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COMMISSION IMPLEMENTING REGULATION (EU) 2023/2632

of 27 November 2023

concerning the authorisation of disodium 5′-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80235 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 and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of disodium 5′-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80235 for all animal species. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of disodium 5′-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80235 as a feed additive for all animal species, requesting that additive to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. The applicant requested the additive to be authorised for use also in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of 'flavouring compounds' for use in water for drinking. Therefore, the use of this additive in water for drinking should not be allowed.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 26 January 2022 ([2]) and 21 March 2023 ([3]) that, under the proposed conditions of use, disodium 5′-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80235 is safe for all animal species, for consumers and for the environment. It concluded that disodium 5′-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80235 should be considered not toxic by inhalation, not irritant to skin or eyes and not a dermal sensitiser. The Authority further concluded that since disodium 5′-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80235 is recognised to flavour food and since its function in feed would be essentially the same as that in food, no further demonstration of efficacy is considered necessary. The Authority 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) In view of the above, the Commission considers that disodium 5′-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80235 satisfies the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised.

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

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2022;20(3):7153.
([3]) *EFSA Journal* 2023;21(4):7958.

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 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, 27 November 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	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: Sensory additives. Functional group: Flavouring compounds								
2b631i	Disodium 5′-inosinate	*Additive composition:* Disodium 5′-inosinate Solid form *Characterisation of active substance:* Disodium 5′-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80235 Purity: min. 97 % on dry matter basis. Chemical formula: $C_{10}H_{11}O_8N_4Na_2P{\cdot}7{,}5H_2O$ CAS number: 4691-65-0 *Analytical method* (1): For the identification of disodium 5'-inosinate (IMP) in the feed additive: FAO JECFA monograph 'disodium 5'-inosinate' For the determination of disodium 5'-inosinate (IMP) in the feed additive, flavouring premixtures and water: – High performance liquid chromatography coupled to UV detection (HPLC-UV)	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 alone or in combination with other authorised disodium 5′-ribonucleotides: 50 mg/kg of complete feedingstuff with a moisture content of 12 %'. 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.	18 December 2033

(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-feedadditives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en