Proposal for a Directive of the European Parliament and of the Council on undesirable substances and products in animal nutrition

(2000/C 89 E/14)

(Text with EEA relevance)

COM(1999) 654 final - 1999/0259(COD)

(Submitted by the Commission on 17 December 1999)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 152 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

- Many amendments need to be made to Council Directive 1999/29/EC of 22 April 1999 on the undesirable substances and products in animal nutrition (¹). In the interests of clarity and efficiency the said Directive should be recast;
- (2) Livestock production occupies a very important place in farming in the Community and satisfactory results depend to a large extent on the use of appropriate good-quality feedingstuffs;
- (3) Rules on feedingstuffs are needed to increase agricultural productivity;
- (4) It has been established that additives can be contaminated with undesirable substances and products. The scope of the Directive should therefore be extended to cover additives;
- (5) Feed materials, feedingstuffs and feed additives may contain undesirable substances or products which can endanger animal health or, because of their presence in livestock products, human health;
- (6) It is impossible to fully eliminate the presence of the substances and products in question but it is important that their content in feed materials and feed additives should be reduced in order to prevent undesirable and harmful effects. It is at present inappropriate to fix this

content below the levels detectable by methods of analysis to be defined for the Community;

- (7) Undesirable substances and products may be present in feed materials, feedingstuffs and feed additives only in accordance with the conditions laid down in this Directive and may not be used in any other way for the purposes of animal feeding. This Directive should therefore apply without affecting other Community provisions on feedingstuffs, and particularly the rules applicable to compound feedingstuffs;
- (8) This Directive must apply to feed materials, feedingstuffs and feed additives as soon as they enter the Community. It should therefore be stipulated that the maximum levels of undesirable substances or products that are set apply in general from the date on which the feed materials, feedingstuffs and feed additives are put into circulation, including all stages of marketing, and in particular as soon as they are imported;
- (9) Feed materials, feedingstuffs and feed additives must be sound, genuine and of merchantable quality. Using or putting into circulation feed materials, feedingstuffs or feed additives containing levels of undesirable substances or products that exceed the maximum levels laid down in Annex I to this Directive should therefore be prohibited;
- (10) The presence of certain undesirable substances or products in complementary feedingstuffs should be limited by fixing appropriate maximum levels;
- (11) While in certain cases a maximum level is fixed, taking account of background levels, continued effort is still needed to restrict the presence of some specific undesirable substances and products to the lowest possible levels in feed materials, feedingstuffs and feed additives so as to reduce their presence in the feed and food chain. It should therefore be permitted, under this Directive, to lay down action thresholds well below the maximum levels fixed. Where such action thresholds are exceeded, investigations must be carried out to identify the sources of contamination and steps taken to reduce or eliminate such sources;
- (12) Where animal or human health is endangered, Member States should still be allowed temporarily to reduce the fixed maximum permissible levels, to fix maximum levels for other substances or products or to prohibit the presence of such substances or products in feedingstuffs. To ensure Member States do not abuse this power, any

^{(&}lt;sup>1</sup>) OJ L 115, 4.5.1999, p. 32.

amendments to the Annex to this Directive should be decided on by emergency Community procedure, on the basis of supporting documents;

- (13) Feed materials, feedingstuffs and feed additives that satisfy the requirements of this Directive should not be subject to restrictions on entry into circulation, as regards the level of undesirable substances and products they contain, other than those provided for in this Directive;
- (14) Member States should make appropriate control arrangements to ensure that the requirements regarding undesirable substances and products are met when feed materials, feedingstuffs and feed additives are circulated;
- (15) As part of the information system introduced by this Directive within the official control departments, Member States should also be informed by operators of cases where this Directive is not being complied with. In such cases, Member States are required to take all the necessary steps to ensure that undesirable substances and products cannot be used in animal nutrition. Member States are obliged, where applicable, to ensure that any batches of feed materials, feedingstuffs or feed additives are actually destroyed, if this course of action has been decided by their owner;
- (16) An appropriate Community procedure is needed for adapting the technical provisions in the Annex to this Directive in the light of developments in scientific and technical knowledge;
- (17) In order to facilitate implementation of the proposed measures, there should be a procedure for close cooperation between the Member States and the Commission within the Standing Committee on Feedingstuffs set up by Decision 70/372/EEC (¹);
- (18) Since the measures necessary for the implementation of this Directive are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (²), they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision;
- (19) This Directive should not affect the Member States' obligation to comply with the deadlines set out in Part B of Annex III thereto for transposition of Directive 1999/29/EC,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

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

2. This Directive shall apply without prejudice to the provisions on:

- (a) additives in feedingstuffs;
- (b) the putting into circulation of feedingstuffs;
- (c) the fixing of maximum permitted levels for pesticide residues in and on products intended for animal feeding, where these residues are not listed in Section B of Annex I to this Directive;
- (d) micro-organisms in feedingstuffs;
- (e) certain products used in animal nutrition;
- (f) feedingstuffs for particular nutritional purposes.

Article 2

For the purposes of this Directive:

- (a) 'feedingstuffs' means 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) 'feed materials' means 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 substrates for premixtures;
- (c) 'complete feedingstuffs' means mixtures of feedingstuffs which, by reason of their composition, are sufficient for a daily ration;
- (d) 'complementary feedingstuffs' means mixtures of feedingstuffs which have a high content of certain substances and which, by reason of their composition, are sufficient for a daily ration only if used in combination with other feedingstuffs;
- (e) 'compound feedingstuffs' means mixtures of feed materials, whether or not containing additives, which are intended for oral animal feeding as complete or complementary feedingstuffs;
- (f) 'daily ration' means the average total quantity of feedingstuffs, calculated on a moisture content of 12%, required daily by an animal of a given species, age class and yield, to satisfy all its needs;
- (g) 'animals' means animals belonging to species normally fed and kept or consumed by man as well as animals living freely in the wild in cases where they are fed with feedingstuffs;
- (h) 'pet animals' means animals belonging to species normally fed and kept but not consumed by man, except animals bred for fur production.

^{(&}lt;sup>1</sup>) OJ L 170, 3.8.1970, p. 1.

^{(&}lt;sup>2</sup>) OJ L 184, 17.7.1999, p. 23.

(i) 'additives' means additives as defined in Article 2 of Council Directive 70/524/EEE of 23 November 1970 on additives in feedingstuffs (¹).

Article 3

1. Feed materials, feedingstuffs and feed additives may be put into circulation in the Community only if they are sound, genuine and of merchantable quality.

2. In particular, feed materials, feedingstuffs and feed additives shall be deemed not to be sound, genuine and of merchantable quality if the level of undesirable substances or products they contain is so high that they cannot comply with the maximum levels fixed for feed materials, feedingstuffs and feed additives in Annex I hereto.

Article 4

1. Member States shall prescribe that the substances and products listed in Annex 1 hereto may be tolerated in feed materials, feedingstuffs and feed additives only subject to the conditions laid down therein.

2. In order to minimise the presence of certain substances and products inevitably found in feed materials, feedingstuffs and feed additives, the Member States shall require investigations to be carried out to identify and reduce or eliminate sources of contamination, not only in cases where the maximum levels are exceeded, but also where significant levels of such inevitable substances and products are detected. If necessary, an action threshold may be laid down in Annex I hereto.

Article 5

Member States shall prescribe that consignments of feed materials, feedingstuffs or feed additives containing levels of an undesirable substance or product that exceed the maximum level fixed in column 3 in Annex I hereto may not be mixed with other consignments of feed materials, feed-ingstuffs or feed additives.

Article 6

Insofar as there are no special provisions for complementary feedingstuffs, Member States shall prescribe that such feedingstuffs may not, allowing for the dilutions prescribed for their use, contain levels of the substances and products listed in Annex I hereto that exceed those fixed for complete feedingstuffs.

Article 7

1. Where a Member State has detailed grounds, based on new information or a reassessment of existing information made since the provisions in question were adopted, demonstrating that a maximum level fixed in Annex I hereto 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 the existing maximum level, fix a maximum level or prohibit the presence of that substance or product in feedingstuffs or feed materials. It shall immediately inform the other Member States and the Commission thereof, stating the grounds for its decision.

2. An immediate decision shall be taken, in accordance with the procedure laid down in Article 12, as to whether Annex I should be amended.

So long as neither the Council nor the Commission has taken a decision, the Member State may maintain the measures it has implemented.

Article 8

The procedure laid down in Article 11 shall be used, in the light of developments in scientific and technical knowledge:

- (a) to adopt amendments to be made to Annex I;
- (b) to draw up a consolidated version of Annex I periodically incorporating the successive amendments made under (a);
- (c) to define criteria for the acceptability of feed materials which have undergone certain decontamination processes.

Article 9

Member States shall ensure that feed materials, feedingstuffs and feed additives which comply with this Directive are not subject to any other restrictions on circulation as regards the presence of undesirable substances and products.

Article 10

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

2. Member States shall inform the other Member States and the Commission of the names of the departments appointed to carry out this monitoring.

3. Member States shall prescribe that where operators (importers, producers, etc.) or persons who, by virtue of their professional activities, are or have been in possession of, or have had direct contact with a consignment of feed materials, feedingstuffs or feed additives, become aware that:

— a given consignment of feed materials is unsuitable for any use in animal nutrition either because it is contaminated with an undesirable substance or product listed in Annex I and therefore does not comply with Article 3(1) and consequently constitutes a serious risk for animal or public health, or because it is contaminated with an unde-

^{(&}lt;sup>1</sup>) OJ L 270, 14.12.1970, p. 1.

sirable substance or product not listed in Annex I but which potentially constitutes a serious risk for animal or public health,

- a given consignment of feedingstuffs is unsuitable for any use in animal nutrition either because it is contaminated with an undesirable substance or product listed in Annex I and therefore does not comply with Annex I and consequently constitutes a serious risk for animal or public health, or because it is contaminated with an undesirable substance or product not listed in Annex I but which potentially constitutes a serious risk for animal or public health,
- a given consignment of additives is unsuitable for any use in animal nutrition either because it is contaminated with an undesirable substance or product listed in Annex I and therefore does not comply with Annex I and consequently constitutes a serious risk for animal or public health, or because it is contaminated with an undesirable substance or product not listed in Annex I but which potentially constitutes a serious risk for animal or public health,

such persons or operators shall immediately inform the official authorities, even if the destruction of the consignment is planned.

After verifying the information received, Member States shall ensure that the necessary measures are taken to ensure that the contaminated consignment is not used in animal nutrition.

Member States shall ensure that the final destination of the contaminated consignment, including possible destruction, cannot have harmful effects on public or animal health or on the environment.

4. If a consignment of feed materials, feedingstuffs or feed additives is likely to be sent to a Member State after it has been judged in another Member State not to comply with this Directive because it contains excessive levels of undesirable substances or products, the latter Member State shall immediately notify the other Member States and the Commission of any useful information concerning that consignment.

Article 11

1. The Commission shall be assisted by the Standing Committee for Feedingstuffs, instituted by Article 1 of Council Decision 70/372/EEC of 20 July 1970 (¹).

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 paragraph 3 and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 12

1. The Commission shall be assisted by the Standing Committee for Feedingstuffs, instituted by Article 1 of Council Decision 70/372/EEC.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply in compliance with Article 7 paragraph 3 and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be fifteen days.

Article 13

1. The Member States shall apply at least the provisions of this Directive to feedingstuffs intended for export to third countries.

2. Paragraph 1 shall not affect the right of Member States to allow consignments of feedingstuffs which do not fulfil the requirements of this Directive to be exported back to an exporting third country.

Article 14

1. Directive 1999/29/EC is hereby repealed, without prejudice to the obligations of the Member States to comply with the deadlines set out in Part B of Annex III thereto for the transposition of the Directives listed in Part A of that Annex.

2. References to Directive 1999/29/EC shall be construed as references to this Directive and should be read in accordance with the correlation table in Annex II.

Article 15

Member States shall bring into force and publish the laws, regulations and administrative provisions necessary to comply with this Directive no later than 30 June 2000. They shall forthwith inform the Commission thereof.

The measures adopted shall apply as from 1 July 2000.

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 procedure for making such reference shall be adopted by Member States.

Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

Article 16

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

Article 17

The Directive is addressed to the Member States.

(¹) OJ L 170, 3.8.1970, p. 1.

ANNEX I

Substances, products	Feedingstuffs	Maximum content in mg/kg (ppm) relative t a feedingstuff with a moisture content of 12
(1)	(2)	(3)
A. Substances (ions or elements)		
1. Arsenic	Feed materials with the exception of:	2
	 meal made from grass, from dried lucerne and from dried clover, and dried sugar beet pulp and dried molasses sugar beet pulp 	4
	 phosphates and feedingstuffs obtained from the processing of fish or other marine animals 	10
	Complete feedingstuffs with the exception of:	2
	- complete feedingstuffs for fish	4
	Complementary feedingstuffs with the exception of:	4
	— mineral feedingstuffs	12
2. Lead	Lead Feed materials with the exception of:	10
	— green fodder	40
	— phosphates	30
	— yeasts	5
	Complete feedingstuffs	5
	Complementary feedingstuffs with the exception of:	10
	— mineral feedingstuffs	30
3. Fluorine	Feed materials with the exception of:	150
	— feedingstuffs of animal origin	500
	— phosphates	2 000
	Complete feedingstuffs with the exception of:	150
	- complete feedingstuffs for cattle, sheep and goats	
	— in milk	30
	— other	50
	— complete feedingstuffs for pigs	100
	- complete feedingstuffs for poultry	350
	- complete feedingstuffs for chicks	250
	Mineral mixtures for cattle, sheep and goats	2 000 (1)
	Other complementary feedingstuffs	125 (²)
4. Mercury	Feed materials with the exception of:	0,1
	 feedingstuffs produced by the processing of fish or other marine animals 	0,5
	Complete feedingstuffs with the exception of:	0,1
	- complete feedingstuffs for dogs and cats	0,4
	Complementary feedingstuffs except:	
	- complementary feedingstuffs for dogs and cats	0,2

(1)	(2)	(3)
5. Nitrites	Fish meal	60 (expressed as sodium nitrite)
	Complete feedingstuffs excluding:	15
	— feedingstuffs intended for pets except birds and aquarium fish	(expressed as sodium nitrite)
6. Cadmium	Feed materials of vegetable origin	1
	Feed materials of animal origin, except:	2
	— feedingstuffs for pets	
	Phosphates	10 (3)
	Complete feedingstuffs for cattle sheep and goats except:	1
	- complete feedingstuffs for calves, lambs and kids	
	Other complete feedingstuffs except:	0,5
	— feedingstuffs for pets	
	Mineral feedingstuffs	5 (4)
	Other complementary feedingstuffs for cattle, sheep and goats	0,5
Products		
1. Aflaxotin B ₁	Feed materials with the exception of:	0,05
	 groundnut, copra, palm-kernel, cotton seed, babassu, maize and products derived from the processing thereof 	0,02
	Complete feedingstuffs for cattle, sheep and goats with the exception of:	0,05
	— dairy cattle	0,005
	— calves and lambs	0,01
	Complete feedingstuffs for pigs and poultry (except young animals)	0,02
	Other complete feedingstuffs	0,01
	Complementary feedingstuffs for cattle, sheep and goats (except complementary feedingstuffs for dairy animals, calves and lambs)	0,05
	Complementary feedingstuffs for pigs and poultry (except young animals)	0,03
	Other complementary feedingstuffs	0,005

(1)	(2)	(3)
2. Hydrocyanic acid	Feed materials with the exception of:	50
	— linseed	250
	— linseed cakes	350
	— manioc products and almond cakes	100
	Complete feedingstuffs with the exception of:	50
	- complete feedingstuffs for chicks	10
3. Free gossypol	Feed materials with the exception of:	20
	— cotton-seed cakes	1 200
	Complete feedingstuffs with the exception of:	20
	- complete feedingstuffs for cattle, sheep and goats	500
	 — complete feedingstuffs for poultry (except laying hens) and calves 	100
	— complete feedingstuffs for rabbits and pigs (except piglets)	60
4. Theobromine	Complete feedingstuffs with the exception of:	300
	- complete feedingstuffs for adult cattle	700
5. Volatile mustard oil	Feed materials with the exception of:	100
	— rapeseed cakes	4 000 (expressed as al isothiocyanate
	Complete feedingstuffs with the exception of:	150 (expressed as al isothiocyanate
	— complete feedingstuffs for cattle, sheep and goats (except young animals)	1 000 (expressed as al isothiocyanate
	— complete feedingstuffs for pigs (except piglets) and poultry	500 (expressed as al isothiocyanate
6. Vinyl thiooxazolidone (Vinyloxazolidine thione)	Complete feedingstuffs for poultry with the exception of	1 000
	— complete feedingstuffs for laying hens	500
7. Rye ergot (Claviceps purpurea)	All feedingstuffs containing unground cereals	1 000
 Weed seeds and unground and uncrushed fruits containing alkaloids, glucosides or other toxic substances separately or in combination including 	All feedingstuffs	3 000
(a) Lolium temulentum L.,		1 000
(b) Lolium remotum Schrank,		1 000
(c) Datura stramonium L.		1 000

(1)	(2)	(3)
9. Castor oil plant — Ricinus communis L.	All feedingstuffs	10 (expressed in terms of castor-oil plant husks)
10. Crotalaria spp.	All feedingstuffs	100
 11. Aldrin 12. Dieldrin singly or combined expressed as dieldrin 	All feedingstuffs with the exception of: — fats	0,01
13. Camphechlor (toxaphene)	All feedingstuffs	0,1
14. Chlordane (sum of cis- and trans-isomers and of	All feedingstuffs with the exception of:	0,02
oxychlordane, expressed as chlordane)	— fats	0,05
15. DDT (sum of DDT-, TDE- and DDE-isomers, expressed as DDT)	All feedingstuffs with the exception of:	0,05
	— fats	0,5
16. Endosulfan (sum of alpha- and beta-isomers and of endosulfansulphate expressed as endosulfan)	All feedingstuffs with the exception of:	0,1
endosunansulphate expressed as endosunan)	— maize	0,2
	— oilseeds	0,5
	- complete feedingstuffs for fish	0,005
17. Endrin (sum of endrin and of delta-ketoi-endrin, expressed as endrin)	All feedingstuffs with the exception of:	0,01
expressed as endrin)	— fats	0,05
18. Heptachlor (sum of heptachlor and of heptach- lorepoxide, expressed as heptachlor)	All feedingstuffs with the exception of:	0,01
iorepointed, engressee as inspiration,	— fats	0,2
19. Hexachlorobenzene (HCB)	All feedingstuffs with the exception of:	0,01
	— fats	0,2
20. Hexachlorocyclo-hexane (HCH)		
20.1 alpha-isomers	All feedingstufs with the exception of:	0,02
	— fats	0,2
20.2 beta-isomers	Compound feedingstuffs with the exception of:	0,01
	- feedingstuffs for dairy cattle	0,005
	Feed materials with the exception of:	0,01
	— fats	0,1
20.3 gamma-isomers	All feedingstuffs with the exception of:	0,2
	— fats	2,0
21. Dioxin (sum of PCDD and PCDF), expressed in inter- national toxic equivalent	Citrus pulp	500 pg I-TEQ/kg (upper bound detection limit) (⁵)

	(1)	(2)	(3)
C. Bot	anical impurities		
1.	Apricots — Prunus armeniaca L.))
2.	Bitter almond — Prunus dulcis (Mill.) D.A. Webb var. amara (DC.) Focke (= Prunus amygdalus Batsch var. amara (DC.) Focke)		
3.	Unhusked beech mast — Fagus silvatica L.		
4.	Camelina — Camelina sativa (L.) Crantz		Seeds and fruit
5.	Mowrah, Bassia, Madhuca — Madhuca longifolia (L.) Macbr. (= Bassia longifolia L. = Illipe malabrorum Engl.) Madhuca indica Gmelin (= Bassia latifolia (Roxb.) = Illipe latifolia (Roscb.) F. Mueller)		of the plant species listed opposite as well as their processed
6.	Purghera — Jatropha curcas L.	All feedingstuffs	derivatives may
7.	Croton — Croton tiglium L.		only be present in feedingstuffs
8.	Indian mustard — Brassica juncea (L.) Czern. And Coss. ssp. integrifolia (West.) Thell.		in trace amounts not quanti- tatively deter-
9.	Sareptian mustard — Brassica juncea (L.) Czern. And Coss. ssp. juncea		minable
10.	Chinese mustard — Brassica juncea (L.) Czern. And Coss. ssp. juncea var. lutea Batalin		
11.	Black mustard — Brassica nigra (L.) Koch		
12.	Ethiopian mustard — Brassica carinata A. Braun	J	J

 $(^{1})$ Member States may also prescribe a maximum fluorine content of 1,25 % of the phosphate content.

(2) Fluorine content per 1% phosphorus.

(3) Member States may also prescribe a maximum cadmium content of 0,5 mg per 1 % phosphorus.

(4) Member States may also prescribe a maximum cadmium content of 0,75 mg per 1% phosphorus.

(5) Upper bound concentrations are calculated assuming that all values of the different congeners less than the limit of detection are equal to the limit of detection.

CORRELATION TABLE		
Directive 1999/29	This Directive	
Article 1	Article 1	
Article 2(a)	Article 2(a)	
Article 2(b)	Article 2(b)	
Article 2(c)	Article 2(c)	
Article 2(d)	Article 2(d)	
Article 2(e)	Article 2(e)	
Article 2(f)	Article 2(f)	
Article 2(g)	Article 2(g)	
Article 2(h)	Article 2(h)	
_	Article 2(i)	
Article 3	Article 3	
Article 4(1)	Article 4(1)	
Article 4(2)	—	
_	Article 4(2)	
Article 5	—	
Article 6	—	
Article 7	Article 5	
Article 8	Article 6	
Article 9	Article 7	
Article 10	Article 8	
Article 11	Article 9	
Article 12	Article 10	
Article 13	Article 11	
Article 14	Article 12	
Article 15	Article 13	
Article 16	—	
_	Article 14	
_	Article 15	
Article 17	Article 16	
Article 18	Article 17	
Annex I	Annex I	
Annex II	-	
Annex III	-	
Annex IV	Annex II	

ANNEX II