



2024/261

18.1.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/261

of 17 January 2024

concerning the authorisation of black pepper essential oil and black pepper oleoresin from *Piper nigrum* L. as feed additives for all animal species and black pepper supercritical extract from *Piper nigrum* L. 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 that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The substances black pepper essential oil and black pepper oleoresin from *Piper nigrum* L. and black pepper supercritical extract from *Piper nigrum* L. were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. These substances were subsequently entered in the Register of Feed Additives as existing products belonging to the category 'sensory additives' and to the functional group '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, an application was submitted for the authorisation of black pepper essential oil, black pepper oleoresin and black pepper supercritical extract from *Piper nigrum* L. as feed additives for all animal species, requesting the additives 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. The applicant subsequently withdrew the application for authorisation of black pepper supercritical extract from *Piper nigrum* L. as regards the use for all animal species except cats and dogs.
- (4) The applicant requested the additives 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 those additives in water for drinking should not be allowed.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 September 2022 ⁽³⁾ that, under the proposed conditions of use, black pepper essential oil, black pepper supercritical extract and black pepper oleoresin from *Piper nigrum* L. are safe for the target species, consumers and the environment. It also concluded that black pepper essential oil, black pepper supercritical extract and black pepper oleoresin should be considered as irritant to skin and eyes, and as dermal and respiratory sensitisers. The Authority further concluded that since the substances are recognised to flavour food and since their function in feed would be essentially the same as that in food, no further demonstration of efficacy is considered necessary. 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.

⁽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 2022;20(11):7599

- (6) In view of the above, the Commission considers that black pepper essential oil, black pepper oleoresin and black pepper supercritical extract from *Piper nigrum* L. satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of these substances should be authorised. The Commission considers that safety reasons do not require the setting of maximum levels for the substances concerned. The large margin of exposure and the lack of substances of concern permit to establish maximum recommended contents. In order to allow better control, the recommended maximum content should be indicated on the label of the feed additives. Where such contents are exceeded, certain information should be indicated on the label of the premixtures concerned. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additives.
- (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 provide for 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,

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

Transitional measures

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 7 August 2024 in accordance with the rules applicable before 7 February 2024 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 specified in the Annex which are produced and labelled before 7 February 2025 in accordance with the rules applicable before 7 February 2024 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 substances specified in the Annex which are produced and labelled before 7 February 2026 in accordance with the rules applicable before 7 February 2024 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, 17 January 2024.

For the Commission
The President
Ursula VON DER LEYEN

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 active substance/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b347-eo	Black pepper essential oil	<p><i>Additive composition</i></p> <p>Black pepper essential oil obtained from fruits of <i>Piper nigrum</i> L.</p> <p>Liquid form</p> <p><i>Characterisation of the active substance</i></p> <p>Black pepper essential oil obtained by steam distillation of dried and crushed unripe fruits from <i>Piper nigrum</i> L. as defined by the Council of Europe ⁽¹⁾.</p> <p>Specifications:</p> <ul style="list-style-type: none">— b-Caryophyllene: 12-40 %— Limonene: 7-20 %— Sabinene (4(10)-thujene): 4-17 %— a-Pinene (pin-2(3)-ene): 2,5-16 %— Safrole: ≤ 0,0003 % <p>CAS number: 8006-82-4</p> <p>FEMA number: 2845</p> <p>CoE number: 347</p>	All animal species	—	—	—	<p>1. The additive shall be incorporated into the feed in the form of a premixture.</p> <p>2. In the directions for use of the additive and pre-mixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>3. On the label of the additive, the following shall be indicated:</p> <p>‘Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %:</p> <ul style="list-style-type: none">— 5 mg for chickens for fattening and minor poultry for fattening— 7 mg for turkeys for fattening— 8 mg for poultry for laying and breeding purposes,— 9,5 mg for piglets, piglets of minor <i>Suidae</i> and pigs for fattening of minor <i>Suidae</i>— 11,5 mg for pigs for fattening— 14 mg for sows— 14 mg for dairy cows and minor dairy ruminants, except dairy sheep and goats— 20 mg for ruminants for fattening, except sheep and goats— 20 mg for sheep and goats— 20 mg for horses— 8,5 mg for rabbits— 20 mg for fish	7 February 2034

		<p><i>Analytical method ⁽²⁾</i></p> <p>For the determination of the phytochemical marker β-caryophyllene: gas chromatography coupled with flame ionisation detection (GC-FID)) based on ISO 3061.</p>					<ul style="list-style-type: none">— 20 mg for dogs and cats— 5 mg for ornamental birds— 5 mg for other animal species and categories.’ <p>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 on the label of the premixture would result in exceeding the content referred to in point 3.</p> <p>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.</p>	
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⁽¹⁾ Natural sources of flavourings – Report No 2 (2007).
⁽²⁾ 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>

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 the active substance/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b347-ex	Black pepper supercritical extract	<p><i>Additive composition</i></p> <p>Black pepper supercritical extract obtained from fruits of <i>Piper nigrum</i> L.</p> <p>Liquid form</p> <p><i>Characterisation of the active substance</i></p> <p>Black pepper supercritical extract obtained by CO₂ supercritical extraction from the dried and crushed unripe fruits of <i>Piper nigrum</i> L. (with no additional solvent addition) as defined by the Council of Europe ⁽¹⁾.</p> <p>Specifications:</p> <ul style="list-style-type: none">— β-Caryophyllene: 8-30 %— Limonene: 10-18 %— Sabinene (4(10)-thujene): 5-17 %— α-Pinene (pin-2(3)-ene): 7-18 %— Safrole: ≤ 0,0003 % <p>CoE number: 347</p>	Cats and dogs	—	—	—	<ol style="list-style-type: none">1. The additive shall be incorporated into the feed in the form of a premixture.2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %: 1,5 mg for cats and dogs.'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 on the label of the premixture would result in exceeding the content referred to in point 3.5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	7 February 2034

		<p><i>Analytical method ⁽²⁾</i></p> <p>For the determination of the phytochemical marker β-caryophyllene: gas chromatography coupled with flame ionisation detection (GC-FID) based on ISO 3061.</p>						
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⁽¹⁾ Natural sources of flavourings – Report No 2 (2007).
⁽²⁾ 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>

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 the active substance/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b347-or	Black pepper oleoresin	<p><i>Additive composition</i></p> <p>Preparation of black pepper oleoresin obtained from fruits of <i>Piper nigrum</i> L. Liquid form</p> <p><i>Characterisation of the active substance</i></p> <p>Black pepper oleoresin produced by organic solvent extraction of the dried unripe fruits of <i>Piper nigrum</i> L. as defined by the Council of Europe ⁽¹⁾.</p> <p>Specifications:</p> <ul style="list-style-type: none">— Piperine: 20-50 %— Safrole: ≤ 0,0003 % <p>CAS number: 84929–41-9</p> <p>FEMA number: 2846</p> <p>CoE number: 347</p> <p><i>Analytical method</i> ⁽²⁾</p> <p>For the determination of the phytochemical marker piperine: high performance liquid chromatography coupled to photometric detection (HPLC-UV) based on ISO 11027.</p>	All animal species	—	—	—	<ol style="list-style-type: none">1. The additive shall be incorporated into the feed in the form of a premixture.2. In the directions for use of the additive and pre-mixtures, the storage conditions and stability to heat treatment shall be indicated.3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %:<ul style="list-style-type: none">— 1 mg for chickens for fattening and minor poultry species for fattening,— 1,3 mg for turkeys for fattening— 1,4 mg for poultry for laying and breeding purposes— 1,7 mg for piglets, piglets of minor <i>Suidae</i> and pigs for fattening of minor <i>Suidae</i>— 2 mg for pigs for fattening.— 2,5 mg for sows— 2,4 mg for dairy cows and minor dairy ruminants, except dairy sheep and goats— 12,5 mg for calves for fattening— 11,5 for ruminants for fattening except sheep and goats— 11,5 mg for sheep and goats— 11,5 mg for horses— 1,5 mg for rabbits	7 February 2034

							<div><div><div>— 13,5 mg for salmonids and minor fin fish</div><div>— 51,5 mg for ornamental fish</div><div>— 14 mg for dogs</div><div>— 3,8 mg for cats</div><div>— 1 mg for ornamental birds</div><div>— 1 mg for other animal species or categories.'</div></div><div>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 on the label of the premixture would result in exceeding the content referred to in point 3.</div><div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.</div></div>	
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(¹) Natural sources of flavourings – Report No 2 (2007).
(²) 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>