Commission Regulation (EC) No 976/2008 of 6 October 2008 amending Regulations (EC) No 2430/1999, (EC) No 418/2001 and (EC) No 162/2003 as regards the terms of the authorisation of the feed additive 'Clinacox', belonging to the group of coccidiostats and other medicinal substances (Text with EEA relevance)

COMMISSION REGULATION (EC) No 976/2008

of 6 October 2008

amending Regulations (EC) No 2430/1999, (EC) No 418/2001 and (EC) No 162/2003 as regards the terms of the authorisation of the feed additive 'Clinacox', belonging to the group of coccidiostats and other medicinal substances

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(1)], and in particular Article 13(3) thereof,

Whereas:

(1) The additive diclazuril (Clinacox 0,5 % Premix), belonging to the group of coccidiostats and other medicinal substances, was authorised under certain conditions in accordance with Council Directive 70/524/EEC[(2)]. Commission Regulations (EC) No 2430/1999[(3)], (EC) No 418/2001[(4)] and (EC) No 162/2003[(5)] authorised that additive for 10 years for use for chickens for fattening, turkeys for fattening and chickens reared for laying respectively, linking the authorisation to the person responsible for putting that additive into circulation. That additive was notified as an existing product in accordance with Article 10 of Regulation (EC) No 1831/2003. Since all the information required under that provision was submitted, that additive was entered into the Community Register of Feed Additives.

(2) Regulation (EC) No 1831/2003 provides for the possibility of modifying the authorisation of an additive further to a request from the holder of the authorisation and an opinion of the European Food Safety Authority (the Authority). The holder of the authorisation of the additive diclazuril (Clinacox 0,5 % Premix) has submitted an application with which it proposes changing the conditions of the authorisation by introducing a maximum residue limit (MRL) as evaluated by the Authority. At the same time it provided the necessary data to support that request.

(3) In its opinion adopted on 16 April 2008[(6)], the Authority concluded that no MRLs are required for chickens and turkeys for fattening. However, in case MRLs were considered necessary, it suggested values. Because it is possible that the chickens reared for laying enter in the food chain, not separately from the other chickens, it is necessary to consider the possibility to provide MRLs also for that animal category. It

Changes to legislation: Commission Regulation (EC) No 976/2008 is up to date with all changes known to be in force on or before 27 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

also considered that applying a withdrawal period of zero days would not compromise consumer safety.

(4) To ensure a high level of safety for the consumers and to improve the controls of the correct use of diclazuril, it is appropriate to establish MRLs as proposed by the Authority. Because there are no relevant physiological differences between the chickens for fattening and chickens reared for laying it is appropriate to establish the same MRLs also for the latter category.

(5) Commission Regulations (EC) No 2430/1999, (EC) No 418/2001 and (EC) No 162/2003 should therefore be amended accordingly.

(6) 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

In Annex I to Regulation (EC) No 2430/1999 the line for E 771 is replaced by the text in Annex I to this Regulation.

Article 2

Annex III to Regulation (EC) No 418/2001 is replaced by the text in Annex II to this Regulation.

Article 3

The Annex to Regulation (EC) No 162/2003 is replaced by the text in Annex III to this Regulation.

Article 4

This Regulation shall enter into force on the 20th 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, 6 October 2008.

For the Commission

Androulla VASSILIOU

Member of the Commission

***Changes to legislation:** Commission Regulation (EC) No 976/2008 is up to date with all changes known to be in force on or before 27 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*

ANNEX I

Registration number of additive	**Name and registration number of person responsible for putting additive into circulation**	**Additive (trade name)**	**Composition, chemical formula, description**	**Species or category of animal**	**Maximum age**	**Minimum content**	**Maximum content**	**Other provisions**	**End of period of authorisation**	**Maximum Residue Limits (MRLs) in the relevant foodstuffs of animal origin**
						mg of active substance/kg of complete feedingstuff				
Coccidiostats and other medicinal substances										
‘E 771	Janssen Pharmaceutica nv	Diclazuril 0,5 g/100 g (Clinacox 0,5 % Premix) Diclazuril 0,2 g/100 g (Clinacox 0,2 % Premix)	*Additive composition*: Diclazuril: 0,5 g/100 g Soybean meal: 99,25 g/100 g Polyvidone K 30: 0,2 g/100 g Sodium hydroxide: 0,0538 g/100 g Diclazuril: 0,2 g/100 g Soybean meal: 39,7 g/100 g Polyvidone K 30: 0,08 g/100 g	*Chicken for fattening*	—	1	1	—	30.9.2009	1 500 µg diclazuril/kg of wet liver 1 000 µg diclazuril/kg of wet kidney 500 µg diclazuril/kg of wet muscle 500 µg diclazuril/kg of wet skin/fat’