



2023/2732

8.12.2023

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2732

of 7 December 2023

concerning the authorisation of a preparation of *Macleaya cordata* mixture as a feed additive for all poultry species for fattening (holder of authorisation: Phytobiotics Futterzusatzstoffe GmbH)

(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 an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Macleaya cordata* mixture as a feed additive. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of a preparation of *Macleaya cordata* mixture as a feed additive for all poultry species (excluding laying and breeding birds), requesting that additive to be classified in the category 'zootechnical additives' and in the functional group 'other zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 12 May 2023 ⁽²⁾ that, under the proposed conditions of use, the preparation of *Macleaya cordata* mixture is safe for chickens for fattening and other poultry species for fattening, and for the environment, and is of low concern for consumers. No conclusion could be drawn on the safety of the preparation of *Macleaya cordata* mixture for poultry species reared for laying and reared for breeding owing to a concern for genotoxicity linked to the presence in the preparation of the DNA intercalators sanguinarine and chelerythrine. It also concluded that the preparation of *Macleaya cordata* mixture was shown to be irritant to the eyes but not irritant to skin or a skin sensitiser, and that the potential of the additive to be a respiratory sensitiser could not be excluded. The Authority further concluded that the preparation of *Macleaya cordata* mixture, under the proposed conditions of use, has the potential to be efficacious in improving performance of chickens for fattening. This conclusion was extended to chickens reared for laying and reared for breeding and extrapolated to all poultry species for fattening, reared for laying or reared for breeding. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The applicant withdrew the application on 19 June 2023 for the authorisation of the preparation of *Macleaya cordata* mixture for poultry species reared for laying and reared for breeding.
- (6) In view of the above, the Commission considers that the preparation of *Macleaya cordata* mixture 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 all poultry species for fattening. 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2023;21(6):8052.

- (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 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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, 7 December 2023.

For the Commission
The President
Ursula VON DER LEYEN

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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 |
|---------------------------------------|-------------------------------------|----------|---|-------------------------------|-------------|--|-----------------|------------------|--------------------------------|
| | | | | | | mg of the additive/kg of complete feedingstuff with a moisture content of 12 % | | | |

Category of zootechnical additives. Functional groups: other zootechnical additives (improvement of performance parameters)

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|------|--------------------------------------|---------------------------------|---|-----------------------------------|---|----|-----|---|------------------|
| 4d26 | Phytobiotics Futterzusatzstoffe GmbH | <i>Macleaya cordata</i> mixture | <p><i>Additive composition:</i> Preparation of: — <i>Macleaya cordata</i> (Willd.) R. Br. extract: 0,5-1,2 % — <i>Macleaya cordata</i> (Willd.) R. Br. processed leaves: 30-64 %.</p> <p>With the following concentrations: — sanguinarine: $\geq 0,4$ % and $\leq 0,7$ % — chelerythrine: $\geq 0,23$ % and $\leq 0,34$ % — sum of sanguinarine, chelerythrine, protopine and allocryptopine: $\leq 1,4$ %.</p> <p>Solid form.</p> <p><i>Characterisation of the active substance:</i> <i>Macleaya cordata</i> (Willd.) R. Br. extract and <i>Macleaya cordata</i> (Willd.) R. Br. processed leaves including: — Sanguinarine (CAS No 2447-54-3) — Chelerythrine (CAS No 34316-15-9) — Protopine (CAS No 130-86-9) — Allocryptopine (CAS No 485-91-6)</p> | All poultry species for fattening | — | 45 | 150 | <ol style="list-style-type: none"> 1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Mixture with other additives is permitted provided that the amounts of sanguinarine and chelerythrine added to feedingstuffs by such mixtures is lower than the one resulting from the use of a single additive at the maximum or recommended level for the species or category of animals. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and eye protective equipment. | 28 December 2033 |
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| | | | <p><i>Analytical method</i> ⁽¹⁾ Determination of sanguinarine (phytochemical marker) in the feed additive: reversed phase high performance liquid chromatography coupled to fluorescence detection (HPLC-FLD). Determination of sanguinarine (phytochemical marker) in premixtures and compound feed: reversed phase high performance liquid chromatography coupled to mass spectrometry detection (HPLC-MS/MS).</p> | | | | | | |
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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