COMMISSION DIRECTIVE 2009/8/EC

of 10 February 2009

amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels of unavoidable carry-over of coccidiostats or histomonostats in non-target feed

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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) 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) Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene [3] provides for specific requirements for feed businesses using coccidiostats and histomonostats in the production of feed. In particular, the operators concerned have to take all appropriate measures concerning facilities and equipment, production, storage and transport in order to avoid any cross-contamination, and this in accordance with the obligations provided for in Articles 4 and 5 of the above mentioned Regulation. The establishment of maximum levels of unavoidable carry-over of coccidiostats and histomonostats in non-target feed in accordance with Directive 2002/32/EC should not interfere with the primary obligation of operators to apply good manufacturing practices aiming at avoiding this cross-contamination. Continued effort is therefore still needed by the operators concerned in order to avoid the presence of such undesirable substances in animal feed.

(4) Taking into account the application of good manufacturing practices, the 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 the above mentioned unavoidable carry-over, a carry-over rate of approximately 3 % compared to the authorised maximum content should be considered as regards feed for less sensitive non-target animal species, while a carry-over rate of approximately 1 % compared to the authorised maximum content should be retained for feed intended to sensitive non-target animal species and 'withdrawal feed', i.e. feed used for the period before slaughter. The carry-over rate of 1 % should also be considered 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. If feed materials are fed directly to the animals or if complementary feedingstuffs are used, their use in a daily ration should not lead to the animal being exposed to a higher levels of an coccidiostat or histomonostat than the corresponding maximum levels of exposure where only complete feedingstuffs are used in a daily ration.

(5) 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.

(6) The unavoidable carry-over in non-target feed of active substances contained in authorised coccidiostats and histomonostats should be considered as undesirable substances in animal feed within the meaning of Directive 2002/32/EC and their presence should not endanger animal health, human health or the environment. Therefore, maximum levels for these substances in animal feed should be established within Annex I of the said Directive in order to prevent undesirable and harmful effects.

(7) Where MRLs have been laid down 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 ([4]) or in the frame of Regulation (EC) No 1831/2003, compliance with those provisions should be ensured when establishing maximum levels of unavoidable carry-over of coccidiostats or histomonostats in non-target feed.

(8) The occurrence of unavoidable carry-over of coccidiostats and histomonostats in non-target feed, even below maximum levels that should be 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, maximum tolerances for the presence of active substances contained in coccidiostats and histomonostats have been established by 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 ([5]), in the context of Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food ([6]).

(9) On a request from the Commission, the European Food Safety Authority (the Authority) adopted several opinions ([7]) 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.

(10) 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.

(11) 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 feed as laid down in the Annexes to this Directive, in order to ensure a proper functioning of the internal market and to protect animal and public health.

(12) The establishment of maximum levels of undesirable substances in animal feed should take place through an adaptation of Annex I of Directive 2002/32/EC, as provided for in Article 8(1) of that Directive. When adapting the technical provisions in Annex I of Directive 2002/32/EC, developments in scientific and technical knowledge have been taken into account through the consideration of scientific opinions of the Authority and of the development of analytical methods in feed. 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.

(13) The maximum levels set in the Annex to this Directive should be continuously adapted to the conditions of use provided for in the authorisations of coccidiostats and histomonostats as feed additives. In view of the occurrence of a possible time gap between the authorisation – or modification, suspension or revocation of the authorisation – of a coccidiostat or histomonostat as feed additive and the consequent amendment to the maximum levels laid down in the Annexes to this Directive, the latter should be considered as without prejudice to the levels of coccidiostats or histomonostats authorised as feed additives in the frame of Regulation (EC) No 1831/2003.

(14) 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 Directive setting maximum levels for the unavoidable carry-over of coccidiostats or histomonostats into non-target feed and the Commission Regulation setting maximum levels for the resulting presence of these substances in food.

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

HAS ADOPTED THIS DIRECTVE:

Article 1

Annex I to Directive 2002/32/EC is amended in accordance with the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 July 2009 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 10 February 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

(1) OJ L 140, 30.5.2002, p. 10.
(2) OJ L 268, 18.10.2003, p. 29.
(3) OJ L 35, 8.2.2005, p. 1.
(4) OJ L 224, 18.8.1990, p. 1.
(5) See page 7 of this Official Journal.
(6) OJ L 37, 13.2.1993, p. 1.
(7) Opinion of the Scientific Panel on Contaminants in the Food chain on a request from the European Commission on Cross-contamination of non-target feedingstuffs by lasalocid authorised for use as a feed additive, *The EFSA Journal* (2007) 553, 1-46.
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/CONTAM_ej553_lasalocid_en.pdf?ssbinary=true
Opinion of the Scientific Panel on Contaminants in the Food chain on a request from the European Commission on cross-contamination of non-target feedingstuffs by narasin authorised for use as a feed additive, *The EFSA Journal* (2007) 552, 1-35.
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/CONTAM_ej552_narasin_en.pdf?ssbinary=true
Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the European Commission on cross-contamination of non-target feedingstuffs by maduramicin authorised for use as a feed additive, *The EFSA Journal* (2008) 594, 1-30.
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/contam_op_ej594_maduramicin_en.pdf?ssbinary=true
Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the European Commission on cross-contamination of non-target feedingstuffs by semduramicin authorised for use as a feed additive, *The EFSA Journal* (2008) 593, 1-27.
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/contam_op_ej593_semduramicin_en.pdf?ssbinary=true
Opinion of the Scientific Panel on Contaminants in the Food chain on a request from the European Commission on cross-contamination of non-target feedingstuffs by salinomycin authorised for use as a feed additive, *The EFSA Journal* (2008) 591, 1-38.
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/contam_op_ej591_salinomycin_en.pdf?ssbinary=true
Opinion of the Scientific Panel on Contaminants in the Food chain on a request from the European Commission on cross-contamination of non-target feedingstuffs by monensin authorised for use as a feed additive, *The EFSA Journal* (2008) 592, 1-40.
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/contam_op_ej592_monensin_en.pdf?ssbinary=true
Opinion of the Scientific Panel on Contaminants in the Food chain on a request from the European Commission on cross-contamination of non-target feedingstuffs by halofuginone hydrobromide authorised for use as a feed additive, *The EFSA Journal* (2008) 657, 1-31.
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/contam_op_ej657_halofuginone_en.pdf?ssbinary=true
Opinion of the Scientific Panel on Contaminants in the Food chain on a request from the European Commission on cross-contamination of non-target feedingstuffs by decoquinate authorised for use as a feed additive, *The EFSA Journal* (2008) 656, 1-26.
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/contam_op_ej656_decoquinate_en.pdf?ssbinary=true
Opinion of the Scientific Panel on Contaminants in the Food chain on a request from the European Commission on cross-contamination of non-target feedingstuffs by robenidine authorised for use as a feed additive, *The EFSA Journal* (2008) 655, 1-29.
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/contam_op_ej655_robenidine_en,0.pdf?ssbinary=true
Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the European Commission on cross-contamination of non-target feedingstuffs by nicarbazin authorised for use as a feed additive, *The EFSA Journal* (2008) 690, 1-34.
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/contam_op_ej690_nicarbazin_en.pdf?ssbinary=true
Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the European Commission on cross-contamination of non-target feedingstuffs by diclazuril authorised for use as a feed additive, *The EFSA Journal* (2008) 716, 1-31.
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/contam_op_ej716_diclazuril_en.pdf?ssbinary=true

ANNEX

The following points are added in Annex I to Directive 2002/32/EC:

'Undesirable substances	Products intended for animal feed (*)	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
1. Lasalocid sodium	Feed materials	1,25
	Compound feed for	
	— dogs, calves, rabbits, equine species, dairy animals, laying birds, turkeys (> 12 weeks) and chickens reared for laying (> 16 weeks);	1,25
	— chickens for fattening, chickens reared for laying (< 16 weeks) and turkeys (< 12 weeks) for the period before slaughter in which the use of lasalocid sodium is prohibited (withdrawal feed);	1,25
	— other animal species.	3,75
	Premixtures for use in feed in which the use of lasalocid sodium is not authorised.	(**)
2. Narasin	Feed materials	0,7
	Compound feed for	
	— turkeys, rabbits, equine species, laying birds and chickens reared for laying (> 16 weeks);	0,7
	— chickens for fattening for the period before slaughter in which the use of narasin is prohibited (withdrawal feed);	0,7
	— other animal species.	2,1
	Premixtures for use in feed in which the use of narasin is not authorised.	(**)
3. Salinomycin sodium	Feed materials	0,7
	Compound feed for	
	— equine species, turkeys, laying birds and chickens reared for laying (> 12 weeks);	0,7
	— 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);	0,7
	— other animal species.	2,1
	Premixtures for use in feed in which the use of salinomycin sodium is not authorised.	(**)
4. Monensin sodium	Feed materials	1,25
	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);	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 monensin sodium is prohibited (withdrawal feed);	1,25
	— other animal species.	3,75
	Premixtures for use in feed in which the use of monensin sodium is not authorised.	(**)

Undesirable substances	Products intended for animal feed (*)	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
5. Semduramicin sodium	Feed materials	0,25
	Compound feed for	
	— laying birds and chickens reared for laying (> 16 weeks);	0,25
	— chickens for fattening for the period before slaughter in which the use of semduramicin sodium is prohibited (withdrawal feed);	0,25
	— other animal species.	0,75
	Premixtures for use in feed in which the use of semduramicin sodium is not authorised.	(**)
6. Maduramicin ammonium alpha	Feed materials	0,05
	Compound feed for	
	— equine species, rabbits, turkeys (> 16 weeks), laying birds and chickens reared for laying (> 16 weeks);	0,05
	— chickens for fattening and turkeys (< 16 weeks) for the period before slaughter in which the use of maduramicin ammonium alpha is prohibited (withdrawal feed);	0,05
	— other animal species.	0,15
	Premixtures for use in feed in which the use of maduramicin ammonium alpha is not authorised.	(**)
7. Robenidine hydrochloride	Feed materials	0,7
	Compound feed for	
	— laying birds and chickens reared for laying (> 16 weeks);	0,7
	— 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);	0,7
	— other animal species.	2,1
	Premixtures for use in feed in which the use of robenidine hydrochloride is not authorised.	(**)
8. Decoquinate	Feed materials	0,4
	Compound feed for	
	— laying birds and chickens reared for laying (> 16 weeks);	0,4
	— chickens for fattening for the period before slaughter in which the use of decoquinate is prohibited (withdrawal feed);	0,4
	— other animal species.	1,2
	Premixtures for use in feed in which the use of decoquinate is not authorised.	(**)
9. Halofuginone hydrobromide	Feed materials	0,03
	Compound feed for	
	— laying birds, chickens reared for laying (> 16 weeks) 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
	— other animal species other than chickens reared for laying (< 16 weeks).	0,09
	Premixtures for use in feed in which the use of halofuginone hydrobromide is not authorised.	(**)

Undesirable substances	Products intended for animal feed (*)	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
10. Nicarbazin	Feed materials	0,5
	Compound feed for	
	— equine species, laying birds and chickens reared for laying (> 16 weeks);	0,5
	— chickens for fattening for the period before slaughter in which the use of nicarbazin (in combination with narasin) is prohibited (withdrawal feed);	0,5
	— other animal species.	1,5
	Premixtures for use in feed in which the use of nicarbazin (in combination with narasin) is not authorised.	(**)
11. Diclazuril	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
	— other animal species other than chickens reared for laying (< 16 weeks), chickens for fattening and turkeys for fattening (< 12 weeks).	0,03
	Premixtures for use in feed in which the use of diclazuril is not authorised.	(**)

(*) Without prejudice to the authorised levels in the frame 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.

(**) 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.'