



2024/231

15.1.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/231

of 12 January 2024

concerning the authorisation of a preparation of halofuginone hydrobromide (Stenorol) as a feed additive for chickens for fattening, turkeys for fattening and turkeys reared for breeding (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) 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) The substance halofuginone hydrobromide was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. That substance was subsequently entered in the Register of feed additives as an existing product belonging to the additive category 'coccidiostats and histomonostats', in accordance with Article 10(1), point (b), 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 authorisation of a preparation of halofuginone hydrobromide (Stenorol) as a feed additive for chickens for fattening and turkeys. The applicant requested the additive to be classified in the additive category 'coccidiostats and histomonostats'. 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 30 September 2020 ⁽³⁾, 23 November 2022 ⁽⁴⁾ and 12 March 2023 ⁽⁵⁾ that, under the proposed conditions of use, the preparation of halofuginone hydrobromide (Stenorol) is safe for chickens for fattening and for turkeys up to a maximum of 12 weeks of age. It is safe for consumers provided a withdrawal period of three days before slaughter is applied and the recommended maximum residue limits (MRLs) are not exceeded, and for the environment. It also concluded that the preparation of halofuginone hydrobromide (Stenorol) is toxic by inhalation, dermal and ocular routes, is very irritant to both the eye and the skin, and is also a skin sensitiser. The Authority further concluded that the preparation of halofuginone hydrobromide (Stenorol) has the potential to control coccidiosis at the proposed conditions of use. It considered that there is a need for specific requirements of post-market monitoring and recommended that field monitoring of *Eimeria* spp. resistance to halofuginone hydrobromide in chickens for fattening and turkeys be undertaken, 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.

⁽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⁾ EFSA Journal 2020;18(11):6169.

⁽⁴⁾ EFSA Journal 2022;20(12):7716.

⁽⁵⁾ EFSA Journal 2023;21(4):7978.

- (5) In view of the above the Commission considers that the preparation of halofuginone hydrobromide (Stenorol) 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, turkeys for fattening and turkeys reared for breeding. It is appropriate to provide for a withdrawal period of three days before slaughter, the maximum residue limits recommended by the Authority and post-market monitoring on the resistance of *Eimeria* spp. to halofuginone hydrobromide. 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) 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.

Article 2

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are produced and labelled before 4 August 2024 in accordance with the rules applicable before 4 February 2024 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the preparation specified in the Annex, which are produced and labelled before 4 February 2025 in accordance with the rules applicable before 4 February 2024 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3

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, 12 January 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the 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	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 %				
Category: coccidiostats and histomonostats										
51764	Huvepharma NV	Halofuginone hydrobromide (Stenorol)	Additive composition Preparation of: — halofuginone hydrobromide: 0,6 % — povidone (polyvinylpyrrolidone): 1 %, — castor oil (macrogol glycerol ricinoleate): 2 %, — corn cobs: 96,4 %. Solid form.	Chickens for fattening	—	2	3	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Use prohibited at least 3 days before slaughter. 3. The additive shall be incorporated in compound feed in the form of a premixture. 4. Halofuginone hydrobromide shall not be mixed with other coccidiostats. 5. A post-market monitoring program on the resistance of <i>Eimeria</i> spp. to halofuginone hydrobromide shall be planned and executed by the holder of authorisation, in accordance with Commission Regulation (EC) No 429/2008 (?).	4 February 2034	50 µg halofuginone/kg of wet liver; 40 µg halofuginone/kg of wet kidney; 3 µg halofuginone/kg of wet muscle; 10 µg halofuginone/kg of wet skin/fat.
				Turkeys for fattening	12 weeks					
				Turkeys reared for breeding	12 weeks					
Characterisation of the active substance Halofuginone hydrobromide: — C ₁₆ H ₁₇ BrClN ₃ •HBr — CAS number: 64924-67-0 — trans-(±)-7-bromo-6-chloro-3-[3-(3-hydroxy-2-piperidyl)-2-oxopropyl]-4(3H)-quinazolinone hydrobromide — Produced by chemical synthesis.										

			Impurities: <i>cis</i>-isomer of halofuginone hydrobromide, cebrazone, methoxy cebegine and melylcebegine: ≤ 0,5 % each. Total impurities: ≤ 1 %. <i>Analytical methods</i> ⁽¹⁾ For the determination of halofuginone hydrobromide in the feed additive and premixtures: high performance liquid chromatography coupled with photometric detection (HPLC-UV). For the determination of halofuginone hydrobromide in compound feed: — High performance liquid chromatography coupled with photometric detection (HPLC-UV) – Commission Regulation (EC) No 152/2009 ⁽²⁾ or — High performance liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS) – EN 17299.					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.		
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			For the determination of halofuginone hydrobromide in tissues: high performance liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS).							
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(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 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

(³) 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).