

## COMMISSION REGULATION (EU) No 574/2011

of 16 June 2011

amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels for nitrite, melamine, *Ambrosia* spp. and carry-over of certain coccidiostats and histomonostats and consolidating Annexes I and II thereto

(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) and the first indent of Article 8(2) thereof,

Whereas:

- (1) Directive 2002/32/EC provides that the use of products intended for animal feed that contain levels of undesirable substances exceeding the maximum levels laid down in Annex I to that Directive is prohibited. For certain undesirable substances, Member States are to carry out investigations identifying the sources of those substances if the thresholds set out in Annex II of that Directive are exceeded.
- (2) As regards nitrite, it was found that the products and by-products from sugar beet and sugarcane and from the starch production contain under certain conditions levels of nitrite exceeding the maximum levels recently established in Annex I to Directive 2002/32/EC. Furthermore, it appears that the method of analysis for the determination of nitrite in feed does not always provide reliable analytical results with regard to the products and by-products from sugar beet and sugarcane and from the starch production. Given that the European Food Safety Authority (EFSA) concluded in its opinion of 25 March 2009 <sup>(2)</sup> that the presence of nitrite in animal products does not raise any concern for human health, the products concerned should be exempted for the time being from the maximum level for nitrite in feed materials, while nitrite levels in those products and appropriate methods of analysis are further examined.

- (3) As regards melamine, the EFSA adopted on 18 March 2010 a scientific opinion on melamine in food and feed <sup>(3)</sup>. EFSA findings show that exposure to melamine can result in the formation of crystals in the urinary tract. These crystals cause proximal tubular damage and have been observed in animals and children as a result of incidents involving adulteration of feed and infant formula with melamine, leading to fatalities in some instances. The Codex Alimentarius Commission has established maximum levels for melamine in feed and food <sup>(4)</sup>. It is appropriate to include these maximum levels in Annex I to Directive 2002/32/EC to protect animal and public health as these levels are in accordance with the conclusions of the EFSA opinion. It is appropriate to exempt some feed additives from the maximum levels as they contain unavoidably a level of melamine above the maximum level as a result of the normal production process.

- (4) As regards *Ambrosia* spp., EFSA concluded in its opinion of 4 June 2010 <sup>(5)</sup> that bird feed may be an important means of *Ambrosia* spp. dispersal, especially in previously uninfested areas, as it often contains significant quantities of unprocessed seeds of *Ambrosia* spp. Therefore, the prevention of the use of bird feed contaminated with unprocessed seeds of *Ambrosia* spp. is likely to attenuate the further dispersal of *Ambrosia* spp. in the Union. *Ambrosia* spp. are of public health concern due to the allergenic properties of their pollen. Inhalation of the plant pollen may, amongst other conditions, cause rhino-conjunctivitis and asthma. There is also some evidence for allergenicity of *Ambrosia* spp. pollen in animals. It is therefore appropriate to limit the presence of *Ambrosia* spp. seeds in feed materials and compound feed containing unground grains and seeds and to establish a maximum level of *Ambrosia* spp. seeds in

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

<sup>(2)</sup> EFSA Panel on Contaminants in the Food Chain, Scientific Opinion on Nitrite as undesirable substances in animal feed, The EFSA Journal (2009) 1017, 1-47. Available online: <http://www.efsa.europa.eu/en/scdocs/doc/1017.pdf>

<sup>(3)</sup> EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Melamine in Food and Feed. EFSA Journal 2010; 8(4):1573. [145 pp.]. doi:10.2903/j.efsa.2010.1573. Available online: <http://www.efsa.europa.eu/en/scdocs/doc/1573.pdf>

<sup>(4)</sup> Report on the Thirty-Third Session of the Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, Geneva, Switzerland, 5-9 July 2010 (ALINORM 10/33/REP).

<sup>(5)</sup> EFSA Panel on Contaminants in the Food Chain (CONTAM), EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) and EFSA Panel on Plant Health (PLH); Scientific Opinion on the effect on public or animal health or on the environment on the presence of seeds of *Ambrosia* spp. in animal feed. EFSA Journal 2010; 8(6):1566 [37 pp.]. doi:10.2903/j.efsa.2010.1566. Available online: <http://www.efsa.europa.eu/en/scdocs/doc/1566.pdf>

unground grains and seeds as low as reasonably achievable (ALARA) by good agricultural practices and cleaning techniques.

- (5) As regards coccidiostats and histomonostats, transfer from one production lot to another may occur when such substances are used as authorised feed additives. Such transfer may result in the contamination of feed produced subsequently by the presence of technically unavoidable traces of such substances, referred to as unavoidable carry-over or cross-contamination, in feed for which coccidiostats and histomonostats are not authorised, referred to as non-target feed. Taking into account the application of good manufacturing practices, maximum levels of unavoidable carry-over of coccidiostats or histomonostats in non-target feed should be established following the ALARA (As Low As Reasonably Achievable) principle. For the purpose of enabling the feed manufacturer to manage unavoidable carry-over, a carry-over rate of approximately 3 % of the authorised maximum content should be considered acceptable as regards feed for less sensitive non-target animal species while a carry-over rate of approximately 1 % of the authorised maximum content should be considered acceptable for feed intended to sensitive non-target animal species and feed used for the period before slaughter. The carry-over rate of 1 % should also be considered acceptable for cross-contamination of other feed for target species to which no coccidiostats or histomonostats are added, and as regards non-target feed for 'continuous food-producing animals', such as dairy cows or laying hens, where there is evidence of transfer from feed to food of animal origin. Where feed materials are fed directly to the animals or where complementary feedingstuffs are used, this should not lead to an exposure of the animals to a higher level of coccidiostats or histomonostats than the corresponding maximum levels of exposure where only complete feedingstuffs are used in a daily ration.
- (6) As regards the coccidiostats narasin, nicarbazin and lasalocid-sodium, Annex I to Directive 2002/32/EC should be amended to take into account recent modifications of the authorisations of those substances and

Commission Regulation (EC) No 124/2009 of 10 February 2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed <sup>(1)</sup> should consequently be amended.

- (7) Annexes I and II to Directive 2002/32/EC had already been adapted substantially and many times in the past. It is therefore appropriate to consolidate those Annexes. To improve the clarity and readability of those Annexes, it is appropriate to restructure them and to harmonise terminology. Given that the provisions contained in the Annexes have a direct application and are binding in their entirety, it is appropriate to establish these Annexes by a Regulation.
- (8) The measures provided for in this Regulation 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 REGULATION

*Article 1*

Annexes I and II to Directive 2002/32/EC are replaced by the text in the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 July 2011.

The provisions as regards *Ambrosia* spp. shall apply from 1 January 2012.

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

Done at Brussels, 16 June 2011.

*For the Commission*

*The President*

José Manuel BARROSO

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<sup>(1)</sup> OJ L 140, 11.2.2009, p. 7.

## ANNEX

Annexes I and II to Directive 2002/32/EC are replaced by the following:

## 'ANNEX I

**MAXIMUM LEVELS OF UNDESIRABLE SUBSTANCES, AS REFERRED TO IN ARTICLE 3(2)**

## SECTION I: INORGANIC CONTAMINANTS AND NITROGENOUS COMPOUNDS

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 <sup>(1)</sup>	Feed materials 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 <sup>(2)</sup> — phosphates and calcareous marine algae, 10 — calcium carbonate, 15 — magnesium oxide and magnesium carbonate, 20 — fish, other aquatic animals and products derived thereof, 25 <sup>(2)</sup> — seaweed meal and feed materials derived from seaweed. 40 <sup>(2)</sup> Iron particles used as tracer. 50 Feed additives belonging to the functional groups of compounds of trace elements 30 with the exception of: — cupric sulphate pentahydrate and cupric carbonate, 50 — zinc oxide, manganous oxide and cupric oxide. 100 Complementary feed 4 with the exception of: — mineral feed. 12 Complete feed 2 with the exception of: — complete feed for fish and fur animals. 10 <sup>(2)</sup>	
2. Cadmium	Feed materials of vegetable origin. 1 Feed materials of animal origin. 2 Feed materials of mineral origin 2 with the exception of: — phosphates. 10 Feed additives belonging to the functional group of compounds of trace elements 10 with the exception of: — cupric oxide, manganous oxide, zinc oxide and manganous sulphate monohydrate. 30	

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 additives belonging to the functional groups of binders and anti-caking agents.	2
	Premixtures (6)	15
	Complementary feed	0,5
	with the exception of:	
	— mineral feed	
	-- containing < 7 % phosphorus (8),	5
	-- containing ≥ 7 % phosphorus (8),	0,75 per 1 % phosphorus (8), with a maximum of 7,5
	— complementary feed for pet animals.	2
	Complete feed	0,5
	with the exception of:	
	— complete feed for cattle (except calves), sheep (except lambs), goats (except kids) and fish,	1
	— complete feed for pet animals.	2
	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,	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	

Undesirable substance	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
4. Lead	— complete feed for chicks,	250
	— complete feed for cattle, sheep and goats	
	-- in lactation,	30
	-- other.	50
	Feed materials	10
	with the exception of:	
	— forage <sup>(3)</sup> ,	30
	— phosphates and calcareous marine algae,	15
	— calcium carbonate,	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
	5. Mercury <sup>(4)</sup>	Feed additives belonging to the functional group of binders and anti-caking agents
with the exception of:		
— clinoptilolite of volcanic origin.		60
Premixtures <sup>(6)</sup> .		200
Complementary feed		10
with the exception of:		
— mineral feed.		15
Complete feed.		5
Feed materials		0,1
with the exception of:		
— fish, other aquatic animals and products derived thereof,	0,5	
— calcium carbonate.	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	

Undesirable substance	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
6. Nitrite <sup>(5)</sup>	Feed materials	15
	with the exception of:	
	— fishmeal,	30
	— silage,	—
	— products and by-products from sugar beet and sugarcane and from starch production.	—
	Complete feed	15
	with the exception of:	
	— complete feed for dogs and cats with a moisture content exceeding 20 %.	—
7. Melamine <sup>(9)</sup>	Feed	2,5
	with the exception of the feed additives:	
	— guanidino acetic acid (GAA),	—
	— urea,	—
	— biuret.	—

(1) The maximum levels refer to total arsenic.

(2) Upon request of the competent authorities, the responsible operator must perform an analysis to demonstrate that the content of inorganic arsenic is lower than 2 ppm. This analysis is of particular importance for the seaweed species *Hizikia fusiforme*.

(3) Forage includes products intended for animal feed such as hay, silage, fresh grass, etc.

(4) The maximum levels refer to total mercury.

(5) The maximum levels are expressed as sodium nitrite.

(6) The maximum level established for premixtures takes into account the additives with the highest level of lead and cadmium and not the sensitivity of the different animal species to lead and cadmium. As provided in Article 16 of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29), in order to protect animal and public health, it is the responsibility of the producer of premixtures to ensure that, in addition to compliance with the maximum levels for premixtures, the instructions for use on the premixture are in accordance with the maximum levels for complementary and complete feed.

(7) Maximum levels refer to an analytical determination of fluorine, whereby extraction is performed with hydrochloric acid 1 N for 20 minutes at ambient temperature. Equivalent extraction procedures can be applied for which it can be demonstrated that the used extraction procedure has an equal extraction efficiency.

(8) The % of phosphorus is relative to a feed with a moisture content of 12 %.

(9) The maximum level refers to melamine only. The inclusion of the structurally related compounds cyanuric acid, ammeline and ammeline in the maximum level will be considered at a later stage.

## SECTION II: MYCOTOXINS

Undesirable substance	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
1. Aflatoxin B <sub>1</sub>	Feed materials	0,02
	Complementary and complete feed	0,01
	with the exception of:	
	— compound feed for dairy cattle and calves, dairy sheep and lambs, dairy goats and kids, piglets and young poultry animals,	0,005

Undesirable substance	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
2. Rye ergot ( <i>Claviceps purpurea</i> )	— compound feed for cattle (except dairy cattle and calves), sheep (except dairy sheep and lambs), goats (except dairy goats and kids), pigs (except piglets) and poultry (except young animals).	0,02
	Feed materials and compound feed containing unground cereals.	1 000

## SECTION III: INHERENT PLANT TOXINS

Undesirable substance	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
1. Free gossypol	Feed materials	20
	with the exception of:	
	— cottonseed,	5 000
	— cottonseed cakes and cottonseed meal.	1 200
	Complete feed	20
	with the exception of:	
	— complete feed for cattle (except calves),	500
	— complete feed for sheep (except lambs) and goats (except kids),	300
2. Hydrocyanic acid	— complete feed for poultry (except laying hens) and calves,	100
	— complete feed for rabbits, lambs, kids and pigs (except piglets).	60
	Feed materials	50
	with the exception of:	
	— linseed,	250
	— linseed cakes,	350
— manioc products and almond cakes.	100	
3. Theobromine	Complete feed	50
	with the exception of:	
	— complete feed for young chickens (< 6 weeks).	10
	Complete feed	300
	with the exception of:	
— complete feed for pigs,	200	
— complete feed for dogs, rabbits, horses and fur animals.	50	

Undesirable substance	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
4. vinyl thiooxazolidone (5-vinyloxazolidine-2-thione)	Complete feed for poultry	1 000
	with the exception of: — complete feed for laying hens.	500
5. Volatile mustard oil <sup>(1)</sup>	Feed materials	100
	with the exception of: — rapeseed cakes.	4 000
	Complete feed	150
	with the exception of: — complete feed for cattle (except calves), sheep (except lambs) and goats (except kids),	1 000
	— complete feed for pigs (except piglets) and poultry.	500

<sup>(1)</sup> The maximum levels are expressed as allyl isothiocyanate.

#### SECTION IV: ORGANOCHLORINE COMPOUNDS (EXCEPT DIOXINS AND PCBs)

Undesirable substance	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
1. Aldrin <sup>(1)</sup>	Feed materials and compound feed	0,01 <sup>(2)</sup>
2. Dieldrin <sup>(1)</sup>	with the exception of: — fats and oils,	0,1 <sup>(2)</sup>
	— compound feed for fish.	0,02 <sup>(2)</sup>
3. Camphechlor (toxaphene) – sum of indicator congeners CHB 26, 50 and 62 <sup>(3)</sup>	Fish, other aquatic animals and products derived thereof	0,02
	with the exception of: — fish oil.	0,2
4. Chlordane (sum of cis- and trans-isomers and of oxychlordane, expressed as chlordane)	Complete feed for fish.	0,05
	Feed materials and compound feed	0,02
5. DDT (sum of DDT-, DDD- (or TDE-) and DDE-isomers, expressed as DDT)	with the exception of: — fats and oils.	0,05
	Feed materials and compound feed	0,05

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 with the exception of: — maize and maize products derived from the processing thereof, — oilseeds and products derived from the processing thereof, except crude vegetable oil, — crude vegetable oil, — complete feed for fish.	0,1  0,2 0,5 1,0 0,005
7. Endrin (sum of endrin and of delta-ketoi-endrin, expressed as endrin)	Feed materials and compound feed with the exception of: — fats and oils.	0,01  0,05
8. Heptachlor (sum of heptachlor and of heptachlorepoxyde, expressed as heptachlor)	Feed materials and compound feed with the exception of: — fats and oils.	0,01  0,2
9. Hexachlorobenzene (HCB)	Feed materials and compound feed with the exception of: — fats and oils.	0,01  0,2
10. Hexachlorocyclohexane (HCH)		
— alpha-isomers	Feed materials and compound feed with the exception of: — fats and oils.	0,02  0,2
— beta-isomers	Feed materials with the exception of: — fats and oils. Compound feed with the exception of: — compound feed for dairy cattle.	0,01  0,1 0,01 0,005
— gamma-isomers	Feed materials and compound feed with the exception of: — fats and oils.	0,2  2,0

(<sup>1</sup>) Singly or combined expressed as dieldrin.

(<sup>2</sup>) Maximum level for aldrin and dieldrin, singly or combined, expressed as dieldrin.

(<sup>3</sup>) Numbering system according to Parlar, prefixed by either CHB or "Parlar":

CHB 26: 2-endo,3-exo,5-endo,6-exo,8,8,10,10-octochlorobornane,

CHB 50: 2-endo,3-exo,5-endo,6-exo,8,8,9,10,10-nonachlorobornane,

CHB 62: 2,2,5,5,8,9,9,10,10-nonachlorobornane.

## SECTION V: DIOXINS AND PCBs

Undesirable substance	Products intended for animal feed	Maximum content in ng WHO-PCDD/F-TEQ/kg (ppt) (1), (2) 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, 1997 (4))	Feed materials of plant origin	0,75
	with the exception of:	
	— vegetable oils and their by-products	0,75
	Feed materials of mineral origin	1,0
	Feed materials of animal origin:	
	— Animal fat, including milk fat and egg fat	2,0
	— Other land animal products including milk and milk products and eggs and egg products.	0,75
	— Fish oil	6,0
	— Fish, other aquatic animals and products derived thereof with the exception of fish oil and fish protein hydrolysates containing more than 20 % fat (3)	1,25
	— Fish protein hydrolysates containing more than 20 % fat.	2,25
	The feed additives kaolinic clay, calcium sulphate dihydrate, 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,	2,25	
— compound feed for fur animals.	—	
2. Sum of dioxins and dioxin-like PCBs (sum of polychlorinated dibenzo- <i>para</i> -dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and polychlorinated biphenyls (PCBs)) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 1997 (4))	Feed materials of plant origin	1,25
	with the exception of:	
	— vegetable oils and their by-products.	1,5
	Feed materials of mineral origin	1,5
	Feed materials of animal origin:	
	— Animal fat, including milk fat and egg fat,	3,0
	— Other land animal products including milk and milk products and eggs and egg products.	1,25
	— Fish oil	24,0
	— Fish, other aquatic animals and products derived thereof with the exception of fish oil and fish protein hydrolysates containing more than 20 % fat (3)	4,5
	— Fish protein hydrolysates containing more than 20 % fat.	11,0

Undesirable substance	Products intended for animal feed	Maximum content in ng WHO-PCDD/F-TEQ/kg (ppt) <sup>(1)</sup> , <sup>(2)</sup> relative to a feed with a moisture content of 12 %
	The feed additives kaolinitic clay, calcium sulphate dihydrate, vermiculite, natrolite-phonolite, synthetic calcium aluminates and clinoptilolite of sedimentary origin belonging to the functional groups of binders and anti-caking agents.	1,5
	Feed additives belonging to the functional group of compounds of trace elements.	1,5
	Premixtures	1,5
	Compound feed	1,5
	with the exception of:	
	— compound feed for pet animals and fish,	7,0
	— compound feed for fur animals.	—

<sup>(1)</sup> Upper-bound concentrations; upper-bound concentrations are calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification.

<sup>(2)</sup> The separate maximum level for dioxins (PCDD/F) remains applicable for a temporary period. The products intended for animal feed mentioned in point 1 have to comply both with the maximum levels for dioxins and with the maximum levels for the sum of dioxins and dioxin-like PCBs during that temporary period.

<sup>(3)</sup> Fresh fish and other aquatic animals directly delivered and used without intermediate processing for the production of feed for fur animals are not subject to the maximum levels, while maximum levels of 4,0 ng WHO-PCDD/F-TEQ/kg product and 8,0 ng WHO-PCDD/F-PCB-TEQ/kg product are applicable to fresh fish and 25,0 ng WHO-PCDD/F-PCB-TEQ/kg product to fish liver used for the direct feeding of pet animals, zoo and circus animals or used as feed material for the production of pet food. The products or processed animal proteins produced from these animals (fur animals, pet animals, zoo and circus animals) cannot enter the food chain and cannot be fed to farmed animals which are kept, fattened or bred for the production of food.

<sup>(4)</sup> WHO-TEFs for human risk assessment based on the conclusions of the World Health Organisation meeting in Stockholm, Sweden, 15-18 June 1997 (Van den Berg et al., (1998) Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, PCDFs for Humans and for Wildlife. Environmental Health Perspectives, 106(12), 775).

Congener	TEF value	Congener	TEF value
<b>Dibenzo-p-dioxins ("PCDDs") and dibenzofurans (PCDFs)</b>		<b>"Dioxin-like" PCBs Non-ortho PCBs + Mono-ortho PCBs</b>	
2,3,7,8-TCDD	1		
1,2,3,7,8-PeCDD	1	<b>Non-ortho PCBs</b>	
1,2,3,4,7,8-HxCDD	0,1	PCB 77	0,0001
1,2,3,6,7,8-HxCDD	0,1	PCB 81	0,0001
1,2,3,7,8,9-HxCDD	0,1	PCB 126	0,1
1,2,3,4,6,7,8-HpCDD	0,01	PCB 169	0,01
OCDD	0,0001	<b>Mono-ortho PCBs</b>	
2,3,7,8-TCDF	0,1	PCB 105	0,0001
1,2,3,7,8-PeCDF	0,05	PCB 114	0,0005
2,3,4,7,8-PeCDF	0,5	PCB 118	0,0001
1,2,3,4,7,8-HxCDF	0,1	PCB 123	0,0001
1,2,3,6,7,8-HxCDF	0,1	PCB 156	0,0005
1,2,3,7,8,9-HxCDF	0,1	PCB 157	0,0005
2,3,4,6,7,8-HxCDF	0,1	PCB 167	0,00001
1,2,3,4,6,7,8-HpCDF	0,01	PCB 189	0,0001
1,2,3,4,7,8,9-HpCDF	0,01		
OCDF	0,0001		

Abbreviations used: "T" = tetra; "Pe" = penta; "Hx" = hexa; "Hp" = hepta; "O" = octa; "CDD" = chlorodibenzodioxin; "CDF" = chlorodibenzofuran; "CB" = chlorobiphenyl.

## SECTION VI: HARMFUL BOTANICAL IMPURITIES

Undesirable substance	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
1. Weed seeds and unground and uncrushed fruits containing alkaloids, glucosides or other toxic substances separately or in combination including — <i>Datura</i> sp.	Feed materials and compound feed	3 000  1 000
2. <i>Crotalaria</i> spp.	Feed materials and compound feed	100
3. Seeds and husks from <i>Ricinus communis</i> L., <i>Croton tiglium</i> L. and <i>Abrus precatorius</i> L. as well as their processed derivatives <sup>(1)</sup> , separately or in combination	Feed materials and compound feed	10 <sup>(2)</sup>
4. Unhusked beech mast – <i>Fagus sylvatica</i> L. 5. Purgheira – <i>Jatropha curcas</i> L. 6. Indian mustard – <i>Brassica juncea</i> (L.) Czern. And Coss. ssp. <i>integrifolia</i> (West.) Thell. 7. Sareptian mustard – <i>Brassica juncea</i> (L.) Czern. And Coss. ssp. <i>juncea</i> 8. Chinese mustard – <i>Brassica juncea</i> (L.) Czern. And Coss. ssp. <i>juncea</i> var. <i>lutea</i> Batalin 9. Black mustard – <i>Brassica nigra</i> (L.) Koch 10. Ethiopian mustard – <i>Brassica carinata</i> A. Braun	Feed materials and compound feed	Seeds and fruit of the plant species listed opposite as well as their processed derivatives may only be present in feed in trace amounts not quantitatively determinable
11. Seeds from <i>Ambrosia</i> spp.	Feed materials  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.  Compound feed containing unground grains and seeds	50  200  50

<sup>(1)</sup> In so far determinable by analytical microscopy.

<sup>(2)</sup> Includes also seed husk fragments.

## SECTION VII: AUTHORISED FEED ADDITIVES IN NON-TARGET FEED FOLLOWING UNAVOIDABLE CARRY-OVER

Coccidiostat	Products intended for animal feed <sup>(1)</sup>	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
1. Decoquinat	Feed materials  Compound feed for — laying birds and chickens reared for laying (> 16 weeks),  — chickens for fattening for the period before slaughter in which the use of decoquinat is prohibited (withdrawal feed),	0,4  0,4  0,4

Coccidiostat	Products intended for animal feed <sup>(1)</sup>	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
2. Diclazuril	— other animal species.	1,2
	Premixtures for use in feed in which the use of decoquinate is not authorised.	(2)
	Feed materials	0,01
	Compound feed for	
	— laying birds, chickens reared for laying (> 16 weeks) and turkeys for fattening (> 12 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
3. Halofuginone hydrobromide	— other animal species other than chickens reared for laying (< 16 weeks), chickens for fattening, guinea fowl and turkeys for fattening (< 12 weeks).	0,03
	Premixtures for use in feed in which the use of diclazuril is not authorised.	(2)
	Feed materials	0,03
	Compound feed for	
	— laying birds, chickens reared for laying and turkeys (> 12 weeks),	0,03
	— chickens for fattening and turkeys (< 12 weeks) for the period before slaughter in which the use of halofuginone hydrobromide is prohibited (withdrawal feed),	0,03
4. Lasalocid sodium	— other animal species.	0,09
	Premixtures for use in feed in which the use of halofuginone hydrobromide is not authorised.	(2)
	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 sodium is prohibited (withdrawal feed),	1,25
5. Maduramicin ammonium alpha	— other animal species.	3,75
	Premixtures for use in feed in which the use of lasalocid sodium is not authorised	(2)
	Feed materials	0,05

Coccidiostat	Products intended for animal feed <sup>(1)</sup>	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
	Compound feed for — equine species, rabbits, turkeys (> 16 weeks), laying birds and chickens reared for laying (> 16 weeks), — chickens for fattening and turkeys (< 16 weeks) for the period before slaughter in which the use of maduramicin ammonium alpha is prohibited (withdrawal feed), — other animal species. Premixtures for use in feed in which the use of maduramicin ammonium alpha is not authorised.	0,05 0,05 0,15 (2)
6. Monensin sodium	Feed materials Compound feed for — equine species, dogs, small ruminants (sheep and goat), ducks, bovine, dairy cattle, laying birds, chickens reared for laying (> 16 weeks) and turkeys (> 16 weeks), — chickens for fattening, chickens reared for laying (< 16 weeks) and turkeys (< 16 weeks) for the period before slaughter in which the use of monensin sodium is prohibited (withdrawal feed), — other animal species. Premixtures for use in feed in which the use of monensin sodium is not authorised.	1,25 1,25 1,25 3,75 (2)
7. Narasin	Feed materials Compound feed for — turkeys, rabbits, equine species, laying birds and chickens reared for laying (> 16 weeks), — other animal species. Premixtures for use in feed in which the use of narasin is not authorised.	0,7 0,7 2,1 (2)
8. Nicarbazin	Feed materials Compound feed for — equine species, laying birds and chickens reared for laying (> 16 weeks), — other animal species.	1,25 1,25 3,75

Coccidiostat	Products intended for animal feed <sup>(1)</sup>	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
9. Robenidine hydrochloride	Premixtures for use in feed in which the use of nicarbazin (alone or in combination with narasin) is not authorised.  Feed materials  Compound feed for — laying birds and chickens reared for laying (> 16 weeks), — chickens for fattening, rabbits for fattening and breeding and turkeys for the period before slaughter in which the use of robenidine hydrochloride is prohibited (withdrawal feed), — other animal species.	(2)  0,7  0,7 0,7 2,1
10. Salinomycin sodium	Premixtures for use in feed in which the use of robenidine hydrochloride is not authorised.  Feed materials  Compound feed for — equine species, turkeys, laying birds and chickens reared for laying (> 12 weeks), — chickens for fattening, chickens reared for laying (< 12 weeks) and rabbits for fattening for the period before slaughter in which the use of salinomycin sodium is prohibited (withdrawal feed), — other animal species.	(2)  0,7  0,7 0,7 2,1
11. Semduramicin sodium	Premixtures for use in feed in which the use of salinomycin sodium is not authorised  Feed materials  Compound feed for — laying birds and chickens reared for laying (> 16 weeks), — chickens for fattening for the period before slaughter in which the use of semduramicin sodium is prohibited (withdrawal feed), — other animal species.  Premixtures for use in feed in which the use of semduramicin sodium is not authorised.	(2)  0,25  0,25 0,75  (2)

<sup>(1)</sup> Without prejudice to the authorised levels in the frame of Regulation (EC) No 1831/2003 of the European Parliament and of the Council (OJ L 268, 18.10.2003, p. 29).

<sup>(2)</sup> The maximum level of the substance in the premixture is the concentration which shall not result in a level of the substance higher than 50 % of the maximum levels established in the feed when the instructions for use of the premixture are followed.

## ANNEX II

## ACTION THRESHOLDS TRIGGERING INVESTIGATIONS BY MEMBER STATES, AS REFERRED TO IN ARTICLE 4(2)

## SECTION: DIOXINS AND PCBs

Undesirable substances	Products intended for animal feed	Action threshold in ng WHO-PCDD/F-TEQ/kg (ppt) <sup>(2)</sup> , <sup>(3)</sup> 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, 1997 <sup>(1)</sup> )	Feed materials of plant origin  with the exception of:	0,5	<sup>(4)</sup>
	— vegetable oils and their by-products,	0,5	<sup>(4)</sup>
	Feed materials of mineral origin	0,5	<sup>(4)</sup>
	Feed materials of animal origin:		
	— Animal fat, including milk fat and egg fat,	1,0	<sup>(4)</sup>
	— Other land animal products including milk and milk products and eggs and egg products.	0,5	<sup>(4)</sup>
	— Fish oil	5,0	<sup>(5)</sup>
	— Fish, other aquatic animals, and products and by-products with the exception of fish oil and fish protein hydrolysates containing more than 20 % fat <sup>(3)</sup> .	1,0	<sup>(5)</sup>
	— Fish protein hydrolysates containing more than 20 % fat.	1,75	<sup>(5)</sup>
	Feed additives belonging to the functional groups of binders and anti-caking agents.	0,5	<sup>(5)</sup>
	Feed additives belonging to the functional group of compounds of trace elements	0,5	<sup>(4)</sup>
	Premixtures	0,5	<sup>(4)</sup>
	Compound feed  with the exception of:	0,5	<sup>(4)</sup>

Undesirable substances	Products intended for animal feed	Action threshold in ng WHO-PCDD/F-TEQ/kg (ppt) <sup>(2)</sup> , <sup>(3)</sup> relative to a feed with a moisture content of 12 %	Comments and additional information (e.g. nature of investigations to be performed)
2. Dioxin-like PCBs (sum of polychlorinated biphenyls (PCBs)) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 1997 <sup>(1)</sup> )	— compound feed for pet animals and fish,	1,75	<sup>(5)</sup>
	— compound feed for fur animals.	—	
	Feed materials of plant origin with the exception of:	0,35	<sup>(4)</sup>
	— vegetable oils and their by-products,	0,5	<sup>(4)</sup>
	Feed materials of mineral origin	0,35	<sup>(4)</sup>
	Feed materials of animal origin:		
	— Animal fat, including milk fat and egg fat,	0,75	<sup>(4)</sup>
	— Other land animal products including milk and milk products and eggs and egg products.	0,35	<sup>(4)</sup>
	— Fish oil	14,0	<sup>(5)</sup>
	— Fish, other aquatic animals, and products derived thereof with the exception of fish oil and fish protein hydrolysates containing more than 20 % fat <sup>(3)</sup> ,	2,5	<sup>(5)</sup>
	— Fish protein hydrolysates containing more than 20 % fat.	7,0	<sup>(5)</sup>
	Feed additives belonging to the functional groups of binders and anti-caking agents.	0,5	<sup>(4)</sup>
	Feed additives belonging to the functional group of compounds of trace elements.	0,35	<sup>(4)</sup>
	Premixtures	0,35	<sup>(4)</sup>
	Compound feed	0,5	<sup>(4)</sup>
with the exception of:			
— compound feed for pet animals and fish,	3,5	<sup>(5)</sup>	

Undesirable substances	Products intended for animal feed	Action threshold in ng WHO-PCDD/F-TEQ/kg (ppt) <sup>(2)</sup> , <sup>(3)</sup> relative to a feed with a moisture content of 12 %	Comments and additional information (e.g. nature of investigations to be performed)
	— compound feed for fur animals.	—	

<sup>(1)</sup> WHO-TEFs for human risk assessment based on the conclusions of the World Health Organisation meeting in Stockholm, Sweden, 15-18 June 1997 (Van den Berg et al., (1998) Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, PCDFs for Humans and for Wildlife. Environmental Health Perspectives, 106(12), 775).

<sup>(2)</sup> Upper-bound concentrations; upper-bound concentrations are calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification.

<sup>(3)</sup> The Commission will review these action levels at the same time as it reviews the maximum levels for the sum of dioxins and dioxin-like PCBs.

<sup>(4)</sup> Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination.

<sup>(5)</sup> In many cases it might not be necessary to perform an investigation into the source of contamination as the background level in some areas is close to or above the action level. However, in cases where the action level is exceeded, all information, such as sampling period, geographical origin, fish species etc ..., must be recorded with a view to future measures to manage the presence of dioxins and dioxin-like compounds in these materials for animal nutrition.

Congener	TEF value	Congener	TEF value
<b>Dibenzo-p-dioxins ("PCDDs") and diobenzofurans ("PCDFs")</b>		<b>"Dioxin-like" PCBs Non-ortho PCBs + Mono-ortho PCBs</b>	
2,3,7,8-TCDD	1		
1,2,3,7,8-PeCDD	1	<b>Non-ortho PCBs</b>	
1,2,3,4,7,8-HxCDD	0,1	PCB 77	0,0001
1,2,3,6,7,8-HxCDD	0,1	PCB 81	0,0001
1,2,3,7,8,9-HxCDD	0,1	PCB 126	0,1
1,2,3,4,6,7,8-HpCDD	0,01	PCB 169	0,01
OCDD	0,0001	<b>Mono-ortho PCBs</b>	
2,3,7,8-TCDF	0,1	PCB 105	0,0001
1,2,3,7,8-PeCDF	0,05	PCB 114	0,0005
2,3,4,7,8-PeCDF	0,5	PCB 118	0,0001
1,2,3,4,7,8-HxCDF	0,1	PCB 123	0,0001
1,2,3,6,7,8-HxCDF	0,1	PCB 156	0,0005
1,2,3,7,8,9-HxCDF	0,1	PCB 157	0,0005
2,3,4,6,7,8-HxCDF	0,1	PCB 167	0,00001
1,2,3,4,6,7,8-HpCDF	0,01	PCB 189	0,0001
1,2,3,4,7,8,9-HpCDF	0,01		
OCDF	0,0001		

Abbreviations used: "T" = tetra; "Pe" = penta; "Hx" = hexa; "Hp" = hepta; "O" = octa; "CDD" = chlorodibenzodioxin; "CDF" = chlorodibenzofuran; "CB" = chlorobiphenyl.