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COMMISSION OF THE EUROPEAN COMMUNITIES

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Draft

**COMMISSION DIRECTIVE**

**of**

**amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels for mercury, gossypol, nitrites and *Madhuca longifolia* L.**

**(Text with EEA relevance)**

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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>, 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 mercury, the European Food Safety Authority (EFSA) concluded in its opinion 20 February 2008<sup>2</sup>, that following assessment of the current occurrence data the current maximum levels for compound feedingstuffs for fish are not in correspondence with the maximum levels for feed materials produced from fish or by the processing of fish or other marine animals. In order to address this, a slight increase of the maximum level for fish feed is appropriate and this increase would not endanger the compliance of farmed fish with the established maximum levels for mercury. Furthermore as EFSA concludes that the current maximum levels for complete feed for cats and dogs appear not to be sufficiently protective against adverse animal health effects, a lowering of the maximum level is appropriate.
- (3) EFSA adopted on 25 March 2009 a scientific opinion on nitrite as undesirable substance in feed<sup>3</sup>. Total nitrite intake for pigs and cattle from feed as representative sensitive food producing species was estimated using the maximum exposure level in complete feed and sufficient margins of safety with respect to the respective No Observed Adverse Effect Level (NOAEL) could be observed. It was furthermore concluded that the presence of nitrite in animal products does not raise any concern for

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

<sup>2</sup> Opinion of the Scientific Panel on Contaminants in the Food chain on a request from the European Commission on mercury as undesirable substance in feed, *The EFSA Journal* (2008) 654, 1-76.

<sup>3</sup> Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on nitrite as undesirable substances in animal feed. *The EFSA Journal* (2009) 1017, 1-47.

human health. Nitrite is authorised for use as preservative in dog and cat feed with a moisture content exceeding 20 %. Furthermore nitrite might also be used as preservative in silages. It is appropriate to exclude dog and cat feed and silage from the application of the maximum level of nitrite as undesirable substance.

- (4) EFSA adopted on 4 December 2008 a scientific opinion on gossypol as undesirable substance in feed<sup>4</sup>. From the opinion it can be derived that the current maximum levels for sheep, including lamb and goats, including kids, is not sufficiently protective against adverse animal health effects, and therefore a significant lowering of the maximum level of gossypol in feed for these animal species is appropriate. The EFSA furthermore concluded that the human exposure to gossypol through the consumption of food products from animal fed cottonseed derived products is probably low and would not result in adverse effects.
- (5) EFSA adopted on 29 January 2009 a scientific opinion on saponins in *Madhuca longifolia* L. as undesirable substance in feed<sup>5</sup>. The EFSA concluded that no adverse animal health effects are expected because of the negligible exposure to target animals in the EU and that human dietary exposure to *Madhuca* saponins in the EU can be considered as negligible. Therefore it is appropriate to delete *Madhuca longifolia* L. as undesirable substance from the Annex.
- (6) Directive 2002/32/EC should therefore be amended accordingly.
- (7) 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 September 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.

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<sup>4</sup> Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on gossypol as undesirable substance in animal feed. *The EFSA Journal* (2008) 908, 1-56.

<sup>5</sup> Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on Saponins in *Madhuca Longifolia* L. as undesirable substances in animal feed. *The EFSA Journal* (2009) 979, 1-36.

*Article 3*

This Directive shall enter into force on the twentieth 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,

*For the Commission*  
*Androulla VASSILIOU*  
*Member of the Commission*

## ANNEX

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

(1) Row 4, Mercury, 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)
"4. Mercury <sup>(*)(**)</sup>	Feed materials with the exception of: <ul style="list-style-type: none"> <li>- feed materials produced from fish or by the processing of fish or other marine animals</li> <li>- calcium carbonate</li> </ul> Compound feed with the exception of <ul style="list-style-type: none"> <li>- compound feed for fish</li> <li>- compound feed for dog, cat and fur animals</li> <li>.</li> </ul>	0.1  0.5 0.3  0.1 0.2 0.3

(\*) The maximum levels refer to total mercury.

(\*\*) Maximum levels refer to an analytical determination of mercury, 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."

(2) Row 5, Nitrites, 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)
"5. Nitrites	Feed materials with the exception of <ul style="list-style-type: none"> <li>- silage</li> </ul> Complete feedingstuffs with the exception of <ul style="list-style-type: none"> <li>- feedingstuffs for dogs and cats with a moisture content exceeding 20 %.</li> </ul>	15 (expressed as sodium nitrite)    15 (expressed as sodium nitrite)"

(3) Row 9, Free gossypol 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: <ul style="list-style-type: none"> <li>- cottonseed</li> <li>- cottonseed cakes and cottonseed meal</li> </ul> Complete feedingstuffs with the exception of <ul style="list-style-type: none"> <li>- complete feedingstuffs for adult cattle</li> <li>- complete feedingstuffs for poultry (except laying hens), goats (except kids) and calves</li> <li>- complete feedingstuffs for rabbits, sheep (except lambs) and pigs (except piglets)</li> </ul>	20 5000 1200  20 500 100  60"

(4) Row 32, *Mowrah*, *Bassia*, *Madhuca* – *Madhuca longifolia* (= *Bassuia longifolia* = *Illiped malabrorum*, *Madhuca indica* (= *Bassia latifolia* = *Illipe latifolia*" is deleted.