# 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 (Text with EEA relevance)

## 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

(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) Niacin (nicotinic acid) and niacinamide (nicotinamide) were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for use on all animal species as part of the group 'Vitamins, pro-vitamins and chemically well-defined substances having similar effect'. Those feed additives were subsequently entered in the Community 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, five applications were submitted for the re-evaluation of niacin and niacinamide, as a feed additive for all animal species, requesting those additives to be classified in the additive category 'nutritional additives'. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 22 May 2012[(3)], 14 June 2012[(4)(5)(6)], and 12 September 2012[(7)] that, under the proposed conditions of use in feed, niacin and niacinamide do not have an adverse effect on animal and consumer health, and are not expected to pose additional risk for the environment. The Authority does not consider that there is a need for specific requirements of post-market monitoring. The Authority also concluded that no safety concerns would arise for users provided that appropriate protective measures are taken. It also verified the

report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of niacin and niacinamide shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those additives should be authorised as specified in the Annex to this Regulation.

(6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for the disposal of existing stocks of the additive, pre-mixtures and compound feed containing it, as authorised by Directive 70/524/EEC.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1*

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 an additive in animal nutrition subject to the conditions laid down in that Annex.

*Article 2*

The substances specified in the Annex and feed containing those substances, which are produced and labelled before 25 January 2014 in accordance with the rules applicable before 25 July 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

*Article 3*

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, 4 July 2013.

*For the Commission*

*The President*

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 642/2013. (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 of nutritional additives. Functional group: vitamins, provitamins and chemically well defined substances having a similar effect | | | | | | | | | |
| 3a314 | — | Niacin | | *Additive composition* Niacin, not less than 99 % *Characterisation of the active substance* Chemical names: niacin, nicotinic acid Chemical formula: $C_6H_5NO_2$ CAS number: 59-67-6 Einecs 200-441-0 *Method of Analysis*[a] — | — | — | — | 1. In directions for use of the additive and premixture, indicate the storage conditions.<br>2. Niacin may be used also via water for drinking.<br>3. For safety: breathing, eye and skin protection shall be used during handling. | 25 July 2023 |

**a** Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

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| | | | | | the feed additive: Titration with sodium hydroxide; European Pharmacopoeia method (Ph. Eur. 6th Edition, monograph 0459) | | | | |
| | | | | — | For the determination of niacin (nicotinic acid) in premixtures, feedingstuffs and water: Ion-pair Reversed Phase High Performance Liquid Chromatography coupled to UV detector (RP-HPLC-UV) | | | | |
| 3a315 | — | Niacinamide | *Additive composition* Niacinamide, not less than 99 % | — | — | — | — | 1. | In the directions for use of the |

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