



2024/1193

25.4.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1193

of 24 April 2024

concerning the renewal of the authorisation of sodium hydroxide as a feed additive for cats, dogs and ornamental fish and repealing Implementing Regulation (EU) No 161/2013

(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 authorisation.
- (2) Sodium hydroxide was authorised for a period of 10 years as a feed additive for cats, dogs and ornamental fish by Commission Implementing Regulation (EU) No 161/2013 ⁽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 hydroxide as a feed additive for cats, dogs and ornamental fish, requesting the 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 that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 September 2023 ⁽³⁾ that sodium hydroxide remains safe for the target species under the conditions of use currently authorised, provided that the resulting total sodium concentration in feed does not compromise the overall electrolyte balance. It reiterated its previous conclusion that the additive is corrosive and also indicated that there is no need for assessing the efficacy of the additive as the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive.
- (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 hydroxide as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c) of Commission Regulation (EC) No 378/2005 ⁽⁴⁾, an evaluation report of the Reference Laboratory is therefore not required.

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

⁽²⁾ Commission Implementing Regulation (EU) No 161/2013 of 21 February 2013 concerning the authorisation of a preparation of sodium hydroxide as a feed additive for cats, dogs and ornamental fish (OJ L 49, 22.2.2013, p. 52). ELI: http://data.europa.eu/eli/reg_impl/2013/161/oj.

⁽³⁾ EFSA Journal 2023;21(9):8249.

⁽⁴⁾ 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>).

- (6) In view of the above, the Commission considers that sodium hydroxide satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. 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) As a consequence of the renewal of the authorisation of sodium hydroxide as a feed additive, Implementing Regulation (EU) No 161/2013 should be repealed accordingly.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of sodium hydroxide, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.
- (9) 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 the authorisation

The authorisation of the substance specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'acidity regulators', is renewed subject to the conditions laid down in that Annex.

Article 2

Repeal of Implementing Regulation (EU) No 161/2013

Implementing Regulation (EU) No 161/2013 is repealed.

Article 3

Transitional measures

1. The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 15 November 2024 in accordance with the rules applicable before 15 May 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 substance specified in the Annex, which are produced and labelled before 15 May 2026 in accordance with the rules applicable before 15 May 2024 may continue to be placed on the market and used until the existing stocks are exhausted.

*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, 24 April 2024.

For the Commission
The President
Ursula VON DER LEYEN

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/kg of complete feedingstuff with a moisture content of 12 %			
Category: technological additives. Functional group: acidity regulators								
1j524	Sodium hydroxide	<p><i>Additive composition</i> Sodium hydroxide 50 % w/w (water solution)</p> <hr/> <p><i>Characterisation of the active substance</i> Sodium hydroxide ≥ 98,0 % total alkali (calculated as NaOH) NaOH CAS No.: 1310-73-2 Produced by chemical synthesis</p> <hr/> <p><i>Analytical method</i> ⁽¹⁾ Determination of sodium hydroxide in feed additive: Titrimetry – FAO JECFA Combined Compendium for Food Additive Specifications, Monograph No 1 (2006) ‘sodium hydroxide’.</p>	Cats, dogs and ornamental fish	-	-	-	<ol style="list-style-type: none"> Indicate in the directions for use of the additive and pre-mixtures: ‘The resulting total sodium concentration in feed shall not compromise the overall electrolyte balance’. For users of the additive and pre-mixtures, 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 pre-mixtures shall be used with personal skin, eye and breathing protective equipment. 	15 May 2034

⁽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.