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То:	General Secretariat of the Council
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Subject:	COMMISSION REGULATION (EU)/ of XXX 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 decoquinate

Delegations will find attached document D049730/04.

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EUROPEAN COMMISSION

> Brussels, XXX SANTE/10057/2017 (POOL/E5/2017/10057/10057-EN.doc) D049730/04 [...](2017) XXX draft

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

of XXX

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 decoquinate

(Text with EEA relevance)

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

of XXX

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 decoquinate

(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 feed¹, 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.

1

- (2) The European Food Safety Authority ('the Authority') adopted a scientific opinion on the safety and efficacy of dicopper oxide as feed additive for all species². In the opinion it is indicated that the levels of lead in dicopper oxide exceed in certain cases the current Union maximum levels for lead but the levels found do not present a safety concern as the animal exposure to lead through the use of that additive would be lower than that resulting from the use of other copper compounds compliant with Union law. Based on the information provided, the maximum level for lead in feed additives belonging to the functional group of compounds of trace elements is not achievable on a consistent basis for dicopper oxide by applying good manufacturing practices. It is appropriate to adapt the maximum level for lead in dicopper oxide.
- (3) Many co-products and by-products of the food industry intended for pet food are mainly from tuna. The current maximum levels of mercury for those co-products and by-products are lower than the maximum level of mercury applicable to tuna for human consumption, which causes a shortage in the supply of such co-products and by-products compliant with the maximum level of mercury for use in pet food. Therefore it is appropriate to adapt the maximum level for mercury for fish, other aquatic animals and products derived intended for the production of compound feed for dogs, cats, ornamental fish and fur animals, whilst keeping a high level of animal health protection.

² EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2016. Scientific opinion on the safety and efficacy of dicopper oxide as feed additive for all animal species. EFSA Journal 2016;14(6):4509, 19 pp. doi:10.2903/j.efsa.2016.4509 <u>http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4509/epdf</u>

- (4) The Authority adopted a scientific opinion on the safety and efficacy of guanidinoacetic acid ('GAA') for chickens for fattening, breeder hens and roosters, and pigs³. The additive guanidinoacetic acid is specified to contain melamine as impurity up to 20 mg/kg. The Authority concluded that the contribution of GAA to melamine content in feed would be of no concern. Maximum level for melamine in feed has been established in Directive 2002/32/EC. No maximum level of melamine is yet established for GAA. Therefore it is appropriate to set a maximum level for melamine in GAA.
- (5) Commission Implementing Regulation (EU) No 291/2014⁴ reduced the withdrawal time for decoquinate from three days to zero days. Therefore the provision for the unavoidable carry-over of decoquinate in withdrawal feed for chickens for fattening should be deleted.
- (6) Directive 2002/32/EC should therefore be amended accordingly.
- (7) The measures provided for in this Regulation are in accordance with the opinion of Standing Committee on Plants, Animals, Feed and Food,

HAS ADOPTED THIS REGULATION:

Article 1

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

³ EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2016. Scientific opinion on the safety and efficacy of guanidinoacetic acid for chickens for fattening, breeder hens and roosters, and pigs. EFSA Journal 2016;14(2):4394, 39 pp. doi:10.2903/j.efsa.2016.4394 http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4394/epdf

⁴ Commission Implementing Regulation (EU) No 291/2014 of 21 March 2014 amending Regulation (EC) No 1289/2004 as regards the withdrawal time and maximum residues limits of the feed additive decoquinate (OJ L 87, 22.3.2014, p. 87).

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