Commission Implementing Regulation (EU) 2018/238 of 15 February 2018 concerning the authorisation of disodium 5′-ribonucleotides, disodium 5′-guanylate and disodium 5′-inosinate as feed additives for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/238

of 15 February 2018

concerning the authorisation of disodium 5′-ribonucleotides, disodium 5′-guanylate and disodium 5′-inosinate as feed additives 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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) Disodium 5′-ribonucleotides, disodium 5′-guanylate and disodium 5′-inosinate (‘substances concerned’) were authorised without a time limit by Directive 70/524/EEC as feed additives for all animal species. Those products were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) 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 re-evaluation of the substances concerned as feed additives for all animal species. The applicant requested those additives be classified in the additive category ‘sensory additives’. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003. Lately the applicant withdrew the application for water for drinking.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 4 March 2014[(3)] that, under the proposed conditions of use the substances concerned do not have adverse effects on animal health, human health or the environment. The Authority further concluded that the function of the substances concerned in feed is similar to that in food. The Authority has already concluded that for food the substances concerned are efficacious, as they increase the food smell or palatability. Therefore,

that conclusion can be extrapolated for feed. The applicant withdrew the application for water for drinking. However, the substances concerned can be used within compound feeds which are subsequently administered via water.

(5) Restrictions and conditions should be provided for to allow better control. Since safety reasons do not require the setting of a maximum content and taking into account the re-evaluation performed by the Authority, recommended contents should be indicated on the label of the additive. Where such contents are exceeded, certain information should be indicated on the label of premixtures and on the labelling of compound feeds and feed materials.

(6) The Authority also concluded that in the absence of data the substances concerned should be considered as potentially hazardous to workers by skin, eyes and mucous membranes or inhalation exposure. Consequently, appropriate protective measures should be taken 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.

(7) The assessment of the substances concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied except for the substances concerned produced by fermentation. The applicant asked for the authorisation of the substances concerned produced by fermentation and RNA hydrolysis. The lack of information on the production strains does not allow to assess the safety of the substances concerned produced by fermentation despite they are '*per se*' safe. Accordingly, the use of the substances concerned should be authorised as specified in the Annex to this Regulation and the authorisation of those additives produced by fermentation should be denied.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/238. (See end of Document for details)*

Article 2

Denial

The authorisation of disodium 5′-ribonucleotides, disodium 5′-guanylate and disodium 5′-inosinate produced by fermentation is denied.

Article 3

Transitional measures

1 The substances specified in the Annex and the substances mentioned in Article 2, and premixtures containing those substances and which are produced and labelled before 15 December 2018 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Compound feed and feed materials containing the substances as specified in the Annex and the substances mentioned in Article 2 which are produced and labelled before 15 September 2019 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3 Compound feed and feed materials containing the substances as specified in the Annex and the substances mentioned in Article 2 which are produced and labelled before 15 September 2020 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 4

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, 15 February 2018.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/238. (See end of Document for details)*

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									
2b635	—	Disodium 5′-ribonucleotide	*Additive composition* Disodium 5′-ribonucleotides *Characterisation of the active substance* Disodium 5′-ribonucleotides: a mixture of disodium 5′-guanylate (GMP) and disodium 5′-inosinate (IMP). Produced by RNA hydrolysis Purity: min.: 97 % assay Chemical formula: —	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance or the combination of	15.3.2028

$C_{10}H_{11}N_4O_8P \cdot nH_2O$

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/238. (See end of Document for details)*

			— $C_{10}H_{12}N_5Na_2O_8P \cdot nH_2O$ *Method of analysis*[a] For the identification of GMP and IMP in the feed additive: JECFA monograph, Specifications for food additives: Disodium 5′-Ribonucleotides. For the determination of GMP and IMP in the feed additive and premixtures of flavourings: High performance Liquid Chromatography coupled to UV detection (HPLC-UV).				disodium 5′-ribonucleotide (2b635), disodium 5′-guanylate (2b627) and disodium 5′-inosinate (2b631) shall be: 50 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: Recommended maximum content of the active substance or the combination of disodium 5′-ribonucleotide, disodium 5′-guanylate

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