



2024/2393

10.9.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2393

of 9 September 2024

**concerning the renewal of the authorisation of sodium bisulphate and the authorisation of new uses
of that substance as a feed additive for certain 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 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 and renewing such an authorisation.
- (2) Sodium bisulphate was authorised for a period of 10 years as a feed additive for all animal species in the additive category 'technological additives', functional group 'preservatives', and for all animal species other than cats, mink, pet and other non-food producing animals in the additive category 'technological additives', functional group 'acidity regulators', by Commission Implementing Regulation (EU) 2015/1416 ⁽²⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of sodium bisulphate as a feed additive for all terrestrial animal species, requesting that additive to be classified in the category 'technological additives' and in the functional group 'preservatives', and for all terrestrial animal species other than cats, mink, pets and other non-food-producing animals, requesting that additive to be classified in the additive category 'technological additives' and in the functional group 'acidity regulators'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003. In accordance with Articles 4(1) and 7 of Regulation (EC) No 1831/2003, the applicant also requested the authorisation of new uses of sodium bisulphate as a feed additive for all pets and other non-food-producing animals except aquatic animals, asking for the substance to be classified in the category 'technological additives', functional group 'acidity regulators', and in the category 'sensory additives', functional group 'flavouring compounds'. The 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 1 February 2024 ⁽³⁾ that, under the current conditions of authorisation, sodium bisulphate remains safe for all terrestrial animal species, consumers of products from animals fed the additive and the environment and that the new uses of the additive as an acidity regulator and sensory additive in pets and other non-food-producing animals except aquatic animals would not introduce risks not already considered in the previous assessment and therefore the same conclusions on all terrestrial animal species, consumers of products from animals fed the additive and the environment would apply. The Authority also concluded that sodium bisulphate is irritant to skin, eyes and respiratory tract, and should be considered as skin and respiratory sensitiser. It also indicated that there is no need for assessing the efficacy of the additive in the context of the renewal of its authorisation as the application does not include a proposal for

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

⁽²⁾ Commission Implementing Regulation (EU) 2015/1416 of 20 August 2015 concerning the authorisation of sodium bisulphate as feed additive for all animal species (OJ L 220, 21.8.2015, p. 11, ELI: http://data.europa.eu/eli/reg_impl/2015/1416/oj).

⁽³⁾ EFSA Journal, 22(3), e8644.

amending or supplementing the conditions of the original authorisation which would have an impact on the efficacy of the additive. The Authority added that the efficacy data assessed in its previous opinion of 13 October 2011 ⁽⁴⁾ concerning sodium bisulphate are considered valid and can cover the new use of the additive as an acidity regulator and a sensory additive (flavouring compound) in feed for pets and non-food-producing animals except aquatic animals. Therefore, it considered that sodium bisulphate has the potential to be efficacious in feed for these species and categories.

- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of sodium bisulphate as a feed additive in the context of the previous authorisation are valid and applicable for the current applications. In accordance with Article 5(4), points (a) and (c), of Commission Regulation (EC) No 378/2005 ⁽⁵⁾, an evaluation report of the Reference Laboratory is therefore not required.
- (6) In view of the above, the Commission considers that the sodium bisulphate satisfies the conditions, as provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive for use in feed for all animal species other than aquatic animals in the category 'technological additives', functional group 'preservatives', and for all terrestrial animal species other than cats, mink, pets and other non-food-producing animals in the additive category 'technological additives', functional group 'acidity regulators' should be renewed, and the new use as feed additive in the category 'technological additives', functional group 'acidity regulators', and in the category 'sensory additives', functional group 'flavouring compounds' for all pets and other non-food-producing animals except aquatic animals, should be authorised. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive. Those protective measures should be without prejudice to other workers' safety requirements under Union law.
- (7) 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

Renewal of authorisation

The authorisation of the substance specified in the Annex belonging to the additive category 'technological additives' and the functional group 'preservatives' for use in feed for all animal species other than aquatic animals, and to the additive category 'technological additives' and the functional group 'acidity regulators' for use in feed for terrestrial animal species other than pets and other non-food-producing animals, is renewed subject to the conditions laid down in that Annex.

Article 2

Authorisation

The substance specified in the Annex, belonging to the additive category 'technological additives' and the functional group 'acidity regulators' and to the additive category 'sensory additives' and the functional group 'flavouring compounds', is authorised as an additive in animal nutrition for pets and other non-food-producing animals other than aquatic animals, subject to the conditions laid down in that Annex.

⁽⁴⁾ EFSA Journal 2011;9(11):2415.

⁽⁵⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8). ELI: <http://data.europa.eu/eli/reg/2005/378/oj>.

*Article 3***Repeal**

Implementing Regulation (EU) 2015/1416 is repealed.

*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, 9 September 2024.

For the Commission
The President
Ursula VON DER LEYEN

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Identification number of the feed 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 additive/kg of complete feedingstuff with a moisture content of 12 %			

Category: technological additives. Functional group: preservatives

1j514ii	Sodium bisulphate	<p><i>Additive composition</i> Sodium bisulphate: ≥ 95,2 % Nickel: maximum 1 mg/kg</p> <p><i>Characterisation of active substance</i> Sodium bisulphate Produced by chemical synthesis Na: 19,15 % SO₄: 80,01 % Chemical formula: NaHSO₄ CAS number: 7681-38-1</p> <p><i>Analytical method</i> ⁽¹⁾ For the determination of sodium bisulphate in the feed additive: Titrimetry – Food Chemical Codex monograph ‘Sodium hydrogen sulfate’.</p>	All animal species other than aquatic animals, cats and mink	-	-	4 000	<ol style="list-style-type: none"> In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated. The total content of sodium bisulphate shall not exceed the maximum permitted levels in complete feedingstuff established for each relevant species. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address 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 skin, eye and breathing protective equipment. 	30 September 2034
			Cats		20 000			
			Mink		10 000			

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

Identification number of the feed 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 additive/kg of complete feedingstuff with a moisture content of 12 %			

Category: technological additives. Functional group: acidity regulators

1j514ii	Sodium bisulphate	<p><i>Additive composition</i> Sodium bisulphate: ≥ 95,2 % Nickel: maximum 1 mg/kg</p> <p><i>Characterisation of active substance</i> Sodium bisulphate Produced by chemical synthesis Na: 19,15 % SO₄: 80,01 % Chemical formula: NaHSO₄ CAS number: 7681-38-1</p> <p><i>Analytical method ⁽¹⁾</i> For the determination of sodium bisulphate in the feed additive: Titrimetry – Food Chemical Codex monograph ‘Sodium hydrogen sulfate’.</p>	All animal species other than aquatic animals, cats and mink	-	-	4 000	<ol style="list-style-type: none"> In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. The total content of sodium bisulphate shall not exceed the maximum permitted levels in complete feedingstuff established for each relevant species. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address 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 skin, eye and breathing protective equipment. 	30 September 2034
			Cats			20 000		
			Mink			10 000		

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

Identification number of the feed 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 additive/kg of complete feedingstuff with a moisture content of 12 %			

Category: Sensory additives. Functional group: flavouring compounds

1j514ii	Sodium bisulphate	<p><i>Additive composition</i> Sodium bisulphate: ≥ 95,2 % Nickel: maximum 1 mg/kg</p> <p><i>Characterisation of active substance</i> Sodium bisulphate Produced by chemical synthesis Na: 19,15 % SO₄: 80,01 % Chemical formula: NaHSO₄ CAS number: 7681-38-1</p> <p><i>Analytical method</i> ⁽¹⁾ For the determination of sodium bisulphate in the feed additive: Titrimetry – Food Chemical Codex monograph ‘Sodium hydrogen sulfate’.</p>	Pets and other non-food-producing animals other than aquatic animals, cats and mink	-	-	4 000	<ol style="list-style-type: none"> The additive shall be incorporated into the feed in the form of a premixture. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. The total content of sodium bisulphate shall not exceed the maximum permitted levels in complete feedingstuff established for each relevant species. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address 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 skin, eye and breathing protective equipment. 	30 September 2034
			Cats			20 000		
			Mink			10 000		

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.