COMMISSION OF THE EUROPEAN COMMUNITIES

COM(93) 636 final

Brussels, 7 December 1993

Amended proposal for a

COUNCIL DIRECTIVE

amending Directive 70/524/EEC
concerning additives in feedingstuffs

(presented by the Commission pursuant to Article 189A(2) of the EC-Treaty)

Explanatory memorandum

At its plenary session of 15-19 November 1993, the European Parliament gave its opinion on the proposal for a Council Directive amending Directive 70/524/EEC on additives in feedingstuffs (COM(93) 110 final).

The Commission has accepted amendments 1 and 2 as proposed, and the part of amendment 3 referring to scientific documents concerning GMOs, as well as amendments 23 and 24 (extending the composition of the Scientific Committee on Animal Nutrition and assessment of enzymes obtained from genetically modified micro-organisms in order to remove risks to human and animal health and the environment).

However, the Commission has not accepted the second part of amendment 3 according to which two authorization procedures should be applied to products obtained from GMOs, i.e. the procedure under Directive 70/524/EEC on additives and the procedure under Directive 90/220 EEC on the deliberate release into the environment of genetically modified organisms. (The Commission would rather opt for integrating the substantive provisions of Directive 90/220/EEC into Directive 70/524/EEC).

The Commission has accepted the spirit of amendments 4, 5, 6 and 7 on the labelling of GMO additives since, in accordance with the position it adopted during the discussion on the Roth-Behrendt report on NOVEL FOODS, such labelling would be on a case-by-case basis to indicate the presence of one or more significant special characteristics due to the manufacturing process.

This proposal amends the Commission's initial proposal in accordance with Article 189A(2) of the Treaty.

AMENDED PROPOSAL

FOR A

COUNCIL DIRECTIVE

amending Directive 70/524/EEC concerning additives in feedingstuffs

(presented by the Commission pursuant to Article 189A(2) of the EC Treaty)

As a result of the opinion delivered by Parliament at its plenary session of 15-19 November 1993 on the proposal for a Directive amending Directive 70/524/EEC concerning additives in feedingstuffs, presented to the Council on 24 March 1993, the Commission has decided to amend its initial proposal as follows, in accordance with Article 189A(2) of the Treaty:

1. After the first recital, the following recitals are added:

"Whereas the inclusion of enzyme and microorganism products 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 that the Scientific Committee for Feedingstuffs should be assisted by experts in the field of genetic engineering 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[3] concerning a specific environmental risk evaluation must be applied in respect of all additives which contain genetically modified organisms; whereas these requirements should therefore be inserted in Directive 87/153/EEC fixing guidelines for the assessment of additives in animal nutrition[4] and that they apply concomitantly with the provisions of the present directive;".

3 OJ No L 117, 8.5.1990, p. 15.
4 OJ No L 64, 7.3.1987, p. 19.

2. The following is inserted in Article 1:

"1. The following Article is inserted after Article 7:

"Article 7a

If an additive contains genetically modified organisms within the meaning of Article 2(1) and (2) of Council Directive 90/220/EEC 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 in order to ensure compliance with Article 7(2):

- a copy of the competent authority's written consent 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 results of the release(s) with respect to the risk in each case to human health and the environment;

- the complete technical file with the information required by Annexes I and II to Directive 90/220/EEC and the environmental risk evaluation carried out on the basis of this information.

3. Point 1(c) (now point 2(c)) of Article 1 is replaced by the following:

"C. for additives belonging to the groups:

(a) of enzymes: the specific name of the active constituent(s) according to its (their) enzymatic activity(ies) in accordance with Annexes 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 name or business name and the adress or registred 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 for the manufacture of feedingstuffs", the directions for use and, where appropriate, a safety recommendation where the column entitled "Other provisions" in the Annexes 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 the Annexes;

(b) of microorganisms: the identification of the strain(s) in accordance with Annexes I or II, the file number of the strain(s), the number of units forming the colonies (CFU/g), 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, 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 for the manufacture of feedingstuffs", the directions for use and, where appropriate, a safety recommendation where the column entitled "Other provisions" in the Annexes 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 the Annexes."

4. Point 2(a) (now point 3(a)) of Article 1 is replaced by the following:

"(a) Subparagraphs (h) and (i) below are added:

(h) enzymes: the specific name of the active constituent(s) according to its (their) enzymatic activity(ies) in accordance with Annexes 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 the Annexes;

(i) microorganisms: the identification of the strain(s) in accordance with Annexes I or II, the file number of the strain(s), the number of units forming the colonies (CFU/g), 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 the Annexes;"

5. Point 3 subparagraphs (h) and (i) (now point 4 subparagraphs (h) and (i)) of Article 1 is replaced by the following:

"(h) for enzymes: the specific name of the active constituent(s) according to its (their) enzymatic activity(ies) in accordance with Annexes 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 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 the Annexes;

(i) for microorganisms: the identification of the strain(s) in accordance with Annexes I or II, the file number of the strain(s), the number of units forming the colonies (CFU/g), the expiry date of the guarantee or 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 column entitled "Other provisions" in the Annexes."

6. Point 4 of Article 4 becomes point 5.

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