Commission Implementing Regulation (EU) 2020/1764 of 25 November 2020 concerning the authorisation of disodium 5'-inosinate produced by fermentation with Corynebacterium stationis KCCM 80161 as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1764

of 25 November 2020

concerning the authorisation of disodium 5'-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80161 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 80161. This application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) This application concerns the authorisation of disodium 5'-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80161 as a feed additive for all animal species. The applicant requested this additive to be classified in the additive category ‘sensory additives’.

(4) The applicant requested the feed 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 disodium 5'#inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80161 in water for drinking should not be allowed. The fact that the additive is not authorised for use as a flavouring in water for drinking does not preclude its use in compound feed administered via water.

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 7 May 2020[(2)] that, under the proposed conditions of use, disodium 5'#inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80161 does not have adverse effects on animal health, consumer health or the environment. The Authority concluded

in the opinion that the additive is not toxic by inhalation, not irritant to skin or eyes and is not a dermal sensitiser. The Authority also concluded that the effect of disodium 5'-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80161 to increase the taste of food is well proven, and therefore, no further demonstration of its efficacy in feed is necessary. 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 additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of disodium 5'-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80161 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of disodium 5'-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80161 should be authorised as specified in the Annex to this Regulation.

(7) Restrictions and conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additive. Where such content is exceeded, certain information should be indicated on the label of premixtures.

(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

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.

Article 2

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, 25 November 2020.

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
						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 *Characterisation of the active substance* Disodium 5'-inosinate Produced by fermentation with *Corynebacterium stationis* (KCCM 80161) Purity: ≥ 97 % (% assay) Chemical formula: $C_{10}H_{11}N_4Na_2O_8P \cdot 7.5H_2O$ CAS number 4691-65-0 *Method of analysis*[a] For the identification	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 premixture, the storage conditions and the stability to heat treatment shall be indicated.	16.12.2030

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

			of disodium 5'-inosinate in the feed additive: FAO JECFA monographs 'disodium 5'-inosinate' and 'disodium 5′-ribonucleotides'. For the determination of disodium 5'-inosinate (IMP) in the feed additive and flavouring premixtures: high performance liquid chromatography coupled to UV detection (HPLC-UV)				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 shall be: 50 mg/kg of complete feedingstuff with a moisture content of 12 %'.
								4.	The functional group, the identification number, the

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									name and the added amount of the active substance shall be indicated on the label of the premixtures, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 50 mg/kg.

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

(**1**) OJ L 268, 18.10.2003, p. 29.

(**2**) EFSA Journal 2020;18(5):6140.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1764.