DIRECTIVES

COMMISSION DIRECTIVE 2009/124/EC

of 25 September 2009

amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels for arsenic, theobromine, *Datura* sp., *Ricinus communis* L., *Croton tiglium* L. and *Abrus precatorius* L.

(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 [1], 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 to that Directive is prohibited.

(2) As regards feedingstuffs obtained from the processing of fish or other marine animals, recent information provided by competent authorities of the Member States on the presence of total arsenic (sum of organic and inorganic arsenic) indicates that it is necessary to increase certain maximum levels for total arsenic. By-products of the fish filleting industry are valuable raw materials for the production of fish meal and fish oil for use in compound feed, in particular fish feed.

(3) The increase of the maximum levels for total arsenic in feedingstuffs obtained from the processing of fish or other marine animals and feedingstuffs for fish entails no change in the maximum levels for inorganic arsenic. Since the potential adverse effects of arsenic to animal and human health are determined by the inorganic fraction in a given feed or food product and the organic arsenic compounds exhibit a very low toxic potential [2], the increased levels for total arsenic do not affect the protection of animal and public health.

(4) In Annex I to Directive 2002/32/EC, arsenic refers to total arsenic for the purpose of setting maximum levels, since there is no standardised routine method for the analysis of inorganic arsenic. But for cases in which the competent authorities request an analysis of the content of inorganic arsenic, that Annex sets out a maximum level for inorganic arsenic.

(5) As the extraction method has in some cases a significant influence on the analytical result on total arsenic, it is appropriate to specify an extraction procedure for reference to be used for official control.

(6) Information provided by competent authorities and stakeholder organisations indicate significant levels of arsenic in additives belonging to the functional group of compounds of trace elements, authorised in application of Regulation (EC) No 1831/2003 of the European Parliament and of the Council [3]. It is appropriate to establish maximum levels for arsenic in these additives to protect animal and public health.

(7) As regards theobromine, the European Food Safety Authority (EFSA) concluded in its opinion of 10 June 2008 [4] that the current maximum levels for theobromine may not fully protect some animal species. It pointed out possible adverse effects on pigs, dogs and horses and on milk production in dairy cows. It is therefore appropriate to establish lower maximum levels.

(8) As regards alkaloids in *Datura* sp., EFSA concluded in its opinion of 9 April 2008 [5] that, since tropane alkaloids are present in all *Datura* sp., it is appropriate for the protection of animal health, in particular for pigs, to extend the maximum levels for *Datura stramonium* L., as set out in Annex I to Directive 2002/32/EC, to all *Datura* sp.

[1] OJ L 140, 30.5.2002, p. 10.

[2] Scientific Opinion of the Panel on contaminants in the Food Chain of the European Food Safety Authority (EFSA) on a request from the European Commission related to arsenic as undesirable substances in animal feed, *The EFSA Journal* (2005) 180, 1-35.

[3] OJ L 268, 18.10.2003, p. 29.

[4] Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on theobromine as undesirable substances in animal feed. *The EFSA Journal* (2008) 725, 1-66.

[5] Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on tropane alkaloids (from *Datura* sp.) as undesirable substances in animal feed. *The EFSA Journal* (2008) 691, 1-55.

(9) As regards ricin (from *Ricinus communis* L.), EFSA concluded in its opinion of 10 June 2008 [1] that, given the similar toxic effects of the toxins from *Ricinus communis* L. (ricin), *Croton tiglium* L. (crotin) and *Abrus precatorius* L. (abrin), it is appropriate to apply the maximum levels for *Ricinus communis* L., as set out in Annex I to Directive 2002/32/EC, also to *Croton tiglium* L. and *Abrus precatorius* L., separately or in combination.

(10) Directive 2002/32/EC should therefore be amended accordingly.

(11) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

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

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 July 2010 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.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 25 September 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

[1] Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on ricin (from *Ricinus communis*) as undesirable substances in animal feed. *The EFSA Journal* (2008) 726, 1-38.

ANNEX

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

1. row 1, Arsenic, 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)
'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
	— palm kernel expeller	4 (***)
	— phosphates and calcareous marine algae	10
	— calcium carbonate	15
	— magnesium oxide	20
	— feedingstuffs obtained from the processing of fish or other marine animals, including fish	25 (***)
	— seaweed meal and feed materials derived from seaweed	40 (***)
	Iron particles used as tracer	50
	Additives belonging to the functional group of compounds of trace elements except:	30
	— copper sulphate pentahydrate and copper carbonate	50
	— zinc oxide, manganese oxide and copper oxide	100
	Complete feedingstuffs with the exception of:	2
	— complete feedingstuffs for fish and complete feedingstuffs for fur animals	10 (***)
	Complementary feedingstuffs with the exception of:	4
	— mineral feedingstuffs	12

(*) The maximum levels refer to total arsenic.
(**) Maximum levels refer to an analytical determination of arsenic, 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.
(***) 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. row 10, Theobromine, 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)
'10. Theobromine	Complete feedingstuffs with the exception of:	300
	— complete feedingstuffs for pigs	200
	— complete feedingstuffs for dogs, rabbits, horses and fur animals	50';

3. row 14, Weed seeds and unground and uncrushed fruits containing alkaloids, glucosides or other toxic substances, 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)
'14. Weed seeds and unground and uncrushed fruits containing alkaloids, glucosides or other toxic substances separately or in combination, including *Datura* sp.	All feedingstuffs	3 000 1 000';

4. row 15, Castor oil plant — *Ricinus communis* L., 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)
'15. Seeds and husks from *Ricinus communis* L., *Croton tiglium* L. *and Abrus precatorius* L. as well as their processed derivatives (****), separately or in combination.	All feedingstuffs	10
(****) In so far determinable by analytical microscopy.';		

5. row 34, Croton — *Croton tiglium* L., is deleted.