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Safety and efficacy of a feed additive consisting of sodium alginate for all animal species (ALGAIA)

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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 safety and efficacy of sodium alginate for all animal species. The additive is intended to be used as a technological additive (functional groups: thickeners and gelling agents). Sodium alginate is intended to be used in feedingstuffs for all animal species at a proposed minimum concentration of 2,000 mg/kg feed and a maximum concentration of to 30,000 mg/kg feed. The data provided for the composition of the additive does not allow a proper assessment of the product consistency, purity and physico-chemical properties. Sodium alginate is not irritant to skin but should be considered irritant to eyes, a skin and respiratory sensitiser and hazardous by inhalation. Sodium alginate is a high-molecular-weight polymer naturally occurring in brown algae. The use of sodium alginate in animal nutrition is considered safe for the consumers and the environment. No conclusion could be drawn on the safety of sodium alginate for the target species or on its efficacy as a thickener or gelling agent in feed.

Keywords: technological additive, thickener, gelling agent, sodium alginate, all animal species, safety, efficacy

Requestor: European Commission

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003[1] 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 a feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from ALGAIA[2] for authorisation of the product sodium alginate, when used as a feed additive for animal species (category: technological additives; functional groups: thickeners and gelling agents).

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). The particulars and documents in support of the application were considered valid by EFSA as of 4 November 2020.

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 product sodium alginate, when used under the proposed conditions of use (see Section 3.1.3).

1.2. Additional information

Sodium alginate is currently authorised for use in feed for fish, pets and other non-food-producing animals, with no minimum and maximum content.[3] The additive is authorised in food by the Regulation (EC) No 1333/2008.[4]

The additive has been assessed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1993). They were considered safe for use in food, and an acceptable daily intake (ADI) 'not specified' was allocated. The additive has been evaluated by the Scientific Committee for Food (SCF) in 1994 (SCF, 1994) who endorsed the evaluation of JECFA for an ADI not specified.

The additive was assessed by the EFSA Panel on Food Additives and Nutrient Sources added to Food (EFSA ANS Panel, 2017), which concluded that there was no need to set a numerical ADI.

Sodium alginate was assessed by the EFSA FEEDAP Panel for use in feed for fish, pets and other non-food-producing animals, with no minimum and maximum content (EFSA FEEDAP Panel, 2017a).

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[5] in support of the authorisation request for the use of sodium alginate (E 401) as a feed additive.

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/marker residue in tissues are valid and applicable for the current application.[6]

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] ALGAIA, ZI de Ménez Bras, 29870, Lannilis, France.
[3] Commission Implementing Regulation (EU) 2018/1533 of 12 October 2018 concerning the authorisation of sodium alginate as a feed additive for cats, dogs, other non-food-producing animals and fish and potassium alginate as a feed additive for cats and dogs. OJ L 257, 15.10.2018, p. 13.
[4] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354 31.12.2008, p. 16.
[5] FEED dossier reference: FAD-2020-0035.
[6] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2010-0266_2013-0026_Alginates.doc_.pdf

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of sodium alginate is in line with the principles laid down in Regulation (EC) No 429/2008[7] 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 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 safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017d), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018) and Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019).

3. Assessment

Sodium alginate is intended to be used as a technological additive (functional groups: thickener and gelling agents) in feed for all animal species.

3.1. Characterisation

Sodium alginate (sodium;3,4,5,6-tetrahydroxyoxane-2-carboxylate; Chemical Abstract Service (CAS) number: 9005-38-3; molecular formula: $(C_6H_7NaO_6)n$) is a natural, high-molecular-weight polymer obtained from fresh or dried brown algae (e.g. *Laminaria digitata, Laminaria hyperborea, Ascophyllum nodosum, Fucus serratus, Lessonia trabeculata, Lessonia nigrescens, Macrocystis pyrifer*), the molecular weight is 198.11 g/mol.

The composition of alginates varies according to the seaweed species and even within different parts of the same seaweed. Alginate molecules occur in the cell walls and intercellular spaces, where they provide both flexibility and strength to the seaweed.

The additive is described as a creamy-white to light-brown powder with neutral odour and taste. It dissolves slowly in water, forming a viscous solution. It is insoluble in ethanol and ether.[8]

The additive is manufactured to meet the specification set for its use as a food additive[9]: sodium alginate minimum 90.8%, maximum 106%, loss on drying < 15% (105°C 4 h), water insoluble matter < 2% on the anhydrous base. The applicant proposed to add the following specification to the ones mentioned above: a maximum 0.1% calcium and pH 6–8.5. The content of sodium alginate, the loss on drying and water insoluble matter were analysed in only one batch resulting in 92.7%, 8.3% and < 2%, respectively.[10] Calcium content (seven batches)[11] ranged from 102 to 370 mg/kg and pH (5 batches) from 6.8 to 7.5.

The purity criteria specified for the food additive are: < 3 mg As/kg, < 5 mg Pb/kg, < 1 mg Hg/kg, < 1 mg Cd/kg and formaldehyde < 50 mg/kg. Seven batches[11] of the additive showed compliance with these specifications (range: 0.26–0.5 mg As/kg, 0.14–< 0.5 (LOQ) mg Pb/kg, 0.01–0.06 mg Hg/kg; Cd was found to be 0.01 mg/kg in one batch and below the LOQs in the other six batches).[12] Formaldehyde was analysed in seven batches resulting in an average of 8.6 mg/kg (2.4–23 mg/kg).[13]

The presence of mycotoxins (aflatoxin B1, B2, G1, G2, ochratoxin A, fumonisin B1, B2, zearalenone, deoxynivalenol) was examined in three batches.[14] All were below the limits of quantification (LOQs) of the analytical methods applied.[15]

[7] 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.

[8] Technical dossier/Section II/Annexes/Annex_II_28.

[9] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p. 1.

[10] Technical dossier/Section II/Annexes/ Annex_II_15.

[11] Technical dossier/Section II/Annexes/ Annex_II_4, Annex_II_5, Annex_II_6, Annex_II_7 and Technical dossier/ SIn_150921/ Section II/Annexes/Annex_II_32, Annex_II_33, Annex_II_34.

[12] Limit of quantification (LOQ): 0.005 mg/kg in four batches, 0.01 or 0.1 mg/kg in the other two batches.

[13] Technical dossier/Section II/Annexes/ Annex_II_4, Annex_II_5, Annex_II_6, Annex_II_7 and Annex_II_12.

[14] Technical dossier/FAD-2020-0035_SIn_150921/Section II/Annexes/ Annex_II_38.

[15] LOQ in μg/kg: 20 for zearalenone, fumonisins B1 and B2 and for T-2 toxin and HT-2 toxin; 50 for deoxynivalenol; 0.1 for aflatoxins B1, B2, G1; 0.2 for aflatoxin G2 and for ochratoxin A.

No analytical evidence was provided to support the compliance with the specification for microbial purity, which includes total plate counts (< 5,000 CFU/g), yeast and moulds (< 500 CFU/g), *Escherichia coli* and *Salmonella* spp. absent in 5 and 10 g, respectively.

Dioxins and the sum of dioxins plus dioxin-like polychlorinated biphenyls (PCBs) concentrations/ levels were analysed in six batches[16] and resulted in 0.051 ng WHO-PCDD/F-TEQ/kg and 0.079 ng WHO-PCDD/F-PCB-TEQ/kg, respectively.

Viscosity was measured in five batches.[17] Results showed a viscosity of 455 centipoise (cp, measured in a 1% aqueous solution at 20°C, 20 rpm).

Three batches of the additive were analysed for particle size distribution, resulting in a minimum 77.2% < 101 μm, 43.9% < 49 μm and 7.5% < 10 μm.[18] No information on the dusting potential of the additive was made available.

3.1.1. Manufacturing process

To produce the additive both fresh and (re-hydrated) dried seaweeds can be used. [redacted]

3.1.2. Stability and homogeneity

Sodium alginate is specified to have a shelf life of 12 months. However, no data supporting this claim was provided.

No analytical evidence on the stability of sodium alginate in feedingstuffs or on its capacity to homogenously distribute in feed was made available.

The Panel notes that the limited data provided does not allow to conclude on the product consistency in terms of composition, microbial purity and physico-chemical and technological properties.

3.1.3. Conditions of use

Sodium alginate is intended to be used as a technological additive (functional group: thickener and gelling agent) in feedingstuffs for all animal species at a proposed minimum concentration of 2,000 mg/kg feed and a maximum concentration of to 30,000 mg/kg feed.

3.2. Safety

The additive, sodium alginate, was first evaluated for its safety by JECFA in 1993 (JECFA, 1993). More recently, the EFSA ANS Panel (2017**)** re-evaluated the safety of alginic acid and its salts (E 400–404) as food additives. The ANS Panel concluded that:

- alginic acid and its salts were practically undigested, not absorbed intact, but partially fermented by intestinal microbiota in humans;

[16] Technical dossier/FAD-2020-0035_SIn_150921/Section II/Annexes/ Annex_II_32, Annex_II_33, Annex_II_34 and Technical dossier/ SIn_150921/Section II/Annexes/A, Annex_II_38.
[17] Technical dossier/FAD-2020-0035_SIn_150921/Section II/Annexes/ Annex_II_8.
[18] Technical dossier/FAD-2020-0035_SIn_150921/Section II/Annexes/ Annex_II_36.

- no adverse effects were reported in subchronic studies in rodents at the highest dose tested of 13,500 mg sodium alginate/kg body weight (bw) per day in rats;
- there was no concern with respect to the genotoxicity of alginic acid and its salts;
- no carcinogenic effects were reported at the highest dose tested of 37,500 mg sodium alginate/kg bw per day in mice;

On this basis, the ANS Panel concluded that there was no need for a numerical ADI for alginic acid and its salts.

To support the safety of the additive the applicant did not provide any specific study done with the additive under assessment. Instead, references were made to the above-mentioned assessments. In addition, some selected papers related to the safety for the target species, consumers and users were provided.

3.2.1. Safety for the target species

The applicant provided seven publications in which sodium alginate was tested when incorporated to feed for two animal species (pigs and poultry). However, none of these studies was further considered due to several limitations (e.g. short duration of the study, no multi-fold of the use-level). Therefore, in the absence of adequate evidence, the Panel cannot conclude on the safety of sodium alginate for the target species.

3.2.2. Safety for the consumer

Sodium alginate is not absorbed as such and no residues of alginic acid or its salts in tissues and products of animal origin are expected; therefore, the exposure of the consumer to the additive from the use of sodium alginate in animal nutrition is considered unlikely. The Panel also notes that sodium alginate is authorised as food additive.[4] Therefore, the use of sodium alginate in animal nutrition is of no concern for the consumer.

3.2.3. Safety for user

No information on the dusting potential of the additive was provided. Given the high proportion of particles of respirable size, exposure via inhalation is regarded as hazardous.

In one publication on the effects of sodium alginate on the respiratory exposure to raw seaweed dust, it has been reported that it causes pulmonary hypersensitivity, although it is not clear that pure sodium alginate would have the same effects (Henderson et al., 1984). However, considering that the product is a dermal sensitiser, the Panel concludes that sodium alginate should be considered also a respiratory sensitiser.

The additive contains formaldehyde (highest value analysed 23 mg/kg), for which concerns were expressed in previous FEEDAP opinions (EFSA FEEDAP Panel, 2014a,b) regarding its carcinogenic potential. In the absence of data on the exposure of the user to formaldehyde, the Panel considers the additive as hazardous by inhalation.

According to a BIBRA report (1988), low concentration of sodium alginate caused little or no irritation on repeated application to rabbit skin and was only mildly irritant to rabbit eyes. No irritant effects have been reported in humans, but occasional skin sensitisation was reported.

Considering all the above, the FEEDAP Panel concludes that sodium alginate is not a skin irritant but should be considered an eye irritant and a skin and respiratory sensitiser and hazardous by inhalation.

3.2.4. Safety for the environment

Alginates are high-molecular-weight polymers naturally occurring in brown algae. [redacted][19] After absorption, formaldehyde is not excreted as such but mainly as formic acid in urine, carbon dioxide, and water. No accumulation in the environment is expected.

The use of the additive in feedingstuffs for all animal species is not expected to pose a risk for the environment.

[19] Technical dossier/FAD-2020-0035_SIn_150921/Section III/Annexes/Annex_III_23.

3.3. Efficacy

Sodium alginate is authorised as a food additive. Considering the different matrices and composition of feedingstuffs compared to food, studies demonstrating the efficacy of sodium alginate as thickener and gelling agent in feedingstuffs for all animal species are considered necessary. The applicant also provided three publications, in which the additive was used for functions different to the ones applied in this evaluation, and five patents, none of which provided evidence of efficacy.

Therefore, the FEEDAP Panel cannot conclude on the efficacy of the additive as a thickener and gelling agent when used in feed for all animal species.

4. Conclusions

The data provided for the composition of the additive does not allow a proper assessment of the product consistency and purity and physico-chemical properties.

In the absence of adequate data, the FEEDAP Panel cannot conclude on the safety of sodium alginate for the target species or on its efficacy as a thickener or gelling agent in feed.

The use of sodium alginate in animal nutrition is considered safe for the consumers and the environment.

Sodium alginate is not irritant to skin but should be considered irritant to eyes, a skin and respiratory sensitiser and hazardous by inhalation.

5. Documentation as provided to EFSA/Chronology

Date	Event
06/05/2019	Reception mandate from the European Commission
12/05/2020	Dossier received by EFSA. Sodium Alginate. Submitted by Algaia.
04/11/2020	Application validated by EFSA – Start of the scientific assessment
05/02/2021	Comments received from Member States
19/5/2021	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation, safety and efficacy*
19/09/2021	Reception of supplementary information from the applicant - Scientific assessment re-started
27/01/2022	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

ADI	acceptable daily intake
ANS	EFSA Scientific Panel on Additives and Nutrient Sources added to Food
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming unit
CV	coefficient of variation
DM	dry matter
EURL	European Union Reference Laboratory
FAO	Food and Agricultural Organization
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOQ	limit of quantification
PCB	polychlorinated biphenyl
PCDD/F	polychlorinated dibenzo-*p*-dioxins and dibenzofurans
NOAEL	no observed adverse effect level
SCF	Scientific Committee on Food
TEQ	toxic equivalent
WHO	World Health Organization