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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of a preparation of semduramicin sodium (Aviax 5%) as a feed additive for chickens for fattening (holder of authorisation: Phibro Animal Health s.a.) and repealing Commission Regulation (EC) No 1443/2006

(Text with EEA relevance)

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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) 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(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[2].

(2) A preparation of semduramicin sodium (Aviax 5%) was authorised for 10 years as a feed additive for chickens for fattening by Commission Regulation (EC) No 1443/2006[3].

(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 authorisation of the preparation of semduramicin sodium (Aviax 5%) as a feed additive for chickens for fattening. The applicant requested the additive to be classified in the additive category ‘coccidiostats and histomonostats’. In this context, the applicant also requested a modification of certain conditions of the existing authorisation, consisting of a replacement of crystalline semduramicin by mycelial semduramicin in the additive composition, and of a reduction of the period between cessation of the administration of the additive and slaughter (hereafter referred to as ‘the withdrawal period’). That modification is to be considered within the context of the re-evaluation of the preparation. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 14 June 2018[4], 29 June 2022[5] and 14 November 2023[6] that, under the proposed

[1] OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.

[2] Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1, ELI: http://data.europa.eu/eli/dir/1970/524/oj).

[3] Commission Regulation (EC) No 1443/2006 of 29 September 2006 concerning the permanent authorisations of certain additives in feedingstuffs and an authorisation for 10 years for a coccidiostat (OJ L 271, 30.9.2006, p. 12, ELI: http://data.europa.eu/eli/reg/2006/1443/oj).

[4] EFSA Journal 2018;16(7):5341.

conditions of use, the preparation of semduramicin sodium (Aviax 5%) is safe for chickens for fattening up to the maximum recommended level (25 mg/kg complete feed) and the environment. It also concluded that the use of semduramicin sodium (Aviax 5%) at a maximum level of 25 mg/kg complete feed is safe for consumers with no withdrawal period and, that consequently, there is no need to set maximum residue limits for semduramicin sodium in foodstuffs derived from chickens fed with the preparation. The Authority could not conclude on the irritancy of the preparation of semduramicin sodium (Aviax 5%) to skin and eye nor on the potential for dermal and respiratory sensitisation. In this regard it reported that the model calculations on inhalation exposure of persons handling the additive indicated a serious risk. The Authority further concluded that the preparation of semduramicin sodium (Aviax 5%) has the potential to effectively control coccidiosis in chickens for fattening. It considered that there is a need for specific requirements of post-market monitoring and recommended carrying out field monitoring of *Eimeria* spp. resistance to semduramicin sodium in chickens for fattening, preferably during the latter part of the period of authorisation. The Authority also verified the report on the methods of analysis of the feed additive in feed and tissues submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) In view of the above the Commission considers that the preparation of semduramicin sodium (Aviax 5%) satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for chickens for fattening. It is appropriate to provide for a post-market monitoring on the resistance of *Eimeria* spp. to semduramicin sodium. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

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

(7) As a consequence of the authorisation of the preparation of semduramicin sodium (Aviax 5%) for chickens for fattening, Regulation (EC) No 1443/2006 should be repealed.

(8) 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 preparation specified in the Annex, belonging to the additive category ‘coccidiostats and histomonostats’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

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5 EFSA Journal 2022;20(8):7432.

6 EFSA Journal. 2023;21:e8467.

Article 2

Transitional measures

1. The feed additive semduramicin sodium (Aviax 5 %), as authorised by Regulation (EC) No 1443/2006, and premixtures containing this additive, which are produced and labelled before [*6 months after the date of entry into force of this Regulation – Date to be inserted by the OP]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the OP*] may continue to be placed on the market and used until the stocks concerned are exhausted.

2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before [*12 months after the date of entry into force of this Regulation – Date to be inserted by the OP*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the OP*] may continue to be placed on the market and used until the stocks concerned are exhausted.

Article 3

Repeal

Regulation (EC) No 1443/2006 is repealed.

Article 4

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,

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: coccidiostats and histomonostats									
51773	Phibro Animal Health s.a.	Semduramicin sodium (Aviax 5%)	***Additive composition*** Preparation of: - Mycelium: 166-333 g/kg additive, containing 48.7-53.9 g semduramicin sodium, - food grade mineral oil: 30-50 g/kg additive, - sodium carbonate: 40 g/kg additive, - sodium aluminosilicate: 20 g/kg additive, - Soybean mill run: quantum satis. Solid form. ***Characterisation of the active substance*** Semduramicin sodium: - $C_{45}H_{75}O_{16}Na$ - CAS number: 119068-77-8 - sodium {(2R,3S,4S,5R,6S)-2,4-dihydroxy-6-[(1R)-1-{(2S,5R,7S,8R,9S)-9-hydroxy-2-[(2S,2'R,3'S,5R,5'R)-5'-[(2S,3S,5R,6S)-6-hydroxy-3,5,6-trimethyloxan-2-yl]-3'-{[(2S,5S,6R)-5-methoxy-6-methyloxan-2-yl]oxy}-2-methyl[2,2'-bioxolan]-5-yl]-2,8-dimethyl-1,6-dioxaspiro[4.5]decan-7-yl}ethyl]-5-methoxy-3-methyloxan-2-yl}acetate Produced from *Actinomadura* spp. ATCC 53664. Related impurities: semduramicin epimer, semduramicin aglycon (without G ring), desmethyl semduramicin (A ring), desmethyl semduramicin (G ring), hydroxyl	Chickens for fattening	-	20	25	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall be incorporated in compound feed in the form of a premixture. 3. Semduramicin sodium shall not be mixed with other coccidiostats. 4. The following shall be indicated on the label of the additive, as well as of premixtures and compound feed containing it: 'This feedingstuff contains an ionophore: simultaneous use with tiamulin is contra-indicated'. 5. A post-market monitoring programme on the resistance of *Eimeria* spp. to semduramicin sodium shall be planned and executed by the holder of authorisation, in accordance with	*[10 years from the date of entry into force of this Regulation.* *To be completed by the Service responsible for the publication]*

			semduramicin (F ring), desmethoxyl semduramicin (A ring) and descarboxyl semduramicin: < 3 % each. Total impurities: ≤ 7 %. ***Analytical methods* (1)** For the quantification of semduramicin sodium in the feed additive and premixtures: High Performance Liquid Chromatography using post-column derivatisation coupled with photometric detection (HPLC-PCD-UV-Vis). For the quantification of semduramicin sodium in compound feeds: − High Performance Liquid Chromatography using single mass spectrometry (HPLC-MS) or post-column derivatisation coupled with photometric detection (HPLC-PCD-UV-Vis) – EN 16158, or − High performance liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS) – EN 17299.					Commission Regulation (EC) No 429/2008 (2). 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 by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

(2) Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/429/oj).