Commission Regulation (EU) No 744/2012 of 16 August 2012 amending Annexes I and II to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels for arsenic, fluorine, lead, mercury, endosulfan, dioxins, Ambrosia spp., diclazuril and lasalocid A sodium and action thresholds for dioxins (Text with EEA relevance)

COMMISSION REGULATION (EU) No 744/2012

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(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[(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. Its Annex II sets action thresholds triggering investigations in cases of increased levels of such substances.

(2) Higher maximum levels (MLs) of arsenic, fluorine, lead and mercury have been established for the feed material calcium carbonate and higher MLs of arsenic and fluorine for the feed material magnesium oxide but not for the feed material calcium and magnesium carbonate, which is the natural mixture of calcium carbonate and magnesium carbonate. For reasons of consistency, it is appropriate to align the MLs for arsenic, fluorine, lead and mercury in the feed material calcium and magnesium carbonate with the existing MLs in calcium carbonate.

(3) The European Food Safety Authority (EFSA) concluded in its Scientific Opinion on safety and efficacy of di copper chloride trihydroxide (tribasic copper chloride, TBCC) as feed additive[(2)] that it would be appropriate to set the same ML of arsenic in this additive as the ML of arsenic in cupric sulphate pentahydrate and cupric carbonate. It is appropriate to modify the ML of arsenic in di copper chloride trihydroxide.

(4) Certain compound feed for pet animals contain a significant proportion of the feed materials fish, other aquatic animals and products derived thereof and/or seaweed meal. These feed materials contain a high level of total arsenic. However the presence of arsenic in these feed materials is mainly as organic arsenic, which is the less toxic form. It is therefore appropriate to modify the ML of arsenic applicable to complementary

and complete feed for pet animals, containing fish, other aquatic animals and products derived thereof and/or seaweed meal.

(5) The two zeolite minerals, natrolite and clinoptilolite are the active constituents of natrolite-phonolite (E566) and clinoptilolite of volcanic origin (E567). Therefore it is appropriate to apply the same ML for lead in natrolite-phonolite (E566) as in clinoptilolite of volcanic origin (E567).

(6) In view of increasing the sustainability of the *Salmonids* fish farming, fish oil is progressively replaced by the use of vegetable oils. However, this substitution, which would very favourable influence the sustainability of the marine environment, is in some cases not possible, because of the very low ML for endosulfan in complete feed for fish. At a request from the Commission the European Food Safety Authority (EFSA) delivered a scientific opinion. In its statement on oral toxicity of endosulfan in fish[(3)], EFSA stated that no significant adverse effects were observed in fish (Atlantic salmon) exposed up to 0,1 mg/kg endosulfan in feed in open-sea cages and only minor adverse effects were observed in Salmon exposed to levels higher than the current ML in feed in tanks. From a limited study, there are some indications that exposure of Nile tilapia to endosulfan via feed in tanks caused adverse effects. Therefore it is appropriate to propose a higher ML for endosulfan in complete feed for *Salmonids*, to favour the evolution for increased sustainability of the fish farming without resulting in adverse effects for fish health and human health.

(7) Recent data indicate that the dioxin levels in crustacea meal, which is a by-product from food production and is used mainly in feed for ornamental fish at a level of 1 % to 3 % in the feed, are higher than the current ML. In order to enable the use of this meal for feed and to reduce the quantity of food waste without endangering animal and public health, it is appropriate to slightly increase the ML for dioxins in crustacea meal.

(8) Directive 2002/32/EC has the objective to avoid the dissemination of viable seeds of *Ambrosia* spp. in the environment. Since the milling or the crushing destroys the germination capacity of the seeds, there is no need to clean the grains and seeds containing non-compliant levels of seeds of *Ambrosia* spp. before milling or crushing, on the condition that prevention measures are taken to avoid dissemination of *Ambrosia* spp. seeds into the environment during transport, storage or processing.

(9) As regards the coccidiostats diclazuril and lasalocid A sodium, amendments should be made to take into account the recently granted authorisations of these substances provided for by Commission Regulation (EU) No 169/2011 of 23 February 2011 concerning the authorisation of diclazuril as a feed additive for guinea fowls (holder of authorisation Janssen Pharmaceutica N.V.)[(4)], Commission Implementing Regulation (EU) No 888/2011 of 5 September 2011 concerning the authorisation of diclazuril as a feed additive for turkeys for fattening (holder of authorisation Janssen Pharmaceutica N.V.) and amending Regulation (EC) No 2430/1999[(5)] and Commission Implementing Regulation (EU) No 900/2011 of 7 September 2011 concerning the authorisation of lasalocid A sodium as a feed additive for pheasants, guinea fowl, quails and partridges other than laying birds (holder of authorisation Alpharma (Belgium) BVBA)[(6)].

(10) Given that an increase of the ML for dioxins in crustacea meal is proposed, it is appropriate that also the action threshold applicable to crustacea meal provided for in Annex II to Directive 2002/32/EC is correspondingly increased.

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

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I and II to Directive 2002/32/EC are amended 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, 16 August 2012.

For the Commission

The President

José Manuel BARROSO

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 744/2012. (See end of Document for details)*

ANNEX

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

(a) row 1 of Section I, Arsenic, is replaced by the following:

Undesirable substance	**Products intended for animal feed**	**Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %**
‘1. Arsenic ([1])	Feed materials	2
	with the exception of:	
	— 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 ([2])
	— phosphates and calcareous marine algae,	10
	— calcium carbonate; calcium and magnesium carbonate ([10]),	15
	— magnesium oxide; magnesium carbonate,	20
	— fish, other aquatic animals and products derived thereof,	25 ([2])
	— seaweed meal and feed materials derived from seaweed.	40 ([2])
	Iron particles used as tracer.	50

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 744/2012. (See end of Document for details)*

Feed additives belonging to the functional group of compounds of trace elements	30
with the exception of:	
— cupric sulphate pentahydrate; cupric carbonate; di copper chloride trihydroxide,	50
— zinc oxide; manganous oxide; cupric oxide.	100
Complementary feed	4
with the exception of:	
— mineral feed,	12
— complementary feed for pet animals containing fish, other aquatic animals and products derived thereof and/or seaweed meal and feed materials derived from seaweed.	10 ([2])
Complete feed	2
with the exception of:	
— complete feed for fish and fur animals,	10 ([2])
— complete feed for pet animals containing fish, other aquatic animals and products derived thereof and/or seaweed meal and feed materials derived from seaweed.	10 ([2])’

(b) row 3 of Section I, Fluorine, row 4 of Section I, Lead, and row 5 of Section I, Mercury, are replaced by the following:

Undesirable substance	**Products intended for animal feed**	**Maximum content in mg/kg (ppm)**