

Safety Assessment on the Safety and Efficacy of a Feed Additive Consisting of Sodium Bisulphate for All Animal Species Except Aquatic Animals (RP1612)

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An application was submitted to the Food Standards Agency in July 2022 from Grillo-Werke AG and Jones-Hamilton Co. ('the applicant') for a renewal authorisation of the additive containing sodium bisulphate, under the category 'technological additive', functional group 'preservative' for all terrestrial animal species, and 'technological additive', functional group 'acidity regulator' for all terrestrial animal species other than cats, mink, pets and other non-food-producing animals. In addition, the applicant requested an authorisation of new use of the additive under the category 'technological additive', functional group 'acidity regulator' and 'sensory additive', functional group 'flavouring compound' for all pets and other non-food-producing animals except aquatic animals.

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) concluded that sodium bisulphate remains safe for all terrestrial animal species, consumers of products from animals fed the additive and the environment, under the conditions of authorisation.

The additive is a skin, eye and respiratory tract irritant and should be considered as a respiratory and skin sensitiser.

The FEEDAP Panel concluded that using the additive as an acidity regulator and sensory additive for pets and other non-food-producing animals, excluding aquatic species, would not introduce any new risks and has the potential to be efficacious.

FSA/FSS has reviewed the applicant's renewal and extension of use application, supporting documentation, and other regulators risk assessments, most notably the EFSA risk assessment opinion and consider sufficient evidence has been demonstrated to conclude without further questions or risk assessment. This document represents the opinion of the FSA and FSS.

1. Introduction

In accordance with Retained EU Regulation 1831/2003 (EC, 2003) on feed additives, the applicant, (Grillo-Werke AG, Weseler Str 1, 47169 Duisburg, Germany; Jones-Hamilton Co., 30354 Tracy Rd, 43465 Walbridge, Ohio, USA), submitted an application of sodium bisulphate under category of 'technological additive', functional group 'preservative' for its use in all terrestrial animal species, and 'technological additive', functional group 'acidity regulator' for all terrestrial animal species other than cats, mink, pets and other non-food-producing animals. In addition, the applicant requested an authorisation of new use of the additive under category of 'technological additive', functional group 'acidity regulator' and 'sensory additive', functional group 'flavouring compound' for its use in all pets and other non-food-producing animals except aquatic animals.

Whilst it was a Member State of the EU, the UK accepted the risk assessments of the European Food Safety Authority (EFSA) in respect of authorisations for regulated food and feed products. When GB left the EU, it retained the same regulations for food and feed regulated products; FSA and FSS also adopted equivalent technical guidance and quality assurance processes to be able to undertake GB risk assessments for regulated product applications.

To ensure regulatory systems of FSA/FSS are risk proportionate and resources are used effectively, FSA and FSS have used the evidence submitted by the applicant and other information in the public domain, including the EFSA opinion, to provide a summary assessment of the evidence of safety presented in this report.

In 2024, EFSA published an opinion (EFSA FEEDAP Panel, 2024) on the renewal of application of sodium bisulphate for its use as a feed additive, including the proposed new use. The Commission subsequently re-authorised the product with the extensions for use. This opinion has been reviewed by FSA/FSS risk assessors. It has been verified that the standard approach taken, when compared to the relevant guidance applied in GB, has been followed and the conclusions made are consistent with the data summarised in the opinion.

Specifically, in reviewing the assessment that EFSA have recently completed, the reviewers have verified that the standard approach taken, when compared to the relevant guidance applied in GB, has been followed and the conclusions made are consistent with the data summarised in the opinion. Consideration has been given to the processes undertaken to ensure the EFSA opinion is robust and whether there are any aspects that would require further review, such as specific issues for the countries of GB. The result of the assessment is that there is sufficient evidence of safety to conclude without requiring further assessment at this time.

The result of the assessment is that there is sufficient evidence of safety for the UK to conclude this assessment at this time. This document represents the opinion of the FSA and FSS.

Table 1. Table showing products included in this assessment.

Title	Product type	Intended use/s	Intended dose/intake
Sodium bisulphate	Feed additive	Technical additive, preservative	A maximum content of 20,000 mg/kg for cats, 10,000 mg/kg for mink and 4000 mg/kg for all other animals (except aquatic) in complete feedstuffs
Sodium bisulphate	Feed additive	Technical additive, acidity regulator	A maximum content of 20,000 mg/kg for cats, 10,000 mg/kg for mink and 4000 mg/kg for other pets and non-food-producing animals (except aquatic) in complete feedstuffs
Sodium bisulphate	Feed additive	Sensory additive, flavouring compound	A maximum content of 20,000 mg/kg for cats, 10,000 mg/kg for mink and 4000 mg/kg for other pets and non-food-producing animals (except aquatic) in complete feedstuffs

2. Details of other Regulators Opinions

The additive sodium bisulphate has previously been authorised in the EU by Commission implementing regulation (EU) 2015/1416 (EC, 2015). In 2024, EFSA published a opinion (EFSA FEEDAP Panel, 2024) on the renewal of application of sodium sulphate for its use as a feed additive. This opinion has been reviewed by FSA/FSS risk assessors.

2.1. Methodology applied in the EFSA Opinion

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) assess the safety and the efficacy sodium bisulphate, in accordance with guidance documents: Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019) and principles in Regulation (EC) No 429/2008 (EC, 2008).

2.1.1. Characterization of the additive

The current authorization for the additive requires a minimum content of the sodium bisulphate (Chemical Abstracts Service (CAS) No 7681-38-1, molecular formula NaHSO_4 , molecular weight 120.07 g/mol) of 95.2 %. An

average of 97.3% (96.1% - 98.7%) was shown in analysis of 10 batches of the additive. It was stated by the applicant that the manufacturing process chemical synthesis with sodium chloride (NaCl) and sulphuric acid (H₂SO₄) was not modified since the last authorization. In addition, the additive contains 0.02% insoluble matter (< 0.01%–0.02%) and 23.3 mg/kg (13.1–50.2) of iron (Fe). Selenium (Se) was found below the limit of quantification (LOQ). Weight loss of 0.1% is attributed to drying.

Analysis of 10 batches of the additive showed that arsenic (As), antimony (Sb), cadmium (Cd), fluoride, lead (Pb) and mercury (Hg) were below LOQ. Chromium (Cr) was detected at concentration of 0.60 mg/kg (< 0.5–0.67) and nickel (Ni) at 0.66 mg/kg (< 0.5–0.66). In addition, testing of 10 batches for polychlorinated dibenzofurans (PCDFs), polychlorinated dibenzo-p-dioxins (PCDDs) and dioxin-like polychlorinated biphenyls (DL-PCBs) showed values below the LOQ of the analytical methods. The calculated upper bound (UB) concentration was 0.127 ng WHO2005-TEQ/kg for the sum of PCDD/Fs, and 0.291 ng WHO2005-TEQ/kg for the sum of PCDD/Fs and DL-PCBs. The UB for the sum of non DL-PCBs was 1.8 ng/kg (all values are expressed based on 88% dry matter).

The Panel concluded that the levels of identified impurities do not give rise to safety concerns with exception of potential presence of nickel which will be addressed in the safety section.

Average solubility of sodium bisulphate of 1046 g/L was demonstrated in a solubility test in line with OECD test guideline No 105.

As the formulation and manufacturing process of the additive have remained the same, the stability and physico-chemical properties data from the previous opinions are considered valid for the current assessment (EFSA FEEDAP Panel, 2011; EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2014).

2.1.2. Conditions of use

Currently, when used as a preservative, a maximum content of 4000 mg/kg in complete feedstuffs is authorized for all animal species other than cats and mink, with higher limits set at 20,000 mg/kg for cats and 10,000 mg/kg for mink. When used as an acidity regulator, a maximum content of 4000 mg/kg in complete feedstuffs is authorized for all animal species other than cats, mink, pets, and other non-food-producing animals.

The following specification are listed under the provisions of the authorisation:

- Storage temperature, storage life and stability to pelleting should be indicated in the directions for use of the additive and premixture.

- The maximum permitted content of sodium bisulphate must not be exceeded in complete feedstuffs.
- During the handling, personal protective equipment such as breathing protection, eye protection and gloves should be used.

No changes to these conditions of use were proposed but the applicant wishes to exclude from the authorisation the use of the additive in feed for aquatic animals. Furthermore, the applicant is seeking authorization for the additive to be used as an acidity regulator and flavouring compound. Proposed maximum content levels are 4000 mg/kg for other pets and non-food-producing animals, excluding aquatic animals, with higher limits proposed at 20,000 mg/kg for cats and 10,000 mg/kg for mink.

2.1.3. Safety

No adverse effects or incidents have been reported from the use since the last authorisation of the additive according to the applicant.

A literature search covering the period 2010-2022 was performed to provide evidence of safety of the additive under the authorised conditions for target species, consumers, user, and the environment involving use of Web of Science platform and 2 different databases. From this search, 29 publications were identified as potentially relevant, with two additional papers found in the search for grey literature. No publications were found relevant to modify the previous conclusions made by the Panel regarding safety assessment. No concerns for the target species, consumers, or the environment are expected from the use of sodium bisulphate under the current conditions of authorization, as the manufacturing process, specifications, and conditions of use remained unchanged.

The applicant provided a chemical safety report mentioning studies on skin and eye irritation and skin sensitization. However, without accessing the full reports the FEEDAP Panel could not reconsider previous conclusions on user safety. Under the Classification, Labelling and Packaging of substances and mixtures (CLP), sodium bisulphate is classified as 'Eye Damage 1'. The additive should be considered a respiratory and skin sensitiser due to the traces of nickel present in the additive. The Panel concluded that sodium bisulphate is irritant to respiratory tract, eyes, and skin, and should be considered as a respiratory and skin sensitiser.

Furthermore, considering that the conditions of use and maximum content levels are the same for all uses, the FEEDAP Panel concluded that using the additive as an acidity regulator and sensory additive for pets and other non-food-producing animals, excluding aquatic species, would not introduce any new risks.

2.1.4. Efficacy

An assessment of efficacy for the renewal of the authorization was not needed, as there was no proposal to amend or supplement the conditions of use of the original authorization. The Panel considered the previously assessed efficacy data valid for assessing the additive as an acidity regulator and sensory additive (flavouring compound) in feed for the proposed species. The Panel concluded that the additive has the potential to be efficacious for all proposed uses in feed for pets and non-food-producing animals, excluding aquatic animals.

3. Analytical method evaluation

FSA/FSS accepts the EURL analytical method evaluation report (EURL-FA, 2010). FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.

4. Other Regulators Opinions and Conclusions

The FEEDAP Panel concluded that sodium bisulphate remains safe for all terrestrial animal species, consumers of products from animals fed the additive and the environment, under the conditions of authorisation.

The additive is a respiratory tract, skin and eyes irritant and should be considered as respiratory and skin sensitiser.

The Panel concluded that using the additive as an acidity regulator and sensory additive for pets and other non-food-producing animals, excluding aquatic species, would not introduce any new risks and has the potential to be efficacious.

The Panel concluded that the additive has the potential to be efficacious for all proposed uses in feed for pets and non-food-producing animals, excluding aquatic animals.

5. Caveats and uncertainties

No caveats and uncertainties were identified.

6. FSA/FSS conclusions for GB risk analysis

The application has been assessed in line with the applicable guidance and is partially based on considerations of detailed proprietary information available to the Panel, which were submitted to FSA/FSS, whilst this is only briefly summarised this description is consistent with the conclusions. The conclusions of the EFSA opinion have been reviewed in detail by FSA and

FSS and are considered appropriate and consistent within the identified caveats and uncertainties identified in the opinion and would be applicable to GB. Sufficient evidence has been demonstrated to conclude without further questions or assessment.

7. Outcome of assessment

FSA/FSS has reviewed the applicant's renewal and new use application, supporting documentation, and other regulators assessments, most notably the EFSA opinion (EC, 2003) and consider sufficient evidence has been demonstrated to conclude without further questions or assessment.

The FSA and FSS conclude that the sodium bisulphate feed additive, as described in this application, is safe and is not liable to have an adverse effect on the target species, worker safety, environmental safety and human health at the intended concentrations of use.

In making this assessment, the following principles have been applied:

- 1) There is not a legal duty to perform a separate risk assessment for GB and therefore, there was sufficient scientific evidence to make a conclusion on safety with no further questions to the applicant, and therefore no further risk assessment activities are necessary.
- 2) Sufficient evidence was available in the literature, for example, where other National food safety authorities had positively assessed the application using the same risk assessment guidance in principle and legal requirements in GB with the exception to changes in the General Food Law.
- 3) Applicants provided sufficient relevant information as requested by FSA/FSS.
- 4) The FSA and FSS review did not find any issues of divergence from guidance or mutual approaches or new scientific issues for consideration.
- 5) There were no other specific issues that would require an assessment for the UK or the nations of the UK.

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Abbreviations

Acronym	Definition
CAS	Chemical Abstracts Service
DL-PCB	dioxin-like polychlorinated biphenyls
EC	European Commission
EU	European Union
EFSA	European Food Safety Authority

Acronym	Definition
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
FSA	Food Standards Agency
FSS	Food Standards Scotland
GB	Great Britain
LOQ	Limits of quantification
OECD	Organisation for Economic Co-operation and Development
PCDD	Polychlorinated dibenzo-p-dioxins
PCDF	Polychlorinated dibenzofurans
RP	Regulated Product
UK	United Kingdom



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