Commission Implementing Regulation (EU) 2020/376 of 5 March 2020 concerning the authorisation of Norbixin (annatto F) as a feed additive for cats and dogs (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/376

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concerning the authorisation of Norbixin (annatto F) as a feed additive for cats and dogs

(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(2) of Regulation (EC) No 1831/2003 provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) Norbixin (annatto F) was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for dogs and cats belonging to the group ‘colourants, including pigments’, under the heading ‘colouring agents authorised for colouring foodstuffs by Community rules other than Patent blue V, Acid brilliant green BS, and Canthaxanthin’. This colourant was not specifically authorised but entered in this generic entry. The additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) 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 Norbixin (annatto F) as a feed additive for dogs and cats. The applicant requested the additive to be classified in the additive category ‘sensory additives’ and in the functional group ‘colourants’. The application was 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 opinion of 22 March 2017[(3)] that, under the proposed conditions of use, Norbixin (annatto F) does not have an adverse effect on animal health. It also concluded that the substance is a strong alkaline solution that makes it corrosive and therefore harmful for the user. Therefore, the Commission considers that appropriate protective measures should be

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taken to prevent adverse effects on human health, in particular as regards the users of the additive. In accordance with Commission Regulation (EC) No 429/2008[4], phase I of the environmental risk assessment has determined that Norbixin (annatto F), as an additive intended for non-food producing animals, is exempted from further assessment due to the unlikelihood of a significant environmental effect, there being no scientifically-based evidence for concern having been identified by the Authority in its above-mentioned opinion. The Authority further concluded that the additive concerned is effective in adding colour to feedingstuffs. 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 additive in feed submitted by the European Union Reference Laboratory set up by Regulation (EC) No 1831/2003. The report of the European Union Reference Laboratory for Feed Additives (EURL-FA) showed that the applicant did not submit any experimental data for the quantification of Norbixin (annatto F) in feedingstuffs. The applicant was requested to provide such data and the method was validated and included in an addendum of the EURL-FA report.

(5) The assessment of Norbixin (annatto F) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that additive 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 of the substance concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(7) 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 substance specified in the Annex, belonging to the additive category ‘sensory additives’ and to the functional group ‘colourants’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1 The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 26 September 2020 in accordance with the rules applicable before 26 March 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Feed materials and compound feed containing the substance specified in the Annex which are produced and labelled before 26 March 2022 in accordance with the rules applicable

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before 26 March 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

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, 5 March 2020.

For the Commission

The President

Ursula VON DER LEYEN

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ANNEX

Identification number of the additive	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: Colourants. (i) substances that add or restore colour in feedingstuffs								
2a160b	Norbixin (annatto F)	**Additive composition** Liquid preparation of annatto F containing 2,3-2,7 % norbixin potassium salt **Characterisation of the active substance:** Alkali processed norbixin,acid precipitated (annatto F) is described as the potassium salt of norbixin (dipotassium 6,6'-diapo-psi,psi-carotenedioate); It is a carotenoid derivative prepared by	Cats Dogs			13 16	1. 2.	26.3.2030

	the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures

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