Commission Regulation (EC) No 2430/1999 of 16 November 1999 linking the authorisation of certain additives belonging to the group of coccidiostats and other medicinal substances in feedingstuffs to persons responsible for putting them into circulation (Text with EEA relevance)

COMMISSION REGULATION (EC) No 2430/1999

of 16 November 1999

linking the authorisation of certain additives belonging to the group of coccidiostats and other medicinal substances in feedingstuffs to persons responsible for putting them into circulation

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs[(1)], as last amended by Commission Regulation (EC) No 1636/1999[(2)], and in particular Article 9h(3)(b) and Article 9i(3)(b) thereof,

Whereas:

(1) because of the risk for human and animal health posed by the circulation in the Community of poor copies of zootechnical additives, Directive 70/524/EEC, as amended by Council Directive 96/51/EC[(3)], provides for the linking of the authorisation of certain classes of additives to the person responsible for putting them into circulation;

(2) in particular Article 9h of Directive 70/524/EEC provides for the replacement of the provisional authorisations of additives included in Annex I after 31 December 1987 and belonging to the group of coccidiostats and other medicinal substances and transferred to Chapter II of Annex B by authorisations linked to the person responsible for putting them into circulation for a period of 10 years;

(3) in particular Article 9i of Directive 70/524/EEC provides for the replacement of the provisional authorisations of additives included in Annex II before 1 April 1998 and belonging to the group of coccidiostats and other medicinal substances and transferred to Chapter III of Annex B by provisional authorisations linked to the person responsible for putting them into circulation;

(4) the additives listed in the Annexes to this Regulation were the subject of new applications for authorisation by the person responsible for the dossier on the basis of which the former authorisations were given or by their successors. The applications relating to those additives were accompanied by the required monographs and identification notes;

(5) the linking of the authorisation to a person responsible for putting the additive into circulation is based on a purely administrative procedure and did not entail a fresh

assessment of the additives. Although the authorisations are given for a specified period they may be withdrawn at any time in accordance with Article 9m and Article 11 of Directive 70/524/EEC. In particular, authorisations of additives may be withdrawn as a result of the re-evaluation carried out under Article 9g of Directive 70/524/EEC;

(6) the measures provided for in this Regulation are in accordance with the opinion of the Standing Committee for Feedingstuffs,

HAS ADOPTED THIS REGULATION:

Article 1

The provisional authorisations of the additives listed in Annex I to this Regulation are replaced by authorisations granted to the person responsible for putting the additive in circulation, inserted in the second column of Annex I.

Article 2

The provisional authorisations of the additives listed in Annex II to this Regulation are replaced by provisional authorisations granted to the person responsible for putting the additive into circulation, inserted in the second column of Annex II.

Article 3

This Regulation shall enter into force on the seventh day of its publication in the *Official Journal of the European Communities*.

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

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**	**Period of authorisation**	**[F2Maximum Residue Limits(MRLs)]**
						mg of active substance/kg of complete feedingstuff				
[F3]										
[F4. . . . .]										
E 764	**[F5**Huvepharma nv**]**	Halofuginone hydrobromide 6 g/kg (Stenorol)	**Additive composition:** Halofuginone hydrobromide 6 g/kg **Active substance:** Halofuginone hydrobromide, $C_{16}H_{17}BrClN_3O_3$, HBr DL-trans-7-bromo-6-chloro-3-	Chickens for laying	16 weeks	2	3	—	30.9.2009	

a **[F1]**

				(3-(3-hydroxy-2-piperidy)acetonyl)quinazolin-4(3H)-one hydrobromide, CAS number: 64924-67-0 Related impurities: Cis-isomer of halofuginone: < 1,5 %						

[F1]

[F6]

[F7]

[F8]

a [F1]

Textual Amendments

F1 Deleted by Council Regulation (EC) No 1756/2002 of 23 September 2002 amending Directive 70/524/EEC concerning additives in feedingstuffs as regards withdrawal of the authorisation of an additive and amending Commission Regulation (EC) No 2430/1999 (Text with EEA relevance).

F2 Inserted by Commission Regulation (EC) No 2037/2005 of 14 December 2005 amending the conditions for authorisation of a feed additive belonging to the group of coccidiostats (Text with EEA relevance).

F3 Deleted by Commission Implementing Regulation (EU) No 532/2011 of 31 May 2011 concerning the authorisation of robenidine hydrochloride as a feed additive for rabbits for breeding and rabbits for fattening (holder of authorisation Alpharma Belgium BVBA) and amending Regulations (EC) No 2430/1999 and (EC) No 1800/2004 (Text with EEA relevance).

F4 Deleted by Commission Regulation (EU) No 874/2010 of 5 October 2010 concerning the authorisation of lasalocid A sodium as a feed additive for turkeys up to 16 weeks (holder of authorisation Alpharma (Belgium) BVBA) and amending Regulation (EC) No 2430/1999 (Text with EEA relevance).

F5 Substituted by Commission Regulation (EC) No 249/2006 of 13 February 2006 amending Regulations (EC) No 2430/1999, (EC) No 937/2001, (EC) No 1852/2003 and (EC) No 1463/2004 as regards the terms of the authorisation of certain additives in feedingstuffs belonging to the group of coccidiostats and other medicinal substances (Text with EEA relevance).

F6 Deleted by Commission Implementing Regulation (EU) No 388/2011 of 19 April 2011 concerning the authorisation of maduramicin ammonium alpha as a feed additive for chickens for fattening (holder of authorisation Alpharma (Belgium) BVBA) and amending Regulation (EC) No 2430/1999 (Text with EEA relevance).

F7 Deleted by Commission Regulation (EU) No 1118/2010 of 2 December 2010 concerning the authorisation of diclazuril as a feed additive for chickens for fattening (holder of authorisation Janssen Pharmaceutica NV) and amending Regulation (EC) No 2430/1999 (Text with EEA relevance).

F8 Deleted by Commission Regulation (EU) No 885/2010 of 7 October 2010 concerning the authorisation of the preparation of narasin and nicarbazin as a feed additive for chickens for fattening (holder of authorisation Eli Lilly and Company Ltd) and amending Regulation (EC) No 2430/1999 (Text with EEA relevance).

ANNEX II

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	Period of authorisation
						mg of active substance/kg of complete feedingstuff			
26	Hoechst Roussel Vet GmbH	Salinomycin sodium 120 g/kg (Sacox 120)	**Additive composition:** Salinomycin sodium ≥ 120 g/kg Silicium dioxide 10-100 g/kg Calcium carbonate: 350-700 g/kg **Active substance:** Salinomycin sodium, $C_{42}H_{69}O_{11}Na$, CAS number: 53003-10-4,	Rabbits fattening	—	20	25	Use prohibited at least five days before slaughter Indicate in the instructions for use: Dangerous for equines This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g. tiamulin)	30.9.2000[a]

a First authorisation: Commission Directive 96/7/EC (OJ L 51, 1.3.1996, p. 45).

b First authorisation: Commission Directive 96/66/EC (OJ L 272, 25.10.1996, p. 32).

c First authorisation: Commission Directive 97/72/EC (OJ L 351, 23.12.1997, p. 55).

				sodium salt of a polyether monocarboxylic acid produced by fermentation of *Streptomyces albus* (DSM 12217)				can be contraindicated	
					Chickens reared for laying	12 weeks	30	50	Indicate in the instructions for use: Dangerous for equines This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g. tiamulin) can be contraindicated	30.9.2000[b]
			Related impurities: < 42 mg elaiophylin/kg salinomycin sodium < 40 g 17-epi-20-desoxy-salinomycin/kg salinomycin sodium							
27	Janssen Animal Health B.V.B.A.	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:	[F9 Turkeys]	[F9 12 weeks]	[F9 1]	[F9 1]	[F9 Use prohibited at least five days before slaughter]	[F9 30.9.2000]
				Chickens reared for laying	16 weeks	1	1	—	30.9.2000[c]

a First authorisation: Commission Directive 96/7/EC (OJ L 51, 1.3.1996, p. 45).

b First authorisation: Commission Directive 96/66/EC (OJ L 272, 25.10.1996, p. 32).

c First authorisation: Commission Directive 97/72/EC (OJ L 351, 23.12.1997, p. 55).

				0,2 g/100 g Sodium hydroxyde: 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 Sodium hydroxide: 0,0215 g/100 g Wheat middlings: 60 g/100 g				
			Active substance:	Diclazuril, $C_{17}H_9Cl_3N_4O_2$, (±)-4-chlorophenyl[2,6-dichloro-4-(2,3,4,5-tetrahydro-3,5-dioxo-1,2,4-triazin-2-yl)phenyl]acetonitrile, CAS number: 101831-37-2				

a First authorisation: Commission Directive 96/7/EC (OJ L 51, 1.3.1996, p. 45).

b First authorisation: Commission Directive 96/66/EC (OJ L 272, 25.10.1996, p. 32).

c First authorisation: Commission Directive 97/72/EC (OJ L 351, 23.12.1997, p. 55).

			Related impurities: Degradation compound (R064318): ≤ 0,2 % Other related impurities (R066891, R066896, R068610, R070156, R068584, R070016): ≤ 0,5 % individually Total impurities: ≤ 1,5 %						
28	Roche Vitamins Europe Ltd	Maduramicin ammonium alpha 1 g/100 g (Cygro 1 %)	**Additive composition:** Maduramicin ammonium alpha: 1 g/100 g Benzyl alcohol: 5 g/100 g Corn cob grits qs 100 g **Active substance:**	Turkeys	16 weeks	5	5	Use prohibited at least five days before slaughter Indicate in the instructions for use: Dangerous for equines This feedingstuff contains an ionophore: simultaneous use with	30.9.2000[b]

a First authorisation: Commission Directive 96/7/EC (OJ L 51, 1.3.1996, p. 45).

b First authorisation: Commission Directive 96/66/EC (OJ L 272, 25.10.1996, p. 32).

c First authorisation: Commission Directive 97/72/EC (OJ L 351, 23.12.1997, p. 55).

				Maduramicin ammonium alpha, $C_{47}H_{83}O_{17}N$, CAS number: 84878-61-5, ammonium salt of a polyether monocarboxylic acid produced by *Actinomadura yumaensis* (ATCC 31585) (NRRL 12515) Related impurities: Maduramicin ammonium beta: < 10 %			certain medicinal substances (e.g. tiamulin) can be contraindicated	

a First authorisation: Commission Directive 96/7/EC (OJ L 51, 1.3.1996, p. 45).

b First authorisation: Commission Directive 96/66/EC (OJ L 272, 25.10.1996, p. 32).

c First authorisation: Commission Directive 97/72/EC (OJ L 351, 23.12.1997, p. 55).

Textual Amendments

F9 Deleted by Commission Implementing Regulation (EU) No 888/2011 of 5 September 2011 concerning the authorisation of diclazuril as a feed additive for turkeys for fattening (holder of authorisation Janssen Pharmaceutica N.V.) and amending Regulation (EC) No 2430/1999 (Text with EEA relevance).

(**1**) OJ L 270, 14.12.1970, p. 1.

(**2**) OJ L 194, 27.7.1999, p. 17.

(**3**) OJ L 235, 17.9.1996, p. 39.

Status:
Point in time view as at 26/09/2011.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EC) No 2430/1999.