COUNCIL DIRECTIVE 93/114/EC

of 14 December 1993

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),

Whereas Council Directive 70/524/EEC concerning additives in feedingstuffs (4) lays down the principles relating to the authorization and the use of additives;

Whereas the inclusion of enzyme and micro-organisms in Directive 70/524/EEC means that products belonging to both of these new categories and their manufacturers are subject to the same requirements which apply to the authorization of additives and to manufacturers in general; whereas it is particularly necessary to ensure that the products marketed are innocuous to the environment, workers, animal owners and consumers of animal products and furthermore that they satisfy the requirements set as regards effectiveness, quality and ability to be checked;

Whereas in order to make possible the evaluation and authorization of enzymes produced by or derived from genetically modified organisms, the Commission must provide an assessment of such products with the aim of preventing damage to human or animal health or the environment;

Whereas it appears necessary for the Scientific Committee for Feedingstuffs to be assisted by experts in the field of genetic engineering and in assessing risks linked to the use of genetically modified organisms, so as to ensure that the testing procedure is such as to rule out any damaging effects on human or animal health or the environment caused by the products concerned;

Whereas in the Community authorization procedure for additives the requirements of Directive 90/220/EEC (5) concerning a specific environmental risk evaluation must be applied in respect of all additives containing or consisting of genetically modified organisms; whereas these requirements should therefore be inserted in Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition (6), and that they apply concomitantly with this Directive;

Whereas advances in scientific and technological knowledge permit the use of certain enzymes, micro-organisms and their preparations in animal nutrition in order to improve the digestibility of nutrients or to stabilize the flora of the digestive system of animals and to reduce the quantity of certain environmentally undesirable substances;

Whereas Directive 93/113/EEC (7) permits the Member States to allow temporarily and subject to certain conditions the use and marketing of enzymes, micro-organisms and their preparations at national level until those products receive Community authorization pursuant to Directive 70/524/EEC;

Whereas the granting of such authorization implies that special labelling provisions be inserted in the abovementioned Directive for this new generation of additives and for the premixtures and feedingstuffs into which they are incorporated,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 70/524/EEC is hereby amended as follows:

1. the following Article shall be inserted after Article 7:

'*Article 7a*

If an additive contains or consists of genetically modified organisms within the meaning of Article 2

(1) OJ No C 117, 17. 4. 1993, p. 11
(2) OJ No C 329, 6. 12. 1993.
(3) OJ No C 201, 26. 7. 1993, p. 33.
(4) OJ No L 270, 14. 12. 1970, p. 1. Directive as last amended by Commission Directive 93/55/EEC (OJ No L 206, 18. 8. 1993, p. 11).

(5) OJ No L 117, 8. 5. 1990, p. 15.
(6) OJ No L 64, 7. 3. 1987, p. 19.
(7) See page 17 of this Official Journal.

(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 to be included in the dossier submitted pursuant to Article 9 of this Directive in order to ensure compliance with the principles set out in Article 7 (2) of this Directive:

— a copy of any written consent or consents of the competent authorities to the deliberate release 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 I and II 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.

(*) OJ No L 117, 8. 5. 1990, p. 15'

2. Article 14 (1) is amended as follows:

(a) the title of point A shall be replaced by the following:

'A. for all additives with the exception of enzymes and micro-organisms:'

(b) in point B, subparagraph (d) shall read as follows:

'(d) trace elements, colorants including pigments, preservatives and other additives with the exception of those belonging to the groups of enzymes and micro-organisms: active substance level.';

(c) the following point shall be added:

'C. for additives belonging to the groups:

(a) of enzymes: the specific name of the active components(s) according to its (their) enzymatic activity(ies) in accordance with Annex I or II, the indentification number according to the International Union of Biochemistry, the activity units (1) (activity units per g or activity units per ml), 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, and 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 words 'to be used exclusively in the manufacture of feedingstuffs', the directions for use and, where appropriate, the safety recommendation where the column entitled 'Other provisions', in Annex I or II contains special provisions concerning the additives, the net weight and for liquid additives either the net volume or the net weight and, where applicable, indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the column entitled 'Other provisions' in Annex I or II;

(b) of micro-organisms: the identification of the strain(s) in accordance with Annex I or II, the file number of the strain(s), the number of colony-forming units (CFU/g), the name or business name and address or registered place of business of the person responsible for the particulars referred to in this paragraph, 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, 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 words 'to be used exclusively in the manufacture of feedingstuffs', the directions for use and, where appropriate, a safety recommendation where the column entitled 'Other provisions' in Annex I or II contains special provisions concerning the additives, the net weight and for liquid additives either the net volume or the net weight and where applicable, indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the column entitled 'Other provisions' in Annex I or II;'

(1) Activity units expressed as μmole of product released per minute per gram of enzymatic preparation.

3. in Article 15 (1) B

(a) subparagraph (h) shall become subparagraph (j) and shall be replaced by the following:

'(j) other additives belonging to the groups referred to in (b) to (i) for which no maximum level is laid down and additives belonging to other groups provided for in Annex I or II: specific name of the additive in accordance with Annex I or II 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';

(b) the following subparagraphs shall be added:

'(h) enzymes: the specific name of the active component(s) according to its (their) enzymatic activity(ies) in accordance with Annex I or II, the identification number according to the International Union of Biochemistry, the activity units (activity units per g or activity units per ml), the expiry date of the guarantee or the storage life from the date of manufacture, 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 and, where applicable, indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the column entitled 'Other provisions' in Annex I or II;

(i) micro-organisms: the identification of the strain(s) in accordance with Annex I or II, the file number of the strain(s), the number of colony-forming units (CFU/g), the expiry date of the guarantee of the storage life from the date of manufacture, 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 and, where applicable, indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the column entitled 'Other provisions' in Annex I or II;'

4. the following subparagraphs shall be added to Article 16 (1):

'(h) for enzymes: the specific name of the active constituent(s) according to its (their) enzymatic activity(ies) in accordance with Annex I or II, the identification number according to the International Union of Biochemistry, the activity units (activity units per kg or activity unit per l), the expiry date of the guarantee or the storage life from the date of manufacture and, where applicable, indication of any particular characteristic due to the manufacturing process, in accordance with the provisions concerning labelling in the column entitled 'Other provisions' in Annex I or II;

(i) for micro-organisms: the identification of the strain(s) in accordance with Annex I or II, the file number of the strain(s), the number of colony-forming units (CFU/kg), 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 column entitled 'Other provisions' in Annex I or II;'

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 October 1994. They shall forthwith notify the Commission thereof.

When Member States adopt these provisions 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 texts of the provisions of national law which they adopt in the field governed by this Directive. The Commission shall inform the other Member States thereof.

Article 3

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 14 December 1993.

for the Council

The President

A. BOURGEOIS