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 (Text with EEA relevance)

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[(1)], and in particular Article 2(3) thereof,

Whereas:

(1) Coccidiostats and histomonostats are substances intended to kill or inhibit protozoa, which may, *inter alia*, be authorised for use as feed additives in accordance with Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(2)]. Authorisations of coccidiostats and histomonostats as feed additives lay down specific conditions for use such as the target animal species or categories for which the additives are intended.

(2) Feed business operators may produce within one establishment a broad range of feeds and different types of products may have to be manufactured after each other in the same production line. It may happen that unavoidable traces of a product remain in the production line and end up in the beginning of the production of another feed product. This transfer from one production lot to another is called ‘carry-over’ or ‘cross-contamination’ and may occur for instance when coccidiostats or histomonostats are used as authorised feed additives. This may result in the contamination of feed produced subsequently by the presence of technically unavoidable traces of those substances in ‘non-target feed’, i.e. in feed for which the use of coccidiostats or histomonostats are not authorised, such as feed intended for animal species or categories not provided for in the additive authorisation. This unavoidable cross-contamination may occur at all stages of production and processing of feed but also during storage and transport of feed.

(3) In order to prevent the adoption by Member States of national rules addressing the issue of unavoidable carry-over of authorised coccidiostats or histomonostats in non-target feed and their resulting presence in derived foodstuffs, which would hinder the functioning of the internal market, it is necessary to adopt harmonised Community rules in this matter.

Changes to legislation: *Commission Regulation (EC) No 124/2009 is up to date with all changes known to be in force on or before 22 December 2020. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(4) The unavoidable carry-over in non-target feed of active substances contained in authorised coccidiostats and histomonostats are considered as undesirable substances in animal feed within the meaning of Directive 2002/32/EC of the European Parliament and of the Council[3] and their presence should not endanger animal health, human health or the environment. Therefore, maximum levels for these substances in animal feed are established by Commission Directive 2009/8/EC[4] amending Annex I to Directive 2002/32/EC.

(5) The occurrence of unavoidable carry-over of coccidiostats and histomonostats in non-target feed, even below maximum levels set under Directive 2002/32/EC, may result in the presence of residues of these substances in food products of animal origin. Therefore, in order to protect public health, and insofar there is no maximum residue limit (MRL) yet fixed for the specific food concerned in the frame of Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin[5] or in the frame of Regulation (EC) No 1831/2003, maximum tolerances for the presence of active substances contained in coccidiostats and histomonostats should be established in food of animal origin originating from the non-target feed concerned, in the context of Regulation (EEC) No 315/93 laying down Community procedures for contaminants in food.

(6) On a request from the Commission, the European Food Safety Authority ('the Authority') adopted several opinions[6] on the risks involved for animal health and public health as the consequence of unavoidable carry-over of coccidiostats or histomonostats authorised as feed additives into non-target feed. For each coccidiostat or histomonostat authorised as feed additive, the Authority's assessment took into account hypothetical carry-over rates of 2 %, 5 % and 10 % from feed produced with the highest authorised dose of the coccidiostats or histomonostats into the afterwards produced non-target feed.

(7) Considering the conclusions of the individual scientific opinions, it can be stated that generally the Authority concluded that the presence of the coccidiostats or histomonostats authorised as feed additives, in non-target feed at levels resulting from an unavoidable carry-over, and taking into account all prevention measures, is unlikely to result in adverse animal health effects and that the risk to consumers' health from the ingestion of residues in products from animals exposed to cross-contaminated feed is negligible.

(8) Taking into account the Authority's opinions and the currently different approaches applied in the Member States to address the unavoidable cross-contamination, it is proposed to set maximum levels for food as laid down in the Annexes to this Regulation, in order to ensure a proper functioning of the internal market and to protect public health. The provisions provided in Annex should be reviewed by 1 July 2011 at the latest to take account of developments in scientific and technical knowledge.

(9) The maximum levels set in the Annex to this Regulation should be continuously adapted to changes of maximum residue levels (MRL) established for the specific food concerned in the frame of Regulation (EEC) No 2377/90 laying down a Community

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procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin or in the frame of Regulation (EC) No 1831/2003. In view of the occurrence of a possible time gap between these amendments and the consequent adaptation to the maximum levels laid down in the Annex to this Regulation, the latter should be considered as without prejudice to the maximum residue levels of coccidiostats or histomonostats established in the frame of Regulation (EEC) No 2377/90 or in the frame of Regulation (EC) No 1831/2003.

(10) Due to the fact that the unavoidable carry-over of coccidiostats or histomonostats into non-target feed may result in the presence of these substances as contaminants in derived food, it is appropriate to take a comprehensive and integrated approach to address the issue through the simultaneous adoption and application of this Regulation and the Directive 2009/8/EC setting maximum levels for the unavoidable carry-over of coccidiostats or histomonostats into non-target feed.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

1 The foodstuffs listed in Annex to this Regulation shall not be placed on the market where they contain a contaminant listed in this Annex at a level exceeding the maximum levels set in the Annex.

In case of a finding of a significant residue below the maximum level set out in the Annex, it is appropriate for the competent authority to carry out investigations to confirm that the residue is present as a consequence of unavoidable carry over in the feed and not as the consequence of illegal administration of the coccidiostat or histomonostat.

Foodstuffs complying with the maximum levels set out in the Annex shall not be mixed with foodstuffs which exceed these maximum levels.

2 When applying the maximum levels set out in the Annex to this Regulation to foodstuffs which are dried, diluted, processed or composed of more than one ingredient, changes of the concentration of the contaminant caused by drying, diluting or processing, as well as the relative proportion of the ingredients in the product, shall be taken into account.

3 The maximum levels established in Annex to this Regulation are without prejudice to the provisions and the MRLs established by Regulation (EEC) No 2377/90 and the MRLs established by Regulation (EC) No 1831/2003.

Article 2

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

It shall apply from 1 July 2009.

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

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