EUROPEAN
COMMISSION

Brussels, XXX
SANTE /10987089/2023 CIS
(POOL/G5/2023/10987089/10987089-EN CIS.docx)
[…](2024) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of nicotinic acid and niacinamide as feed additives for all animal species and repealing Implementing Regulation (EU) No 642/2013

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

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concerning the renewal of the authorisation of nicotinic acid and niacinamide as feed additives for all animal species and repealing Implementing Regulation (EU) No 642/2013

(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 an authorisation.

(2) Niacin and niacinamide were authorised for a period of 10 years as feed additives for all animal species by Commission Implementing Regulation (EU) No 642/2013[2].

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, two applications were submitted for the renewal of the authorisation of niacin and niacinamide for all animal species, requesting the additives to be classified in the additive category ‘nutritional additives’ and in the functional group ‘vitamins, pro-vitamins and chemically well-defined substances having similar effect’. Those applications were accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003. The Commission considers that the name of the additive “niacin” used in the initial authorisation should be replaced by the name “nicotinic acid” as the term “niacin” is one of the generic names used for nicotinic acid but also for other substances such as nicotinamide and related derivatives.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 26 September 2023[3] that the applicant provided evidence that nicotinic acid and niacinamide remain safe for all animal species, consumers and the environment under the conditions of use currently authorised. The Authority concluded that nicotinic acid and niacinamide remain efficacious as an effective source of niacin in animal nutrition and that nicotinic acid and niacinamide are not irritant to skin but irritant to eyes. The Authority further concluded that they are not dermal sensitisers and the exposure through inhalation is likely. It did not consider that there is a need for specific requirements of post-market monitoring.

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1 OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.

2 Commission Implementing Regulation (EU) No 642/2013 of 4 July 2013 concerning the authorisation of niacin and niacinamide as feed additives for all animal species (OJ L 186, 5.7.2013, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2013/642/oj).

3 EFSA Journal 2023;21(10):8359 and EFSA Journal 2023;21(10):8357.

(5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of nicotinic acid and niacinamide as feed additives in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005[4], an evaluation report of the Reference Laboratory is therefore not required.

(6) In view of the above, the Commission considers that nicotinic acid and niacinamide satisfy the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of those additives should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of nicotinic acid, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation as a result of the change of the name of the additive "niacin" by "nicotinic acid".

(8) As a consequence of the renewal of the authorisation of nicotinic acid and niacinamide, Implementing Regulation (EU) No 642/2013 should be repealed.

(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
Renewal of the authorisation

The authorisation of 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', is renewed, subject to the conditions laid down in that Annex.

Article 2
Repeal

Implementing Regulation (EU) No 642/2013 is repealed.

Article 3
Transitional measures

1. The substance nicotinic acid specified in the Annex and premixtures containing that substance which are produced and labelled before [6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the

[4] Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: http://data.europa.eu/eli/reg/2005/378/oj).

publication] may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the substance nicotinic acid specified in the Annex, which are produced and labelled before [12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] 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 substance nicotinic acid specified in the Annex, which are produced and labelled before [24 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] 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,

For the Commission
The President
Ursula VON DER LEYEN