge a fee for additives or examining the dossier concerning very simple technological additives; whereas the fee should be paid to the Member State acting as rapporteur at the time of submission of the dossier;
(11) Whereas, until the Council has adopted legal provisions regarding fees, a Member State acting as rapporteur should be able to adopt provisions or retain the legal provisions which it has adopted in this area;
(12) Whereas the introduction of fees must be accompanied by the assurance that a decision will be reached by a given deadline on the application for authorization to put an additive into circulation;
(13) Whereas certain feed additives may reach the human food chain; whereas it is necessary for the Scientific Committee for Animal Nutrition to be able to collaborate with the Scientific Committee for Food on such matters which may influence consumer health;
(14) Whereas the search for new additives belonging to the group of substances for which authorization is linked to those persons responsible for putting them into circulation requires costly investment; whereas protection for a period fixed at ten years should therefore be afforded to scientific data or information included in the dossier on the basis of which the first authorization is granted; whereas protection should also be afforded to new data supplied with a view to renewal or alteration of the conditions of the original authorization for a shorter period which is fixed at five years; whereas, during those periods of protection, any new applicant for authorization will be obliged to submit a dossier drawn up in accordance with Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition (5) unless the parties reach agreement on shared use of the data; whereas where two or more persons benefit from the authorization granted to a single additive, they must respond individually or collectively to any request from the Commission for scientific information on pain of losing the benefit of the authorization;
(15) Whereas, in order to put an end to the differences between Member States regarding the arrangements for admitting the additives in Annex II onto their territory, the provisional authorization of additives meeting a minimum number of conditions should be extended throughout the Community; whereas such authorizations become definitive for certain additives or are valid for a period of 10 years for other additives when all the conditions for authorization are fulfilled, although that may occur no later than the date of expiry of the period of provisional authorization;
(16) Whereas for applications for authorization concerning additives referred to in Article 2 (aaa) and (aaaa) lodged before 1 April 1998 and in respect of which provisional authorization has been given before 1 October 1999, Member States may allow the putting into circulation and use of the additive on their national territory for a period not exceeding five years from the date of adoption of the authorizing regulation;
(17) Whereas for applications for authorization concerning additives referred to in Article 2 (aaa) and (aaaa) submitted with effect from 1 April 1998 and in respect of which provisional authorization has been given before 1 October 1999, Member States may allow the putting into circulation and use of the additive for a period not exceeding five years from the date of adoption of the authorizing regulation;

(18) Whereas it is necessary to have transitional arrangements for the changeover from the old to the new authorization system; whereas the date of entry into force of the relevant provisions must therefore be brought forward;
(19) Whereas account should be taken of developments in techniques for using additives; whereas provision should therefore be made, in certain cases, for the possibility of administering additives, under certain conditions, by means other than incorporation in feedingstuffs;
(20) Whereas, in the present state of scientific and technical knowledge and taking account of the methods of inspection, the use of antibiotics, coccidiostats and other medicinal substances and growth promoters should not be authorized by any mode of administration other than incorporation in feedingstuffs;
(21) Whereas monographs of zootechnical additives should no longer be published; whereas an information note on the additives in question should be published instead in order to facilitate their identification during controls;
(22) Whereas the national authorities should be provided with a standard sample to enable them to carry out checks;
(23) Whereas the mixing of additives belonging respectively to the groups of antibiotics, coccidiostats, other medicinal substances and growth promoters with micro-organisms must be prohibited, unless the specific authorization of the micro-organism allows such mixing;
(24) Whereas, in view of the deletion of Annexes I and II, in the interests of clarity and transparency, there should be published annually the list of persons responsible for putting the additives referred to in Article 2 (aaa) into circulation and a list of producers who have received from an authorized person the right to manufacture additives as well as a list of all authorized additives,
HAS ADOPTED THIS DIRECTIVE:

Article 1
Directive 70/524/EEC is hereby amended as follows:
1) Article 1 shall be replaced by the following:
'SCOPE
Article 1
1. This Directive shall apply to additives in feedingstuffs.
2. This Directive shall not apply to processing aids used deliberately as substances in the processing of feed materials or of feedingstuffs in order to achieve a certain technological objective during treatment or processing which may result in the unintentional but technically unavoidable presence of residues of the substances or their derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product.
3. Provided they are not products specially enriched with substances corresponding to additives, substances present in their natural state in feed materials which are part of the normal composition of feedingstuffs and which correspond to a substance authorized under this Directive shall not be regarded as additives.`;
2) the following title shall be inserted between Articles 1 and 2:
'DEFINITIONS`;
3) Article 2 shall be amended as follows:
(i) point (a) shall be replaced by the following:
'(a) additives: substances or preparations used in animal nutrition in order to:
- affect favourably the characteristics of feed materials or of compound feedingstuffs or of animal products; or
- satisfy the nutritional needs of animals or improve animal production, in particular by affecting the gastro-intestinal flora or the digestibility of feedingstuffs; or

- introduce intro nutrition elements conducive to attaining particular nutritional objectives or to meeting the specific nutritional needs of animals at a particular time; or
- prevent or reduce the harmful effects caused by animal excretions or improve the animal environment;
(aa) "micro-organisms": micro-organisms forming colonies;
(aaa) additives subject to authorization linked to the person responsible for putting them into circulation: the additives listed in Part I of Annex C;
(aaaa) other additives: additives not subject to authorization linked to the person responsible for putting them into circulation and referred to in Part II of Annex C; `
(ii) point (f) shall be replaced by the following:
'(f) feed materials: various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding either directly as such or after processing, in the preparation of compound feedingstuffs or as carriers of premixtures, hereinafter referred to as "feed materials"; `
(iii) the following points shall be added:
'(k) "putting into circulation" or "circulation": the holding of products for the purposes of sale, including offering for sale, or any other form of transfer, whether free or not, to third parties, and the sale and other forms of transfer themselves;
(l) person responsible for putting into circulation: the natural or legal person who has responsibility for the conformity of the additive which has been granted Community authorization and for putting it into circulation.`;
4) Articles 3 to 9 shall be replaced by the following:
'PROCEDURE FOR THE AUTHORIZATION OF ADDITIVES
Article 3
Member States shall require that no additive may be put into circulation unless a Community authorization has been granted. This authorization shall be granted under a Commission regulation in accordance with the procedure laid down in Article 4.
Article 3a
Community authorization of an additive shall be given only if:
(a) when used in animal nutrition it has one of the effects referred to in Article 2 (a);
(b) taking account of the conditions of use, it does not adversely affect human or animal health or the environment, nor harm the consumer by impairing the characteristics of animal products;
(c) its presence can be monitored:
- as an additive per se,
- in premixtures,
- in feedingstuffs or, where appropriate, in feed materials;
(d) at the level permitted, treatment or prevention of animal disease is excluded; this condition shall not apply to additives belonging to the group of coccidiostats and other medicinal substances;
(e) for serious reasons concerning human or animal health its use must not be restricted to medical or veterinary purposes.
Article 4
1. In order to obtain the Community authorization for a substance or a preparation as an additive or for a new use in the case of an already authorized additive, the applicant for authorization shall select a Member State to act as rapporteur during the scrutiny procedure on the dossier he has compiled in accordance with the provisions of Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition (*). Where the applicant is established in a third country, he must have a representative in the Community.
2. The Member State acting as rapporteur shall check that:
(a) the dossier has been compiled in accordance with Directive 87/153/EEC;

(b) the substance or preparation, according to the information given, appears to meet the conditions laid down in Article 3a.
3. The applicant for Community authorization shall dispatch to the Commission, via the Member State acting as rapporteur, an application accompanied by the dossier, sending copies to the other Member States, which shall acknowledge receipt at the earliest opportunity. That dispatch shall be affected no later than one year after the date of submission of the applicant's dossier in the Member State acting as rapporteur, unless the latter is rejected or postponed. The Member State acting as rapporteur shall inform the applicant, the other Member States and the Commission of the reasons for rejection or postponement of the dossier.
4. Member States shall have a period of sixty days from the date on which the dossier was dispatched to them in which to check whether the dossier has been compiled in accordance with Directive 87/153/EEC and, where appropriate, to submit their comments in writing to the Commission and the other Member States.
If, on expiry of the period referred to in the first paragraph, no objection has been made, the representative of the Commission shall have a period of thirty days in which to include the authorization application on the agenda for the Standing Committee for Feedingstuffs.
5. If, after consultation of the Standing Committee for Feedingstuffs, it is deemed that the rules on presentation of dossiers have not been complied with, a representative of the Commission shall so notify the applicant for authorization to put into circulation and the Member State acting as rapporteur; where necessary, a new application must be submitted in accordance with the above provisions.
6. The Commission shall ensure that a decision is taken, in accordance with the procedure laid down in Article 23, on the application for Community authorization within 320 days following its inclusion on the agenda for the Standing Committee for Feedingstuffs in accordance with the second subparagraph of paragraph 4. However, this time limit shall be interrupted where a request is made for additional information by a Member State in the Standing Committee for Feedingstuffs, or at the request of the Scientific Committee for Animal Nutrition.
Where an application for Community authorization to put an additive into circulation is rejected or the decision on it is postponed, a representative of the Commission shall inform the applicant for authorization and the Member State acting as rapporteur of the reasons for the rejection or postponement of the decision.
(*) OJ No L 64, 7. 3. 1987, p. 19. Directive as last amended by Directive 95/11/EC (OJ No L 106, 11. 5. 1995, p. 23).
Article 5
Amendments to Directive 87/153/EEC:
- which arise from developments in scientific and technical knowledge and
- take account of the provisions of Article 9b (1), Article 9c (3), Article 9o and Article 9q (5)
shall be adopted in accordance with the procedure laid down in Article 23.
Article 6
1. A fee may be charged, according to the additive groups and the nature of the Community authorization requested, by the Member State acting as rapporteur for the examination of dossiers arising from the obligations laid down in Articles 4 (2), 9b (1), 9c (3) and 9g (4). This fee shall be paid at the time of submission of the dossier.
2. Before 1 October 1999, the Council, acting by a qualified majority on a proposal from the Commission, shall fix the level of the fee referred to in paragraph 1.
Article 7
1. Member States and the Commission shall ensure that any information which, if disseminated, could affect industrial and commercial property rights is kept confidential.
2. Confidentiality shall not apply to:
- the name and composition of the additive,
- the physico-chemical and biological characteristics of the additive,

- the interpretation of the pharmacological, toxicological and ecotoxicological data relating to the additive,
- the analytical methods for monitoring the additive itself and the additive in premixtures, in the feedingstuffs and, where appropriate, in feed materials,
- the methods for testing for residues of the additive or metabolites thereof in animal products.

Article 7a

If an additive contains or consists of genetically modified organisms within the meaning of Article 2 (1) and (2) of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (*), a specific environmental risk assessment similar to that laid down in the abovementioned Directive shall be carried out; for this purpose, the following documents shall be included in the dossier submitted pursuant to Article 4 of this Directive in order to ensure compliance with the principles set out in Article 3a:
- a copy of any written consent or consents of the competent authorities to the deliberate release into the environment of genetically modified organisms for research and development purposes pursuant to Article 6 (4) of Directive 90/220/EEC and the result of the release(s) with respect to the risk in each case to human health and the environment,
- the complete technical dossier supplying the information requested in Annexes II and III to Directive 90/220/EEC and the environmental risk assessment resulting from this information; the results of any investigations performed for the purposes of research or development.

Articles 11 to 18 of Directive 90/220/EEC shall not apply to additives consisting of or containing genetically modified organisms.

(*) OJ No L 117, 8. 5. 1990, p. 15. Directive as last amended by Directive 94/15/EC (OJ No L 103, 22. 4. 1994, p. 20).

Article 8

1. The Scientific Committee for Animal Nutrition established by Commission Decision 76/791/EEC (*) shall be responsible for assisting the Commission, at the latter's request, on all scientific questions relating to the use of additives in animal nutrition.

2. At the request of the Commission, the Member State acting as rapporteur shall ensure that all or part of the dossier referred to in Article 4 is officially forwarded to the members of the Committee referred to in paragraph 1.

(*) OJ No L 279, 9. 10. 1976, p. 35. Decision as amended by Decision 86/105/EEC (OJ No L 93, 8. 4. 1986, p. 14).

ARRANGEMENTS APPLICABLE TO AUTHORIZATIONS FOR ADDITIVES LINKED TO THE PERSON RESPONSIBLE FOR PUTTING THEM INTO CIRCULATION

Authorization given for 10 years

Article 9

Additives as referred to in Article 2 (aaa) which meet the conditions laid down in Article 3a shall be authorized and included in Chapter I of the list referred to in Article 9t (b).

Provisional authorization for a maximum of four years

Article 9a

1. In the case of the additives referred to in Article 2 (aaa), provisional authorization may be given at Community level for the use of a new additive or a new use of an additive already authorized, provided that the conditions laid down in Article 3a (b), (c), (d) and (e) are met and it is reasonable to assume, in view of the available results, that the other condition laid down in Article 3a (a) is also met. These additives shall be included in Chapter II of the list referred to in Article 9t (b).

2. Provisional authorization as referred to in paragraph 1 may not exceed four years from the date on which it takes effect.

Renewal of authorization after 10 years

Article 9b

1. Community authorization of additives referred to in Article 2 (aaa) shall be valid for 10 years from the date on which final authorization takes effect and shall be renewable for 10-year periods. In the event of renewal, the authorization holder shall send to the Commission, via the Member State acting as rapporteur, an application accompanied by a dossier complying with the provisions to be laid down for the renewal of authorizations for additives in Directive 87/153/EEC. The application and the dossier shall be sent, at least one year before the date of expiry of the authorization, to the Commission, which shall acknowledge receipt thereof at the earliest opportunity. A copy of the renewal application, together with the dossier, shall be officially forwarded by the authorization holder via the Member State acting as rapporteur to the other Member States, which shall acknowledge receipt thereof at the earliest opportunity.
2. Articles 3, 3a, 4, 7, and 7a shall apply mutatis mutandis to applications for renewal.
3. Where, for reasons beyond the control of the authorization holder, no decision may be taken on the renewal application before the expiry date of the authorization, the period of authorization of the additive shall be automatically extended until the Commission takes a decision.

DATA PROTECTION

Article 9c

1. In the case of the additives referred to in Article 2 (aaa), the scientific data and other information in the initial dossier submitted for the purpose of the first authorization may not be used for the benefit of other applicants for a period of 10 years:
(a) from the date on which the first authorization by means of regulation takes effect for the additives referred to in Article 9g (1), Article 9h (1) and Article 9i (1), or
(b) for other additives from the data on which the first authorization by means of regulation takes effect or counting from 1 October 1999 if the latter date of taking effect is earlier,
unless the applicant has agreed with the authorization holder that such data and information may be used.
During this period, however, authorizations for putting into circulation may be granted to persons other than the person responsible for first putting the additive into circulation provided that the conditions in Articles 3a and 4 are met.
2. Where additional information is supplied on an additive which has been provisionally authorized under Article 9a, for the purpose of obtaining authorization of the additive under Article 3a, that information shall be considered as an integral part of the initial dossier and shall consequently cease to be protected at the same time as the information in the initial dossier.
3. On expiry of the 10-year period referred to in paragraph 1, the findings of all or part of the evaluation conducted on the basis of the scientific data and information in the dossier which led to authorization of the additive may be used by the Commission or by a Member State for the benefit of another applicant for authorization to put an additive which has already been authorized into circulation.
In such a case, an application accompanied by a dossier in accordance with the provisions to be laid down for this purpose in Directive 87/153/EEC shall be addressed by the new applicant, via a Member State acting as rapporteur, to the Commission, which shall acknowledge receipt thereof as quickly as possible. A copy of the application, together with the dossier, shall be officially forwarded by the new applicant, via a Member State acting as rapporteur, to the other Member States, which shall acknowledge receipt thereof at the earliest opportunity.
The provisions of Articles 3, 3a, 4, 7 and 7a shall apply mutatis mutandis.
4. The provisions of paragraph 3 shall also apply to the use of data from a dossier concerning an additive which has been the subject of withdrawal of authorization at the request of the holder of that authorization.
5. The additional scientific data and information required for modification of the conditions for listing an additive or for renewal of the authorization in accordance with Article 9b (1) or any new scientific data or information provided during the period of authorization of the additive may not be used by the Commission or by a Member State for the benefit of another applicant for a

period of five years from the date on which the authorization of a new use, the renewal or the submission of new scientific data or information takes effect.
Where the data-protection period granted for modification of the conditions for listing an additive expires before the end of the period provided for in paragraph 1, the five-year period shall be extended so that both periods expire simultaneously.
6. Without prejudice to paragraph 1, an applicant for an authorization for an additive referred to in Article 2 (3) (aaa) shall, before beginning toxicological tests on vertebrates, check whether his product or its active substance has not already been authorized. If necessary, he shall find out from a Member State's competent authorities whether the product or active substance concerned is the same as that already authorized.
If the product or active substance concerned has already been authorized, the applicant and the holder(s) of earlier authorizations shall take all necessary steps to reach agreement on sharing the use of information, in order not to repeat the toxicological tests on vertebrates.
If, however, the applicant and the holder(s) of previous authorizations for the same product do not reach agreement on sharing the information, the Member States may take national measures to oblige the applicant and the holder(s) of previous authorizations established within their territories to share the information, in order to avoid repeating toxicological tests on vertebrates undertaken on their territory and may lay down conditions for the use of the information while ensuring a reasonable balance between the interests of the parties concerned.
ARRANGEMENTS APPLICABLE TO AUTHORIZATION OF OTHER ADDITIVES
Authorization without a time limit
Article 9d
1. Additives as referred to in Article 2 (aaaa) which meet the conditions laid down in Article 3a shall be authorized and included in Chapter III of the list referred to in Article 9t (b).
2. Additives as referred to in Article 2 (aaaa) included in Annex I before 1 April 1998 shall be authorized and included in Chapter III of the list referred to in Article 9t (b).
Provisional authorization for a maximum of four or five years
Article 9e
1. In the case of the additives referred to in Article 2 (aaaa), provisional authorization may be given at Community level for the use of a new additive or a new use of an additive already authorized, provided that the conditions laid down in Article 3a (b), (c), (d) and (e) are met and it is reasonable to assume that the condition laid down in Article 3a (a) is also met. These additives shall be included in Chapter IV of the list referred to in Article 9t (b).
2. Provisional authorization as referred to in paragraph 1 may not exceed four years from the date on which it takes effect.
3. Additives as referred to in Article 2 (aaa), included in Annex II before 1 April 1998, may continue to be the subject of national provisional authorizations; they shall be included in Chapter IV of the list referred to in Article 9t (b). The period of provisional authorization of these additives may not exceed five years taking account of the period of inclusion in Annex II referred to above.
TRANSITIONAL ARRANGEMENTS APPLICABLE TO AUTHORIZATIONS FOR ADDITIVES LINKED TO THE PERSON RESPONSIBLE FOR PUTTING THEM INTO CIRCULATION
Article 9f
Notwithstanding Article 3, Member States shall permit the additives listed in Annex B to be put into circulation.
Additives included in Annex I before 1 January 1988
Article 9g
1. Additives as referred to in Article 2 (aaaa) included in Annex I before 1 January 1988 shall be provisionally authorized as from 1 April 1998 and transferred to Chapter I of Annex B with a

view to their re-evaluation as additives linked to a person responsible for putting them into circulation.
2. With a view to their re-evaluation, the additives as referred to in paragraph 1 must, before 1 October 1998, be the subject of new applications for authorization; such applications, accompanied by the monographs and the identification notes provided for in Articles 9n and 9o respectively, shall be addressed by the person responsible for the dossier on the basis of which the former authorization was granted or by his successor or successors, via the Member State acting as rapporteur, to the Commission, sending copies to the other Member States, which shall acknowledge receipt thereof.
3. In accordance with the procedure laid down in Article 23, provisional authorization of the additives shall be withdrawn through the adoption of a Regulation and they shall be deleted from the list in Chapter I of Annex B before 1 October 1999:
(a) if the documents prescribed in paragraph 2 are not submitted within the time allowed or
(b) if, after scrutiny of the documents, it is established that the monographs and identification notes are not in accordance with the date in the dossier on the basis of which the original authorization was given.
4. Member States shall ensure that the person responsible for putting an additive as referred to in paragraph 1 into circulation submits, as provided for in Article 4 and not later than 30 September 2000, the dossier referred to in Article 4 with a view to re-evaluation. Where he fails to do so, the authorization of the additive in question shall be withdrawn through the adoption of a regulation in accordance with the procedure laid down in Article 23 and it shall be deleted from the list in Chapter I of Annex B.
5. The Commission shall take all necessary measures to ensure that re-evaluation of the dossiers referred to in paragraph 4 is completed no later than three years after the dossier is submitted.
In accordance with the procedure laid down in Article 23, authorizations of the additives referred to in Article 1:
(a) shall be withdrawn and they shall be deleted from the list in Chapter I of Annex B through the adoption of a regulation, or
(b) shall be replaced by authorizations linked to the person responsible for putting them into circulation for a period of 10 years through the adoption of a regulation taking effect no later than 1 October 2003 and included in Chapter I of the list referred to in Article 9t (b).
6. The provisions of Article 9b (3) shall apply mutatis mutandis.
Additives included in Annex I after 31 December 1987
Article 9h
1. Additives as referred to in Article 2 (aaa) included in Annex I after 31 December 1987 shall be authorized provisionally as from 1 April 1998 and transferred to Chapter II of Annex B with a view to their authorization for a period of 10 years as additives linked to a person responsible for putting them into circulation in accordance with paragraphs 2 and 3.
2. The additives referred to in paragraph 1 must, before 1 October 1998, be the subject of new applications for authorization; such applications, accompanied by the monographs and the identification notes provided for in Articles 9n and 9o respectively, shall be addressed by the person responsible for the dossier on the basis of which the former authorization was given or by his successor or successors, via the Member State acting as rapporteur, to the Commission, sending copies to the other Member States, which shall acknowledge receipt thereof.
3. In accordance with the procedure laid down in Article 23, provisional authorizations of the additives referred to in paragraph 1:
(a) shall be withdrawn and they shall be deleted from the list in Chapter II of Annex B, through the adoption of a regulation, if the documents prescribed in paragraph 2 are not submitted within the time allowed or if, after scrutiny of the documents, it is established that the monographs or the identification notes are not in accordance with the data in the dossier on the basis of which the original authorization was given, or

(b) shall be replaced by authorizations linked to the person responsible for putting them into circulation, which shall be given for a period of ten years through the adoption of a regulation taking effect no later than 1 October 1999 and included in Chapter I of the list referred to in Article 9t (b).
4. The provisions of Article 9b (3) shall apply mutatis mutandis.
Additives included in Annex II before 1 April 1998
Article 9i
1. Additives as referred to in Article 2 (aaa) included in Annex II before 1 April 1998 may continue to be the subject of national provisional authorizations; they shall be authorized and transferred to Chapter III of Annex B with a view to their authorization as additives linked to a person responsible for putting them into circulation; the period of provisional authorization of these additives may not exceed five years taking account of the period of inclusion in Annex II referred to above.
2. The additives as referred to in paragraph 1 must, before 1 October 1998, be the subject of new applications for authorization; such applications, accompanied by the monographs and identification notes provided for in Articles 9n and 9o respectively, shall be addressed by the person responsible for the dossier on the basis of which the former authorization was given or by his successor or successors, via the Member State acting as rapporteur, to the Commission, sending copies to the other Member States, which shall acknowledge receipt thereof.
3. In accordance with the procedure laid down in Article 23, provisional authorizations of the additives referred to in paragraph 1:
(a) shall be withdrawn and they shall be deleted from the list in Chapter III of Annex B through the adoption of a regulation if the documents prescribed in paragraph 2 are not submitted within the time allowed or if, after scrutiny of the documents, it is established that the monographs and identification notes are not in accordance with the data in the dossier on the basis of which the original authorization was given, or
(b) shall be replaced by provisional authorizations as referred to in paragraph 1 linked to the person responsible for putting them into circulation through the adoption of a regulation taking effect no later than 1 October 1999 and the additives shall be included in Chapter II of the list referred to in Article 9t (b).
4. The provisions provided for in Article 9b (3) shall apply mutatis mutandis.
Article 9j
Applications for authorization to put into circulation submitted between 1 April 1998 and 30 September 1999 in respect of which the Commission has not yet given a ruling at that date shall be examined in accordance with Articles 3, 3a, 7, 7a, 9, 9a, 9b, 9c, 9d, 9e, 9n and 9o, as appropriate.
DISTRIBUTION AND USE OF ADDITIVES
Article 9k
1. Member States shall ensure that in the field of animal nutrition only additives authorized in accordance with this Directive may be put into circulation and that they may be used only if incorporated in feedingstuffs under the conditions set out in the authorization regulation.
2. Notwithstanding paragraph 1, additives belonging to groups other than "antibiotics", "coccidiostats and other medicinal substances", and growth promoters may be used if administered by a method other than incorporation in feedingstuffs, on condition that that method is provided for in the authorization regulation.
3. Member States shall, in particular, ensure that additives are added to feed materials and to straight feedingstuffs only where their use is expressly provided for in the authorization regulation.
REGISTRATION
Article 9l

1. Where additives as referred to in Article 2 (aaa) are authorized, the person(s) responsible for putting them into circulation shall be given a registration number and the additive shall be given a Community registration number.
2. Authorized additives as referred to in Article 2 (aaaa) shall be given a Community registration number.

WITHDRAWAL OF ADDITIVES

Article 9m

A regulation shall be adopted to withdraw the authorization of an additive:
- at the request of the person responsible for putting the additive into circulation, if the additive is one of those referred to in Article 2 (aaa),
- if any of the conditions for the authorization of the additive referred to in Article 3a are no longer met,
- if a standard sample of the additive is not supplied to the official authorities which have requested it or if an additive put into circulation does not correspond to the standard sample of the authorized additive,
- if a reference sample of the active substance is not supplied to the official authorities which have requested it,
- if the person responsible for putting the additive into circulation does not provide, within a given period of time, the information requested by a person responsible at the Commission.

However, such additives may continue to be authorized in order to use up stocks for a period of no longer than one year if at least the conditions laid down in Article 3a (b) and (e) continue to be met.

MONOGRAPHS AND IDENTIFICATION NOTES

Article 9n

1. In accordance with Directive 87/153/EEC, Member States shall ensure that applicants present a monograph for additives as referred to in Article 2 (aaa).
2. During the authorization procedure for additives as referred to in Article 2 (aaa), the Standing Committee for Feedingstuffs shall give an opinion, if appropriate after having made the necessary amendments, on the monograph of the additive presented in the dossier provided for in Article 4. The Commission shall approve the opinion given by the Standing Committee for Feedingstuffs on the monograph and its amendments in accordance with the procedure laid down in Article 23.
3. Monographs may also be approved for additives other than those referred to in paragraph 1 in accordance with the procedure laid down in paragraph 2.
4. The competent authorities of the Member States shall have recourse to the monograph:
(a) to determine whether an additive for which authorization to put into circulation has been requested constitutes an innovation or should be considered as a copy;
(b) to ascertain whether the additive put into circulation actually corresponds to the additive described in the dossier on the basis of which the Community authorization was granted.
5. Subsequent amendments to be made to monographs on account of developments in scientific and technical knowledge shall be submitted to the Standing Committee for Feedingstuffs for its opinion in accordance with the procedure laid down in Article 23.

Article 9o

1. In accordance with Directive 87/153/EEC, Member States shall ensure that the applicant presents an identification note summarizing the characteristics and properties of the additive. In the case of the additives referred to in Article 2 (aaa), or should Article 9n (3) be applied, the identification note shall contain a summary of the most important characteristics and properties given in the monograph referred to in Article 9n.
2. The following shall be adopted in accordance with the procedure laid down in Article 23:
- the identification note,
- subsequent amendments to the identification note as a result of developments in scientific and technical knowledge.

3. In order to facilitate identification of the additives referred to in paragraph 1 during official checks, the identification note provided for in that paragraph shall be published in the Official Journal of the European Communities.

STANDARD SAMPLE

Article 9p

1. For the additives referred to in Article 2 (aaa) a standard sample having the characteristics and properties described in the monograph referred to in Article 9n together with a reference sample of the active substance shall be made available, upon request, to the national inspection authorities of the Member States by the person responsible for putting them into circulation.

2. If the characteristics or properties of the additive are modified, a new standard sample corresponding to the new monograph shall be provided.

3. Detailed rules concerning the provision and maintenance of standard samples shall be adopted in accordance with the procedure laid down in Article 23.

MIXTURES AND ADDITIVE LEVELS

Article 9q

1. The maximum and minimum levels set for certain additives shall refer to complete feedingstuffs with a moisture content of 12 % insofar as no special provisions are laid down in the authorization regulation.

If the substance permitted as an additive also exists in the natural state in certain feed materials, the amount of additive to be incorporated 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 authorization regulation.

2. The mixing of additives shall be permitted in premixtures and feedingstuffs only where there is physico-chemical and biological compatibility between the components of the mixture in relation to the effects desired.

3. Unless the mixture concerned is the subject of a specific authorization as an additive, Member States shall require that:

(a) antibiotics and growth promoters may not be mixed together, either with substances from their own group or with substances from the other group;

(b) coccidiostats and other medicinal substances may not be mixed with antibiotics and growth promoters where coccidiostats also act, for the same category of animal, as an antibiotic or as a growth promoter;

(c) coccidiostats and other medicinal substances may not be mixed together if their effects are similar.

4. Mixing antibiotics, growth promoters, coccidiostats and other medicinal substances with micro-organisms shall be prohibited unless such a mixture is authorized by the regulation authorizing the micro-organisms.

5. By way of derogation from Article 3 and paragraphs 2 and 3 of this Article, Member States may authorize, but only for practical tests conducted for scientific purposes and for non-commercial ends, the use as additives of products which are not authorized at Community level or the use of additives under conditions other than those laid down in the authorization regulation, provided that:

- the tests are carried out in accordance with the principles and conditions to be laid down in Directive 87/153/EEC, and
- an adequate official inspection has been performed.

AMENDMENTS TO THE ANNEXES

Article 9r

Amendments to be made to the Annexes shall be adopted in accordance with the procedure laid down in Article 23.

INFORMATION ON PRODUCERS OF ADDITIVES

Article 9s

Member State shall ensure that the persons responsible for putting the additives referred to in Article 2 (aaa) into circulation forward to the Commission as quickly as possible the name or corporate name and the address or registered office of the producers to whom they have granted the right to manufacture the additive and, if the producers are established in a third country, also the name or corporate name and the address or registered office of their representatives in the Community.

PUBLICATION IN THE OFFICIAL JOURNAL

Article 9t

The Commission shall publish in the Official Journal of the European Communities, "C" Series, not later than 30 November each year:

(a) the list of persons responsible for putting additives into circulation as referred to in Article 9s, the names of the producers to whom they have granted the right to manufacture the additives and their representatives in the Community if such producers are established in a third country;

(b) the list of authorized additives subdivided as follows:

- Chapter I: list of additives linked to a person responsible for putting them into circulation and authorized for a period of 10 years,
- Chapter II: list of additives linked to a person responsible for putting them into circulation and authorized on a provisional basis for no longer than four years or five years in the case of additives which have been the subject of provisional authorization before 1 April 1998,
- Chapter III: list of other additives authorized for an unlimited period,
- Chapter IV: list of other additives authorized on a provisional basis for no longer than four years or five years in the case of additives which have been the subject of provisional authorization before 1 April 1998.`

5) The following title shall be inserted between Articles 9t and 10:

'PACKAGING`.

6) The following title shall be inserted between Articles 10 and 11:

'SAFEGUARD AND MEASURES`.

7) In Article 11 (1), 'listed in Annex I` shall be replaced by 'authorized`.

8) The following title shall be inserted between Articles 11 and 12:

'ADDITIVE LEVELS IN COMPLEMENTARY FEEDINGSTUFFS`.

9) The following title shall be inserted between Articles 12 and 13:

'RULES FOR THE DISTRIBUTION AND INCORPORATION IN FEEDINGSTUFFS OF ADDITIVES AND PREMIXTURES`.

10) Article 13 shall be replaced by the following:

'Article 13

1. Member States shall require that certain additives covered by this Directive, premixtures prepared from those additives with a view to their being incorporated in compound feedingstuffs and compound feedingstuffs containing those premixtures may be put into circulation or used only by the establishments or intermediaries which meet the conditions laid down, as appropriate, in 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 (*).

2. Member States shall require that:

(a) additives referred to in Part A of Annex A may be supplied only by approved establishments:

(i) to intermediaries or establishments which manufacture premixtures and which have been approved in accordance with the provisions laid down in Article 3 (1) or Article 2 (2) (b) respectively of Directive 95/69/EC, and

(ii) in the form of premixtures, only to intermediaries or establishments which manufacture compound feedingstuffs with a view to putting them into circulation or for the exclusive requirements of their holding and which have been approved in accordance with the provisions laid down in Article 3 (1) or Article 2 (2) (c) or (e) respectively of the above Directive;

(b) additives listed in Part B of Annex A may be supplied only by approved establishments:
(i) to intermediaries or establishments which manufacture premixtures and which have been approved in accordance with the provisions laid down in Article 3 (1) or Article 2 (2) (b) respectively of the above Directive, and
(ii) in the form of premixtures, only to:
- intermediaries which have been approved in accordance with the provisions laid down in Article 3 of the above Directive, or
- establishments which manufacture compound feedingstuffs with a view to putting them into circulation or for the exclusive requirements of their holding and which have been registered in accordance with the provisions laid down in Article 7 (2) (c) or (d) respectively of the said Directive or, as appropriate, approved in accordance with the provisions laid down in Article 2 (2) (c) or (e) of this Directive.
3. Member States shall require that additives referred to in Annex A (a) and (B) may be incorporated in compound feedingstuffs only if they have been prepared beforehand in the form of premixtures containing a carrier substance by establishments which meet the conditions laid down in Article 2 (2) (b) of Directive 95/69/EC. Such premixtures may be incorporated in compound feedingstuffs only in a proportion of at least 0,2 % by weight.
By way of derogation from the first subparagraph, Member States may allow premixtures to be incorporated in compound feedingstuffs in a proportion as low as 0,05 % by weight, provided that the quantitative and qualitative composition of the premixture so permits and that they have first established that the establishments satisfy the conditions set out in Chapter I.2 (b) of the Annex, with a view to achieving homogeneous distribution of premixtures and observing the additive levels set for the whole feedingstuff.
These manufacturers as referred to in the second paragraph shall be entered on the national list under a special heading as follows: "Manufacturers of compound feedingstuffs authorized to use a minimum proportion of 0,05 % by weight of premixtures".
4. By way of derogation from paragraph 2, Member States shall require that:
(a) additives referred to in Annex A (B) may be supplied to approved intermediaries or registered establishments which manufacture compound feedingstuffs for pets and fulfil the conditions laid down, as appropriate, in Article 3 (1) or Article 3 (2) (c) or (d) of Directive 95/69/EC;
(b) additives referred to in Annex A (A) or (B) may be delivered at the last stage of circulation to establishments which manufacture compound feedingstuffs, provided that:
- the Community regulation authorizing the additive provides, in the case of a specific preparation of the additive, for direct addition to feedingstuffs, and
- the manufacturer of compound feedingstuffs is approved in accordance with Article 2 (2) (c) of the above Directive for the additives referred to in Annex A (A) or is registered in accordance with Article 7 (2) (c) of the above Directive for the additives referred to in Annex A (B), and
- it has been checked on the spot that the manufacturer is in possession of the appropriate technology defined in Chapter I (3) (b) or Chapter II (c) of the Annex to the above Directive in order to add the preparation in question directly to the compound feedingstuff.
Such manufacturers shall appear on the national list under a special heading as follows: "Manufacturers of compound feedingstuffs referred to in point (b) authorized to add antibiotics, cocciodiostats and other medicinal substances, and growth promoters directly to compound feedingstuffs" or "Manufacturers of compound feedingstuffs authorized to add copper, selenium and vitamins A and D directly to compound feedingstuffs".
5. By way of derogation from Article 7 of Directive 95/69/EC and paragraphs 1 and 2 of this Article, Finland and, as regards that part of its territory situated to the north of latitude 60°, Sweden shall be authorized, in view of the special feeding conditions on their farms, to allow premixtures of vitamins, provitamins and chemically well-defined substances having similar effect to be supplied to stock farmers for direct addition to feed materials of vegetable origin, provided that:

- the directions for use state precisely the dosage to be complied with according to the species or category of animals and the type of fodder used, and
- special measures are taken by Finland and Sweden to monitor use of such premixtures.
(*) OJ No L 332, 30. 12. 1995, p. 15.`
11) The following title shall be inserted between Articles 13 and 14:
'LABELLING OF ADDITIVES`
12) Articles 14 to 16 shall be replaced by the following:
'Article 14
1. Member States shall require that authorized additives may be put into circulation for use in feedingstuffs only if the following particulars, which must be clearly visible, readily legible and indelible and must place responsibility on the producer, packer, importer, seller or distributor established within the Community, are given on the package, the container or a label affixed thereto:
A. for all additives, with the exception of enzymes and micro-organisms:
(a) the specific name given to the additive upon authorization, the EC registration number of the additive and, in the case of an additive within the meaning of Article 2 (aaa), the trade name and the registration number given to the person responsible for putting it into circulation;
(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 paragraph;
(c) the net weight and, in the case of liquid additives, either the net volume or the net weight;
(d) as applicable, 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 the above Directive.
B. In addition, with regard to:
(a) antibiotics, growth promoters, coccidiostats and other medicinal substances: the name or business name and the address or registered place of business of the manufacturer, if he is not responsible for the particulars in the label, the active-substance level, 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 use in the case of additives which are the subject of special provisions upon authorization;
(b) vitamin E: the alpha-tocopherol level and the expiry date of the guarantee of that level or storage life from the date of manufacture;
(c) vitamins, other than vitamin E, provitamins and substances having a similar effect: the active-substance level and the expiry date of the guarantee of that level or storage life from the date of manufacture;
(d) trace elements, colourants including pigments, preserving agents and other additives, with the exception of those belonging to the enzyme and micro-organism groups: the active-substance level.
C. For additives belonging to the groups:
(a) of enzymes: the specific name of the active component or components in accordance with their enzyme activities, in conformity with the authorization given, the International Union of Biochemistry identification number, units of activity (*) (units of activity per gram or units of activity per millilitre), the EC registration number of the additive, the name or business name and the address or registered place of business of the person responsible for the particulars on the label, the name or business name and the address or registered place of business of the manufacturer, if he is not responsible for the particulars on the label, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of Directive 95/69/EC, 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 specifying in particular the recommended dose, in the form of a range if appropriate, in accordance with the percentage(s) by

weight of target feed material(s) per kilogram of the whole feedingstuff in accordance with the requirements laid down on a case-by-case basis in the authorization for the additive and, where applicable, safety recommendations as provided for in the authorization for the additive, the net weight and, in the case of liquid additives, either the net volume or the net weight, where appropriate indication of special significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization for the additive;
(b) of micro-organisms: identification of the strain(s) in accordance with the authorization granted, the file number of the strain(s), the number of colony-forming units (CFU per gram), the EC registration number of the additive, the name or business name and the address or registered place of business of the person responsible for the particulars on the label, the name or business name and the address or registered place of business of the manufacturer, if he is not responsible for the particulars on the label, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of Directive 95/69/EC, 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 applicable, safety recommendations as provided for in the authorization for the additive, the net weight and, in the case of liquid additives, either the net volume or the net weight, where appropriate an indication of special significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive.
2. Member States shall require that the specific name of the additive may be accompanied, in cases where the indications are not required by virtue of paragraph 1:
(a) by the trade name;
(b) by the name or business name and the address or registered place of business of the manufacturer, if he is not responsible for the particulars on the label, the directions for use and, where appropriate, a safety recommendation regarding use.
3. Member States shall require that information other than that required or authorized pursuant to paragraphs 1 and 2 may appear on packages, containers or labels, provided that they are clearly separated from the abovementioned marking particulars.
(*) Units of activity expressed in micromoles of product released per minute, per gram of enzyme preparation.
Article 15
1. Member States shall require that premixtures may be marketed only if the following particulars, which must be clearly visible, readily legible and indelible and must place responsibility on the producer, packer, importer, seller or distributor established within the Community, are given on the package, the container or a label affixed thereto:
A. For all premixtures:
(a) the description "premixture";
(b) directions for use, and any safety recommendations regarding the use of the premixtures;
(c) the animal species or category of animals for which the premixture is intended;
(d) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this paragraph;
(e) the net weight and, in the case of liquids, either the volume or net weight;
(f) as applicable, 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 the above Directive.
B. In addition, for the premixtures incorporating the additives listed below:
(a) antibiotics, growth promoters, coccidiostats and other medicinal substances: the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the details on the label, specific name given to the additive upon authorization, active substance level and expiry date of the guarantee of that level, or storage life from the date of manufacture;

(b) substances having antioxidant effects: specific name given to the additive upon authorization, and active substance level, provided that a maximum level is fixed for complete feedingstuffs on authorization of the additive;
(c) colourants, including pigments: specific name given to the additive upon authorization, and active substance level, provided that a maximum level is fixed for complete feedingstuffs upon authorization of the additive;
(d) vitamin E: specific name given to the additive upon authorization, alpha-tocopherol level and expiry date of the guarantee of that level or storage life from the date of manufacture;
(e) vitamins other than vitamin E, provitamins and substances having a similar effect: specific name given to the additive upon authorization, active substance level and expiry date of the guarantee of that level or storage life from the date of manufacture;
(f) trace elements: specific name given to the additive upon authorization, and level of the various elements insofar as a maximum level is fixed for complete feedingstuffs upon authorization of the additive;
(g) preserving agents: specific name given to the additive upon authorization, and active substance level, provided that a maximum level is fixed for complete feedingstuffs upon authorization of the additive;
(h) enzymes: the specific name of the active component(s) according to its (their) enzymatic activity(ies) in accordance with the authorization given, the identification number according to the International Union of Biochemistry, the activity units (activity units per g or activity units per ml), the additive's EC registration number, the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label, 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 specifying in particular the recommended dose, in the form of a range if appropriate, in accordance with the percentage(s) by weight of target feed material(s) per kilogram of the whole feedingstuff in accordance with the requirements laid down on a case-by-case basis in the authorization for the additive and, where applicable, indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive;
(i) micro-organisms: the identification of the strain(s) in accordance with the authorization given, the file number of the strain(s) in accordance with the authorization given, the file number of the strain(s), the number of colony-forming units (CFU/g), the additive's EC registration number, the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label, the expiry date of the guarantee of the storage life from the date of manufacture and, where applicable, indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive;
(j) other additives belonging to the groups referred to in (b) or (i) for which no maximum level is laid down and additives belonging to other groups authorized: specific name given to the additive upon authorization and active substance level, provided that these additives fulfil a function in the feedingstuff as such and the amounts present can be determined by official methods of analysis or, failing this, by valid scientific methods.
2. Member States shall require that:
(a) the specific name of additives may be accompanied by the tradename;
(b) the name of the producer of the additives referred to in paragraph 1 (B) (a) may be indicated in the labelling of premixtures. However, they may stipulate that this indication shall be compulsory;
(c) the specific name of the additives authorized may be accompanied by the additive's EC registration number.

3. Where, pursuant to paragraph 1, the expiry date of the guarantee or storage life from the date of manufacture of several additives belonging to the same group or different groups has to be stated, Member States shall require that a single date of guarantee or a single reference to the storage life may be indicated for all the additives, namely the deadline which will be reached first.
4. Member States shall require that information other than that required or authorized pursuant to paragraphs 1 to 3 may appear on packages, containers or labels, provided that they are clearly separated from the abovementioned marking particulars.
Article 16
1. Member States shall require that feedingstuffs incorporating the additives belonging to the groups listed below may be put into circulation only if the following particulars, which must be clearly visible, readily legible and indelible and must place responsibility on the producer, packer, importer, seller or distributor established within the Community, are given on the package, the container or a label affixed thereto:
(a) for antibiotics, coccidiostats and other medicinal substances and growth promoters: the specific name given to the additive upon authorization, the active substance level and the expiry date of the guarantee of that level or storage life from the date of manufacture, the approval number assigned to the establishment in accordance with Article 5 of Directive 95/69/EC;
(b) for substances having antioxidant effects:
- in the case of pet foods: use of the words "with antioxidant" followed by the specific name given to the additive upon authorization,
- in the case of compound feedingstuffs other than pet foods: the specific name given to the additive upon authorization;
(c) for colourants, including pigments provided that these are used for the colouration of feedingstuffs or animal products:
- in the case of pet foods: use of the words "colourant" or "coloured with" followed by the specific name given to the additive upon authorization,
- in the case of compound feedingstuffs other than pet foods: the specific name given to the additive upon authorization;
(d) for vitamin E: the specific name given to the additive upon authorization, the alpha-tocopherol level and the expiry date of the guarantee of that level or storage life from the date of manufacture;
(e) for vitamins A and D: the specific name given to the additive upon authorization, the active substance level and the expiry date of the guarantee of that level or storage life from the date of manufacture;
(f) for copper: the specific name given to the additive upon authorization and the level expressed in Cu;
(g) for preserving agents:
- in the case of pet foods: use of the words "preservative" or "preserved with" followed by the specific name given to the additive upon authorization,
- in the case of compound feedingstuffs other than pet foods: the specific name given to the additive upon authorization;
(h) for enzymes: the specific name of the active constituent(s) according to its (their) enzymatic activity(ies) in accordance with the authorization given, the identification number according to the International Union of Biochemistry, the activity units (activity units per kilogram or activity unit per litre), the EC registration number of the additive, the expiry date of the guarantee or the storage life from the date of manufacture and, where applicable, indication of any particular significant characteristic due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive;
(i) for micro-organisms: the identification of the strain(s) in accordance with the authorization given, the file number of the strain(s), the number of colony-forming units (CFU/kg), the EC registration number of the additive, the expiry date of the guarantee or the storage life from the

date of manufacture and, where applicable, indication of any particular significant characteristic due to the manufacturing process, in accordance with the provisions concerning labelling in the authorization of the additive.
2. In addition to the particulars provided for by paragraph 1, particulars concerning the proper use of the feedingstuffs may be laid down in the authorization of the additive in accordance with the procedure provided for in Article 23.
Member States shall require that these particulars must appear on the package or the container or on a label affixed thereto.
3. The presence of trace elements other than copper and of vitamins other than vitamins A, D and E, provitamins and additives having a similar effect may be indicated if the amounts of these substances can be determined by official methods of analysis or, failing this, by valid scientific methods of analysis. In such cases the following details shall be given:
(a) for trace elements other than copper: the specific name of the additive in accordance with the authorization given and level of the various elements;
(b) for vitamins other than vitamins A, D and E, provitamins and substances having a similar chemical effect: the specific name of the additive in accordance with the authorization given, the active substance level and the expiry date of the guarantee of that level or storage life from the date of manufacture;
4. Member States shall require that:
(a) the details provided for in paragraphs 1 to 3 shall be printed close to the particulars which have to appear on the package, container or the label affixed thereto in accordance with Community rules on feedingstuffs;
(b) where a level or a quantity is stated pursuant to paragraphs 1 to 3, such statement shall refer to the amount of additive incorporated in the feedingstuff;
(c) the details of additives may be accompanied by the EC registration number of the additive or the trade name where those particulars are not required by virtue of paragraph 1.
5. Where, pursuant to paragraph 1, the expiry date of the guarantee or storage life from the date of manufacture of several additives belonging to the same group or different groups has to be stated, Member States shall require that a single date of guarantee or a single reference to the storage life from the date of manufacture may be indicated for all the additives, namely the deadline which will be reached first.
6. In the case of feedingstuffs distributed by road tankers or similar vehicles or in bulk, the details provided for in paragraphs 1 to 3 shall be given in the accompanying document.
Where small quantities intended for the end-user are involved, it shall be sufficient for such details to be conveyed to the purchaser by a suitable notice.
7. Member States shall require that, in the case of pet foods containing colourants, preservatives or substances having antioxidant effects and put up in packages having a net weight of not more than 10 kilograms, it shall be sufficient for the package to bear the words "coloured with", or "preserved with", or the words "with antioxidant" as appropriate, followed by the words "EC additives", provided that:
(a) the package, container or label bears a reference number by means of which the feedingstuff may be identified, and
(b) the manufacturer gives, on request, the specific name, or names, of the additive or additives used.
8. Any reference to additives other than in the form provided for in this Directive shall be prohibited.`
13) In Article 17 (1), the second subparagraph shall be replaced by the following:
'This information must be in accordance with the conditions of use prescribed upon authorization of the additive.`.
14) The following title shall be inserted between Articles 20 and 21:
'INSPECTION MEASURES`.

15) The following shall be added after Article 21:
'MONITORING OF UNDESIRABLE INTERACTIONS
Article 21a
Where there is found to be unforeseen undesirable interaction between additives referred to in Article 2 (aaa) and other additives or veterinary medicines, Member States shall require that the person responsible for putting the additive into circulation, or his representative within the Community where additives originate in third countries, gathers all the relevant information and forwards it to the competent authorities.`.
16) The following title shall be inserted between Articles 21a and 22:
'EXPORTS TO THIRD COUNTRIES`.
17) The following title shall be inserted between Articles 22 and 23:
'IMPLEMENTATION POWERS OF THE COMMISSION`.
18) The following title shall be inserted between Articles 24 and 25:
'FINAL PROVISIONS`.
19) Annexes I, II and III shall be deleted.
20) The Annexes A, B and C set out in the Annex to this Directive shall be added.

Article 2
1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with:
(a) the following provisions provided for in Article 1:
- point (4): Article 6 (1), Article 9d (2), Article 9e (3), Article 9f, Article 9g, Article 9h, Article 9i, Article 9j, Article 9n, Article 9o,
- points 10, 12, 19 and 20,
on 1 April 1998;
(b) the other provisions of this Directive by 1 October 1999.
They shall forthwith inform the Commission thereof.
When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.
2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

Article 3
This Directive is addressed to the Member States.

Done at Brussels, 23 July 1996.
For the Council
The President
I. YATES

(1) OJ No C 218, 12. 8. 1993, p. 1.
(2) OJ No C 128, 9. 5. 1994, p. 97.
(3) OJ No C 52, 19. 2. 1994, p. 18.
(4) OJ No L 270, 14. 2. 1970, p. 1. Directive as last amended by Directive 92/25/EC (OJ No L 125, 23. 5. 1996, p. 35).
(5) OJ No L 64, 7. 3. 1987, p. 19. Directive as last amended by Commission Directive 95/11/EC (OJ No L 106, 11. 5. 1995, p. 23).

ANNEX
'Annex A
referred to in Article 13
PART A
- Antibiotics: all additives belonging to this group
- Coccidiostats and other medicinal substances: all additives belonging to this group
- Growth promoters: all additives belonging to this group
PART B
- Trace elements: copper and selenium
- Vitamins, provitamins and chemically well-defined substances with similar effects: vitamins A and D.`

ANNEX B

CHAPTER I Additives linked to a person responsible for putting them into circulation, inserted in Annex I before 1 January 1988
>TABLE POSITION>

CHAPTER II Additives linked to a person responsible for putting them into circulation, inserted in Annex I after 31 December 1987
>TABLE POSITION>

CHAPTER III Additives linked to a person responsible for marketing, inserted in Annex II before 1 April 1998
>TABLE POSITION>

ANNEX C

PART I
Additives subject to authorization linked to the person responsible for putting them into circulation referred to in Article 2 (aaa) of the Directive:
- antibiotics: all additives belonging to this group,
- coccidiostats and other medicinal substances: all additives belonging to this group,
- growth promoters: all additives belonging to this group.

PART II
Other additives referred to in Article 2 (aaaa) of the Directive:
- antioxidant substances: all additives belonging to this group,
- flavouring and appetizing substances,
- emulsifying and stabilizing agents, thickeners and gelling agents: all additives belonging to this group,
- colourants, including pigments: all additives belonging to this group,
- preservatives,
- vitamins, provitamins and chemically well-defined substances having similar effect: all additives belonging to this group,
- trace elements: all additives belonging to this group,
- binders, anti-caking agents and coagulants: all additives belonging to this group,

- acidity regulators: all additives belonging to this group,
- enzymes: all additives belonging to this group,
- micro-organisms: all additives belonging to this group.