COMMISSION IMPLEMENTING REGULATION (EU) 2018/1559

of 17 October 2018

concerning the authorisation of cumin tincture (*Cuminum cyminum* L.) as a feed additive for all animal species

(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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of cumin tincture (*Cuminum cyminum* L.) as a feed additive for all animal species. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003. The applicant requested that the additive be classified in the additive category 'sensory additives'.

(3) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 April 2018 ([2]) that, under the proposed conditions of use, cumin tincture (*Cuminum cyminum* L.) does not have adverse effects on animal health, human health or the environment. The Authority has concluded that since cumin seeds are universally recognised to flavour food and their function in feed would be essentially the same as that in food, no further demonstration of efficacy is necessary. Therefore, that conclusion can be extrapolated for feed. The Authority further noted that for the safety of the additive for users a potential to be dermal/eye irritant cannot be excluded. In addition, the additive contains a variety of compounds known to cause allergic reactions in sensitive persons. Therefore, sensitisation may occur. Consequently, appropriate protective measures should be taken.

(4) 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) The assessment of this additive shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this additive should be authorised as specified in the Annex to this Regulation.

(6) The applicant proposed use levels for the substances concerned to the Authority. Having regard to that proposal, the Authority considered that certain use levels are safe. For the purpose of official controls along the food chain, the recommended maximum content of the active substance should be indicated on the label of the feed additive.

(7) The fact that the use of the substance concerned in water for drinking is not authorised should not preclude their use in compound feed, which is administered via water.

(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 substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', is authorised as a feed additive in animal nutrition subject to the conditions laid down in that Annex.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2018;16(5):5273

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, 17 October 2018.

For the Commission
The President
Jean-Claude JUNCKER

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
						ml of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b161	—	Cumin tincture	*Additive composition* Cumin tincture of *Cuminum cyminum* L. *Characterisation of the active substance* Tincture from *Cuminum cyminum* L. seeds as defined by the Council of Europe (1). — 98 % ± 0,5 % of a water/ethanol (3:1, v/v) mixture; — 2 ± 0,5 % of plant derived compounds; — total flavonoids ≤ 300 ppm; — total polyphenols ≤ 560 ppm; — total p-menth-3-en-7-al ≤ 8 ppm; — phytochemical marker: 4-iso-propylbenzaldehyde (cuminaldehyde): 25 ± 5 ppm. Liquid form CoE No 161 *Method of analysis* (2) For the quantification of the phytochemical marker (4-iso-propylbenzaldehyde) in the feed additive: gas chromatography coupled with flame ionisation detection (GC-FID)	All animal species	—		—	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,03 ml/kg feed' 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. 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 protection, safety glasses and gloves.	7 November 2028

(1) Natural sources of flavourings — Report No 2 (2007)
(2) Details of the methods of analysis are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports