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Assessment of the application for renewal of the authorisation of a feed additive consisting of sodium hydroxide for dogs, cats and ornamental fish (Brenntag Holding GmbH and Electroquímica de Hernani, S.A.)

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Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the assessment of the application for renewal of authorisation of sodium hydroxide as a technological additive (acidity regulator) for dogs, cats and ornamental fish. The applicants have provided evidence that the additive currently on the market complies with the existing conditions of authorisation. There is no evidence that would lead the FEEDAP Panel to reconsider its previous conclusions. Thus, the Panel concluded that the additive remains safe for all animal species and the environment under the authorised conditions of use. Regarding user safety, the additive is corrosive and therefore the provision of the authorisation that 'breathing protection, eye protection, gloves and protective clothing shall be used during handling' should be confirmed. There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest one year before the expiry date of the authorisation.

The European Commission received a request from Brenntag Holding GmbH and Electroquímica de Hernani, S.A.^{2,3} for the renewal of the authorisation of the additive consisting of sodium hydroxide, when used as a feed additive for dogs, cats and ornamental fish (category: technological additives; functional group: acidity regulator).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 14(1) (renewal of the authorisation). EFSA received directly from the applicants the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 24 January 2023.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicants, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the feed additive consisting of sodium hydroxide, when used under the proposed conditions of use (see **Section 3.1.3**).

1.2. Additional information

The additive consists, by specification, of a minimum of 98.0% sodium hydroxide (NaOH) or alkali in the solid form, with the content of solutions scaled accordingly. The additive is currently authorised for use in feed for cats, dogs and ornamental fish without a minimum and maximum use level (1j524).⁴ The additive is produced and sold as a solution in water.

Sodium hydroxide is approved as a food additive for use as an acidity regulator without limitation (*quantum satis*) (Aschberger et al., 2008) in jams, jellies, marmalades, sweetened chestnut purée, other similar fruit and vegetable spreads, processed cereal-based foods and baby foods, other foods for young children, dietary foods for infants for special medical purposes and special formulas for infants. Sodium hydroxide is also approved for use in food additives, food enzymes, food flavourings and nutrients with no limitation (*quantum satis*).⁵

Sodium hydroxide was assessed by the Joint FAO/WHO (Food and Agriculture Organization/World Health Organization) Committee on Food Additives (JECFA, 1966) and the Scientific Committee for Food (European Commission, 1991), and both set an acceptable daily intake (ADI) as 'not specified'. Sodium hydroxide has also been assessed under the framework of the OECD (Organisation for Economic Cooperation and Development) HPV (High Production Volume) Chemicals Programme (OECD, 2002) and by the Scientific Committee on Health and Environmental Risks (SCHER, 2006). EFSA FEEDAP Panel delivered an opinion on sodium hydroxide for cats, dogs and ornamental fish in 2012 (EFSA FEEDAP Panel, 2012). This assessment regards the renewal of the authorisation of sodium hydroxide for the above-mentioned animal species.

¹ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

² Brenntag Holding GmbH, Messeallee 11, Essen – Germany. Electroquímica de Hernani, S.A., Entidad Epele 29 Hernani – Spain.

³ Electroquímica de Hernani is the producer of the additive under assessment. Brenntag Holding GmbH is a distributor of the product manufactured in Electroquímica de Hernani's site.

⁴ Commission Implementing Regulation (EU) No 161/2013 of 21 February 2013 in OJ L 49, 22.2.2013, p. 52.

⁵ Commission Regulation (EU) No 1130/2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients.

2. Data and Methodologies

2.1. Data

The present assessment is based on data submitted by the applicants in the form of a technical dossier⁶ in support of the authorisation request for the use of sodium hydroxide as a feed additive. The dossier was received on 17/6/2022 and the general information and supporting documentation is available at <https://open.efsa.europa.eu/questions/EFSA-Q-2022-00376>.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 24 January 2023 to 24 April 2023 for which the received comments were considered for the assessment.

In accordance with Article 38 of the Regulation (EC) No 178/2002⁷ and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,⁸ a non-confidential version of the dossier has been published on Open.EFSA at <https://open.efsa.europa.eu/questions/EFSA-Q-2022-00376>.

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,⁸ EFSA carried out a public consultation on the non-confidential version of the technical dossier from 26 June to 17 July 2023 for which no comments were received.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the active substance/agent in animal feed are valid and applicable for the current application.⁹

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of sodium hydroxide is in line with the principles laid down in Regulation (EC) No 429/2008¹⁰ and the relevant guidance document: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021).

3. Assessment

3.1. Characterisation

3.1.1. Characterisation of the additive

The additive under assessment is currently authorised as a feed additive as a 50% w/w solution of sodium hydroxide in water. The active substance consists, by specification, of a minimum of 98.0% sodium hydroxide (Chemical Abstracts Service (CAS) number 1310-73-2, European Inventory of Existing Commercial Chemical Substances (EINECS) number 215-185-5) or alkali in the solid form. Sodium hydroxide is a white, dry and very deliquescent solid. Its density is 2.13 g/cm³ and its solubility in water at 20°C is 1,110 g/L. It is freely soluble in alcohol. It is strongly alkaline and corrosive. When exposed to air, it rapidly absorbs moisture and carbon dioxide. Sodium hydroxide is produced via electrolysis of sodium chloride. No changes have been introduced to the manufacturing process.

The applicants submitted the analysis of 18 batches of the additive¹¹ as a 50% w/w solution; the results of the titration showed an average NaOH of 50% w/w (range: 49.3–50.9%); the Panel notes

⁶ Dossier reference: FEED-2022-4391.

⁷ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

⁸ Decision available online: <https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>

⁹ Evaluation report available on the EU Science Hub online: <https://joint-research-centre.ec.europa.eu/system/files/2013-02/FinRep-FAD-2011-0006.pdf>

¹⁰ Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

¹¹ All the batches were submitted by Electroquímica de Hernani, which is the manufacturer of the additive.

that the concentration in two batches was slightly lower than the authorised level (49.3% and 49.4% vs 50%). The density of the additive was on average 1,467 g/L at 15°C (range: 1,273–1,536 g/L).¹²

Six further batches¹³ of the additive at 25% w/w solution were submitted, resulting in an average of 25.1% w/w (range: 24.6–25.5%) and a density of 1,277 g/L at 15°C (range: 1,273–1,281 g/L).

Three batches of the additive (50% w/w solution) were analysed for impurities, resulting in¹⁴: < 0.050 mg/kg lead, < 0.050 mg/kg arsenic, < 0.050 mg/kg mercury, < 0.010–< 0.05 mg/kg cadmium, 0.33 mg/kg Nickel (range: 0.11–0.69 mg/kg) and 0.42 mg/kg chromium (range: 0.23–0.52 mg/kg).¹⁵ Selenium and carbonate (expressed as sodium carbonate) were measured in the same three batches resulting in < 0.10–< 0.50 mg/kg selenium and < 0.40% carbonate.

Two further batches of the additive at two different concentrations (32.7% w/w and 25.5% w/w, respectively) were analysed for impurities, with the following results¹⁶: < 0.050 and < 0.20 mg/kg lead, < 0.050 and < 0.40 mg/kg arsenic, < 0.050 and < 0.10 mg/kg mercury, < 0.015–< 0.1 mg/kg cadmium, < 0.15 and < 0.20 mg/kg nickel, < 0.15 and 0.24 mg/kg chromium.¹⁵ Selenium was < 0.11–< 1 mg/kg respectively, carbonate (expressed as sodium carbonate) resulted in < 0.40% in both batches.

3.1.2. Stability and homogeneity

No new data on the shelf-life of the additive and the stability of the additive in feedingstuffs and premixtures were provided. Stability studies are normally not required for mineral-based products. Similar considerations can be applied to sodium hydroxide. For this application, sodium hydroxide is added to feed only in the form of a water solution. Due to the high solubility of sodium hydroxide, no further information on the homogeneous distribution of the aqueous solution of the additive in feedingstuffs is considered necessary.

3.1.3. Conditions of use

Sodium hydroxide is authorised for use as an acidity regulator in feed for dogs, cats and ornamental fish, without restrictions on age or levels in feed.

Under 'other provisions' it is stated:

1. For safety: breathing protection, eye protection, gloves and protective clothing shall be used during handling.
2. For use: the resulting total sodium concentration in feed shall not compromise the overall electrolyte balance.'

3.2. Safety

The applicants state that no adverse effects or incidents/accidents have been reported from the use of the feed additive since the first authorisation of the product.¹⁷

No new information on the impact of sodium hydroxide on the safety for the target species was made available.

In its previous opinion, the FEEDAP Panel evaluated the safety of sodium hydroxide for the target species based on the metabolism of the cations and anions, which constitute the major electrolytes present in all biological materials (EFSA FEEDAP Panel, 2012). In that opinion the Panel concluded that no safety problems are likely to arise, provided that the contributions from feed intake do not disturb the homeostatic mechanisms controlling the electrolyte balance of the body. Sodium hydroxide was therefore considered to be safe for cats, dogs and ornamental fish, provided that the resulting total sodium concentration in feed does not compromise the overall electrolyte balance. Regarding the safety for the user, in the previous opinion the FEEDAP Panel concluded that sodium hydroxide at a concentration > 8% is corrosive. The FEEDAP Panel is not aware of any information that would modify its previous conclusions.

¹² Analyses of impurities NaOH 50% confidential version.pdf and CoAs NaOH 50% EHER confidential version.pdf

¹³ CoAs blackened version.pdf and Analysis of impurities blackened version.pdf

¹⁴ Analyses of impurities NaOH 50% confidential version.pdf

¹⁵ The sign '<' refers to the limit of quantification (LOQ) of the analytical method used.

¹⁶ Analysis of impurities blackened version.pdf

¹⁷ Safety of use of the additive for the target animals and Safety for the user.

3.3. Efficacy

The present 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. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

3.4. Post-market monitoring

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation¹⁸ and Good Manufacturing Practice.

4. Conclusions

The applicants provided evidence that the additive currently in the market complies with the existing conditions of authorisation and that the production process has not been modified.

Sodium hydroxide supplementation in feed for cats, dogs and ornamental fish according to currently authorised conditions of use remains safe for the target species, provided that the resulting total sodium concentration in feed does not compromise the overall electrolyte balance.

The additive is corrosive and therefore the provision of the current authorisation that 'breathing protection, eye protection, gloves and protective clothing shall be used during handling' should be confirmed. There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

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Abbreviations

ADI	acceptable daily intake
CAS	Chemical Abstracts Service
EINECS	European Inventory of Existing Chemical Substances
EURL	European Union Reference Laboratory
FAO	Food Agricultural Organization
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed

¹⁸ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

HACCP	hazard analysis and critical control points
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
LOD	limit of detection
LOQ	limit of quantification
OECD	Organisation for Economic Co-operation and Development
SCF	Scientific Committee on Food
WHO	World Health Organization