

# Safety and efficacy of a feed additive consisting of sodium bisulphate for all animal species except aquatic animals (Grillo Werke AG & Jones-Hamilton Co.)

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## Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the assessment of the application for renewal of authorisation of sodium bisulphate (SBS) as a feed additive for all terrestrial animal species (category: technological additive; functional group: preservative), and for all terrestrial animal species other than cats, mink, pets and other non-food-producing animals (category: technological additive; functional group: acidity regulator). EFSA has also been asked to assess the new use of the product as an acidity regulator and flavouring compound in all pets and other non-food-producing animals except aquatic animals. The applicant provided evidence that the additive currently in 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 terrestrial animal species, consumer and the environment under the authorised conditions of use. The FEEDAP Panel considers that the proposed new use 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. Regarding user safety, the additive is irritant to the skin, eyes and the respiratory tract, and should be considered a skin and respiratory sensitiser. There is no need to assess the efficacy of the additive in the context of the renewal of the authorisation. The Panel considers that the additive has the potential to be efficacious as an acidity regulator and sensory additive (flavouring compound) in feed for pet and non-food-producing animals (except aquatic animals).

## KEY WORDS

acidity regulator, efficacy, flavouring, preservative, renewal, safety, technological additives

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## 1 | INTRODUCTION

### 1.1 | Background and Terms of Reference

Regulation (EC) No 1831/2003<sup>1</sup> establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of feed additive shall submit an application in accordance with Article 7. 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 Grillo Werke AG & Jones-Hamilton Co.<sup>2</sup> for the renewal of the authorisation of the additive consisting of sodium bisulphate, when used as a feed additive for all terrestrial animal species (category: technological additive; functional group: preservative), for all terrestrial animal species other than cats, mink, pets and other non-food-producing animals (category: technological additive; functional group: acidity regulator) and for a new use of the additive (categories: technological additives and sensory additives, functional groups: acidity regulator and flavouring compounds) for all pets and other non-food-producing animals with the exception of aquatic species.

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 4(1) (authorisation of a feed additive or new use of a feed additive) and under Article 14(1) (renewal of the authorisation). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 20 March 2023.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, 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 bisulphate, when used under the proposed conditions of use (see **Section 3.1.2**).

### 1.2 | Additional information

The additive under assessment is sodium bisulphate (SBS). EFSA issued one opinion on the safety and efficacy of SBS for all animal species as preservative and silage additive, for pets and other non-food-producing animals (non-food fur animals) as acidity regulator and for pets as flavouring (EFSA FEEDAP Panel, 2011) and one on the safety and efficacy of SBS for all species as preservative and silage additive (EFSA FEEDAP Panel, 2014).

SBS is currently authorised as a preservative in feed for all animal species and as an acidity regulator in feed for all animal species other than cats, mink, pets and other non-food-producing animals (1j514ii).<sup>3</sup>

SBS was also authorised as an acidity regulator and flavouring compound for pets and other non-food-producing animals. However, these authorisations expired on 8 March 2022.<sup>4</sup>

## 2 | DATA AND METHODOLOGIES

### 2.1 | Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier<sup>5</sup> in support of the authorisation request for the use of SBS as a feed additive. The dossier was received on 23 June 2022 and the general information and supporting documentation is available at <https://open.efsa.europa.eu/questions/EFSA-Q-2022-00402>.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 20 March 2023 to 20 June 2023 for which the received comments were considered for the assessment.

In accordance with Article 38 of the Regulation (EC) No 178/2002<sup>6</sup> and taking into account the protection of confidential information and of personal data in accordance with Articles 39–39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,<sup>7</sup> a non-confidential version of the dossier has been published on Open.EFSA.

<sup>1</sup>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.

<sup>2</sup>Jones-Hamilton Co., 30354 Tracy Road, Walbridge, OH 43465–9792, USA; Grillo-Werke AG, Weseler Straße 147169 Duisburg, Germany; represented in the EU by Pen&Tec Consulting SLU, Plaza Ausias March 1, 4th Floor, D01, Mirasol, 08195, Sant Cugat del Vallès, Spain.

<sup>3</sup>Commission Implementing Regulation (EU) 2015/1416 of 20 August 2015 concerning the authorisation of sodium bisulphate as feed additive for all animal species.

<sup>4</sup>Commission Regulation (EC) No 136/2012 of 16 February 2012 concerning the authorisation of sodium bisulphate as feed additive for pets and other non-food-producing animals. OJ L 46, 17.2.2012, p. 3.

<sup>5</sup>Dossier reference: FEED-2021-000102.

<sup>6</sup>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.

<sup>7</sup>Decision available at: <https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>

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, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 28 August 2023 to 18 September 2023 for which no comments were received.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers, other scientific reports and experts' (elicitation) knowledge, to deliver the present output. 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 SBS in animal feed are valid and applicable for the current application.<sup>8</sup>

## 2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of SBS is in line with the principles laid down in Regulation (EC) No 429/2008<sup>9</sup> and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the target species (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 environment (EFSA FEEDAP Panel, 2019) and Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021).

## 3 | ASSESSMENT

The additive SBS is currently authorised for use as a technological additive, as a functional group preservative for all animal species and as an acidity regulator in feed for all animal species other than cats, mink, pets and other non-food-producing animals.

The applicant requests the renewal of the authorisation of SBS as a preservative for all food-producing animals, pets and other non-food-producing animals with the exception of aquatic animals, and as an acidity regulator in all food-producing animals except aquatic animals; the applicant also requests for a new use as an acidity regulator and as a flavouring compound for all pets and other non-food-producing animals except aquatic animals.

### 3.1 | Characterisation

#### 3.1.1 | Characterisation of the additive

SBS (sodium hydrogen sulphate; acid sodium sulphate; nitre cake), Chemical Abstracts Service (CAS) No 7681-38-1, molecular formula  $\text{NaHSO}_4$ , molecular weight 120.07 g/mol, is currently authorised with a minimum content of 95.2% SBS.

SBS is manufactured by chemical synthesis with sodium chloride ( $\text{NaCl}$ ) and sulphuric acid ( $\text{H}_2\text{SO}_4$ ) which are used as starting materials. No changes in the manufacturing process or the composition of the additive have been introduced since the last authorisation according to the applicant.

Analytical data to confirm the specifications were provided for 10 batches<sup>10</sup> of the additive, showing the following average values: 97.3% SBS (96.1%–98.7%), 0.02% insoluble matter (<0.01%–0.02%) and <0.1% loss on drying.<sup>11</sup> Selenium and iron were analysed in the same batches and they were found below the limit of quantification (LOQ)<sup>12</sup> and at an average of 23.3 mg/kg (13.1–50.2), respectively.

The same 10 batches of the additive were analysed for impurities. Arsenic, cadmium, lead, mercury, antimony and fluoride concentrations were below the LOQ.<sup>13</sup> Chromium and nickel were 0.60 mg/kg (<0.5–0.67) and 0.66 mg/kg (<0.5–0.66), respectively. Polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (DL-PCBs) were analysed in the same 10 batches. All values were below the corresponding LOQ. The calculated upper bound (UB) concentration was 0.127 ng WHO2005-TEQ/kg for the sum of PCDD/Fs, and 0.291 ng

<sup>8</sup>Evaluation report received on 4 May 2010 and available on the EU Science Hub [https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports\\_en](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en)

<sup>9</sup>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.

<sup>10</sup>Annex\_II\_1\_3\_1\_Grillo\_Grillopet\_CoAs.pdf and Annex\_II\_3\_1\_JH\_PetSBS\_CoAs.pdf.

<sup>11</sup>The symbol "<" refers to the limit of quantification (LOQ).

<sup>12</sup>LOQ: 0.1 mg/kg selenium.

<sup>13</sup>LOQ: 0.1 mg/kg arsenic, 0.1 mg/kg cadmium, 0.5 mg/kg lead, 0.01 mg/kg mercury, 0.1 mg/kg antimony, 10 mg/kg fluoride.

WHO 2005-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).<sup>14</sup>

The FEEDAP Panel considers that the amounts of the detected impurities do not raise safety concerns, except for the potential presence of nickel, which will be addressed in the safety section.

SBS is very soluble<sup>15</sup> in water; a solubility test in line with OECD test guideline 105 was submitted,<sup>16</sup> showing an average solubility of 1046 g/L.<sup>17</sup>

No other new data were provided regarding the physico-chemical properties or stability of the additive. Since no changes were introduced in the manufacturing process according to the applicant, the data described in the previous opinions (EFSA FEEDAP Panel, 2011, 2014) still apply.

### 3.1.2 | Conditions of use

The additive is currently authorised to be used in feed as:

- (i) Preservative in complete feedingstuffs at a maximum content of 4000 mg/kg for all animal species other than cats and mink, 20,000 mg/kg for cats and 10,000 mg/kg for mink.
- (ii) Acidity regulator in complete feedingstuffs at a maximum content of 4000 mg/kg for all animal species other than cats, mink, pets and other non-food-producing animals.

Under other provisions of the authorisations, it is specified that:

- In the directions for use of the additive and premixture, indicate the storage, temperature, storage life and stability to pelleting.
- For safety: breathing protection, eye protection and gloves shall be used during handling.
- The total content of SBS must not exceed the maximum permitted levels in complete feedingstuffs established for each relevant species.

The applicant has requested to maintain the same conditions of use but to exclude from the authorisation the use of the additive in feed for aquatic animals.

In addition, the applicant is requesting the authorisation of the additive for use as an acidity regulator and sensory additive (flavouring compound) at a proposed 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 animals.

## 3.2 | Safety

The safety of the additive was assessed in previous opinions of the FEEDAP Panel (EFSA FEEDAP Panel, 2011, 2014). In those opinions, the FEEDAP Panel concluded that SBS is safe for cats at 20,000 mg/kg complete feed, for minks at 10,000 mg/kg and for all other animal species at 4000 mg/kg. The Panel also concluded that SBS used in animal nutrition is safe for the consumers and the environment and that SBS is irritant to skin, eye and the respiratory tract, and should be considered a potential skin sensitiser.

The applicant stated that no adverse effects or incidents/accidents have been reported from the use of the feed additive since the first authorisation of the product.<sup>18</sup>

In line with the requirements established in the EFSA guidance on the renewal (EFSA FEEDAP Panel, 2021), the applicant performed a literature search to provide evidence that in the light of the current knowledge the additive remains safe under the approved conditions for target species, consumers, user and the environment.

The timeline of the search was the period 2010–2022, no limitations were set for the language of publication. The search was conducted using the Web of Science platform and covered two databases (CAB Abstracts and the Food Science Resource). The search terms used and the strategy followed were reported. The literature search retrieved 145 publications of which 29 were considered potentially relevant for the assessment. Two additional papers were identified in a search for grey literature.

None of the papers reviewed provided information relevant to the safety for the target species, consumers and the environment that would lead the Panel to modify its previous conclusions. Therefore, considering the above and the fact that the manufacturing of the additive, specifications and conditions of use have not been modified, the FEEDAP Panel concludes that the SBS remains safe for target species, consumers and the environment under the current conditions of authorisation.

<sup>14</sup>Annex\_II\_3\_1\_1\_Grillo\_Grillopet\_CoAs and Annex\_II\_3\_1\_JH\_PetSBS\_CoAs. Upper bound concentrations are calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification. TEQ= toxic equivalency factors for dioxins, furans and dioxin-like PCBs established by WHO in 2005 (van den Berg et al., 2006).

<sup>15</sup>For solubility terms, see Table 2 of the Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (EFSA Scientific Committee, 2021).

<sup>16</sup>Annex\_II\_1\_5\_1\_Grillo\_Grillopet\_Solubility.

<sup>17</sup>The solubility is above the threshold set in Section 2.3.1 of the Guidance on Particle-TR (EFSA Scientific Committee, 2021); therefore, the additive is expected to be fully solubilised either in the feed matrix or in the gastrointestinal tract of the target species.

<sup>18</sup>Annex\_V\_Grillo.pdf and Annex\_V\_JH.pdf.

Regarding user safety, the literature search identified no relevant studies and no new information was provided other than a chemical safety report, in which studies on skin and eye irritation and skin sensitization were mentioned. However, in the absence of the full study reports, the FEEDAP Panel cannot assess these studies, and therefore, reconsiders its previous conclusions. The Panel notes that SBS is classified under CLP as 'Eye damage 1'. Due to the presence of traces of nickel, the additive should be considered a skin and respiratory sensitiser. Thus, the FEEDAP Panel concludes that SBS is irritant to skin, eyes and respiratory tract, and should be considered a skin and respiratory sensitiser.

The Panel also considers that the new uses of the additive as an acidity regulator and sensory additive in pets and other non-food-producing animals (except aquatic species) would not introduce risks not already considered, considering that the conditions of use and the maximum use levels proposed are the same for all uses.

### 3.3 | Efficacy

The present application for the 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 to assess the efficacy of the additive in the context of the renewal of the authorisation.

The efficacy data assessed in the previous opinion (EFSA FEEDAP Panel, 2011) 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, the Panel considers that the additive has the potential to be efficacious in feed for these species and categories.

## 4 | CONCLUSIONS

The applicant provided evidence that the additive currently in the market complies with the existing conditions of authorisation.

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

SBS is irritant to skin, eyes and respiratory tract, and should be considered a skin and respiratory sensitiser.

The Panel also considers that the new uses of the additive as an acidity regulator and sensory additive in pets and other non-food-producing animals (except aquatic species) would not introduce risks not already considered.

There is no need to assess the efficacy of the additive in the context of the renewal of the authorisation. The Panel considers that the additive has the potential to be efficacious as an acidity regulator and sensory additive (flavouring compound) in feed for pets and non-food-producing animals (except aquatic animals).

### ABBREVIATIONS

AFC	EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food
ANS	EFSA Scientific Panel on Additives and Nutrient Sources added to Food
CAS	Chemical Abstracts Service
CV	coefficient of variation
EC	European Commission
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Chemical Substances
EMA	European Medicines Agency
EURL	European Union Reference Laboratory
FAO	Food Agricultural Organization
FCR	feed conversion ratio
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
FLAVIS	The EU Flavour Information System
FL-no	FLAVIS number
IUPAC	International Union of Pure and Applied Chemistry
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
LOQ	limit of quantification
OECD	Organisation for Economic Co-operation and Development
RH	relative humidity
SCAN	Scientific Committee on Animal Nutrition
SCF	Scientific Committee on Food
UB	upper bound
WHO	World Health Organization

### CONFLICT OF INTEREST

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## REQUESTOR

European Commission

## QUESTION NUMBER

EFSA-Q-2022-00402

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