

ADOPTED: 5 July 2017

AMENDED: 23 FEBRUARY 2018

doi: 10.2903/j.efsa.2017.4945

Safety and efficacy of sodium and potassium alginate for pets, other non food-producing animals and fish

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Guido Rychen, Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli, Gerhard Flachowsky, Boris Kolar, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Maria Saarela, Roberto Edoardo Villa, Robert John Wallace, Pieter Wester, Anne-Katrine Lundebye, Carlo Nebbia, Derek Renshaw, Matteo Lorenzo Innocenti and Jürgen Gropp

Abstract

Sodium and potassium alginate are intended to be used as technological additives (functional groups: emulsifiers, stabilisers, thickeners, gelling agents and binders). Sodium alginate is intended to be used in feedingstuffs for pets, other non food-producing animals and fish, with no maximum recommended use level. Potassium alginate is intended to be used in feedingstuffs for cats and dogs at levels up to 40,000 mg/kg feed (on dry matter). Since the functional properties of the additives are determined by the alginate content, sodium and potassium alginate were considered equivalent. The maximum dose considered safe for cats, dogs, other non food-producing animals, salmonids and other fish is 40,000 mg alginates (sodium and potassium salts)/kg complete feed. The use of alginates in feedingstuffs for fish is of no concern for the consumer. Alginates are reported not to be irritant to the skin but mildly irritant to the eyes. They are considered as potential sensitisers to the skin and the respiratory tract. Alginates are high-molecular-weight polymers naturally occurring in brown algae. Their use in feedingstuffs for fish does not pose a risk for the aquatic environment. Alginates are effective as stabilisers, thickeners, gelling agent and binders. No conclusion could be drawn on the efficacy of alginates as emulsifiers.

© 2017 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: sodium alginate, potassium alginate, technological additive, pets, safety, efficacy

Requestor: European Commission

Question number: EFSA-Q-2013-00678 and EFSA-Q-2013-00751

Correspondence: feedap@efsa.europa.eu

Panel members: Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Coconcelli, Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Guido Rychen, Maria Saarela, Roberto Edoardo Villa, Robert John Wallace and Pieter Wester.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Coconcelli PS, Flachowsky G, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Lundebye A-K, Nebbia C, Renshaw D, Innocenti ML and Gropp J, 2017. Scientific Opinion on the safety and efficacy of sodium and potassium alginate for pets, other non food-producing animals and fish. *EFSA Journal* 2017;15(7):4945, 13 pp. <https://doi.org/10.2903/j.efsa.2017.4945>

ISSN: 1831-4732

© 2017 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the [Creative Commons Attribution-NoDerivs License](https://creativecommons.org/licenses/by/4.0/), which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.



The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.



Summary

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 sodium alginate and potassium alginate.

Sodium and potassium alginate are intended to be used as technological additives, functional groups: (c) emulsifiers, (d) stabilisers, (e) thickeners, (f) gelling agents and (g) binders in feedingstuffs. Sodium alginate is intended to be used in feedingstuffs for pets, other non food-producing animals and fish, with no maximum recommended use level. Potassium alginate is intended to be used in feedingstuffs for cats and dogs at levels up to 40,000 mg/kg feed (on dry matter).

Since the functional properties of the additives are determined by the alginate content, sodium and potassium alginate were considered equivalent.

The maximum dose considered safe for cats, dogs, other non food-producing animals, salmonids and other fish is 40,000 mg alginates (sodium and potassium salts)/kg complete feed.

The use of alginates in feedingstuffs for fish is of no concern for the consumer.

Alginates are reported not to be irritant to the skin but mildly irritant to the eyes. They are considered as potential sensitisers to the skin and the respiratory tract.

Alginates are high-molecular-weight polymers naturally occurring in brown algae. Their use in feedingstuffs for fish does not pose a risk for the aquatic environment.

Alginates are effective as stabilisers, thickeners, gelling agent and binders. No conclusion could be drawn on the efficacy of alginates as emulsifiers.

Table of contents

Abstract.....	1
Summary.....	3
1. Introduction.....	5
1.1. Background and Terms of Reference.....	5
1.2. Additional information.....	5
2. Data and methodologies.....	5
2.1. Data.....	5
2.2. Methodologies.....	6
3. Assessment.....	6
3.1. Characterisation.....	6
3.1.1. Manufacturing process.....	6
3.1.2. Characterisation of the additives.....	6
3.1.2.1. Potassium alginate.....	7
3.1.2.2. Sodium alginate.....	8
3.1.3. Stability and homogeneity.....	8
3.1.4. Conditions of use.....	8
3.2. Safety.....	8
3.2.1. Absorption, distribution, metabolism and excretion and toxicological profile.....	8
3.2.2. Safety for the target species.....	9
3.2.2.1. Safety for dogs.....	9
3.2.2.2. Safety for cats.....	9
3.2.2.3. Safety for fish.....	9
3.2.2.4. Conclusions on safety for the target species.....	9
3.2.3. Safety for the consumer.....	10
3.2.4. Safety for the user.....	10
3.2.5. Safety for the environment.....	10
3.3. Efficacy.....	10
4. Conclusions.....	11
Documentation provided to EFSA.....	11
References.....	11
Abbreviations.....	12
Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for sodium alginate and potassium alginate.....	13

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 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 and Article 10(2) of that Regulation also specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, at the latest 1 year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of 7 years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC.

The European Commission received two requests from FMC BioPolymer UK Limited² for authorisation/re-evaluation of the product sodium alginate, when used as a feed additive for pets and other non food-producing animals and fish [category: technological additive; functional groups: (c) emulsifiers, (d) stabilisers, (e) thickeners, (f) gelling agents and (g) binders] and for authorisation of the product potassium alginate, when used as a feed additive for cats and dogs (category: technological additive; functional groups: (c) emulsifiers, (d) stabilisers, (e) thickeners, (f) gelling agents and (g) binders).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the applications to the European Food Safety Authority (EFSA) as applications under Article 4(1) (authorisation of a feed additive or new use of a feed additive) and under Article 10(2) (re-evaluation of an authorised feed additive). EFSA received directly from the applicant two technical dossiers in support of these applications. The particulars and documents in support of the applications for sodium alginate and for potassium alginate were considered valid by EFSA as of 9 September 2013 and 5 September 2013, respectively.

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 sodium alginate and potassium alginate, when used under the proposed conditions of use (see Section 3.1.4).

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. Potassium alginate is currently not authorised for use as a feed additive.

Both alginates are authorised as food additives by the Directive 95/2/EC³.

The compounds have 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 additives have been evaluated by the Scientific Committee for Food (SCF) in 1994 (SCF, 1994) who endorsed the evaluation of JECFA for an ADI not specified.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of two technical dossiers in support of the authorisation request for the use of sodium alginate⁴ and potassium alginate⁵ as feed additives. The technical dossiers were prepared following the provisions of Article 7

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 FMC BioPolymer UK Limited, Ladyburn Works, KA26 9JN, Girvan (Scotland), United Kingdom.

³ European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners. OJ L 61, 18.3.1995, p. 1.

⁴ FEED dossier reference: FAD-2010-0266.

⁵ FEED dossier reference: FAD-2013-0026.

of Regulation (EC) No 1831/2003, Regulation (EC) No 429/2008⁶ and the applicable EFSA guidance documents.

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, to deliver the present output.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of sodium and potassium alginate in animal feed. The Executive Summary of the EURL report can be found in Annex A.⁷

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of sodium and potassium alginate is in line with the principles laid down in Regulation (EC) No 429/2008 and the relevant guidance documents: Guidance on technological additives (EFSA FEEDAP Panel, 2012a), Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011a), Technical Guidance for assessing the safety of feed additives for the environment (EFSA, 2008a), Guidance for the preparation of dossiers for the re-evaluation of certain additives already authorised under Directive 70/524/EEC (EFSA, 2008b), Guidance for the preparation of dossiers for additives already authorised for use in food (EFSA FEEDAP Panel, 2012b), Guidance for establishing the safety of additives for the consumer (EFSA FEEDAP Panel, 2012c), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012d), Guidance on the assessment of additives intended to be used in pets and other non food-producing animals (EFSA FEEDAP Panel, 2011b), and Technical Guidance: Extrapolation of data from major species to minor species regarding the assessment of additives for use in animal nutrition (EFSA, 2008c).

3. Assessment

The additives under assessment are sodium alginate and potassium alginate. Sodium and potassium alginate are intended to be used as technological additives, functional groups: (c) emulsifiers, (d) stabilisers, (e) thickeners, (f) gelling agents and (g) binders in feedingstuffs.

Sodium alginate is intended to be used in feedingstuffs for pets, other non food-producing animals and fish, and potassium alginate is intended to be used in feedingstuffs for cats and dogs.

3.1. Characterisation

Alginates are natural, high-molecular-weight polymers occurring in brown algae (Phaeophyceae). The chemical 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.

3.1.1. Manufacturing process⁸

After harvest, the brown algae can be processed fresh or washed and dried. Alginic acid is extracted from brown algae by acidic and subsequent alkaline treatment.

Alginic acid is precipitated as calcium salt, re-acidified and neutralised with sodium or potassium carbonate. The resulting sodium and potassium salts are then dried and milled.

3.1.2. Characterisation of the additives⁹

Sodium and potassium alginate are salts of alginic acid. Alginic acid is a polysaccharide composed of two monomer units of polyuronic acids: β -D-mannuronic acid (M) and its C-5 epimer, α -L-guluronic acid (G), both linked through (1,4)-glycosidic bonds. The units building the linear copolymer are arranged in a block by block pattern with homopolymeric regions of G sequences (G-blocks) and a

⁶ 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.

⁷ The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2010-0266_2013-0026_Alginates.doc_.pdf

⁸ This section has been amended following the provisions of Article 8(6) and Article 18 of Regulation (EC) No 1831/2003.

⁹ This section has been amended following the provisions of Article 8(6) and Article 18 of Regulation (EC) No 1831/2003.

homopolymeric region of M residues (M-blocks) interspersed by heteropolymeric blocks of alternating M and G (MG-blocks) (Figures 1 and 2). After processing, alginates usually have a degree of polymerisation in the range 50–3,000, corresponding to molecular weights of approximately 10–600 kDa. The linear copolymers react with multivalent cations gelling or forming three-dimensional structures.

The FEEDAP Panel considers the two salts as equivalent regarding the assessment of the safety and of the efficacy of the additives.

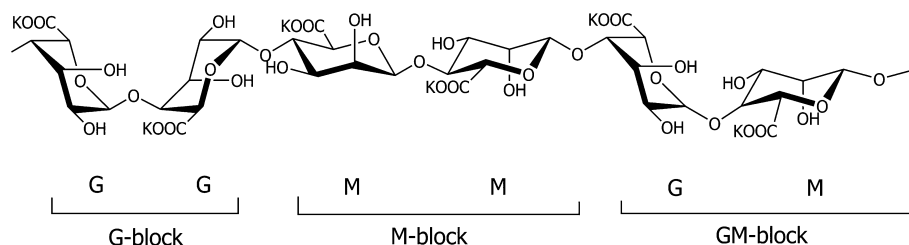


Figure 1: Structural formula of potassium alginate

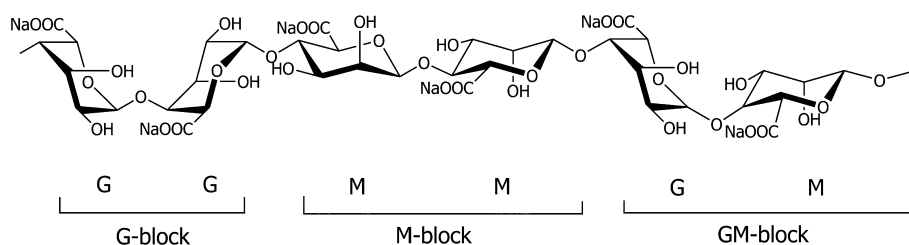


Figure 2: Structural formula of sodium alginate

3.1.2.1. Potassium alginate

Potassium alginate is provided as a white to yellowish free-flowing powder. It dissolves slowly in water, forming a viscous solution. Its viscosity depends on the molecular weight of the polymer.

Potassium alginate as a food additive (Commission Regulation (EU) No 231/2012¹⁰) is specified to yield, on the anhydrous basis, not less than 16,5% and not more than 19,5% of carbon dioxide corresponding to not less than 89,2% and not more than 105,5% of potassium alginate (calculated on an equivalent weight basis of 238). Eight batches of the feed additive were analysed for batch to batch variation showing dry matter (DM) content of 91,08–92,02% and CO₂ from alginate of 18,1–18,6%, corresponding to 95,6–98,1% potassium alginate in DM; potassium content varied between 14,4% and 15,7%.¹¹ Eight batches of the additive were also subject of Fourier transform infrared spectroscopy (FT-IR) analysis. The results confirmed the identity of the additive.¹²

Potassium alginate is specified to contain < 3 mg As/kg, < 5 mg Pb/kg, < 1 mg Hg/kg, < 1 mg Cd/kg, total plate count < 1,000 CFU/g, yeast and moulds < 500 CFU/g, *Escherichia coli* and *Salmonella* spp. absent in 5 and 10 g of the additive, respectively. Eleven batches¹³ of the additive were analysed for impurities, showing compliance with these specifications.

Eight batches of the additive were analysed for particle size distribution (laser diffraction)¹⁴ and for dusting potential (Stauber-Heubach method).¹⁵

¹⁰ 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. 1–295.

¹¹ Supplementary Information July 2014/Annex_2_FMC_2014_Potassium_alginate_CoAs.

¹² Supplementary Information July 2014/Annex_1_FMC_2014_Potassium_alginate_quality_variation_final.

¹³ Supplementary Information May 2015/Annex_10_FMC_2014_CONF_Potassium_alginate_Stability; Supplementary Information July 2014/Annex_2_FMC_2014_Potassium_alginate_CoAs.

¹⁴ Supplementary Information July 2014/Annex_1_FMC_2014_Potassium_alginate_quality_variation_final.

¹⁵ Supplementary Information April 2014/Annex_1_FMC_Potassium_alginate_Dusting_potential.

3.1.2.2. Sodium alginate

Sodium alginate is a white to brown free-flowing powder. It dissolves slowly in water, forming a viscous solution. Its viscosity depends on the molecular weight of the polymer.

Sodium alginate is specified to yield, on the anhydrous basis, not less than 18% and not more than 21% of carbon dioxide corresponding to not less than 90.8% and not more than 106.0% of sodium alginate (calculated on equivalent weight basis of 222). No specific information was provided on carbon dioxide yield. Three batches of the additive showed DM content of 85.7–87.7%; sodium content varied between 8.4% and 8.9%.¹⁶ Three batches of the additive were analysed with FT-IR. The resulting spectra were compared with a standard sodium alginate sample, confirming the identity of the additive.¹⁷

Ten batches of the additive showed compliance with the specifications (described above) regarding microbiological impurities (total plate count, yeast and moulds, *E. coli* and *Salmonella* spp.).¹⁷ No data were provided regarding heavy metals and arsenic concentrations. The applicant stated that, since the additive is manufactured from the same starting material (alginic acid) as potassium alginate, a similar concentration of impurities is to be expected.

Three batches of the additive were analysed for particle size distribution (laser diffraction),¹⁸ dusting potential (Stauber–Heubach method)¹⁹ and particle size distribution of the dust (laser diffraction).²⁰

3.1.3. Stability and homogeneity

Three studies²¹ were made with alginates (either Na or K salts) stored at different conditions.

For technological additives belonging to the functional groups emulsifiers, stabilisers, thickeners, gelling agents and binders, stability in feedingstuffs can be demonstrated by the persistence of the effect over time. Similarly, a demonstration of homogeneous distribution of the additive in feedingstuffs is not considered necessary provided that efficacy is demonstrated. The applicant has provided evidence of the stability of the additive, when used in high moisture feedingstuffs for dogs.

3.1.4. Conditions of use

Sodium alginate is intended to be used in feedingstuffs for pets, other non food-producing animals and fish, with no minimum and maximum content. Potassium alginate is intended to be used in feedingstuffs for cats and dogs, at levels up to 40,000 mg/kg feed (on DM).

3.2. Safety

Since the properties of the additives are determined by the alginate content, sodium and potassium alginate are considered equivalent.

3.2.1. Absorption, distribution, metabolism and excretion and toxicological profile

JECFA (1993) has exhaustively reviewed the existing data on toxicokinetics and toxicology of alginic acid and its salts. The main conclusions drawn by JECFA are summarised below:

- alginic acid and its salts were practically undigested and not absorbed intact
- 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
- there is no need for an ADI for alginic acid and its salts

The FEEDAP Panel is not aware of any new information that would modify these conclusions.

¹⁶ Technical dossier/ Annex_II_3_CoA.

¹⁷ Supplementary Information June 2016/Annex_5_FMC_2015_Sodium alginate_stability.

¹⁸ Supplementary Information June 2016/Annex_02_CONF_FMC_2015_Sodium alginate_PSD.

¹⁹ Supplementary Information June 2016/Annex_01_CONF_FMC_2015_Sodium alginate_Dusting potential_SHM.

²⁰ Supplementary Information June 2016/ Annex_03_CONF_FMC_2015_Sodium alginate_PSD_Dust.

²¹ Technical dossier/Annex_II_9_stability; Supplementary Information 2016/Annex_5_FMC_2015_Sodium alginate_stability; Supplementary Information May 2015/Annex_10_FMC_2014_CONF_Potassium alginate_Stability.

3.2.2. Safety for the target species²²

To support the safety for the target species, the applicant has provided three studies with dogs, four with cats and four published studies with fish. In two studies with dogs, no multifold levels were tested, and the inclusion level was lower than the proposed maximum content proposed for potassium alginate. In one study with cats the test substance used was not the alginates under assessment (propylene glycol alginate), feed was restricted, and the general health status of the animals appeared to be not satisfactory. In two other studies, no multifold levels were tested, and the inclusion level was lower than the proposed maximum content. In one of the studies with fish, the inclusion levels were lower than the maximum proposed by the applicant and no parameters that could be related to the tolerance of the target species to the additive were studied. These studies were therefore no further considered.

A 1-year study with dogs, a tolerance trial with cats and three studies with fish were considered relevant for the assessment of the safety of alginates for the target species, and are summarised below.

3.2.2.1. Safety for dogs

In a one year study, beagle dogs were fed diets supplemented with 0, 46,000 or 140,000 mg sodium alginate/kg. The FEEDAP Panel did not identify any adverse effect of sodium alginate supplementation of dog feed.

3.2.2.2. Safety for cats

Shorthair domestic cats were fed diets supplemented with 0, 5,000, 10,000, 20,000 or 40,000 mg potassium alginate/kg. No treatment related and clinically relevant effects were identified.

3.2.2.3. Safety for fish

No specific tolerance studies with alginates in feedingstuffs for fish were provided. However, some information is available in the public literature.

Storebakken (1985) fed dry, wet and moist diets to juvenile rainbow trout (*Oncorhynchus mykiss*) with graded alginate contents up to 10,000 mg/kg dry feedingstuffs. The author measured in different experiments apparent nutrient digestibility, voluntary feed intake, transit time, growth parameters and body composition. In general, alginate reduced in a dose dependent manner apparent protein and fat digestibility, as well as faecal DM content, depressed voluntary feed intake but did not influence transit time of ingesta through the gastrointestinal tract. However, feeding experiments did not show a negative effect of alginate inclusion on feed intake, growth and feed to gain ratio; also body composition was not influenced (with the exception of one study showing an increase in fat content of fillet in the fish receiving alginate).

In a second study, Storebakken and Austreng (1987) compared six alginates with different gelation properties when added to fish feed at about 50,000 mg/kg complete feed on nutrient digestibility in rainbow trout. In general, the findings of the previous study were confirmed for all alginates.

In contrast to the results observed in rainbow trout, sodium alginate up to 80,000 mg/kg in dry feed for sea bass (*Dicentrarchus labrax*) of about 60 g body weight did not influence apparent protein and fat digestibility (Spyridakis, et al., 1989). Inclusion of sodium alginate at 150,000 mg/kg did however reduce both apparent digestibility figures.

Although alginate reduced in a dose-dependent manner, the apparent digestibility of protein and fat in rainbow trout, it did not affect zootechnical parameters when included up to 100,000 mg/kg complete feed. However, it should be noted that the influence of the digestibility could become measurable when the nutrient concentration of the diet is close to the requirements, which is the case for current diets formulation.

3.2.2.4. Conclusions on safety for the target species

Since the properties of the additives are determined by the alginate content, sodium and potassium alginate are considered equivalent.

No adverse effects of alginates were identified in the studies with dogs at concentrations up to 140,000 mg/kg complete feed and with cats at doses up to 40,000 mg/kg complete feed. Consequently, the maximum dose proposed for potassium alginate (40,000 mg/kg complete feed) is considered safe for both species.

²² This section has been amended following the provisions of Article 8(6) and Article 18 of Regulation (EC) No 1831/2003.

The FEEDAP Panel considers that the same conclusion on the safety of alginates could be extrapolated to other non food-producing animals.

No adverse effects on performance of a salmonid were identified at sodium alginate concentrations up to 100,000 mg/kg complete feed, when an excess of protein was included in the diet. Therefore, the Panel concludes that a maximum concentration of 40,000 mg alginates/kg complete feed is considered safe for salmonids under current practical feeding conditions. The Panel also considers that this concentration could be applied to other fish species.

3.2.3. Safety for the consumer

Only the sodium salt is applied for use in feed for food-producing animals (fish).

The additive sodium alginate is authorised as a food additive, with no maximum content. The acceptable daily intake (ADI) for alginic acid and its salts (Na, K, and Ca) is 'not specified'.

No specific information on residues of alginate in fish is available. Sodium alginate is substantially not absorbed in the gastrointestinal tract; therefore no residues in fish are expected.

The FEEDAP Panel concludes that the use of sodium alginate in feedingstuffs for fish is of no concern for the consumer.

3.2.4. Safety for the user

No specific information on the safety of sodium and potassium alginate for the user was provided.

From the available information, the only effect reported for alginate is a pulmonary hypersensitivity in an occupational context (Henderson et al., 1984). Given the high dusting potential and the high proportion of particles of respirable size, exposure via inhalation is regarded as hazardous.

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.

3.2.5. Safety for the environment

Alginates are high-molecular-weight polymers naturally occurring in brown algae. Their use in feedingstuffs for fish is not expected to pose a risk for the environment.

3.3. Efficacy²³

Sodium and potassium alginate are authorised as food additives with no minimum or maximum concentration (*quantum satis*). The two additives are applied for authorisation under the classification of technological feed additives, functional groups: (d) stabiliser, (e) thickener, (f) gelling agent and (g) binders. Since the functional properties of the additives are determined by the alginate content, sodium and potassium alginate are considered equivalent.

In principle, since the functions of the additive are the same in both food and feed, no further evidence of efficacy would be considered necessary. However, considering the different matrices and composition of feedingstuffs compared to food, the applicant was requested to provide further evidence of efficacy in relevant feedingstuffs. The applicant has provided two sets of studies performed with potassium alginate in feedingstuffs for dogs and cats in order to support the efficacy of sodium and potassium alginate as stabiliser, thickener, gelling agent and binders; no data were made available to support the efficacy of the additives as emulsifiers.²⁴ The results of the two sets of studies supported the efficacy of potassium alginate as stabiliser, thickener and gelling agent, and the stability of the additive, as well as the maintenance of the effect over time.

Rodríguez-Miranda et al., (2012) published a study on the influence of sodium alginate on the physical and functional properties of an extruded fish meal-based (62%) fish feed. Complete feeds were supplemented with 0, 5,000, 15,000 or 20,000 mg sodium alginate/kg before extrusion in a simple-screw extruder at 120°C, 20% moisture content, each treatment in duplicate. Hardness of the extruded feed pellet significantly increased with the addition of all concentration of sodium alginate with the highest breaking force recorded in the feed supplemented with 20,000 mg/kg (3.31 Newton (N) vs 1.98 N for the control).

²³ This section has been amended following the provisions of Article 8(6) and Article 18 of Regulation (EC) No 1831/2003.

²⁴ Supplementary Information March 2015/ Annex_23_2015c_CONF_Potassium_Alginate_Stability_Homogeneity_Efficacy.

4. Conclusions

The conclusions refer equally to both sodium and potassium alginate.

The maximum dose considered safe for cats, dogs, other non food-producing animals, salmonids and other fish is 40,000 mg alginates (sodium and potassium salts)/kg complete feed.

The use of alginates in feedingstuffs for fish is of no concern for the consumer.

Alginates are reported not to be irritant to the skin but mildly irritant to the eyes. They are considered as potential sensitisers to the skin and the respiratory tract.

Alginates are high-molecular-weight polymers naturally occurring in brown algae. Their use in feedingstuffs for fish does not pose a risk for the aquatic environment.

Alginates are effective as stabilisers, thickeners, gelling agent and binders. No conclusion could be drawn on the efficacy of alginates as emulsifiers.

Documentation provided to EFSA

- 1) Sodium alginate (E 401). November 2010. Submitted by FMC BioPolymer UK Limited.
- 2) Sodium alginate (E 401). Supplementary information. June 2016. Submitted by FMC BioPolymer UK Limited.
- 3) Sodium alginate (E 401). Supplementary information. March 2017. Submitted by FMC BioPolymer UK Limited.
- 4) Potassium alginate (E 402). June 2013. Submitted by FMC BioPolymer UK Limited.
- 5) Potassium alginate (E 402). Supplementary information. April 2014. Submitted by FMC BioPolymer UK Limited.
- 6) Potassium alginate (E 402). Supplementary information. July 2014. Submitted by FMC BioPolymer UK Limited].
- 7) Potassium alginate (E 402). Supplementary information. March 2015. Submitted by FMC BioPolymer UK Limited.
- 8) Potassium alginate (E 402). Supplementary information. June 2016. Submitted by FMC BioPolymer UK Limited.
- 9) Potassium alginate (E 402). Supplementary information. March 2017. Submitted by FMC BioPolymer UK Limited.
- 10) Evaluation report of the European Union Reference Laboratory for Feed Additives on the Methods(s) of Analysis for sodium alginate and potassium alginate.
- 11) Comments from Member States.

References

- BIBRA (Bibra Toxicology Advice & Consulting), 1988. Toxicity Profile for Alginic Acid and its Common Salts. BIBRA, Wallington, UK, pp. 1-8. Available online: <https://www.bibra-information.co.uk/downloads/toxicity-profile-for-alginic-acid-and-its-commonsalts-1988/>
- EFSA (European Food Safety Authority), 2008a. Technical Guidance of the Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) for assessing the safety of feed additives for the environment. EFSA Journal 2008,6(10):842, 28 pp. <https://doi.org/10.2903/j.efsa.2008.842>
- EFSA (European Food Safety Authority), 2008b, revised in 2009. Guidance of the Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) for the preparation of dossiers for the re-evaluation of certain additives already authorised under Directive 70/524/EEC. EFSA Journal 2008,6(9):779, 9 pp. <https://doi.org/10.2903/j.efsa.2008.779>
- EFSA (European Food Safety Authority), 2008c. Technical Guidance: Extrapolation of data from major species to minor species regarding the assessment of additives for use in animal nutrition. EFSA Journal 2008;6(9):803, 5 pp. <https://doi.org/10.2903/j.efsa.2008.803>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011a. Technical guidance: Tolerance and efficacy studies in target animals. EFSA Journal 2011;9(5):2175, 15 pp. <https://doi.org/10.2903/j.efsa.2011.2175>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011b. Guidance on the assessment of additives intended to be used in pets and other non food-producing animals. EFSA Journal 2011;9(2):2012, 3 pp. <https://doi.org/10.2903/j.efsa.2011.2012>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012a. Guidance for the preparation of dossiers for technological additives. EFSA Journal 2012;10(1):2528, 23 pp. <https://doi.org/10.2903/j.efsa.2012.2528>

- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012b. Guidance for the preparation of dossiers for additives already authorised for use in food. *EFSA Journal* 2012;10(1):2538, 4 pp. <https://doi.org/10.2903/j.efsa.2012.2538>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012c. Guidance for establishing the safety of additives for the consumer. *EFSA Journal* 2012;10(1):2537, 12 pp. <https://doi.org/10.2903/j.efsa.2012.2537>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012d. Guidance on studies concerning the safety of use of the additive for users/workers. *EFSA Journal* 2012;10(1):2539, 5 pp. <https://doi.org/10.2903/j.efsa.2012.2539>
- Henderson AK, Ranger AF, Lloyd J, McSharry C, Mills RJ and Moran F, 1984. Pulmonary hypersensitivity in the alginate industry. *Scottish Medical Journal*, 29, 90–95.
- JECFA (Joint FAO/WHO expert Committee on Food Additives), 1993. 755. Alginic acid and its ammonium, calcium, potassium and sodium salts. *WHO Food Additives Series* 30.
- SCF (Scientific Committee for Food), 1994. Revision of previous opinions on alginates. *Foodscience and techniques. Reports from the Scientific Committee for Food*, 32nd series.
- Spyridakis P, Metailler R and Gabaudan J, 1989. Studies on nutrient digestibility in European sea bass (*Dicentrarchus labrax*) – 2. Effect of sodium alginate on protein and lipid digestibility. *Aquaculture*, 77, 71–73.
- Storebakken T, 1985. Binders in Fish Feed – 1. Effect of alginate and guar gum on growth, digestibility, feed intake and passage through the gastrointestinal tract of rainbow trout. *Aquaculture*, 47, 11–26.
- Storebakken T and Austreng E, 1987. Binders in Fish Feed – II. Effect of different alginates on the digestibility of macronutrients in rainbow trout. *Aquaculture*, 60, 121–131.
- Rodríguez-Miranda J, Delgado-Licon E, Hernández-Santos B, Medrano-Roldan H, Aguilar-Palazuelos E, Navarro-Cortez RO, Gómez-Aldapa CA and Castro-Rosas J, 2012. Effect of sodium alginate on functional properties of extruded feed for fish for human consumption. *Journal of Animal Science Advances*, 2, 608–615.

Abbreviations

ADI	acceptable daily intake
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming unit
DM	dry matter
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
FT-IR	Fourier transform infrared spectroscopy
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOD	limit of detection
RH	relative humidity
SCF	Scientific Committee for Food

Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for sodium alginate and potassium alginate

In the current application, authorisation is sought under articles 4(1) and 10(2) for sodium alginate (E 401) and potassium alginate (E 402) under the category/functional group 1(c,d,e,f,g) 'technological additives'/emulsifiers, stabilisers, thickeners, gelling agents and binders' according to Annex I of Regulation (EC) No 1831/2003. The authorisation is sought for the use of the feed additive for cats and dogs and for pets and other non food-producing animals and fish. Sodium alginate and potassium alginate are white to brown and yellowish free-flowing powders, composed of two monomer units of polyuronic acids. The commercially available alginates are natural high-molecular-weight polymers produced from brown algae. The Applicant stated that the purity criteria set in the Commission Directive 2009/10/EC for the food additive apply to the requirement for the both feed additives. Both feed additives are intended to be incorporated directly into feedingstuffs. While no minimum or maximum concentration limits were recommended for sodium alginate in feedingstuffs, the Applicant suggested a maximum concentration for potassium alginate of 40 g/kg feedingstuffs. For the identification of sodium alginate and potassium alginate in the feed additives, the Applicant proposed the methods described in the internationally recognised FAO JECFA monographs for food additives based on: the tests for alginates, sodium and potassium; the precipitate formation in the presence of calcium chloride or ammonium sulfate; and the assay for the carbon dioxide determination by decarboxylation. These methods are also recommended in Commission Directive 2009/10/EC laying down specific purity criteria on food additives other than colours and sweeteners. Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned FAO JECFA methods to identify sodium alginate and potassium alginate in the feed additives. The accurate determination of sodium alginate and potassium alginate in feedingstuffs is not achievable experimentally. Therefore, the EURL cannot evaluate nor recommend any method for official control to determine sodium alginate and potassium alginate in feedingstuffs. Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005) is not considered necessary.