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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of lutein and lutein/zeaxanthin extracts from *Tagetes erecta* as feed additives for poultry (except turkeys) for fattening and laying and for minor poultry species for fattening and laying

(Text with EEA relevance)

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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 nutrition¹, 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/EEC² and Article 4 for the authorisation of a new use of an additive.
- (2) Lutein and lutein/zeaxanthin extracts from *Tagetes erecta* were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for poultry belonging to the group ‘Colourants, including pigments’, under the heading ‘Carotenoids and xanthophylls’. These two extracts were authorised under the common name “lutein” without any specification so the request for this two forms lutein and lutein/zeaxanthin fell within the generic entrance ‘lutein’. The additives were 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 4 and 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the authorisation of lutein and lutein/zeaxanthin extracts from *Tagetes erecta* in water for drinking and the re-evaluation of lutein and lutein/zeaxanthin” from *Tagetes erecta* as feed additives for poultry (except turkeys) for fattening and for laying and minor poultry species for fattening and for laying. The applicant requested the additives to be classified in the additive category ‘sensory additives’ and in the functional group ‘colourants: (ii) substances which, when fed to animals, add colours to food of animal origin’. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

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).

- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 3 April 2019³ that, under the proposed conditions of use, lutein and lutein/zeaxanthin extracts from *Tagetes erecta* do not have an adverse effect on animal health, consumer safety or the environment. It stated that the conclusion on the safety and efficacy of lutein and lutein/zeaxanthin extracts from *Tagetes erecta* for poultry (except turkeys) for fattening and for laying can be extrapolated to minor poultry for fattening and for laying. It also concluded that the active substances are viscous substances, so operators will not be exposed by inhalation. The applicant recognises that the active substances may be irritant to skin and eyes. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular, as regards the users of the additive, including the use of the additives in the form of a preparation, where toxicity by inhalation or due to the potential skin/eye irritant nature of the substance cannot be excluded. The Authority further concluded that the additives concerned are effective in adding colour to food of animal origin. 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.
- (5) As regards the use in water for drinking, the Commission considers that the simultaneous use of the additives in water for drinking and feed is difficult to manage, as there are maximum levels established for safety reasons and there are also other additives containing xanthophylls and carotenoids that may be used in feed. The simultaneous use lutein and lutein/zeaxanthin extracts from *Tagetes erecta* in water for drinking and feed increases the ways of administration and the risk to exceed the maximum levels authorised for additives containing carotenoids and xanthophylls. For lutein 80 mg/kg alone or with other carotenoids or xanthophylls and lutein/zeaxanthin 50mg/kg alone or with other carotenoids or xanthophylls. Consequently, the use in water for drinking is denied.
- (6) The assessment shows that the conditions for authorisation for lutein and lutein/zeaxanthin extracts from *Tagetes erecta*, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that 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 of 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,

³ EFSA Journal 2019; 17(5):5698.

HAS ADOPTED THIS REGULATION:

Article 1

The substances specified in the Annex, belonging to the additive category ‘sensory additives’ and to the functional group ‘flavouring compounds’, are authorised as feed additives in animal nutrition subject to the conditions laid down in that Annex.

Article 2

1. The substances specified in the Annex and premixtures containing those substances, 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 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 substances as 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.

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,

For the Commission
The President
Ursula von der LEYEN