II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1914

of 19 October 2017

concerning the authorisation of salinomycin sodium (Sacox 120 microGranulate and Sacox 200 microGranulate) as a feed additive for chickens for fattening and chickens reared for laying and repealing Regulations (EC) No 1852/2003 and (EC) No 1463/2004 (holder of authorisation Huvepharma NV)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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 9(2) and 13(3) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) Salinomycin sodium 120 g/kg (Sacox 120 microGranulate) was authorised for 10 years in accordance with Directive 70/524/EEC as feed additive for chickens reared for laying by Commission Regulation (EC) No 1852/2003 ([3]) and for chickens for fattening by Commission Regulation (EC) No 1463/2004 ([4]). That additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of salinomycin sodium 120 g/kg (Sacox 120 microGranulate) as a feed additive for chickens for fattening and chickens reared for laying. In accordance with Article 7 of that Regulation, an application was submitted for the authorisation of the new formulation of salinomycin sodium 200 g/kg (Sacox 200 microGranulate) requesting that additive to be classified in the additive category 'coccidiostats and histomonostas'. In accordance with Article 13(3) of that Regulation, an application was submitted requesting the reduction of the withdrawal time before slaughter from one to zero days and requesting a modification of the Maximum Residue Levels ('MRLs') for that additive from 5 µg/kg of all wet tissues to 0,150 mg/kg of liver, 0,040 mg/kg of kidney, 0,015 mg/kg of muscle and 0,150 mg/kg of skin/fat. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).
([3]) Commission Regulation (EC) No 1852/2003 of 21 October 2003 authorising the use for 10 years of a coccidiostat in feedingstuffs (OJ L 271, 22.10.2003, p. 13).
([4]) Commission Regulation (EC) No 1463/2004 of 17 August 2004 concerning the authorisation for 10 years of the additive 'Sacox 120 microGranulate' in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances (OJ L 270, 18.8.2004, p. 5).

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 6 December 2016 ([1]) that, under the proposed conditions of use, the salinomycin sodium 120 g/kg (Sacox 120 microGranulate) and salinomycin sodium 200 g/kg (Sacox 200 microGranulate) do not have an adverse effect on animal health, human health or the environment. The Authority further concluded that the use of the salinomycin sodium 120 g/kg (Sacox 120 microGranulate) and of salinomycin sodium 200 g/kg (Sacox 200 microGranulate) is effective in the control of coccidiosis in chickens for fattening and that, by the provided studies, the conclusion is extended to chickens reared for laying. The Authority also concluded that the exposure estimates at the highest use level indicated an acceptable withdrawal time of zero days. The Authority also concluded that it is not necessary to set MRLs. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) However for control reasons, MRLs, as applied for, should be set for liver, kidney, muscle and skin/fat. It was also considered that field monitoring of *Eimeria* spp. resistance to salinomycin sodium shall be undertaken, preferably during the latter part of the period of authorisation.

(6) The assessment of the salinomycin sodium (Sacox 120 microGranulate and Sacox 200 microGranulate) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(7) Regulations (EC) No 1852/2003 and (EC) No 1463/2004 should be repealed.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparations specified in the Annex, belonging to the additive category 'coccidiostats and histomonostas' are authorised as a coccidiostat in animal nutrition, subject to the conditions laid down in the Annex.

Article 2

Repeal of Regulation (EC) No 1852/2003

Regulation (EC) No 1852/2003 is repealed.

Article 3

Repeal of Regulation (EC) No 1463/2004

Regulation (EC) No 1463/2004 is repealed.

Article 4

Transitional measures

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 9 May 2018 in accordance with the rules applicable before 9 November 2017 may continue to be placed on the market and used until the existing stocks are exhausted.

([1]) EFSA Journal 2017; 15(1):4670.

Article 5

Entry into force

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, 19 October 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive (trade name)	Composition, chemical formula, description, analytical method	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 with a moisture content of 12 %				
Coccidiostats and histomonostats										
51766	Huvepharma NV.	Salinomycin sodium 120 g/kg (Sacox 120 microGranulate) Salinomycin sodium 200 g/kg (Sacox 200 microGranulate)	*Additive composition* (Sacox120 microGranulate): Salinomycin sodium: 114-132 g/kg Silicon dioxide: 10-100 g/kg Calcium carbonate: 500-700 g/kg Solid form (Sacox 200 microGranulate): Salinomycin sodium: 190-220 g/kg Silicon dioxide: 50-150 g/kg Calcium carbonate: 50-150 g/kg Solid form *Characterisation of the active substance* Salinomycin sodium, $C_{42}H_{69}Na\ O_{11}$, CAS number: 55721-31-8,	Chickens for fattening	—	50	70	1. The additives shall be incorporated in compound feed in the form of a premixture. 2. The following shall be indicated in the instructions for use: 'Dangerous for equines and turkeys. This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g. tiamulin) can be contra-indicated'. 3. Salinomycin sodium shall not be mixed with other coccidiostats. 4. A post-market monitoring program on the resistance to bacteria and *Eimeria* spp. shall be planned and executed by the holder of authorisation.	9 November 2027	150 µg salinomycin sodium/kg of liver; 40 µg salinomycin sodium/kg of kidney; 15 µg salinomycin sodium/kg of muscle, and 150 µg salinomycin sodium/kg. skin/fat.
				Chickens reared for laying	12 weeks	50	50			

Identification number of the additive	Name of the holder of authorisation	Additive (trade name)	Composition, chemical formula, description, analytical method	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 with a moisture content of 12 %				
			sodium salt of a polyether monocarboxylic acid produced by fermentation of *Streptomyces azureus* (DSM 32267) Related impurities: — ≤ 10 mg elaiophylin/kg salinomycin sodium. — ≤ 2 g 17-epi-20-desoxy-salinomycin/kg salinomycin sodium. — ≤ 10 g 20-desoxysalinomycin/kg salinomycin sodium. — ≤ 10 g 18,19-dihydrosalinomycin/kg salinomycin sodium. — ≤ 10 g methylated salinomycin/kg salinomycin sodium. *Analytical method* (1) For the quantification of salinomycin in the feed additive: High Performance Liquid Chromatography using post-column derivatisation coupled to spectrophotometric detection (HPLC-PCD-UV-Vis).					5. Zero days of withdrawal time. 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing, eyes and skin protections.		

Identification number of the additive	Name of the holder of authorisation	Additive (trade name)	Composition, chemical formula, description, analytical method	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 with a moisture content of 12 %				
			For the quantification of salinomycin in premixtures and feedingstuffs: High Performance Liquid Chromatography using post-column derivatisation coupled to spectrophotometric detection (HPLC-PCD-UV-Vis) — EN ISO 14183.							

([1]) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports