II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 21 July 1986

amending Directive 74/63/EEC on the fixing of maximum permitted levels for undesirable substances and products in feedingstuffs, Directive 77/101/EEC on the marketing of straight feedingstuffs and Directive 79/373/EEC on the marketing of compound feedingstuffs

(86/354/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 43 and 100 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 the definitions of straight feedingstuffs and the various types of compound feedingstuffs in Directives 74/63/EEC (4), 77/101/EEC (5) and 79/373/EEC (6), as last amended by Directives 86/299/EEC (7), 83/87/EEC (8) and 82/957/EEC (9) respectively, should be aligned on the new definitions in Council Directive 84/587/EEC of 29 November 1984 amending Directive 70/524/EEC concerning additives in feedingstuffs (10); whereas 'milk replacer feeds' should also be defined;

Whereas it should be made clear that the provisions of Directives 74/63/EEC, 77/101/EEC and 79/373/EEC are without prejudice to the provisions of Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition (11);

Whereas Directive 74/63/EEC concerns undesirable substances and products in feedingstuffs; whereas, therefore, the maximum permitted levels laid down in the Annex to that Directive do not apply to the raw materials used for preparing compound feedingstuffs;

Whereas the fixing of maximum levels or the limiting of the presence of certain undesirable substances and products in raw materials is at the moment governed by divergent provisions in the Member States;

Whereas the consequences of the presence, above a certain level, of these substances or products are likely to prove harmful to human health and whereas it is therefore necessary to guarantee, in an appropriate and uniform manner,the safe use of these products and substances throughout the Community;

Whereas, moreover, the divergent provisions in the national legislation of Member States leads to substantial barriers in intra-Community trade and whereas it is desirable to adopt appropriate measures within the context of Directive 74/63/EEC;

Whereas, in addition, Directives 77/101/EEC and 79/373/EEC should be adopted to better facilitate the marketing of straight and compound feedingstuffs;

Whereas it is desirable to define the concept of raw materials in order to set clear limits to the scope of the measures relating to that class of products, which is also referred to by the term 'ingredients' in other Directives on animal feedingstuffs;

(1) OJ No C 258, 26. 9. 1984, p. 7.
(2) OJ No C 175, 15. 7. 1985, p. 21.
(3) OJ No C 87, 9. 4. 1985, p. 4.
(4) OJ No L 38, 11. 2. 1974, p. 31.
(5) OJ No L 32, 3. 2. 1977, p. 1.
(6) OJ No L 86, 6. 4. 1979, p. 30.
(7) OJ No L 189, 11. 7. 1986, p. 40.
(8) OJ No L 56, 3. 3. 1983, p. 31.
(9) OJ No L 386, 31. 12. 1982, p. 42.
(10) OJ No L 319, 29. 11. 1984, p. 13.
(11) OJ No L 213, 21. 7. 1982, p. 8.

Whereas the provisions in question apply exclusively to raw materials intended for animal feed which are to be entered into circulation in the form of straight feedingstuffs or as carriers of premixtures of additives or, after being mixed with other products, as compound feedingstuffs ;

Whereas, in order to ensure that certain particularly undesirable substances are not present in feedingstuffs, it is necessary not only to limit their presence in raw materials to an acceptable level but also to restrict the use of those raw materials to persons who have the requisite skill, apparatus and equipment for the diluting operations which ensure that the maximum levels laid down in the Directive for compound feedingstuffs are observed ;

Whereas the minimum conditions laid down in Annex III to Council Directive 70/524/EEC for a person to be entered on a national list of manufacturers of compound feedingstuffs must also be applied to manufacturers of compound feedingstuffs using raw materials which contain a level of undesirable substances and products higher than that permitted in straight feedingstuffs ; whereas it is desirable, however, that Member States should be able to confine the delivery of such highly contaminated raw materials to those manufacturers who produce compound feedingstuffs for sale where their inspection services are unable to monitor at farm level those manufacturers of compound feedingstuffs who are also livestock farmers and who use all or part of their production for their own requirements ;

Whereas, for certain raw materials whose level of undesirable substances and products is not restricted in Annex II (A), provision should be made for the possibility of imposing appropriate labelling provisions if the quantity of the undesirable substance or product present in the raw materials exceeds the maximum level laid down for the corresponding straight feedingstuffs ; whereas this measure is indispensable in order to ensure that such raw materials are not delivered to livestock farmers and to inform manufacturers of the nature and quantity of the undesirable substance or product present ;

Whereas the Member States should provisionally be authorized to retain the national provisions which they have adopted concerning raw materials contaminated by aflatoxin other than those referred to in Annex II (A) or relating to undesirable substances or products other than aflatoxin affecting the quality of the raw materials ; whereas a Community decision should be taken before 3 December 1990 so that by that date uniform Community rules exist regarding the presence of undesirable substances and products in raw materials used in the preparation of feedingstuffs ;

Whereas, in order to guarantee the safety of feedingstuffs, rules should be laid down governing the presence of undesirable substances and products and processes sought for decontaminating raw materials ; whereas, on the basis of the results obtained, the criteria should be laid down with which products subject to certain decontamination processes must comply ;

Whereas the procedure introducing close cooperation between the Member States and the Commission within the Standing Committee for Feedingstuffs should be applied in order to facilitate implementation of the measures proposed and to make, *inter alia*, amendments and additions concerning the fixing of maximum levels or labelling rules for raw materials contaminated by certain undesirable substances or products and the establishment of acceptability criteria for decontaminated raw materials ;

Wheras an information procedure must be established for notifying Member States of cases of non-compliance with Community provisions in order to facilitate supervision of the application of Directive 74/63/EEC ;

Whereas the experience gained in the implementation of Directive 79/373/EEC shows the need to improve or supplement the labelling of compound feedingstuffs in certain cases ;

Whereas, in particular, an indication of the name or business name and address of the manufacturer must be stipulated where the latter is not responsible for the labelling particulars ; whereas, however, account must be taken of the particular control systems in certain Member States and whereas such Member States should be authorized, for feedingstuffs produced and marketed in their territory, to replace these particulars by the official code number given to each manufacturer,

HAS ADOPTED THIS DIRECTIVE :

Article 1

Directive 74/63/EEC is hereby amended as follows :

1. The title of the Directive shall be replaced by the following : 'Council Directive on undesirable substances and products in animal nutrition.'

2. In Article 1 :

   (a) paragraph 1 shall be replaced by the following :

   '1. This Directive deals with undesirable substances and products in animal nutrition.'

   (b) The following point (e) shall be added to paragraph 2 :

   '(e) certain products used in animal nutrition.'

3. In Article 2 :

   (a) points (a), (b) and (h) shall be replaced by the following :

   '(a) feedingstuffs : 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, used singly or in mixtures, whether or not containing additives, for oral animal feeding ;

(b) straight feedingstuffs : the various vegetable or animal products in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and various organic or inorganic substances, whether or not containing additives, intended as such for oral animal feeding :

(h) compound feedingstuffs : mixtures of products of vegetable or animal origin in the natural state, fresh or preserved, and products derived from the industrial processing thereof, or of organic or inorganic substances, whether or not containing additives, for oral animal feeding in the form of complete feedingstuffs or complementary feedingstuffs ;'

(b) the following point shall be added :

'(i) raw materials (ingredients) ; 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 to be entered for circulation as straight feedingstuffs or for the preparation of compound feedingstuffs or as carriers of premixtures ;'

4. Article 3 shall be replaced by the following :

'Article 3

1. Member States shall prescribe that the substances and products listed in Annex I shall be tolerated in feedingstuffs only under the conditions therein set out.

2. Member States may authorize the maximum permitted levels provided for in Annex I in respect of feedingstuffs to be exceeded in the case of fodder which is produced and used in the same state on the same agricultural holding, where this is necessary for particular local reasons. The Member States concerned shall ensure that neither animal nor human health can suffer harm thereby.'

5. The following Articles shall be inserted :

'Article 3a

1. Member States shall prescribe that the raw materials listed in Annex II (A) may be marketed only if their content of the undesirable substance or product mentioned in column 1 of the said Annex does not exceed the maximum level laid down in column 3 of that Annex.

2. Where the content of the undesirable substance or product listed in column 1 of Annex II (A) exceeds the level laid down in column 3 of Annex I in respect of the straight feedingstuff, the raw material listed in column 2 of Annex II (A) may, without prejudice to paragraph 1, be marketed only if :

(a) it is intended for use by manufacturers of compound feedingstuffs entered on a national list as provided for in Article 13 (3) of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (1),

and

(b) it is accompanied by a document stating :

— that the raw material is intended for manufacturers of compound feedingstuffs who fulfil the conditions laid down in paragraph (a),

— that the raw material may not be fed unprocessed to livestock,

— the amount of the undesirable substance or product contained in the raw material.

3. Member States shall prescribe that paragraph 2 (a) and (b) shall also apply to the raw materials and undesirable substances or products listed in Annex II (B) the maximum level of which is not restricted in Annex II (A), if the level of the undesirable substance or product present in the raw material exceeds that laid down in column 3 of Annex I for the corresponding straight feedingstuffs.

'Article 3b

Member States may restrict the application of Article 3a (2) (a) to those manufacturers of compound feedingstuffs who use the materials in question for the production and marketing of compound feedingstuffs.'

(1) OJ No L 270, 14. 12. 1970, p. 1.'

6. In Article 4, 'in this Directive' shall be replaced by 'in Annex I.'

7. In Article 5 :

(a) the text of paragraph 1 shall be replaced by the following :

'1. Where a Member State, as a result of new information or of a reassessment of existing information made since the provisions in question were adopted, has detailed grounds for establishing that a maximum content fixed in Annex I or II or a substance or product not listed therein constitutes a danger to animal or human health or the environment, that Member State may provisionally reduce that content, fix a maximum content or prohibit the presence of that substance or product in feedingstuffs or raw materials. It shall immediately inform the other Member States and the Commission thereof, giving reasons for its decision.'

(b) in paragraph 2, 'the Annex' shall be replaced by 'the Annexes'.

8. Article 6 shall be replaced by the following :

'Article 6

In accordance with the procedure laid down in Article 9 and in the light of developments in scientific and technical knowledge :

(a) the amendments to be made to the Annexes shall be adopted;

(b) a consolidated version of the Annexes shall be drawn up periodically incorporating the successive amendments made pursuant to (a);

(c) criteria for the acceptability of raw materials which have undergone certain decontamination processes may be defined.'

9. The following Article shall be added:

'Article 6a

1. Until a Community decision is taken, Member States may retain measures governing the importation and entry for circulation within their territories of:

(a) raw materials contaminated by aflatoxin other than the raw materials referred to in Annex II (A), and

(b) raw materials contaminated by undesirable substances or products other than aflatoxin.

2. Not later than the 31 January 1987, Member States shall notify the Commission of the national provisions which they intend to retain by virtue of paragraph 1.

3. The amendments to be made to Annex II to remove discrepancies resulting from the application of paragraph 1 shall be adopted by 3 December 1990 at the latest.'

10. In Article 7, 'and raw materials' shall be inserted after 'feedingstuffs'.

11. In Article 8:

(a) paragraph 1 shall be replaced by the following:

'1. Member States shall take all necessary measures to ensure that feedingstuffs and raw materials are officially controlled, at least by random sampling, to verify whether the conditions laid down in this Directive are satisfied.'

(b) the following paragraph 3 shall be added:

'3. If a consignment of raw material is likely to be sent to a Member State after it has been judged not to comply with the provisions of this Directive on account of an excessive content of undesirable substances or products in another Member State, the latter Member State shall immediately give the other Member States and the Commission any useful information concerning that consignment of raw material.'

12. In Article 11, 'and raw materials' shall be inserted after 'feedingstuffs',

13. The Annex shall be amended as follows:

(a) 'I' shall be added after the word 'ANNEX';

(b) the three columns of Annex I shall be numbered 1, 2 and 3 respectively;

(c) in Annex I (B), the heading of column 3 shall be replaced by the following:

'Maximum content in mg/kg (ppm) of feedingstuffs referred to a moisture content of 12 %'.

14. The following shall be added as Annex II:

ANNEX II

A

Substances, products	Raw materials	Maximum content in mg/kg (ppm) of raw material, referred a moisture content of 12 %
(1)	(2)	(3)
1. Aflatoxin B_1	Groudnut, copra, palm-kernel, cotton seed, babassu, maize and products derived from the processing thereof	0,2

B

Substances, products	Raw materials
(1)	(2)'

15. 'Alimenti per animali' throughout the Directive in the Italian text shall be replaced by 'mangimi'.

Article 2

Directive 77/101/EEC is hereby amended as follows:

1. In Article 1 (2):

(a) point (b) shall be replaced by the following:

'(b) undesirable substances and products in animal nutrition;'

(b) the following point shall be added:

'(d) certain products used in animal nutrition.'

2. Article 2 shall be replaced by the following:

'Article 2

For the purposes of this Directive, straight feedingstuffs shall mean the various vegetable or animal products in their natural state, fresh or preserved, and products derived from the industrial processing thereof, as well as various organic or inorganic substances, whether or not containing additives, intended as such for oral animal feeding.'

3. 'Alimenti per animali' throughout the Directive in the Italian text shall be replaced by 'mangimi'.

Article 3

Directive 79/373/EEC is hereby amended as follows:

1. In Article 1 (2):

(a) point (c) shall be replaced by the following:

'(c) undesirable substances and products in animal nutrition;'

(b) the following point shall be added:

'(f) certain products used in animal nutrition.'

2. In Article 2:

(a) the text of points (a) and (b) shall be replaced by the following:

'(a) Feedingstuffs: 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, used singly or in mixtures, whether or not containing additives, for oral animal feeding.

(b) Compound feedingstuffs: mixtures of products of vegetable or animal origin in their natural state, fresh or preserved, and products derived from the industrial processing thereof, or of organic or inorganic substances, whether or not containing additives, for oral animal feeding in the form of complete feedingstuffs or complementary feedingstuffs.'

(b) the following points shall be added:

'(j) Milk replacer feeds: compound feedingstuffs administered in dry form or after dilution in a given quantity of liquid for feeding young animals as a supplement to, or substitute for, post-colostral milk or for feeding calves intended for slaughter.

(k) Ingredients (raw 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 to be entered for circulation as straight feedingstuffs or for the preparation of compound feedingstuffs or as carriers of premixtures.'

3. In Article 5:

(a) paragraph 1, point (a) shall be replaced by the following:

'(a) the description "complete feedingstuff", "complementary feedingstuff", "mineral feedingstuff", "molassed feedingstuff", "complete milk replacer feed", "complementary milk replacer feed", as appropriate;'

(b) in paragraph 4 the following point shall be added:

'(g) the name or business name and address or registered place of business of the producer, where the latter is not responsible for the labelling particulars;'

(c) the following paragraph shall be inserted:

'4a. Member States shall be authorized, for feedingstuffs produced and marketed in their territory, to prescribe instead of the particulars referred to in Article 5 (4) (g) indication of an official code number corresponding to the producers established in their territory.'

(d) in paragraph 5 the following point shall be added:

'(h) an indication of the physical condition of the feedingstuff or the specific processing it has undergone.'

(e) the following paragraph shall be inserted:

'7a. Paragraph 7 shall not apply where ingredients (raw materials) must be mentioned on the label of compount feedingstuffs pursuant to Directive 82/471/EEC.'

(f) paragraph 8 shall be supplemented by the following subparagraph:

'Such information

— may not mislead the purchaser in particular by attributing to the feedingstuff effects or properties that it does not possess or by suggesting that it possesses special characteristics when in fact all similar feedingstuffs possess such characteristics,

— must relate to objective or quantifiable factors which can be substantiated.'

4. The following Articles shall be inserted:

'Article 5a

In English, 'complementary feedingstuff' and 'complete feedingstuff' may be replaced, in the case of feedingstuff for pets, respectively by 'complementary pet food' and 'complete pet food'.

Article 5b

Without prejudice to the provisions of Article 5, Member States shall stipulate that the labelling of compound feedingstuffs for pet animals may draw particular attention to the presence or low content of one or more ingredients that are essential for the characteristics of the feedingstuff. In such case the minimum or maximum content, expressed in terms of the percentage by weight of the ingredient(s) incorporated, must be clearly indicated either opposite the statement drawing particular attention to it or them or in the list of ingredients or by mentioning it or them and the percentage(s) by weight concerned opposite the corresponding category of ingredients.'

5. 'Alimenti per animali' throughout the Directive in the Italian text shall be replaced by 'mangimi'.

Article 4

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 3 December 1988. They shall forthwith inform the Commission thereof.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 21 July 1986.

For the Council

The President

G. HOWE