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

of XXX

concerning the authorisation of undec-10-enal, terpineol acetate, d,l borneol, l-carvone, d-camphor, d,l-isobornyl acetate, 3-propylideneephthalide, phenylacetic acid, methyl salicylate, thymol, carvacrol, benzothiazole, terpinolene, d,l-isoborneol, trans-menthone, d,l-bornyl acetate, 3-butylideneephthalide, phenylacetaldehyde, phenethyl acetate, phenethyl phenylacetate, methyl phenylacetate, ethyl phenylacetate, isobutyl phenylacetate, 3-methylbutyl phenylacetate, 2-methoxyphenol, 2-methoxy-4-methylphenol, 4-ethylguaiacol, 2-methoxy-4-vinylphenol, 4-ethylphenol, 2-methylphenol, 4-methylphenol, 2,6-dimethoxyphenol, phenol, 2,6-dimethylphenol, 2-isopropylphenol, benzene-1,3-diol, alpha-phellandrene, alpha-terpinene, gamma-terpinene and l-limonene as feed additives for all animal species and amending Implementing Regulation (EU) 2018/245 as regards the terms of authorisation of d,l-isomenthone as a feed additive for all animal species

(Text with EEA relevance)

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concerning the authorisation of undec-10-enal, terpineol acetate, d,l borneol, l-carvone, d-camphor, d,l-isobornyl acetate, 3-propylidenephthalide, phenylacetic acid, methyl salicylate, thymol, carvacrol, benzothiazole, terpinolene, d,l-isoborneol, trans-menthone, d,l-bornyl acetate, 3-butylidenephthalide, phenylacetaldehyde, phenethyl acetate, phenethyl phenylacetate, methyl phenylacetate, ethyl phenylacetate, isobutyl phenylacetate, 3-methylbutyl phenylacetate, 2-methoxyphenol, 2-methoxy-4-methylphenol, 4-ethylguaiacol, 2-methoxy-4-vinylphenol, 4-ethylphenol, 2-methylphenol, 4-methylphenol, 2,6-dimethoxyphenol, phenol, 2,6-dimethylphenol, 2-isopropylphenol, benzene-1,3-diol, alpha-phellandrene, alpha-terpinene, gamma-terpinene and l-limonene as feed additives for all animal species and amending Implementing Regulation (EU) 2018/245 as regards the terms of authorisation of d,l-isomenthone as a feed additive 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 nutrition¹, and in particular Articles 9(2) and 13(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 and modifying such authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC².
- (2) The substances undec-10-enal, terpineol acetate, d,l borneol, l-carvone, d-camphor, d,l-isobornyl acetate, 3-propylidenephthalide, phenylacetic acid, methyl salicylate, thymol, carvacrol, benzothiazole, terpinolene, d,l-isoborneol, trans-menthone, d,l-bornyl acetate, 3-butylidenephthalide, phenylacetaldehyde, phenethyl acetate, phenethyl phenylacetate, methyl phenylacetate, ethyl phenylacetate, isobutyl phenylacetate, 3-methylbutyl phenylacetate, 2-methoxyphenol, 2-methoxy-4-methylphenol, 4-ethylguaiacol, 2-methoxy-4-vinylphenol, 4-ethylphenol, 2-methylphenol, 4-methylphenol, 2,6-dimethoxyphenol, phenol, 2,6-dimethylphenol, 2-isopropylphenol, benzene-1,3-diol, alpha-phellandrene, alpha-terpinene, gamma-terpinene and l-limonene were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. Those substances were subsequently entered in the Register of Feed Additives as existing products belonging

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

² Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1., ELI: <http://data.europa.eu/eli/dir/1970/524/oj>).

to the functional group of flavouring compounds, in accordance with Article 10(1), point (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, nine applications were submitted for the authorisation of undec-10-enal, terpineol acetate, d,l borneol, l-carvone, d-camphor, d,l-isobornyl acetate, 3-propylidene-phthalide, phenylacetic acid, methyl salicylate, thymol, carvacrol, benzothiazole, terpinolene, d,l-isoborneol, trans-menthone, d,l-bornyl acetate, 3-butylidene-phthalide, phenylacetaldehyde, phenethyl acetate, phenethyl phenylacetate, methyl phenylacetate, ethyl phenylacetate, isobutyl phenylacetate, 3-methylbutyl phenylacetate, 2-methoxyphenol, 2-methoxy-4-methylphenol, 4-ethylguaiacol, 2-methoxy-4-vinylphenol, 4-ethylphenol, 2-methylphenol, 4-methylphenol, 2,6-dimethoxyphenol, phenol, 2,6-dimethylphenol, 2-isopropylphenol, benzene-1,3-diol, alpha-phellandrene, alpha-terpinene, gamma-terpinene and l-limonene ('the substances concerned') as feed additives for all animal species. The applicant requested the additives to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. The applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The applicant requested the substances concerned 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 applicant withdrew the application for water for drinking for all the substances concerned.
- (5) The use of d,l-isomenthone as a feed additive was authorised for all animal species by Commission Implementing Regulation (EU) 2018/245³.
- (6) In accordance with Article 13(1) of Regulation (EC) No 1831/2003, the Commission requested the European Food Safety Authority ('the Authority') to issue an opinion on whether the authorisation of d,l-isomenthone as a feed additive would still meet the conditions laid down in Article 5 of Regulation (EC) No 1831/2003, considering a modification of the terms of that authorisation. That modification consists in an increase of the maximum recommended level of d,l-isomenthone to 5 mg/kg for all animal species. The request was accompanied by the relevant supporting data.
- (7) The Authority concluded in its opinions of 1 February 2012⁴, 6 March 2012⁵, 7 March 2012⁶, 13 June 2012⁷, 13 November 2012⁸, 10 March 2015⁹, 8 March 2016¹⁰, 20 April 2016¹¹, 12 July 2016¹² and 26 September 2023¹³ that, under the proposed conditions of

³ Commission Implementing Regulation (EU) 2018/245 of 15 February 2018 concerning the authorisation of menthol, d-carvone, menthyl acetate, d,l-isomenthone, 3-methyl-2-(pent-2(cis-enyl)cyclopent-2-en-1-one, 3,5,5-trimethylcyclohex-2-en-1-one, d-fenchone, fenchyl alcohol, carvyl acetate, dihydrocarvyl acetate and fenchyl acetate as feed additives for all animal species (OJ L 53, 23.2.2018, p. 87, ELI: http://data.europa.eu/eli/reg_impl/2018/245/oj).

⁴ EFSA Journal 2012;10(2):2573.

⁵ EFSA Journal 2012;10(3):2622.

⁶ EFSA Journal 2012;10(3):2625.

⁷ EFSA Journal 2012;10(7):2785.

⁸ EFSA Journal 2012;10(11):2966.

⁹ EFSA Journal 2015;13(3):4053.

¹⁰ EFSA Journal 2016;14(6):4441.

¹¹ EFSA Journal 2016;14(6):4475.

¹² EFSA Journal 2016;14(8):4559.

¹³ EFSA Journal 2023;21(10):8340.

use, the substances concerned are safe for all animal species, consumers and the environment. It stated that for 2-methoxyphenol, thymol, 2-methoxy-4-methylphenol, 4-ethylguaiaicol, 2-methoxy-4-vinylphenol, 4-ethylphenol, 2-methylphenol, 4-methylphenol, carvacrol, 2,6-dimethoxyphenol, phenol, 2,6-dimethylphenol, 2-isopropylphenol and benzene-1,3-diol no new data on the safety for the user was provided but that potential hazards for skin and eye contact and respiratory exposure of various severity are recognised for these substances. For 3-butylidenephthalide and 3-propylidenephthalide the material safety data sheets provided by the suppliers identify those substance as irritant to skin, eye and the respiratory tract and harmful if swallowed. For phenylacetaldehyde, phenylacetic acid, phenethyl acetate, phenethyl phenylacetate, methyl phenylacetate, ethyl phenylacetate, isobutyl phenylacetate, methyl salicylate and 3-methylbutyl phenylacetate, the Authority considered it prudent to treat all those compounds as irritants to skin, eyes and respiratory tract, skin sensitisers and harmful if swallowed. For terpineol acetate, it considered it prudent to treat it as irritant to skin, eyes and respiratory tract and as skin sensitiser. Terpinolene, alpha-phellandrene, alpha-terpinene, gamma-terpinene and l-limonene should be considered irritant to skin, eyes and respiratory tract and as skin sensitisers. The Authority stated that for benzothiazole, d,l-borneol, d,l-isoborneol, l-carvone, trans-menthone, d-camphor, d,l-bornyl acetate, undec-10-enal and d,l-isobornyl acetate, hazards for skin and eye contact and respiratory exposure are recognised and that they are classified as irritating to the respiratory system. The Authority finally concluded that all the substances concerned are recognised to flavour food and their function in feed would be essentially the same as that in food and therefore that no further demonstration of efficacy is considered necessary. The Authority considered that there was no need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003. Furthermore, the Authority concluded in the opinion of 26 September 2023 that for d,l-isomenthone, the maximum recommended level of 5 mg/kg is safe for all animal species, consumers and the environment.

- (8) In view of the above, the Commission considers that the substances concerned satisfy the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003. In addition, the Commission considers that the authorisation of d,l-isomenthone still meets the conditions provided for in Article 5 of Regulation (EC) No 1831/2003, when modifying the terms thereof as regards the increase of the maximum recommended level to 5 mg/kg for all animal species. Accordingly, the use of the substances concerned should be authorised and the terms of authorisation for d,l-isomenthone should be modified. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the substances concerned.
- (9) The Commission considers that for l-carvone, methyl salicylate, thymol and carvacrol, safety reasons require the establishments of maximum contents and that those additives cannot be used in combination with other additives containing such substances. For undec-10-enal, terpineol acetate, d,l borneol, d-camphor, d,l-isobornyl acetate, 3-propylidenephthalide, phenylacetic acid, benzothiazole, terpinolene, d,l-isoborneol, trans-menthone, d,l-bornyl acetate, 3-butylidenephthalide, phenylacetaldehyde, phenethyl acetate, phenethyl phenylacetate, methyl phenylacetate, ethyl phenylacetate, isobutyl phenylacetate, 3-methylbutyl phenylacetate, 2-methoxyphenol, 2-methoxy-4-methylphenol, 4-ethylguaiaicol, 2-methoxy-4-vinylphenol, 4-ethylphenol, 2-methylphenol, 4-methylphenol, 2,6-

dimethoxyphenol, phenol, 2,6-dimethylphenol, 2-isopropylphenol, benzene-1,3-diol, alpha-phellandrene, alpha-terpinene, gamma-terpinene and l-limonene safety reasons do not require the setting of maximum contents. However, in order to allow better control, a recommended maximum content should be indicated on the label of those additives. Where the recommended maximum content is exceeded, certain information should be indicated on the label of the premixtures concerned.

- (10) Implementing Regulation (EU) 2018/245 should therefore be amended accordingly.
- (11) 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 provide for a transitional period for the interested parties to prepare themselves to meet the new requirements resulting from the authorisation. In addition, since safety reasons do not require the immediate application of the modification to the terms of authorisation for d,l-isomenthone, it is appropriate to provide for a transitional period for the interested parties to prepare themselves to meet the requirements resulting from that modification.
- (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 substances specified in the Annex, belonging to the additive category ‘sensory additives’ and to the functional group ‘flavouring compounds’, are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2
Amendment to Implementing Regulation (EU) 2018/245

In the entry for d,l-isomenthone in the Annex to Implementing Regulation (EU) 2018/245, points 3 to 5 of the column “Other provisions” are replaced by the following:

“3. On the label of the additive the following shall be indicated: “Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg for all animal species.

“ 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level suggested on the label of the premixture would result in exceeding the level referred to in point 3.”

5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds 5 mg/kg for all animal species.”.

Article 3
Transitional measures

1. The feed additives undec-10-enal, terpineol acetate, d,l borneol, l-carvone, d-camphor, d,l-isobornyl acetate, 3-propylidene-phthalide, phenylacetic acid, methyl salicylate, thymol, carvacrol, benzothiazole, terpinolene, d,l-isoborneol, trans-menthone, d,l-bornyl acetate, 3-butylidene-phthalide, phenylacetaldehyde, phenethyl acetate, phenethyl phenylacetate, methyl phenylacetate, ethyl phenylacetate, isobutyl phenylacetate, 3-methylbutyl phenylacetate, 2-methoxyphenol, 2-methoxy-4-methylphenol, 4-ethylguaiacol, 2-methoxy-4-vinylphenol, 4-ethylphenol, 2-methylphenol, 4-methylphenol, 2,6-dimethoxyphenol, phenol, 2,6-dimethylphenol, 2-isopropylphenol, benzene-1,3-diol, alpha-phellandrene, alpha-terpinene, gamma-terpinene and l-limonene, as authorised pursuant to Directive 70/524/EEC, and the feed additive d,l-isomenthone (identification number: 2b07078) authorised by Implementing Regulation (EU) 2018/245, and premixtures containing these feed additives, which are produced and labelled before *[6 months from 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 stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are produced and labelled before *[12 months from 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 stocks concerned are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are produced and labelled before *[24 months from 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 stocks concerned are exhausted if they are intended for non-food producing animals.

Article 4
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