COMMISSION IMPLEMENTING REGULATION (EU) 2019/901

of 29 May 2019

concerning the authorisation of riboflavin produced by *Ashbya gossypii* (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5′-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) (sources of vitamin B_2) 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) Riboflavin produced by *Ashbya gossypii* (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5′-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) were authorised as sources of vitamin B_2 without a time limit as feed additives for all animal species in accordance with Directive 70/524/EEC. Those additives 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, two applications were submitted for the re-evaluation of riboflavin produced by Ashbya gossypii (DSM 23096), riboflavin produced by Bacillus subtilis (DSM 17339 and/or DSM 23984) and riboflavin 5′-phosphate sodium salt produced by Bacillus subtilis (DSM 17339 and/or DSM 23984) for all animal species, requesting those additives to be classified in the additive category 'nutritional additives'. One application concerns riboflavin produced by *Ashbya gossypii* (DSM 23096) and the other application concerns riboflavin and riboflavin 5′-phosphate ester monosodium salt, both produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984). Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) In accordance with Article 7 of Regulation (EC) No 1831/2003, one of the two applications also requested the authorisation of riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5′-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) as feed additives for all animal species for use in water for drinking. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003 for the use in water for drinking.

(5) The European Food Safety Authority ('the Authority') concluded in its opinions of 3 December 2015 ([3]) and 13 June 2018 ([4]) that, under the proposed conditions of use, riboflavin produced by *Ashbya gossypii* (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5′-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) do not have adverse effects on animal health, consumer safety or the environment. It also concluded that the additives containing riboflavin produced by Ashbya gossypii (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5′-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) are not irritant to skin and eyes. In the absence of data, the Authority cannot conclude on skin sensitisation. Riboflavin is a recognised as photosensitiser, which may elicit skin and eye photoallergic reactions. Workers might be exposed to a respirable dust when handling riboflavin and riboflavin 5′-phosphate sodium salt; in the absence of data on inhalation toxicity, the Authority cannot conclude on a possible risk by inhalation. Therefore, the Commission

([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 2016;14(1):4349.
([4]) EFSA Journal 2018;16(7):5337.

consider that appropriate protective measures should be taken to prevent effects on human health, in particular as regards the users of the additive. The Authority further concluded that riboflavin produced by *Ashbya gossypii* (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5′-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) are effective sources of vitamin B_2 in covering the animal's nutritional requirements. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis in feed and, where applicable, in water, submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of riboflavin produced by *Ashbya gossypii* (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5′-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied for the use in feed and for riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5′-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) also for the use in water for drinking. Accordingly, the use of those additives should be authorised as specified in the Annex to this Regulation.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for 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.

(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 substances specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional Measures

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 23 June 2019 in accordance with the rules applicable before 23 June 2019 may continue to be placed on the market and used until 23 December 2019.

2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 23 June 2020 in accordance with the rules applicable before 23 June 2019 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 which are produced and labelled before 23 June 2021 in accordance with the rules applicable before 23 June 2019 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 3

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, 29 May 2019.

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 additive/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: Vitamins, provitamins and chemically well-defined substances having similar effect.									
3a825i	—	'Riboflavin' or 'Vitamin B_2'	*Additive composition* Riboflavin produced by *Ashbya gossypii* DSM 23096 *Characterisation of the active substance* Riboflavin $C_{17}H_{20}N_4O_6$ CAS number: 83-88-5 Riboflavin solid form produced by *Ashbya gossypii* DSM 23096 Purity criteria: min. 80 % of riboflavin *Method of analysis* (1) For the determination of Riboflavin in the feed additive: spectrophotometry at 444 nm For the determination of Riboflavin in premixtures: high-Performance Liquid Chromatography coupled to UV detector, HPLC-UV (VDLUFA Bd.III, 13.9.1) For the determination of Riboflavin in feedingstuffs: high Performance Liquid Chromatography with Fluorescence detection, HPLC-FL (EN 14152)	All animal species	—	—	—	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. 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.	23 June 2029

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 additive/kg of complete feedingstuff with a moisture content of 12 %			
3a825ii	—	'Riboflavin' or 'Vitamin B_2'	*Additive composition* Riboflavin *Characterisation of the active substance* Riboflavin $C_{17}H_{20}N_4O_6$ CAS number: 83-88-5 Riboflavin solid form produced by *Bacillus subtilis* DSM 17339 and/or DSM 23984 Purity criteria: min. 96 %, *Method of analysis* (1) For the determination of Riboflavin in the feed additive: spectrophotometry at 444 nm (Ph.Eur.6.0, method 01/2008:0292) For the determination of Riboflavin in premixtures: high-Performance Liquid Chromatography coupled to UV detector, HPLC-UV (VDLUFA Bd.III, 13.9.1) For the determination of Riboflavin in feedingstuffs and water: high Performance Liquid Chromatography with Fluorescence detection, HPLC-FL (EN 14152)	All animal species	—	—	—	1. Riboflavin may be placed on the market and used as an additive consisting of a preparation. 2. May be used in water for drinking. 3. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 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.	23 June 2029

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 additive/kg of complete feedingstuff with a moisture content of 12 %			
3a 826		'Riboflavin 5′-phosphate monosodium salt' or 'Vitamin B_2'	*Additive composition* Riboflavin 5′-phosphate ester monosodium salt *Characterisation of the active substance* Riboflavin 5′-phosphate monosodium salt $C_{17}H_{22}N_4O_9PNa$ CAS number: 130-40-5 Riboflavin 5′-phosphate ester monosodium salt solid form produced after phosphorylation of riboflavin 98 % produced by *Bacillus subtilis* DSM 17339 and/or DSM 23984. Purity criteria: min. 65 %, *Method of analysis* (1) For the determination of Riboflavin 5′-phosphate monosodium salt in feed additive: spectrophotometry method at 444 nm (Ph.Eur.6.0, method 01/2008:0786) For the determination of Riboflavin in premixtures: high-Performance Liquid Chromatography coupled to UV detector, HPLC-UV (VDLUFA Bd.III, 13.9.1) For the determination of Riboflavin 5′-phosphate monosodium salt (as total Vitamin B_2) in feedingstuffs and water: high Performance Liquid Chromatography with Fluorescence detection, HPLC-FL (EN 14152)	All animal species	—	—	—	1. May be used in water for drinking. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. 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.	23 June 2029

(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