II

(Non-legislative acts)

REGULATIONS

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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).
([3]) *EFSA Journal* 2014;12(3):3606.

(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.

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

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: — $C_{10}H_{11}N_4O_8P \cdot nH_2O$ — $C_{10}H_{12}N_5Na_2O_8P \cdot nH_2O$ *Method of analysis* (1) 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).	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 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 and disodium 5′-inosinate of complete feedingstuff with a moisture content of 12 %: 50 mg/kg’.	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of premixtures and on the labelling of feed materials and compound feedingstuffs, if the following content of the active substance or the combination of disodium 5′-ribonucleotide, disodium 5′-guanylate and disodium 5′-inosinate in complete feedingstuff with a moisture content of 12 % is exceeded: 50 mg/kg. 6. 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.	
2b627	—	Disodium 5′-guanylate	*Additive composition* Disodium 5′-guanylate (GMP) *Characterisation of the active substance* Disodium 5′-guanylate Produced by RNA hydrolysis	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.	15.3.2028

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 %			
			Purity: min.: 97 % assay Chemical formula: $C_{10}H_{12}N_5Na_2O_8P \cdot n\ H_2O$ CAS number: 5550-12-9 *Method of analysis* ([1]) For the identification of GMP in the feed additive: JECFA monograph, Specifications for food additives: Disodium 5′-Ribonucleotides. For the determination of GMP in the feed additive and premixtures of flavourings: High performance Liquid Chromatography coupled to UV detection (HPLC-UV).					3. The recommended maximum content of the active substance or the combination of 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 and disodium 5′-inosinate of complete feedingstuff with a moisture content of 12 %: 50 mg/kg'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of premixtures and on the labelling of feed materials and compound feedingstuffs, if the following content of the active substance or the combination of disodium 5′-ribonucleotide disodium 5′-guanylate and disodium 5′-inosinate in complete feedingstuff with a moisture content of 12 % is exceeded: 50 mg/kg.	

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 %			
								6. 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.	
2b631	—	Disodium 5′-inosinate	*Additive composition* Disodium 5′-inosinate (IMP) *Characterisation of the active substance* Disodium 5′-inosinate Produced by RNA hydrolysis Purity: min. 97 % assay Chemical formula: $C_{10}H_{11}N_4O_8P \cdot nH_2O$ CAS number 4691-65-0 *Method of analysis* (1) For the identification of IMP in the feed additive: JECFA monograph, Specifications for food additives: Disodium 5′-Ribonucleotides.	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 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 %.	15.3.2028

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 %			
			For the determination of IMP in the feed additive and premixtures of flavourings: High performance Liquid Chromatography coupled to UV detection (HPLC-UV).					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 and disodium 5′-inosinate of complete feedingstuff with a moisture content of 12 %: 50 mg/kg'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of premixtures and on the labelling of feed materials and compound feedingstuffs, if the following content of the active substance or the combination of disodium 5′-ribonucleotide, disodium 5′-guanylate and disodium 5′-inosinate in complete feedingstuff with a moisture content of 12 % is exceeded: 50 mg/kg. 6. 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.	

(1) 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