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

[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).

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[1] 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 arrangemens 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

[1] 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).

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 tchnological 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).