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)

COMMISSION REGULATION (EU) No 574/2011

of 16 June 2011

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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) 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[(2)] 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[(3)]. 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[(4)]. 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[(5)] 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 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[(6)] 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

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 574/2011. (See end of Document for details)*

ANNEX

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

ANNEX MAXIMUM LEVELS OF UNDESIRABLE SUBSTANCES, AS REFERRED TO IN ARTICLE 3(2)SECTION I:INORGANIC CONTAMINANTS AND NITROGENOUS COMPOUNDSThe maximum levels refer to total arsenic.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.Forage includes products intended for animal feed such as hay, silage, fresh grass, etc.The maximum levels refer to total mercury.The maximum levels are expressed as sodium nitrite.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.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.The % of phosphorus is relative to a feed with a moisture content of 12 %.The maximum level refers to melamine only. The inclusion of the structurally related compounds cyanuric acid, ammeline and ammelide in the maximum level will be considered at a later stage.Undesirable substanceProducts intended for animal feedMaximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %1.

Arsenic[a]

Feed materials2with 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—

phosphates and calcareous marine algae,

10—

calcium carbonate,

15—

magnesium oxide and magnesium carbonate,

20—

fish, other aquatic animals and products derived thereof,

25—

seaweed meal and feed materials derived from seaweed.

40Iron particles used as tracer.50Feed additives belonging to the functional groups of compounds of trace elements30with the exception of:—

cupric sulphate pentahydrate and cupric carbonate,

50—

zinc oxide, manganous oxide and cupric oxide.

100Complementary feed4with the exception of:—

mineral feed.

12Complete feed2with the exception of:—

complete feed for fish and fur animals.

102.

Cadmium
Feed materials of vegetable origin.1Feed materials of animal origin.2Feed materials of mineral origin2with the exception of:—
phosphates.
10Feed additives belonging to the functional group of compounds of trace elements10with the exception of:—
cupric oxide, manganous oxide, zinc oxide and manganous sulphate monohydrate.
30Feed additives belonging to the functional groups of binders and anti-caking agents.2Premixtures15Complementary feed0,5with the exception of:—
mineral feed
- -
containing < 7 % phosphorus[h],
5- -
containing ≥ 7 % phosphorus[h],
0,75 per 1 % phosphorus, with a maximum of 7,5—
complementary feed for pet animals.
2Complete feed0,5with the exception of:—
complete feed for cattle (except calves), sheep (except lambs), goats (except kids) and fish,
1—
complete feed for pet animals.
23.
Fluorine[g]
Feed materials150with 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 000Vermiculite (E 561).3 000Complementary feed:—
containing ≤ 4 % phosphorus[h],
500—
containing > 4 % phosphorus[h].
125 per 1 % phosphorusComplete feed150with 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
- -
in lactation,
30- -
other.
504.