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

(**1**) OJ L 140, 30.5.2002, p. 10.

(**2**) 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

(**3**) 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

(**4**) 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).

(**5**) 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

(**6**) OJ L 140, 11.2.2009, p. 7.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) No 574/2011, Introductory Text.