

**COMMISSION DIRECTIVE 2005/87/EC****of 5 December 2005****amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council on undesirable substances in animal feed as regards lead, fluorine and cadmium****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

lead as undesirable substance in animal feed on 2 June 2004.

Having regard to the Treaty establishing the European Community,

- (4) Contamination of food with lead is of public health concern. Lead accumulates to some extent in kidney and liver tissue, muscle tissues contain very low residual amounts of lead and carry-over into milk is limited. Therefore foods of animal origin are not a major source of human exposure to lead.

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>, and in particular Article 8(1) thereof,

- (5) Cattle and sheep seem to be the most sensitive animal species with respect to acute lead toxicity. Individual intoxications have been reported, resulting from ingestion of feed material originating from polluted areas or accidental ingestions of lead sources. However, the levels found in commercial feed materials in the European Union do not induce clinical signs of toxicity.

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition<sup>(2)</sup>, and in particular the third sentence of Article 13(2) 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.

- (6) The existing legal provisions as regards lead in products intended for animal feed are generally appropriate to ensure that these products do not represent any danger to human health, animal health or adversely affect the livestock production.

- (2) When Directive 2002/32/EC was adopted, the Commission stated that the provisions laid down in Annex I to that Directive 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.

- (7) Cattle and sheep seem to be the most sensitive animal species and green fodder is a major component of their daily ration, it is important to provide for a review in view of a possible further reduction of the maximum level of lead in green fodder.

- (3) The Scientific Panel on contaminants in the Food Chain of the European Food Safety Authority (EFSA) adopted an opinion on a request from the Commission related to

- (8) In addition the establishment of a maximum level of lead for additives belonging to the functional group of trace elements, binders and anti-caking agents and for premixtures is appropriate. The maximum level established for premixtures takes into account the additives with the highest level of lead and not the sensitivity of the different animal species to lead. In order to protect animal and public health, it is therefore the responsibility of the producer of premixtures to ensure that, in addition to compliance with the maximum levels for premixtures, the instructions for use on the premixture are in accordance with the maximum levels for complementary and complete feedingstuffs.

<sup>(1)</sup> OJ L 140, 30.5.2002, p. 10. Directive as last amended by Commission Directive 2005/8/EC (OJ L 27, 29.1.2005, p. 44).

<sup>(2)</sup> OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

- (9) The Scientific Panel on contaminants in the Food Chain of the EFSA adopted an opinion on a request from the Commission related to fluorine as undesirable substance in animal feed on 22 September 2004.
- (10) Fluoride accumulates particularly in calcifying tissues. In contrast, transmission into edible tissues including milk and eggs is limited. Hence, the fluoride concentrations in foods from animal origin contribute only marginally to human exposure.
- (11) In the European Union, fluoride levels in pastures, herbage and compound feeds are generally low and subsequently exposure of animals to fluoride is generally below the level causing detrimental effects. However, in certain distinct geographic areas and incidentally in the proximity of industrial sites with high fluoride emission, excessive exposure to fluoride is associated with dental and skeleton abnormalities.
- (12) The existing legal provisions as regards fluorine in products intended for animal feed are appropriate to ensure that these products do not represent any danger to human health, animal health or adversely affect the livestock production.
- (13) The extraction procedure used has a large influence on the analytical result and it is therefore appropriate to determine the extraction procedure. Equivalent procedures with demonstrated equal extraction efficiency can be used.
- (14) The level for fluorine in marine crustaceans such as marine krill has to be amended in order to take into account new processing techniques to improve the nutritional quality and to reduce the biomass loss but which also results in higher levels of fluorine in the final end product.
- (15) Commission Directive 84/547/EEC of 26 October 1984 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs<sup>(1)</sup> establishes a maximum level for fluorine in vermiculite (E 561). The scope of Directive 2002/32/EC provides for the possibility of the establishment of maximum levels of undesirable substances in feed additives and the rules governing undesirable substances should be collected in a single text for greater clarity.
- (16) The Scientific Panel on contaminants in the Food Chain of the EFSA adopted an opinion on a request from the Commission related to cadmium as undesirable substance in animal feed on 2 June 2004.
- (17) Contamination of food with cadmium is of public health concern. Accumulation of cadmium in animal tissue is function of dietary concentration and duration of exposure. The short life span of animals like fattening pigs and poultry minimizes the risk of undesirable cadmium concentrations in edible tissues of these animals. Ruminants and horses however may be exposed during their entire lifespan to cadmium present in pastures. In distinct regions this may result in an undesirable cadmium accumulation particularly in kidneys.
- (18) Cadmium is toxic to all animal species. In most of the domestic animal species, including pigs which are considered the most sensitive species, gross clinical symptoms are unlikely to occur if dietary cadmium concentrations remain below 5 mg/kg feed.
- (19) The existing legal provisions as regards cadmium in products intended for animal feed are appropriate to ensure that these products do not represent any danger to human health, animal health or adversely affect the livestock production.
- (20) No maximum level is currently established for pet food and feed materials of mineral origin other than phosphates. It is appropriate to establish a maximum level for these products intended for animal feed. It is appropriate to amend the current maximum level for cadmium for fish feed in order to take into account recent developments in formulating fish feed incorporating higher ratios of fish oil and fishmeal. In addition the establishment of a maximum level of cadmium for additives belonging to the functional group of trace elements, binders and anti-caking agents and for premixtures is appropriate. The maximum level established for premixtures takes into account the additives with the highest level of cadmium and not the sensitivity of the different animal species to cadmium. As provided in Article 16 of Regulation (EC) No 1831/2003, in order to protect animal and public health, it is the responsibility of the producer of premixtures to ensure that, in addition to compliance with the maximum levels for premixtures, the instructions for use on the premixture are in accordance with the maximum levels for complementary and complete feedingstuffs.

<sup>(1)</sup> OJ L 297, 15.11.1984, p. 40.

(21) Directive 2002/32/EC and Directive 84/547/EEC should therefore be amended accordingly.

(22) 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 amended in accordance with the Annex to this Directive.

*Article 2*

Without prejudice to the other conditions for the authorisation of the additive vermiculite, belonging to the group of binders, anti-caking agents and coagulants, laid down in Directive 70/524/EEC, the maximum fluorine content shall be as set out in the Annex to this Directive.

*Article 3*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive 12 months after the 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 4*

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

*Article 5*

This Directive is addressed to the Member States.

Done at Brussels, 5 December 2005.

*For the Commission*

Markos KYPRIANOU

*Member of the Commission*

## ANNEX

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

1. Row 2, lead, 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)
'2. Lead (*)	Feed materials with the exception of:	10
	– green fodder (**)	30 (***)
	– phosphates and calcareous marine algae	15
	– calcium carbonate	20
	– yeasts	5
	Additives belonging to the functional group of compounds of trace elements except	100
	– zinc oxide	400 (***)
	– manganous oxide, iron carbonate, copper carbonate	200 (***)
	Additives belonging to the functional groups of binders and anti-caking agents except	30 (***)
	– clinoptilolite of volcanic origin	60 (***)
	Premixtures	200 (***)
	Complementary feedingstuffs with the exception of	10
– mineral feedingstuffs	15	
Complete feedingstuffs	5	

(\*) Maximum levels refer to an analytical determination of lead, whereby extraction is performed in nitric acid (5 % w/w) for 30 minutes at boiling temperature. Equivalent extraction procedures can be applied for which it can be demonstrated that the used extraction procedure has an equal extraction efficiency.

(\*\*) Green fodder includes products intended for animal feed such as hay, silage, fresh grass, etc.

(\*\*\*) The levels shall be reviewed by 31 December 2007 with the aim of reducing the maximum levels.'

2. Row 3, Fluorine, 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)
3. Fluorine (*)	Feed materials with the exception of: <ul style="list-style-type: none"> <li>- feedingstuffs of animal origin with the exception of marine crustaceans such as marine krill</li> <li>- marine crustaceans such as marine krill</li> <li>- phosphates</li> <li>- calcium carbonate</li> <li>- magnesium oxide</li> <li>- calcareous marine algae</li> </ul> Vermiculite (E 561)  Complementary feedingstuffs <ul style="list-style-type: none"> <li>- containing ≤ 4 % phosphorus</li> <li>- containing &gt; 4 % phosphorus</li> </ul> Complete feedingstuffs with the exception of <ul style="list-style-type: none"> <li>- complete feedingstuffs for cattle sheep and goats               <ul style="list-style-type: none"> <li>- - in lactation</li> <li>- - other</li> </ul> </li> <li>- complete feedingstuffs for pigs</li> <li>- complete feedingstuffs for poultry</li> <li>- complete feedingstuffs for chicks</li> </ul>	150 500 3 000 2 000 350 600 1 000 3 000 (**) 500 125 per 1 % phosphorus 150 30 50 100 350 250

(\*) Maximum levels refer to an analytical determination of fluorine, whereby extraction is performed with hydrochloric acid 1 N for 20 minutes at ambient temperature. Equivalent extraction procedures can be applied for which it can be demonstrated that the used extraction procedure has an equal extraction efficiency.

(\*\*) The levels shall be reviewed by 31 December 2007 with the aim of reducing the maximum levels.'

3. Row 6, cadmium, 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)
'6. Cadmium (*)	Feed materials of vegetable origin	1
	Feed materials of animal origin	2
	Feed materials of mineral origin except	2
	– phosphates	10
	Additives belonging to the functional group of compounds of trace elements except	10
	– copper oxide, manganous oxide, zinc oxide and manganous sulphate monohydrate	30 (**)
	Additives belonging to the functional groups of binders and anti-caking agents	2
	Premixtures	15 (**)
	Mineral feedingstuffs	
	– containing < 7 % phosphorus	5
	– containing ≥ 7 % phosphorus	0,75 per 1 % phosphorus, with a maximum of 7,5
	Complementary feedingstuffs for pet animals	2
	Other complementary feedingstuffs	0,5
Complete feedingstuffs for cattle, sheep and goats and feedingstuffs for fish except	1	
– complete feedingstuffs for pets	2	
– complete feedingstuffs for calves, lambs and kids and other complete feedingstuffs	0,5	

(\*) Maximum levels refer to an analytical determination of cadmium, whereby extraction is performed in nitric acid (5 % w/w) for 30 minutes at boiling temperature. Equivalent extraction procedures can be applied for which it can be demonstrated that the used extraction procedure has an equal extraction efficiency.

(\*\*) The levels shall be reviewed by 31 December 2007 with the aim of reducing the maximum levels.'