

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)

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.

⁽¹⁾ OJ L 140, 30.5.2002, p. 10.

⁽²⁾ EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP); Scientific Opinion on safety and efficacy of di copper chloride tri hydroxide (tribasic copper chloride, TBCC) as feed additive for all species. *EFSA Journal* 2011; 9(9):2355. [18 pp.] doi:10.2903/j.efsa.2011.2355. Available online: www.efsa.europa.eu/efsajournal

⁽³⁾ *EFSA Journal* 2011; 9(4):2131. Available online: www.efsa.europa.eu/efsajournal

- (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.) ⁽¹⁾, 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 ⁽²⁾ 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) ⁽³⁾.
- (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

⁽¹⁾ OJ L 49, 24.2.2011, p. 6.

⁽²⁾ OJ L 229, 6.9.2011, p. 9.

⁽³⁾ OJ L 231, 8.9.2011, p. 15.

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
	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) relative to a feed with a moisture content of 12 %
3. Fluorine ⁽⁷⁾	Feed materials	150
	with the exception of:	
	— feed materials of animal origin except marine crustaceans such as marine krill,	500
	— marine crustaceans such as marine krill,	3 000
	— phosphates,	2 000
	— calcium carbonate; calcium and magnesium carbonate ⁽¹⁰⁾ ,	350
	— magnesium oxide,	600
	— calcareous marine algae.	1 000
	Vermiculite (E 561).	3 000
	Complementary feed:	
	— containing ≤ 4 % phosphorus ⁽⁸⁾ ,	500
	— containing > 4 % phosphorus ⁽⁸⁾ .	125 per 1 % phosphorus ⁽⁸⁾
	Complete feed	150
	with the exception of:	
	— complete feed for pigs,	100
	— complete feed for poultry (except chicks) and fish,	350
	— complete feed for chicks,	250
	— complete feed for cattle, sheep and goats	
4. Lead	- - in lactation,	30
	- - other.	50
	Feed materials	10
	with the exception of:	
	— forage ⁽³⁾ ,	30
	— phosphates and calcareous marine algae,	15
	— calcium carbonate; calcium and magnesium carbonate ⁽¹⁰⁾ ,	20
	— yeasts.	5
	Feed additives belonging to the functional group of compounds of trace elements	100
	with the exception of:	
	— zinc oxide,	400
	— manganous oxide, ferrous carbonate, cupric carbonate.	200
	Feed additives belonging to the functional groups of binders and anti-caking agents	30

Undesirable substance	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
	with the exception of:	
	— clinoptilolite of volcanic origin; natrolite-phonolite,	60
	Premixtures ⁽⁶⁾	200
	Complementary feed	10
	with the exception of:	
	— mineral feed.	15
	Complete feed.	5
5. Mercury ⁽⁴⁾	Feed materials	0,1
	with the exception of:	
	— fish, other aquatic animals and products derived thereof,	0,5
	— calcium carbonate; calcium and magnesium carbonate ⁽¹⁰⁾ .	0,3
	Compound feed	0,1
	with the exception of:	
	— mineral feed,	0,2
	— compound feed for fish,	0,2
	— compound feed for dogs, cats and fur animals.	0,3'

(c) in Section I, the following endnote is added:

⁽¹⁰⁾ Calcium and magnesium carbonate refers to the natural mixture of calcium carbonate and magnesium carbonate as described in Commission Regulation (EU) No 575/2011 of 16 June 2011 on the Catalogue of feed materials (OJ L 159, 17.6.2011, p. 25).';

(d) row 6 of Section IV, Endosulfan (sum of alpha- and beta-isomers and of endosulfansulphate expressed as endosulfan), 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 %
'6. Endosulfan (sum of alpha- and beta- isomers and of endosulfansulphate expressed as endosulfan)	Feed materials and compound feed	0,1
	with the exception of:	
	— maize and maize products derived from the processing thereof,	0,2
	— oilseeds and products derived from the processing thereof, except crude vegetable oil,	0,5
	— crude vegetable oil,	1,0
	— complete feed for fish except for <i>Salmonids</i> ,	0,005
	— complete feed for <i>Salmonids</i> .	0,05'

- (e) row 1 of Section V, Dioxins [sum of polychlorinated dibenzo-*para*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 2005)], is replaced by the following:

Undesirable substance	Products intended for animal feed	Maximum content in ng WHO-PCDD/F-TEQ/kg (ppt) ⁽¹⁾ , relative to a feed with a moisture content of 12 %
‘1. Dioxins [sum of polychlorinated dibenzo- <i>para</i> -dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 2005) ⁽²⁾]	Feed materials of plant origin	0,75
	with the exception of:	
	— vegetable oils and their by-products.	0,75
	Feed materials of mineral origin	0,75
	Feed materials of animal origin:	
	— Animal fat, including milk fat and egg fat,	1,50
	— Other land animal products including milk and milk products and eggs and egg products.	0,75
	— Fish oil,	5,0
	— Fish, other aquatic animals, and products derived thereof with the exception of fish oil, hydrolysed fish protein containing more than 20 % fat ⁽³⁾ and crustacea meal,	1,25
	— Hydrolysed fish protein containing more than 20 % fat; crustacea meal.	1,75
	The feed additives kaolinitic clay, vermiculite, natrolite-phonolite, synthetic calcium aluminates and clinoptilolite of sedimentary origin belonging to the functional groups of binders and anti-caking agents.	0,75
	Feed additives belonging to the functional group of compounds of trace elements.	1,0
	Premixtures	1,0
	Compound feed	0,75
	with the exception of:	
	— compound feed for pet animals and fish,	1,75
	— compound feed for fur animals.	—

- (f) row 11 of Section VI, Seeds from *Ambrosia* spp., 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 %
‘11. Seeds from <i>Ambrosia</i> spp.	Feed materials ⁽³⁾	50
	with the exception of	
	— Millet (grains of <i>Panicum miliaceum</i> L.) and sorghum (grains of <i>Sorghum bicolor</i> (L) Moench s.l.) not directly fed to animals ⁽³⁾ .	200
	Compound feed containing unground grains and seeds.	50

(g) in Section VI, the following endnote is added:

‘⁽³⁾ In case unequivocal evidence is provided that the grains and seeds are intended for milling or crushing, there is no need to perform a cleaning of the grains and seeds containing non-compliant levels of seeds of *Ambrosia* spp. before milling or crushing. Prevention measures shall be taken to avoid dissemination of *Ambrosia* spp. seeds into the environment during transport, storage or processing of these seeds and grains.’;

(h) row 2 of Section VII, Diclazuril, is replaced by the following:

Coccidiostat	Products intended for animal feed ⁽¹⁾	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
‘2. Diclazuril	Feed materials	0,01
	Compound feed for	
	— laying birds and chickens reared for laying (> 16 weeks),	0,01
	— rabbits for fattening and breeding for the period before slaughter in which the use of diclazuril is prohibited (withdrawal feed),	0,01
	— other animal species other than chickens reared for laying (< 16 weeks), chickens for fattening, guinea fowl and turkeys for fattening.	0,03
	Premixtures for use in feed in which the use of diclazuril is not authorised.	⁽²⁾

(i) row 4 of Section VII, Lasalocid A sodium, is replaced by the following:

Coccidiostat	Products intended for animal feed ⁽¹⁾	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
‘4. Lasalocid A sodium	Feed materials	1,25
	Compound feed for	
	— dogs, calves, rabbits, equine species, dairy animals, laying birds, turkeys (> 16 weeks) and chickens reared for laying (> 16 weeks),	1,25
	— chickens for fattening, chickens reared for laying (< 16 weeks) and turkeys (< 16 weeks) for the period before slaughter in which the use of lasalocid A sodium is prohibited (withdrawal feed),	1,25
	— pheasants, guinea fowl, quails and partridges (except laying birds) for the period before slaughter in which the use of lasalocid A sodium is prohibited (withdrawal feed),	1,25
	— other animal species.	3,75
	Premixtures for use in feed in which the use of lasalocid A sodium is not authorised.	⁽²⁾

- (2) row 1, Dioxins [sum of polychlorinated dibenzo-*para*-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 2005)] of the Section: Dioxins and PCBs, of Annex II to Directive 2002/32/EC is replaced by the following:

Undesirable substances	Products intended for animal feed	Action threshold in ng WHO-PCDD/F-TEQ/kg (ppt) ⁽²⁾ , relative to a feed with a moisture content of 12 %	Comments and additional information (e.g. nature of investigations to be performed)
1. Dioxins [sum of polychlorinated dibenzo- <i>para</i> -dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 2005) ⁽¹⁾]	Feed materials of plant origin	0,5	⁽³⁾
	with the exception of:		
	— vegetable oils and their by-products.	0,5	⁽³⁾
	Feed materials of mineral origin	0,5	⁽³⁾
	Feed materials of animal origin:		
	— Animal fat, including milk fat and egg fat,	0,75	⁽³⁾
	— Other land animal products including milk and milk products and eggs and egg products,	0,5	⁽³⁾
	— Fish oil,	4,0	⁽⁴⁾
	— Fish, other aquatic animals and products derived thereof with the exception of fish oil, hydrolysed fish protein containing more than 20 % fat and crustacea meal,	0,75	⁽⁴⁾
	— Hydrolysed fish protein containing more than 20 % fat; crustacea meal.	1,25	⁽⁴⁾
	Feed additives belonging to the functional groups of binders and anti-caking agents	0,5	⁽³⁾
	Feed additives belonging to the functional group of compounds of trace elements	0,5	⁽³⁾
	Premixtures	0,5	⁽³⁾
	Compound feed with the exception of:	0,5	⁽³⁾
	— compound feed for pet animals and fish,	1,25	⁽⁴⁾
	— compound feed for fur animals.	—	