

**COMMISSION DIRECTIVE 2003/100/EC**  
**of 31 October 2003**

**amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council on**  
**undesirable substances in animal feed**

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed <sup>(1)</sup>, as amended by Commission Directive 2003/57/EC <sup>(2)</sup>, and in particular Article 8(1) thereof,

Whereas:

- (1) Directive 2002/32/EC provides that the use of products intended for animal feed which contain levels of undesirable substances exceeding the maximum levels laid down in Annex I thereto is prohibited.
- (2) When Directive 2002/32/EC was adopted, it was stated that the provisions laid down in Annex I would be reviewed on the basis of updated scientific risk assessments and taking into account the prohibition of any dilution of contaminated non-complying products intended for animal feed.
- (3) The Scientific Committee for Animal Nutrition (SCAN) was accordingly requested to provide updated scientific risk assessments without delay. SCAN adopted an opinion on undesirable substances in feed on 20 February 2003, which was updated on 25 April 2003. That opinion provides a comprehensive overview of the possible risks for animal and public health as the consequence of the presence of different undesirable substances in animal feed.
- (4) SCAN nevertheless acknowledged that additional detailed risk assessments are necessary to permit a complete review of Annex I to Directive 2002/32/EC. Since May 2003, the European Food Safety Authority (EFSA) has taken over from the European Commission the responsibility for the scientific assessment of feed and food safety issues. EFSA has been asked to carry out those detailed risk assessments.
- (5) In the meantime, it has been pointed out that the supply of some essential and valuable feed materials could be endangered because the level of an undesirable substance in some feed materials due to normal background contamination is close to or exceeds the maximum level laid down in the Annex I to Directive 2002/32/EC. Also some inconsistencies have been found between the provisions of the Annex.

- (6) The Annex should therefore be amended on a provisional basis, pending the detailed scientific risk assessments, maintaining a high level of protection for public and animal health and the environment.
- (7) With a view to maintaining such a high level of protection for public and animal health and the environment, it is acknowledged that if feed materials are fed directly to the animals or if complementary feedingstuffs are used, their use in a daily ration should not lead to the animal being exposed to a higher level of an undesirable substance than the corresponding maximum levels of exposure where only complete feedingstuffs are used in a daily ration.
- (8) SCAN confirms that arsenic in its organic forms has a limited toxicity. The determination of total arsenic in feed may, therefore, not always accurately reflect the risk posed by the inorganic forms. However, organic and inorganic forms of arsenic can be distinguished only by a complex method of analysis, which is not readily applicable in the framework of official controls. It is therefore appropriate for the maximum levels to refer to total arsenic with the residual possibility to require more detailed analysis particularly in case of the presence of *Hizikia fusiforme*. In the absence of a Community method of analysis for the determination of total arsenic, it is necessary to prove the satisfactory performance of the used sample treatment procedure and method of analysis by making use of certified reference materials, containing a significant part of the arsenic in its organic form.
- (9) It is also necessary to take account of the fact that more than 95 % of the arsenic present in feed materials of marine origin is in the less toxic organic forms and of recent developments in formulating fish feed incorporating higher ratios of fish oil and fishmeal.
- (10) The current maximum levels for arsenic, lead and fluorine in some mineral feed materials do not reflect the current normal background contamination levels. Given the low bioavailability of these undesirable substances in mineral feedingstuffs, it is appropriate to ensure that those essential and valuable feed materials can be supplied without endangering animal and public health and the environment.

<sup>(1)</sup> OJ L 140, 30.5.2002, p. 10.

<sup>(2)</sup> OJ L 151, 19.6.2003, p. 38.

- (11) Aflatoxin B1 is a genotoxic carcinogen which is detected in milk in the form of its metabolite aflatoxin M1. It is appropriate to keep the maximum levels for aflatoxin as low as reasonably achievable in order to protect public health. Proper handling and drying practices can keep the aflatoxin levels in the different feed materials low, and efficient decontamination procedures exist to reduce levels of the aflatoxin B1. It is appropriate that the same maximum level of aflatoxin B1 should apply to all feed materials.
- (12) Whole cottonseed contains high levels of free gossypol as natural constituent. It is therefore appropriate to set specific maximum limits for free gossypol in whole cottonseed.
- (13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

Annex I to Directive 2002/32/EC is hereby amended in accordance with the Annex to this Directive.

*Article 2*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive 12 months after its entry into force at the latest. They

shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. 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 3*

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 31 October 2003.

*For the Commission*

David BYRNE

*Member of the Commission*

## ANNEX

Annex I to Directive 2002/32/EC is amended as follows:

1. Points 1, 2 and 3 are replaced by the following:

Undesirable substances	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
1. Arsenic <sup>(8)</sup>	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
	— palm kernel expeller	4 <sup>(9)</sup>
	— phosphates and calcareous marine algae	10
	— calcium carbonate	15
	— magnesium oxide	20
	— feedingstuffs obtained from the processing of fish or other marine animals	15 <sup>(9)</sup>
	— seaweed meal and feed materials derived from seaweed	40 <sup>(9)</sup>
	Complete feedingstuffs with the exception of:	2
	— complete feedingstuffs for fish and complete feedingstuffs for fur animals	6 <sup>(9)</sup>
	Complementary feedingstuffs with the exception of:	4
	— mineral feedingstuffs	12
	2. Lead	10
	Feed materials with the exception of:	40
2. Lead	— green fodder	40
	— phosphates and calcareous marine algae	15
	— calcium carbonate	20
	— yeasts	5
	Complete feedingstuffs	5
	Complementary feedingstuffs with the exception of:	10
	— mineral feedingstuffs	15
	3. Fluorine	150
	Feed materials with the exception of:	500
	— feedingstuffs of animal origin with the exception of marine crustaceans such as marine krill	500
	— phosphates and marine crustaceans such as marine krill	2 000
	— calcium carbonate	350
	— magnesium oxide	600
	— calcareous marine algae	1 000
3. Fluorine	Complete feedingstuffs with the exception of:	150
	— complete feedingstuffs for cattle, sheep and goats	
	— in lactation	30
	— other	50

Undesirable substances	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
	— complete feedingstuffs for pigs	100
	— complete feedingstuffs for poultry	350
	— complete feedingstuffs for chicks	250
	Mineral mixtures for cattle, sheep and goats	2 000 <sup>(1)</sup>
	Other complementary feedingstuffs	125 <sup>(2)</sup>

<sup>(1)</sup> Member States may also prescribe a maximum fluorine content of 1,25 % of the phosphate content.

<sup>(2)</sup> Fluorine content per 1 % phosphorus.

<sup>(3)</sup> The maximum levels refer to total arsenic.

<sup>(9)</sup> Upon request of the competent authorities, the responsible operator must perform an analysis to demonstrate that the content of inorganic arsenic is lower than 2 ppm. This analysis is of particular importance for the seaweed species *Hizikia fusiforme*.

2. Point 7 is replaced by the following:

Undesirable substances	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
'7. Aflatoxin B1	All feed materials	0,02
	Complete feedingstuffs for cattle, sheep and goats with the exception of:	0,02
	— complete feedingstuffs for dairy animals	0,005
	— complete feedingstuffs for 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)	0,02
	Complementary feedingstuffs for pigs and poultry (except young animals)	0,02
	Other complementary feedingstuffs	0,005'

3. Point 9 is replaced by the following:

Undesirable substances	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
'9. Free gossypol	Feed materials with the exception of:	20
	— cottonseed	5 000
	— cottonseed cakes and cottonseed meal	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. Point 22 is replaced by the following:

Undesirable substances	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
'22. Endosulfan (sum of alpha- and beta-isomers and of endosulfansulphate expressed as endosulfan)	All feedingstuffs with the exception of: — maize and products derived from the processing thereof — oilseeds and products derived from the processing thereof — complete feedingstuffs for fish	0,1 0,2 0,5 0,005'