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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of petitgrain bigarade essential oil as a feed additive for all animal species

(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 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. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[2].

(2) Petitgrain bigarade essential oil was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. That additive was subsequently entered in the Register of feed additives as 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 petitgrain bigarade essential oil for all animal species.

(4) The applicant requested petitgrain bigarade essential oil to be authorised for use also in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of flavouring compounds for use in water for drinking. Therefore, the use of petitgrain bigarade essential oil in water for drinking should not be allowed.

(5) The applicant requested the additive to be classified in the additive category ‘sensory additives’ and in the functional group ‘flavouring compounds’. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(6) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 5 May 2021[3] that, under the proposed conditions of use, petitgrain bigarade essential oil does not have adverse effects on animal health, consumer health or the environment. The Authority also concluded that petitgrain bigarade essential oil should be considered as an irritant to skin and eyes, and as a skin and respiratory sensitiser.

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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).

3 EFSA Journal 2021;19(6):6624.

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.

(7) The Authority concluded, that petitgrain bigarade essential oil is recognised to flavour food and its function in feed would be essentially the same as that in food, therefore, no further demonstration of efficacy is considered necessary. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(8) The assessment of petitgrain bigarade essential oil 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.

(9) Certain conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additive. Where such content is exceeded, certain information should be indicated on the label of premixtures.

(10) The fact that petitgrain bigarade essential oil is not authorised for use as a flavouring in water for drinking does not preclude its use in compound feed which is administered via water.

(11) 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.

(12) 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 ‘flavouring compounds’, 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 this 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 OP]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the OP*] 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 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 OP*] in accordance with the rules

applicable before [*the date of entry into force of this Regulation – Date to be inserted by the OP*] 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 as 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 OP*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the OP*] 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 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,

For the Commission
The President
Ursula VON DER LEYEN