COMMISSION IMPLEMENTING REGULATION (EU) 2015/244

of 16 February 2015

concerning the authorisation of Quinoline Yellow as a feed additive for non food-producing animals

(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) Quinoline Yellow was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for non food-producing animals and for food-producing animals as regards certain processed feedingstuffs as part of the group 'Colourants'. This substance was subsequently entered in the Register of feed additives established in Article 17 of Regulation (EC) No 1831/2003 as an existing product, 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 Quinoline Yellow as a feed additive for non food-producing animals and, in accordance with Article 7 of that Regulation, the applicant requested that additive to 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.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 10 July 2013 that, under the proposed conditions of use in feed, Quinoline Yellow does not have an adverse effect on animal health, human health or the environment. Considering the evidence provided by the applicant, the Authority also concluded that the efficacy of Quinoline yellow with respect to the dose and the nature of the feedingstuffs and their processing cannot be assessed. However, the Authority also stated that for this additive, which is authorised in food, where the function for feed is the same as that for food, no further demonstration of efficacy might be necessary. As the recommended maximum level proposed by the Authority for this additive is similar to the levels authorised for food in different types of products, the Commission considered that there is sufficient evidence of the efficacy of this substance. 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.

(5) The assessment of Quinoline Yellow 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 substance 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 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,

([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).

HAS ADOPTED THIS REGULATION:

Article 1

The substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'colourants: substances that add or restore colour in feedingstuffs', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

The substance specified in the Annex and feed containing that substance, and which are produced and labelled before 9 March 2017 in accordance with the rules applicable before 9 March 2015, 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, 16 February 2015.

For the Commission

The President

Jean-Claude JUNCKER

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 of kg of complete feedingstuff with a moisture content of 12 %			
Category of sensory additives. Functional group: Colourants. (i) substances that add or restore colour in feedingstuffs								
2a104	Quinoline Yellow	*Additive composition* Quinoline Yellow Quinoline Yellow is described as the sodium salt as the principal component *Characterisation of the active substance* Percentage for the components of Quinoline yellow is: — 2-(2-quinolyl) indan-1,3-dione-disulfonates: ≥ 80 %, — 2-(2-quinolyl) indan-1,3-dione-monosulfonates: ≤ 11 %, — 2-(2-quinolyl) indan-1,3-dione-trisulfonates: ≤ 7 %. Chemical formula: $C_{18}H_9N\ Na_2O_8S_2$ (sodium salt) CAS No: 8004-92-0 (principal component) Quinoline Yellow solid form, produced by chemical synthesis Purity criteria: Colouring matter ≥ 70 % of, calculated as the sodium salt Calcium and potassium salts ≤ 30 % *Analytical methods* (1) For the quantification of total colouring matters content of Quinoline Yellow in the feed additive and feedingstuffs: spectrophotometry at 411 nm (FAO JECFA monographs No 1, Vol. 4).	Non food-producing animals	—	—	25	1. In the directions for use of the additive and premixture, indicate the storage and the stability conditions. 2. For safety: breathing protection, safety glasses and gloves should be worn during handling.	9 March 2025

(1) Details of the analytical methods are available at the following address of European Union Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports