COMMISSION OF THE EUROPEAN COMMUNITIES

COM(93) 119 final

Brussels, 26 March 1993

Proposal for a

COUNCIL DECISION

concerning the use and marketing of enzymes microorganisms and their preparations in animal nutrition

(presented by the Commission)

Explanatory Memorandum

1. Introduction

The draft Council Regulation in question forms part of the general framework of Community rules on animal nutrition and, more particularly, of the approval arrangements introduced by Council Directive 70/524/EEC concerning additives in feedingstuffs.

The use of enzymes, very frequent in food for human consumption, has increased rapidly in animal feed in recent years. The same is true in the case of microorganisms.

The role of microorganisms and enzymes in feedingstuffs is, from a nutritional point of view, of the utmost importance, and the resulting economic advantages are far from negligible. These products, each according to its characteristics, improve the digestibility of nutrients present in feedingstuffs by facilitating their metabolization by the animal and, by stabilizing the flora of the animal's digestive system, they spontaneously reduce the proliferation of pathogenic microorganisms.

The latter quality helps considerably to reduce the mortality rate among young animals and increase the level of homogeneity in animals at birth and later at the adult stage.

In terms of the environment, the positive effect on the capacity of animals to absorb certain nutrients (phosphorus, nitrogen, etc.) appears to be the way in which the quantity of phosphates or nitrates present in excreta is to be sharply reduced in the future. This latter aspect is of the greatest interest to the national authorities of those countries which are faced with the serious problems of pollution posed by the elimination of effluent in areas of intensive pig farming.

2. Purpose of the rules

In the absence of specific rules for the examination of this new generation of products, several Member States have, without further delay, tacitly allowed or even temporarily permitted that enzymes or microorganisms be used in animal feed. Other Member States opposed the entry into free circulation of the products in question over the same period.

The situation has become critical in recent months owing to the distortions of competition which have progressively occurred in Member States at the level of both producers of enzymes and microorganisms and users thereof, i.e. manufacturers of feedingstuffs and stock farmers.

This state of affairs has led some Member States to ask the Commission rapidly to regularize the situation (in some Member States production units are in place but are not operational due to the absence of authorization for the product).

With a view to progressively eliminating current distortions of competition and achieving the level of harmonization required by Community law relating to the authorization of additives in feedingstuffs, it is proposed that:

- a status quo be established enabling Member States provisionally to permit the use of enzymes and microorganisms used or likely to be used on their territory pending a Community Decision in accordance with Directive 70/524/EEC;

- a timetable be adopted for the establishment of:

  = an inventory of all the products permitted in each Member State,
  = an identification note for the various products used,
  = a dossier drawn up in accordance with Directive 87/153/EEC with a view to deciding at Community level on the authorizations to be given at national level,

- rules on labelling be drawn up to which will be subject enzymes and microorganisms, and premixtures and feedingstuffs containing them.

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THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic 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),

Whereas Council Directive 70/524/EEC concerning additives in feedingstuffs(4), as last amended by Directive 92/113/EEC(5) lays down the principles relating to the authorization and the use of additives;

Whereas Council Directive 87/153 fixing guidelines for the assessment of additives in feedingstuffs(6) constitutes a guide for defining the scientific information necessary to identify and characterize the products concerned, as well as the studies necessary to evaluate, in particular, their efficacy and innocuouness for humans, animals and the environment;

Whereas advances in scientific and technological knowledge permit the use of certain enzymes, microorganisms and their preparations in animal nutrition in order to improve the disgestibility of nutrients, or to stabilize the flora of the digestive system of animals, and to reduce the content of certain substances dangerous to the environment, whereas at the moment no criteria exist for the examination of requests for authorization for use as additives of this new generation of products;

Whereas it is essential, in the expectation of an amendment to the guidelines and in order to allow the submission of dossiers for these products, to allow provisionally the use and marketing of enzymes, microorganisms and their preparations at national level, provided they do not present any danger to human or animal health.

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(1)
(2)
(3)
(4) O.J. n° L 270 of 14.12.1970, p. 1
(5) O.J. n° L 16 of 25.01.1993, p. 2
(6) O.J. n° L 64 7.3.1987, p. 19

Whereas the authorization of these products requires an inventory of them at the level of Member States, and the transmission to the Commission of certain information justifying their inclusion in national lists;

Whereas Member States may not restrict the marketing of livestock products obtained from feeds containing enzymes, microorganisms or their preparations when these are included on a national list established according to the provisions of this Decision;

Whereas the provisions of this Decision do not apply to enzymes, microorganisms, or to their preparations when used as silage agents;

Whereas this Decision applies without prejudice to Directive 70/524/EEC subject to the amendments which should still be made to this Directive in order to allow the coexistence of the temporary regime;

Whereas it is advisable as a consequence to amend Directive 87/153/EEC, and quickly, with a view to having available the necessary rules for the specific examination of additives belonging to the new group of enzymes and microorganisms, whereas in the meantime, the dossiers which will be submitted with a view to assessing products included in the national lists should be prepared according to the guidelines established for additives in general.

Whereas it is advisable that industry is given sufficient time to apply the new provisions provided for enzymes, microorganisms and their preparations as well as premixtures and feedingstuffs containing them.

HAS ADOPTED THIS DECISION

Article 1

1. This Decision shall apply to the use and marketing of enzymes, microorganisms and their preparations in animal nutrition.

2. This Decision applies without prejudice to the provisions of Directive 70/524/EEC and particularly to the provisions concerning the authorization of enzymes, microorganisms and their preparations for use as additives.

Article 2

By way of derogation from Article 3 of Directive 70/524/EEC Member States shall allow the use and marketing of enzymes, microorganisms and their preparations in feedingstuffs on their territory, provided that, on the basis of the available information, the products do not present a danger to human or animal health, and that they are included in the list which has been established by virtue of Article 3.

Article 3

On the basis of the information they receive Member States shall forward :

- to the Commission before 1 January 1994 a list of enzymes and microorganisms and their preparations used on their teritories, accompanied by an identification note established for each product according to the model given in the Annex;

- to the Commission and to other Member States before 1 January 1996, the dossiers justifying these authorizations by the manufacturer(s) having requested inclusion of their products in the list referred to in the first indent above.

Article 4

1. The Commission shall communicate to Member States the lists of enzymes, microorganisms and their preparations, which have been sent to them in accordance with the provisions of Article 3.

2. Where, either an enzyme, microorganism or a preparation manufactured from them are included in several national lists, it may be agreed between the Member States concerned that only one dossier is presented by one of them.

3. The Commission shall publish in the Official Journal of the Communities, Part C, before 31 March 1996, on the basis of the dossiers which have been presented to them in accordance with Article 3, a list of enzymes, microorganisms and their preparations permitted in different Member States.

Article 5

Before 1 January 1998, a ruling will be given in accordance with the procedure provided by Directive 70/524/EEC on the dossiers referred to in the second indent of Article 3 concerning the authorization of additives in animal nutrition

Article 6

Where Member States find it impossible to satisfy one of the conditions referred to in Article 4, for an enzyme, microorganism, or a preparation used on their territory, they shall take all the necessary measures to ensure that the enzyme, microorganism or preparation obtained from them is no larger used.

Article 7

Enzymes, microorganisms and their preparations, as well as premixtures and compound feedingstuffs in which they have been incorporated, may only be marketed if the particulars listed below, which should be clearly visible, legible and indelible and for which the producer, packer, importer, seller or distributor established within the Community shall be held responsible are shown on the packaging, container or on a label attached thereto :

A. For enzymes

a) the specific name of the active constituent(s) according to their enzymatic activity(ies) and the identification number(s) according to International Union of Biochemistry;

b) the activity units (activity units[7] per g or activity units per ml);

c) the name or business name and the address or registered place of business of the person responsible for the particulars in this paragraph;

d) the name or business name and address or registered place of business of the manufacturer if he is not responsible for the particulars on the label;

e) the expiry date of the guarantee or the storage life from the date of manufacture;

f) the batch reference number and the date of manufacture;

g) directions for use and where appropriate, a safety recommendation;

h) the net weight and for liquid additives either the net volume or the net weight;

i) the indication "to be used exclusively for the manufacture of feedingstuffs".

(7) Units of activity expressed as µmole product released per minute per gram of enzymatic preparation.

B. For microorganisms :

a) the identification of the strain(s) according to the recognized International Code of Nomenclature and the depositing number of the strain(s);

b) the number of colony-forming units (CFU/g);

c) the name or business name and address or registered place of business of the person responsible for the particulars referred to in this paragraph;

d) the name or business name and address or registered place of business of the manufacturer if he is not responsible for the particulars on the label;

e) the expiry date of the guarantee, or the storage life from the date of manufacturer;

f) the batch reference number and the date of manufacturer;

g) the directions for use and where appropriate, a safety recommendation;

h) the net weight, and for liquid additives either the net volume or the net weight;

i) the indication "to be used exclusively for the manufacture of feedingstuffs".

C. For premixtures containing enzymes :

a) the description "premixture";

b) the indication "to be used exclusively in the manufacture of feedingstuffs";

c) the directions for use and any safety recommendations regarding the use of premixtures;

d) the animal species or category of animals for which the premixture is intended;

e) 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;

f) the net weight and, in the case of liquids, either the volume or net weight;

g) the specific name of the active constituent(s) according to their enzymatic activity(ies) and the identification number(s) according to the International Union of Biochemistry;

h) the activity units (activity units per g or activity units per ml);

i) the expiry date of the guarantee or the storage life from the date of manufacturer;

j) the name or business name and address or registered place of business of the manufacturer if he is not responsible for the particulars on the label.

D. For premixtures containing microorganisms :

a) the description "premixture";

b) the indication "to be used exclusively in the manufacture of feedingstuffs";

c) the directions for use and any safety recommendations regarding the use of premixtures;

d) the animal species or category of animals for which the premixture is intended;

e) 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;

f) the net weight and, in the case of liquids, either the volume or net weight;

g) the identification of the strain(s) according to the recognized International Code of Nomenclature and the depositing number of the strain(s);

h) the number of colony-forming units (CFU/g);

i) the name or business name and address or registered place of business of the person responsible for the particulars referred to in this paragraph;

j) the name or business name and address or registered place of business of the manufacturer if he is not responsible for the particulars on the label.

E. For compound feeds in which enzymes have been incorporated :

a) the specific name of the active constituent(s) according to their enzymatic activity(ies) conforming with Annexes I or II and the identification number according to International Union of Biochemistry;

b) the activity units (activity units per g) or activity units per ml;

c) the expiry date of the guarantee or the storage life from the date of manufacture.

F. For compound feeds in which microorganisms have been incorporated :

a) the identification of the strain(s) according to the recognized International Code of Nomenclature and the depositing number of the strain(s);

b) the number of colony-forming units (CFU/g);

c) the expiry, date of the guarantee or the storage life from the date of manufacture.

2. Information other than that prescribed in paragraph 1, under A, B, C and D such as the commercial name, may he included on the packaging, containers or on a label attached thereto provided that it clearly separated from the indications mentioned above.

Article 8

This Decision is applicable from 1 July 1993. However Article 7 is only applicable form 1 January 1994.

Article 9

This Decision is addressed to the Member States.

Done at .....

For the Council
The President

A N N E X

MODEL OF IDENTIFICATION NOTE

1. Identity of the product

   - Trade name;

   - Qualitative and quantitative composition

     . active substance(s),
     . other components,
     . impurities,
     . undesirable substances;

   - Name or business name and the address or registered place of business of the manufacturer;

   - Place of manufacture;

   - Name or business name and the address or registered place of business of the manufacturer.

2. Specifications concerning the active substance

2.1 For Microorganisms :

   - Name and taxonomic description according to the International Codes of Nomenclature(1);

   - Name and place of culture collection where the strain is registered and deposited and the number of registration and deposit;

   - Possible genetic manipulation;

   - The number of colony-forming units (CFU/g) for each species.

2.2 For enzymes

   - Name according to main enzymatic activities and EC number(2);

   - Biological origin;

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(1) Such as "Bergey's Manual of Systematic Bacteriology "The Yeasts, a taxonomic study "by Lodder and Kreger van Rij"; Ainsworths and Bisby's Dictionary of the Fungi "by Hawksworth, Sutton and Ainsworth on "The genus Aspergillus" by Raper and Fennell

(2) Enzyme Nomenclature recommendations (1984) of the Nomenclature Committee of the International Union of Biochemistry, Acdemic Press 1984.

- Relevant activities with regard to appropriate types of substrates, chemically pure (expressed in activity units[3] per g)

N.B. If the active substance is a mixture of active components, all the components must be described separately with an indication of their proportion in the mixture.

3. Qualities of the product

- Main sought after effect;
  - . Information concerning efficency
  - . Justification for the presence of each component if the substance is a mixture of effective components.
- Other effects

4. Conditions for the use of product

- Uses provided for in animal nutrition (species or categories of animal, type of feedingstuffs for animal, period of use, etc.);
- Proposed dosage in premixes and feedingstuffs (approriate units of biological activity such as CFU per gram of product for microorganisms or activity units per gram for enzyme preparations);
- Other known uses of the active substance or the preparation (in foodstuffs, human or veterinary medicine, industry etc...);
- Recommendations concerning the product in relation to targeted species, the consumer and the environment;
- If necessay, measures for the prevention of risks and means of protection during manufacture and handling;

5. Technological information

- Stability of product
  - . with regard to atmospheric agents,
  - . during the preparation of premixes and feedingstuffs,
  - . in the case of presentation of premixes and feedstuffs.

(3) Activity units expressed as µmole of product released per mimte, per gram of the enzymatic preparations.

- Detailed description of process of manufacture and methods used concerning the control of the quality of the product during its manufacture.

6. Control

Methods of analysis for the determination of the product
- in premixtures
- in feedingstuffs

Where possible information provided in the identification note must be accompanied by existing scientific data.

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DOCUMENTS

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