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Delegations will find attached document D057573/04.

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**COMMISSION REGULATION (EU) .../...**

**of **XXX****

**amending and correcting Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels for certain undesirable substances in animal feed**

(Text with EEA relevance)

# COMMISSION REGULATION (EU) .../...

of **XXX**

## **amending and correcting Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels for certain undesirable substances in animal feed**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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) Data have been received from competent authorities and concerned feed business operators indicating that the general maximum level of 2 mg/kg for arsenic in feed materials of plant origin, is not achievable in the specific feed materials leonardite and peat. It is therefore appropriate to increase the maximum level for total arsenic in these feed materials to ensure the supply. The increase does not adversely affect the animal or public health as the maximum level laid down for arsenic in complementary feed and complete feed remains unchanged.
- (3) Data have been received from concerned feed business operators indicating that the general maximum level of 30 mg/kg for arsenic in feed additives belonging to the functional group of compounds of trace elements is not achievable for the trace element dimanganese chloride trihydroxide. It is therefore appropriate to increase the maximum level for arsenic in dimanganese chloride trihydroxide, based on the data obtained by the analytical method Inductively Coupled Plasma Mass Spectrometry (ICP-MS). The European Reference Laboratory for metals and nitrogenous compounds has confirmed that this method provides the correct results as regards the presence of arsenic in trace elements. This increase does not adversely affect the animal or public health as the maximum level laid down for arsenic in complementary feed and complete feed remains unchanged.
- (4) The Joint Research Centre of the European Commission has examined in co-operation with the concerned parties certain findings concerning fluorine in calcareous marine algae. That examination has established that the background presence of fluorine in calcareous marine algae in some instances exceeds the maximum level laid down for fluorine in calcareous marine algae. It is therefore appropriate to increase the maximum level for fluorine in calcareous marine algae from 1000 mg/kg to 1250 mg/kg. This increase does not adversely affect the animal or public health as the

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

maximum level established for fluorine in complementary feed and complete feed remains unchanged.

- (5) Commission Regulation (EU) 2017/2229<sup>2</sup> amended Annex I to Directive 2002/32/EC as regards, *inter alia*, lead. For reasons of clarity the whole entry for lead was replaced. In this replacement, in the list of feed materials for which the maximum level of 15 mg/kg is applicable, the feed material calcareous marine shells was erroneously omitted. Regulation (EU) 2017/2229 established also a new maximum level for lead in dicopper oxide. However, the International Union of Pure and Applied Chemistry (IUPAC) name of the additive is copper(I) oxide. In line with the European Food Safety Authority's ('EFSA') recommendation in its opinion on cupric oxide<sup>3</sup> the additive should be named copper(I) oxide, which was not done in the English, Italian and Slovak language versions of the Regulation. Those errors should be corrected.
- (6) Certain feed materials belonging to the category of 'fish, other aquatic animals and products derived thereof' are placed on the market as canned wet feed material for direct feeding of dogs and cats. As this canned wet feed material replaces the compound feed, it is therefore appropriate to apply the same maximum level of mercury to this canned wet feed material as the maximum level applicable to compound feed as this change does not adversely affect the animal health.
- (7) EFSA adopted a scientific statement on the presence of free gossypol in whole cottonseed<sup>4</sup>. It concluded that an update to the Scientific opinion as regards the animal health risks of the presence of gossypol as an undesirable substance in animal feed was not necessary, . Taking into account the occurrence data referred to in that statement, it is appropriate to establish a higher maximum level for free gossypol in the feed material cottonseed. This increase does not adversely affect the animal health as the maximum level laid down for free gossypol in complete feed remains unchanged.
- (8) Directive 2002/32/EC establishes a maximum level for dioxins, sum of dioxins and dioxin-like PCBs and non-dioxin-like PCBs only in certain feed additives belonging to the functional groups of binders and anti-caking agents. However, recent findings notified through the Rapid Alert System for Food and Feed show high levels of dioxins and dioxin-like PCBs, in other feed additives belonging to that functional group. It is therefore appropriate to establish the maximum level for dioxins and PCBs to all feed additives belonging to the functional groups of binders and anti-caking agents. Furthermore, those maximum levels should also apply where the same feed additives are authorised in the functional groups "Substances for the control of radionuclide contamination" and "Substances for reduction of the contamination of feed by mycotoxins"
- (9) Directive 2002/32/EC should therefore be amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals Food and Feed,

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<sup>2</sup> Commission Regulation (EU) 2017/2229 of 4 December 2017 amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels for lead, mercury, melamine and decoquinat (OJ L 319, 5.12.2017, p. 6).

<sup>3</sup> EFSA Journal 2015;13(4):4057.

<sup>4</sup> <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4850>

HAS ADOPTED THIS REGULATION:

*Article 1*

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

*Article 2*

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

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*