

## II

(Non-legislative acts)

## REGULATIONS

## COMMISSION REGULATION (EU) No 610/2012

of 9 July 2012

**amending 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)

THE EUROPEAN COMMISSION,

(EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <sup>(4)</sup>.

Having regard to the Treaty on the Functioning of the European Union,

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

Whereas:

(1) Maximum levels have been set for certain coccidiostats and histomonostats in food 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 <sup>(2)</sup> in order to ensure a proper functioning of the internal market and to protect public health.

(2) The maximum levels should be continuously adapted in order to take account of developments in scientific and technical knowledge and the changes of maximum residue limits established for the specific food concerned in the framework of Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin <sup>(3)</sup> or in the framework of Regulation

(3) Maximum residue limits have been established for lasalocid sodium in food of animal origin from bovine species in the framework of Regulation (EC) No 470/2009 by Commission Implementing Regulation (EU) No 86/2012 of 1 February 2012 amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance lasalocid <sup>(5)</sup>. Therefore, it is necessary to amend the provisions as regards lasalocid sodium.

(4) New technical information, namely specific studies on transfer ratio of maduramicin from feed into eggs from laying hens has become available. These studies demonstrate that feed for laying hens containing maduramicin due to cross-contamination but below the maximum level results in levels of maduramicin in eggs higher than the currently allowed maximum level. In accordance with the conclusions of the EFSA opinion on cross-contamination of non-target feedingstuffs by maduramicin <sup>(6)</sup> and the scientific opinion on safety and efficacy of maduramicin ammonium for chickens for fattening <sup>(7)</sup>, these higher levels do not result in an appreciable risk

<sup>(4)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(5)</sup> OJ L 30, 2.2.2012, p. 6.

<sup>(6)</sup> 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. Available online: <http://www.efsa.europa.eu/en/efsajournal/doc/594.pdf>

<sup>(7)</sup> EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP); Scientific Opinion on safety and efficacy of Cygro® 10G (maduramicin ammonium α) for chickens for fattening. *EFSA Journal* 2011;9(1):1952. [2 pp.]. doi:10.2903/j.efsa.2011.1952. Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

<sup>(1)</sup> OJ L 37, 13.2.1993, p. 1.

<sup>(2)</sup> OJ L 40, 11.2.2009, p. 7.

<sup>(3)</sup> OJ L 152, 16.6.2009, p. 11.

to consumers' health. Therefore it is appropriate to amend the provisions as regards maduramicin accordingly.

- (5) The conditions of authorisation of nicarbazin and diclazuril as feed additives have been modified by Commission Regulation (EU) No 875/2010 of 5 October 2010 concerning the authorisation for 10 years of an additive in feedingstuffs<sup>(1)</sup> and Commission Regulation (EU) No 169/2011 of 23 February 2011 concerning the authorisation of diclazuril as a feed additive for guinea fowls<sup>(2)</sup> respectively. Those developments require significant changes to the maximum levels set for nicarbazin and minor changes for diclazuril in the Annex to Regulation (EC) No 124/2009. In accordance with the conclusions of the EFSA opinion on cross-contamination of non-target feedingstuffs by nicarbazin<sup>(3)</sup> and the scientific opinion on safety and efficacy of nicarbazin for chickens for fattening<sup>(4)</sup>, the proposed maximum levels for nicarbazin in food as a consequence of unavoidable carry-over in non-target feed do not result in an appreciable risk to consumers'

health. Therefore it is appropriate to amend the provisions as regards diclazuril and nicarbazin.

- (6) Therefore, Regulation (EC) No 124/2009 should be amended accordingly.
- (7) 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*

The Annex to Regulation (EC) No 124/2009 is amended in accordance with the Annex to this Regulation.

*Article 2*

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

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

Done at Brussels, 9 July 2012.

*For the Commission*

*The President*

José Manuel BARROSO

<sup>(1)</sup> OJ L 263, 6.10.2010, p. 4.

<sup>(2)</sup> OJ L 49, 24.2.2001, p. 6.

<sup>(3)</sup> 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, Available online: <http://www.efsa.europa.eu/en/efsajournal/doc/690.pdf>

<sup>(4)</sup> EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP); Scientific Opinion on the safety and efficacy of Koffogran (nicarbazin) as a feed additive for chickens for fattening. *EFSA Journal* 2010; 8(3):1551. [40 pp.]. doi:10.2903/j.efsa.2010.1551. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

## ANNEX

The Annex to Regulation (EC) No 124/2009 is amended as follows:

- (1) The entry No 1 concerning Lasalocid sodium is replaced by the following:

"1. Lasalocid sodium	Food of animal origin from animal species other than poultry and bovine:	
	— milk;	1
	— liver;	50
	— kidney;	20
	— other food.	5"

- (2) The entry No 6 concerning Maduramicin is replaced by the following:

"6. Maduramicin	Food of animal origin from animal species other than chickens for fattening and turkeys:	
	— eggs;	12
	— other food.	2"

- (3) The entry No 10 concerning Nicarbazin is replaced by the following:

"10. Nicarbazin (residue: 4,4'- dinitrocarbanilide (DNC))	Food of animal origin from animal species other than chickens for fattening:	
	— eggs;	300
	— milk;	5
	— liver;	300
	— kidney;	100
	— other food.	50"

- (4) The entry No 11 concerning Diclazuril is replaced by the following:

"11. Diclazuril	Food of animal origin from animal species other than chickens for fattening, turkeys for fattening, guinea fowl, rabbits for fattening and breeding, ruminants and porcine:	
	— eggs;	2
	— liver and kidney;	40
	— other food.	5"