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Safety and efficacy of a feed additive consisting of acacia gum (gum Arabic) for all animal species (A.I.P.G. Association for International Promotion of Gums)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Fašmon Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Paul Brantom, Kettil Svensson, Lucilla Gregoretti, Gloria López-Gálvez, Konstantinos Sofianidis and Matteo Innocenti

Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of acacia gum (gum Arabic) as a feed additive for all animal species. Acacia gum is safe up to approximately 280 mg/kg complete feed for chickens for fattening, 375 mg/kg complete feed for turkeys for fattening, 400 mg/kg complete feed for rabbit, 500 and 600 mg/kg complete feed for piglets and pigs for fattening, respectively, 1,100 mg/kg complete feed for cattle for fattening and 1,250 mg/kg complete feed for veal calves and salmonids. No conclusions can be reached on the safety for long living and reproductive animal, until the genotoxic potential of the additive is fully assessed in the framework of its use as a feed additive. No exposure of the consumer to the additive or its metabolites is expected. Therefore, the use of the additive in animal nutrition is considered safe for the consumers. Acacia gum is a potential dermal and respiratory sensitiser. No conclusion can be reached on the irritating potential to the skin or eyes. The use of acacia gum in animal nutrition is considered safe for the environment. The FEEDAP Panel is not in the position to conclude on the efficacy of acacia gum.

Keywords: technological additive, emulsifiers, gelling agents, stabilisers, thickeners, acacia gum, gum Arabic, safety, efficacy

Requestor: European Commission

Question number: EFSA-Q-2013-01022

Correspondence: feedap@efsa.europa.eu

Panel members: Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Fašmon Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, 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 one 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 seven 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 a request from A.I.P.G. Association for International Promotion of Gums[2] for re-evaluation of the product acacia gum (gum Arabic), when used as a feed additive for all animal species (category: technological additives; functional groups: emulsifiers, gelling agents, stabilisers, thickeners).

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 10(2) (re-evaluation of an authorised feed additive). 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 06/08/2014.

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 acacia gum (gum Arabic), when used under the proposed conditions of use (see Section 3.1.3).

1.2. Additional information

Acacia gum is currently authorised as a feed additive[3] and subject to re-evaluation according to Article (10) of Regulation EC 1831//2003. Acacia gum is authorised to be used as a food additive in accordance with Annex II to Regulation (EC) No 1333/2008[4] with specific purity criteria defined in Commission Regulation (EU) No 231/2012[5].

Acacia gum has not been previously assessed by EFSA as a feed additive. It has been assessed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1982). The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) delivered an 'opinion on the re-evaluation of acacia gum (E 414) as a food additive' (EFSA ANS Panel, 2017) and in 2019 the EFSA Panel on Food Additives and Flavourings (FAF) issued an 'Opinion on the re-evaluation of acacia gum (E 414) as a food additive in foods for infants below 16 weeks of age and the follow-up of its re-evaluation as a food additive for uses in foods for all population groups' (EFSA FAF Panel, 2019). In these opinions, the ANS and the FAF Panels concluded that a numerical average daily intake (ADI) is not necessary, and that the additive is safe when used in food.

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[6] in support of the authorisation request for the use of acacia gum as a feed additive.

[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] A.I.P.G. Association for International Promotion of Gums, Sonnistrasse 28, D-20097, Hamburg, Germany.
[3] Commission Directive of 8 July 1985 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs, https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1985:245:0001:0032:EN:PDF
[4] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:en:PDF
[5] 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, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0231&from=EN
[6] FEED dossier reference: FAD-2010-0159.

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' knowledge, 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 the acacia gum 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 acacia gum is in line with the principles laid down in Regulation (EC) No 429/2008[8] and the relevant guidance documents: Guidance for the preparation of dossiers for technological additives (EFSA FEEDAP Panel, 2012a), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012b), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c), 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

The product under assessment, acacia gum, is the dried exudation obtained from the stems and branches of natural strains of *Acacia senegal* (L.) Willdenow or closely related species of *Acacia* (family Leguminosae), intended to be used as a technological feed additive (functional groups: emulsifiers, stabilisers, thickeners and gelling agents) in feedingstuffs for all animal species.

3.1. Characterisation

3.1.1. Characterisation of the additive

The additive consists of pure acacia gum (synonym: gum Arabic, Chemical Abstracts Service (CAS) number 9000-01-5, European Inventory of Existing Commercial Chemical Substances (EINECS) number 232-519-5), a white to yellowish-white powder. Acacia gum is a natural exudate obtained by incision of the trunk and branches of acacia trees. The gum is hand-collected from the trees. To obtain the additive, the raw gum is kibbled to a mesh size and purified (i) by pulverisation and sieving or (ii) by dissolution in water to form a syrup, which is filtered, centrifuged, submitted to high temperature and then dried.

Acacia gum is constituted by high molecular weight polysaccharides, whose sugar chain is made of neutral sugars (galactose, arabinose and rhamnose) and acidic sugars (glucuronic acid and/or their salts).

Five batches each of two acacia gum exudates were analysed (after hydrolysis) for molar distribution of the sugars.[9] Galactose was in the range 28.3–37.1% (molar), arabinose 31.7–53.6% (molar), rhamnose 1.9–16.3% (molar) and glucuronic acid 5.3–16.3% (molar). The same batches showed also concentrations of arabinogalactoprotein in the range 6.8–36.9% (molar), and concentrations of arabinogalactan plus glycoprotein fraction ranging from 63.1% to 93.2 % (molar); the molecular weights varied between 373,000 and 1,071,100 Da.

The feed additive acacia gum is manufactured to meet the specifications set for its use as a food additive.[5] The specifications as food and feed additive are: loss on drying < 10%, total ash < 4%, acid-insoluble matter < 1% and acid-insoluble ash < 0.5%. The analysis of five batches of the additive[10] resulted in: loss on drying 7.6–9.3%, total ash 3.4–3.6%, acid-insoluble matter 0.04–0.05% and acid-insoluble ash < 0.5%. The batches were also in compliance with the additional specifications as food

[7] The full report is available on the EURL website: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

[8] 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.

[9] Technical dossier/Supplementary Information April 2016/1_REVISED_12thApril2016_Dossier_ACACIA_EFSA-Q-2013-01022_FAD-2010-0159.

[10] Technical dossier/Section II/Annexes Sect. II/Acacia Gum CO1 to 5.

additive for tannins and starch or dextrin (no changes in colour or precipitation after treatment with ferric chloride solution or iodine, respectively). A 25% water solution of the same batches of the additive also showed the following characteristics: pH 4.1–4.4 and viscosity 105–110 mPa-s. No data on the solubility of the additive under assessment was provided.

The analysis of the same five batches of the additive[10] showed concentrations of lead, mercury, cadmium and of arsenic in compliance with the specifications set for the use of acacia gum as a food additive (< 1, < 3, < 1 and < 1 mg/kg, respectively). Five additional batches of the additive were analysed for impurities and contaminants.[11] Lead concentration varied between < 0.02 (limit of quantification, LOQ) and 0.036 mg/kg, mercury, cadmium and arsenic were below the respective LOQs.[12] Aluminium concentration was in the range 3.7–14.7 mg/kg, iron 3.2–16.5 mg/kg, copper 1.1–1.59 mg/kg, and zinc and tin below the respective LOQs.[13] Ochratoxin A was below the LOQ (0.5 μg/kg in four batches and 0.02 μg/kg in one batch), as well as aflatoxins B1, B2, G1 and G2 (< 0.01 μg/kg for all of them in four batches, < 0.02 μg/kg in one batch). The sum of polychlorinated dibenzo-*p*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) was in the range of 0.032–0.13 ng PCDD/F WHO-TEQ/kg, dioxin-like polychlorinated biphenyls (PCBs) were in the range 0.015–0.06 ng WHO-TEQ/kg, and the sum of dioxins and dioxins-like PCBs in the range 0.047–0.19 ng PCDD/F + PCB WHO-TEQ/kg. The pesticides were not detected in a multiresidue analysis (> 30 compounds of different groups). *Escherichia coli* (in 5 g) and *Salmonella* spp. (in 25 g) were absent in all the batches.

The detected amounts of the above impurities do not raise concerns.

The dusting potential (Stauber–Heubach) tested in one batch of the additive (three replicated analysis) showed values of 1.62–2.16 g/m^3.[14] The analysis of the five batches of the additive showed that < 15% of the particles had a diameter of < 63 μm (sieve analysis).[10] No information on the presence of small particles, including nanoparticles, was provided.

3.1.2. Stability and homogeneity

For technological additives, stability can be demonstrated by the persistence of the effect; no demonstration of homogenous distribution is considered necessary if the efficacy of the additive is demonstrated. The applicant provided studies to support the stability of the additive, described below, and the stability/efficacy in feedingstuffs (reported in Section 3.3).

One sample of acacia gum was stored for 2 years in aluminium bags at temperatures of 5°C, 25°C or 40°C.[15] The samples were tested for viscosity in a 10% water solution, measured at 20°C, with a rotation speed of the probe of 60 rpm. The measurements were done after manufacturing and after 1 and 2 years of storage at ambient conditions. The results showed no substantial changes in viscosity of the solution in any sample stored at any temperature, compared to the initial result (13.5 mPa·s).

3.1.3. Conditions of use

The additive is intended to be used as a technological additive (functional groups: emulsifiers, gelling agents, stabilisers and thickeners) in feedingstuffs for all animal species, with no minimum or maximum content. The applicant proposed the following typical use levels: 10,000–50,000 mg/kg pelleted feed, i.e. bolus-tablets (as a binder); 50,000–300,000 mg/kg liquid feed (as a thickener); 20,000–50,000 mg/kg kibbled feed (as a binder/glazing agent); 20,000–50,000 mg/kg fat filled feed (as a coating agent); 20,000–100,000 mg/kg granulated powder (as granulating agent); 250,000–900,000 mg/kg in feed containing flavourings, vitamins, trace elements and probiotics (as emulsifier, stabiliser and carrier).

3.2. Safety

The safety of acacia gum was assessed by JECFA (JECFA, 1982) and most recently by the EFSA ANS and FAF Panels in two opinions (EFSA ANS Panel, 2017; EFSA FAF Panel, 2019). To support the safety of the additive, the applicant made reference to the conclusions reached in these evaluations

[11] Technical dossier/Supplementary Information April 2016/2016_AIPG_FAD-2010-0159 Acacia Gum-supplementary information-Annex.
[12] Limit of quantification: mercury 0.005 mg/kg; cadmium 0.01 mg/kg; arsenic 0.01 mg/kg.
[13] Limit of quantification: zinc 1 mg/kg; tin 1 mg/kg.
[14] Technical dossier/Supplementary Information April 2016/2016_AIPG_FAD-2010-0159 Acacia Gum-supplementary information-Annex_7.
[15] Technical dossier/Supplementary Information April 2016/2016_AIPG_FAD-2010-0159 Acacia Gum-supplementary information-Annex_8.

but made available for the present assessment only some of the studies used by EFSA in its previous evaluations (EFSA ANS Panel, 2017; EFSA FAF Panel, 2019). The main results of the previous assessments are summarised below, in the respective sections.

In addition, the applicant conducted three literature searches to identify in the scientific literature data which could support the safety of the additive. The first one was done using PubMed as database platform, covering the period between years 2016 and 2021, and using as keywords: Acacia gum; Gum Arabic or E 414.[16] The second one was done using 50 cumulative databases (including LIVIVO, AGRICOLA, MEDLINE, PubMed and OVID, 15 single databases, and 8 publisher databases including IngentaConnect, Wiley and SpringerLink), using as keywords: Gum acacia; Gum Arabic; Acacia extra pure; Acacia gum or 9000-01-5, and limiting the search to cats, dogs and fish.[17] The third one done using PubMed as database platform, covering the period between years 2016 and 2021, and using as keywords: Acacia gum, Gum Arabic hypersensibility; Acacia gum, Gum Arabic allergenicity; Acacia gum, Gum Arabic food intolerance.[18]

3.2.1. Absorption, Distribution, Metabolism and Excretion

In its assessments of acacia gum as a food additive, the ANS Panel considered the available *in vitro* (several animal species and human gut bacteria) and *in vivo* (rats and humans) studies (EFSA ANS Panel, 2017). The ANS Panel concluded that 'Overall, the *in vitro* degradation and the *in vivo* digestibility of acacia gum have been investigated in animal and human models. These studies demonstrated that acacia gum would not be absorbed intact and would not be metabolised by enzymes present in the gastrointestinal tract. However, it would be partially fermented during its passage through the large intestine by the action of the intestinal tract microflora. The rate of hydrolysis in the gastrointestinal tract in humans is unknown, but it is expected that the limited extent of hydrolysis of acacia gum would lead to the production of its fermentation products such as [short chain fatty acids] SCFAs. Based on the available knowledge on the role of SCFA as end products of the fermentation of dietary fibres by the anaerobic intestinal microflora (Topping and Clifton, 2001; Den Besten et al., 2013), the Panel considered that their potential formation as fermentation products from acacia gum does not raise a safety concern'.

The FEEDAP Panel supports the above conclusions and does not see any reasons to consider that the additive would behave differently in the gut of the target species.

3.2.2. Toxicology

3.2.2.1. General toxicology

For the current evaluation, the applicant submitted the relevant studies that were evaluated in the EFSA ANS Panel opinion (EFSA ANS Panel, 2017) and additional papers from the literature (see Section 3.2).

Regarding general toxicity, the ANS Panel assessed several acute (in rat, hamster and rabbit), sub-acute (in rats) and short term (in rats) studies, four sub-chronic studies (in rats and mice), a carcinogenicity study (in rats and mice), three reproductive toxicity studies (in rats) and several developmental studies (in rats, mice, hamsters and rabbits). The ANS Panel concluded that 'Overall, the short-term and sub-chronic administration of oral doses up to 5,000 mg acacia gum/kg bw per day to rats and 20,000 mg acacia gum/kg bw per day to mice, the highest doses tested, did not induce any biologically relevant adverse effects'. In some studies, caecal enlargement was observed. The Panel considered that an increased caecum weight in animals fed high amounts of carbohydrates is considered as a physiological response to an increased fermentation by the intestinal microbiota. 'Acacia gum was tested for carcinogenicity in rats and mice receiving diets containing 2.5% and 5% acacia gum in the feed for 103 weeks equivalent to 1,250 and 2,500 mg acacia gum/kg bw per day in rats, and 3,750 and 7,500 mg acacia gum/kg bw per day in mice. From this study, the Panel considered that acacia gum is not of concern with respect to carcinogenicity. In a dietary combined fertility and developmental toxicity study in rats, a no observed adverse effect level (NOAEL) of 10,647 mg acacia gum/kg bw per day for reproductive, developmental and parental effects was identified, the highest dose tested. In addition, other reproductive studies in rats showed no effects at the highest dose tested. In the identically performed prenatal developmental tests with acacia gum by gavage in

[16] Technical dossier/Supplementary Information April 2021/Annex 1-1.
[17] Technical dossier/Supplementary Information April 2021/Annex 2.
[18] Technical dossier/Supplementary Information April 2021/Annex 3.

mice, rats and hamsters, 1,600 mg/kg bw per day (the highest doses tested) showed no dose-related developmental effects'.

The applicant retrieved 17 publications on ADME or toxicology of acacia gum which were published after the opinion of the ANS Panel was delivered (EFSA ANS Panel, 2017). None of these studies was designed to study the toxicological effects of acacia gum; in addition, in most of the studies the additive was administered in combination with other substances/microorganisms or was administered to sick animals. None of these studies were therefore further considered for the assessment of the safety of acacia gum.

The FEEDAP Panel, having reviewed the relevant studies previously evaluated by the ANS Panel, supports the above conclusions.

3.2.2.2. Genotoxicity

In the report provided by the applicant (Newell and Maxwell, 1972, Stanford Research Institute),[19] acacia gum (unspecified origin, reported as gum Arabic, FDA n. 71-15) was tested *in vitro and in vivo* for the induction of gene mutations, mitotic recombination, and chromosomal aberrations. The FEEDAP Panel identified limitations in most of these studies, in agreement with the evaluation performed by the ANS Panel (2017). Therefore, it was confirmed their low relevance for risk assessment.

The ANS Panel assessed several additional *in vitro* and *in vivo* genotoxicity studies (investigating induction of gene mutations, mitotic recombination and chromosomal aberrations). Although some limitations were identified for different aspects, taking into consideration the negligible absorption of acacia gum, the ANS Panel concluded that: 'Overall, based on the data available, the Panel concluded that there is no concern with respect to the genotoxicity of acacia gum' (EFSA ANS Panel, 2017).

The FEEDAP Panel also noted that the evaluation of potential aneugenic effect (following the indications of the EFSA Scientific Committee (SC) guidance on aneugenicity assessment (EFSA Scientific Committee, 2021)) was not covered by *in vivo* studies made available to the ANS Panel for their evaluation.

On the basis of the information provided in the ANS Panel opinion, the FEEDAP Panel would support the conclusions therein reached. However, in the absence of most of the original reports of the studies on which these conclusions were based and considering that the potential aneugenic effect was not covered by the available studies, the FEEDAP Panel cannot fully evaluate the potential genotoxicity of acacia gum in the framework of its authorisation as a feed additive.

3.2.3. Safety for the target species

No specific studies aimed to demonstrate the safety of the additive in the target species were made available. A literature search was conducted, focusing in particular on publications related to the use of acacia gum in dogs and cats (see Section 3.2). However, none of the studies identified could be considered in this assessment, because of the shortcomings in the study design and the lack of the endpoints and parameters considered necessary for the assessment of the safety for the target species. The maximum safe concentration of the additive in complete feed could be derived using the results of the toxicological studies (EFSA FEEDAP Panel, 2017b) . Among the studies evaluated in the assessment, the FEEDAP Panel considered that the results of the chronic toxicity study in rats are the most appropriate to identify a NOAEL (2,500 mg/kg bw per day). An uncertainty factor of 100 was used to cover the intra- and interspecies variation. The results are reported in Table 1.

Table 1: Maximum safe concentration in feed of acacia gum for different target animal category

Animal category	Default values		Maximum safe concentration in feed (mg/kg feed)(1)
	Body weight (kg)	Feed intake (g DM/day)	
Chicken for fattening	2	158	278
Laying hen	2	106	415
Turkey for fattening	3	176	375
Piglet	20	880	500

[19] Technical dossier/Supplementary information September 2021/Spontaneous_150921_31_Newell_Study of mutagenic effects of gum Arabic_1972.

Animal category	Default values		Maximum safe concentration in feed (mg/kg feed)(1)
	Body weight (kg)	Feed intake (g DM/day)	
Pig for fattening	60	2,200	600
Sow lactating	175	5,280	729
Veal calf (milk replacer)	100	1,890	1,164
Cattle for fattening	400	8,000	1,100
Dairy cow	650	20,000	715
Sheep/goat	60	1,200	1,100
Horse	400	8,000	1,100
Rabbit	2	100	440
Salmon	0.12	2.1	1,257
Dog	15	250	1,320
Cat	3	60	1,100
Ornamental fish	0.012	0.054	4,889

DM: dry matter.
(1): Complete feed DM = 88%, milk replacer DM = 94.5%.

The calculated safe values ranged between 278 mg/kg feed in chickens for fattening and 4,889 mg/kg feed in ornamental fish. However, considering that the genotoxic potential of the additive could not be fully assessed, the FEEDAP Panel is not in the position to conclude on a safe concentration for reproductive and long living animals.

The FEEDAP Panel concludes that acacia gum is safe up to approximately 280 mg/kg complete feed for chickens for fattening, 375 mg/kg complete feed for turkeys for fattening, 500 and 600 mg/kg complete feed for piglets and pigs for fattening, respectively, 1,150 mg/kg complete feed for veal calves, 1,100 mg/kg complete feed for cattle for fattening, 400 mg/kg complete feed for rabbit and 1,260 mg/kg complete feed for salmonids.

3.2.4. Safety for the consumer

The additive is not absorbed as such in the gastrointestinal tract of the target animals. Its fermentation products in the gut (short-chain fatty acids) will be metabolised following the normal metabolic pathways of such substances. Any deposition of the additive or its fermentation by-products in tissues and products from animal origin is unlikely. Since no exposure of the consumer to the additive or its metabolites is expected, the use of the additive in animal nutrition is considered safe for the consumer.

3.2.5. Safety for user

The limited data provided show that the additive has a high dusting potential (1.6–2.2 g/m^3). Exposure via inhalation is therefore possible.

No information was provided on the irritant potential for eyes or skin. Four publications on the sensitisation potential of the additive (Strobel et al., 1982; Fötisch et al. 1998; Sander et al., 2006; Viinanen et al., 2011) were provided (see section 3.2), all confirming the dermal sensitising potential of acacia gum (gum Arabic) in exposed workers.

Owing to the absence of data, the FEEDAP Panel was not in the position to fully evaluate the potential genotoxicity of acacia gum and its implications for user safety.

The FEEDAP Panel concludes that acacia gum is a potential dermal and respiratory sensitiser. No conclusion can be reached on the irritant potential for skin or eye.

3.2.6. Safety for the environment

Acacia gum is a natural plant derived product, whose components are ubiquitous in nature, therefore its use in animal nutrition is considered safe for the environment.

3.3. Efficacy

To support the efficacy of acacia gum, the applicant submitted an *in vitro* study done in dog chews, three patents, one technical bulletin for a commercial product and a publication on the use of biopolymers in microencapsulation. The study done in dog chews showed several shortcomings (e.g. absence of control group, concentration of acacia gum in feed not reported, results presented only in graphic form), and therefore was not further considered.[20] The publication (Pedroza-Islas et al., 1999) on the comparison of different biopolymer blends in microencapsulation of feeds did not include any detail on the efficacy of the additive, and the three patents[21,22,23] and the bulletin[24] did not contain details of the studies referenced to support the claims. Therefore, none of them could be used to assess the efficacy of acacia gum.

The FEEDAP Panel, in the absence of information, is not in the position to conclude on the efficacy of acacia gum.

4. Conclusions

Acacia gum is safe up to ~ 280 mg/kg complete feed for chickens for fattening, 375 mg/kg complete feed for turkeys for fattening, 400 mg/kg complete feed for rabbit, 500 and 600 mg/kg complete feed for piglets and pigs for fattening, respectively, 1,100 mg/kg complete feed for cattle for fattening and 1,250 mg/kg complete feed for veal calves and salmonids. No conclusions can be reached on the safety for long living and reproductive animals, until the genotoxic potential of the additive has been fully assessed in the framework of its use as a feed additive.

The use of the additive in animal nutrition is considered safe for the consumer and the environment.

Acacia gum is a potential dermal and respiratory sensitiser. No conclusion can be reached on the irritant potential for skin or eye.

In the absence of adequate data, the FEEDAP Panel is not in the position to conclude on the efficacy of acacia gum as an emulsifier, gelling agent, stabiliser and thickener.

5. Documentation as provided to EFSA/Chronology

Date	Event
13/10/2010	Dossier received by EFSA. Acacia gum (gum Arabic) for all animal species. Submitted by A.I.P.G. (Association for International Promotion of Gums).
11/12/2013	Reception mandate from the European Commission
06/08/2014	Application validated by EFSA – Start of the scientific assessment
06/11/2014	Comments received from Member States
27/11/2014	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterization, efficacy*
05/12/2014	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
20/04/2016	Reception of supplementary information from the applicant - Scientific assessment re-started
03/08/2016	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: safety for target species*
31/03/2017	Reception of supplementary information from the applicant - Scientific assessment re-started
14/01/2021	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: safety for target species, safety for user*

[20] Technical dossier/Supplementary Information April 2016/2016_AIPG_FAD-2010-0159 Acacia Gum-supplementary information-Annex_8

[21] Technical dossier/Supplementary Information April 2016/2016_AIPG_FAD-2010-0159 Acacia Gum-supplementary information-Annex_10.

[22] Technical dossier/Supplementary Information April 2016/2016_AIPG_FAD-2010-0159 Acacia Gum-supplementary information-Annex_11.

[23] Technical dossier/Supplementary Information April 2016/2016_AIPG_FAD-2010-0159 Acacia Gum-supplementary information-Annex_12.

[24] Technical dossier/Supplementary Information April 2016/2016_AIPG_FAD-2010-0159 Acacia Gum-supplementary information-Annex_14.

Date	Event
13/04/2021	Reception of supplementary information from the applicant - Scientific assessment re-started
23/03/2022	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

ADI	average daily intake
ADME	absorption, distribution, metabolism and excretion
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
EINECS	European Inventory of Existing Chemical Substances
EURL	European Union Reference Laboratory
FAO	Food Agricultural Organization
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
LOD	limit of detection
LOQ	limit of quantification
NOAEL	no observed adverse effect level
PCB	polychlorinated biphenyl
PCDD	polychlorinated dibenzo-*p*-dioxin
PCDF	polychlorinated dibenzofuran
SD	Standard Deviation
SCF	Scientific Committee on Food
TEQ	toxic equivalent
WHO	World Health Organization

Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for acacia gum

In the current applications authorisation is sought under article 10(2) for Acacia gum under the 'category'/'functional groups' 1(c), 1(d), 1(e) and 1(f) 'technological additives'/'emulsifiers', 'stabilisers', 'thickeners' and 'gelling agents' according to the classification system of Annex I of Regulation (EC) No 1831/2003. Specifically, authorisation is sought for the use of the feed additive for all animal species. The feed additive is a dried natural exudate obtained from the stems and branches of natural strains of Acacia Senegal Willdenow or Acacia Seyal belonging to the family Leguminosae. Acacia gum consists mainly of high molecular weight polysaccharides and their calcium, magnesium and potassium salts. Acacia gum can be used in the form of flakes, granulates, powder and spray-dried material. The Applicant stated that the purity criteria/specification set in Commission Regulation (EU) 231/2012 for the food additive are applicable also for the feed additive [3]. The feed additive is intended to be incorporated into feedingstuffs through premixtures with no recommended minimum or maximum inclusion levels. For the characterisation of Acacia gum the Applicant refers to the Commission Regulation (EU) 231/2012 which requires a solubility test and the following quantitative assays: - loss on drying; - total ash; - acid-insoluble ash; and – acid-insoluble matter. These methods are described in the FAO JECFA Compendium for food additives. Furthermore, two European Pharmacopoeia monographs are available for the characterisation of crude and spray-dried Acacia gums. The two monographs are very similar, the main difference residing on loss on drying and insoluble matter characteristics. The monographs include also a test for viscosity. Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned methods for the characterisation of Acacia gum described in the European Pharmacopoeia monographs and the Commission Regulation (EU) 231/2012. Since the accurate quantification of Acacia gum added to premixtures or feedingstuffs is not achievable experimentally the EURL cannot evaluate nor recommend any method for official control to quantify Acacia gum in premixtures or 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.