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Re-evaluation of acacia gum (E 414) as a food additive

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Abstract

The Panel on Food Additives and Nutrient Sources added to Food (ANS) provides a scientific opinion re-evaluating the safety of acacia gum (E 414) as a food additive. In the EU, acacia gum has not been formally evaluated by the Scientific Committee for Food (SCF), and therefore, no ADI has been allocated. However, it was accepted for use in weaning food (SCF, 1991). In 1999, the SCF considered 'that the use of acacia gum/gum arabic in coatings for nutrient preparations containing trace elements is acceptable provided carry-over levels in infant formulae, follow-on formulae or FSMP do not exceed 10 mg/kg'. Acacia gum was evaluated by JECFA in 1982 and 1990 and the specifications were amended in 1998. Based on the lack of adverse effects in the available toxicity studies, an ADI 'not specified' was allocated. Following the conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EU) No 257/2010, the Panel considered that adequate exposure and toxicity data were available. Acacia gum is unlikely to be absorbed intact and is slightly fermented by intestinal microbiota. No adverse effects were reported in subchronic and carcinogenicity studies at the highest dose tested and there is no concern with respect to the genotoxicity. Oral daily intake of a large amount of acacia gum up to 30,000 mg acacia gum/person per day (approximately equivalent 430 mg acacia gum/kg bw per day) for up to 18 days was well tolerated in adults but some individuals experienced flatulence which was considered by the Panel as undesirable but not adverse effect. The Panel concluded that there is no need for a numerical ADI for acacia gum (E 414), and there is no safety concern for the general population at the refined exposure assessment of acacia gum (E 414) as a food additive.

Keywords: Acacia gum (E 414), gum arabic, CAS Registry Number 9000-01-5, food additive

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Summary

Following a request from the European Commission, the Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to re-evaluate the safety of acacia gum (E 414) when used as a food additive.

The Panel was not provided with a newly submitted dossier and based its evaluation on previous evaluations and reviews, additional literature that has come available since then and the data available following a public call for data. The Panel noted that not all original studies on which previous evaluations were based were available for re-evaluation by the Panel.

Acacia Gum (E 414) is authorised as a food additive in the European Union (EU) in accordance with Annex II and Annex III to Regulation (EC) No 1333/2008 on food additives.

In the EU, acacia gum has not been formally evaluated by the Scientific Committee for Food (SCF) and therefore no acceptable daily intake (ADI) has been allocated. However, it was accepted for use in weaning food (SCF, 1991). In 1999, the SCF considered 'that the use of acacia gum/gum arabic in coatings for nutrient preparations containing trace elements is acceptable provided carry-over levels in infant formulae, follow-on formulae or FSMP do not exceed 10 mg/kg' (SCF, 1999). Acacia gum was evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1982 and 1990 (JECFA, 1982, 1990). Based on the lack of adverse effects in the available toxicity studies, an ADI 'not specified' was allocated. It was stressed that the evaluation covered only acacia gum from *Acacia senegal* and closely related species; the specifications were amended in 1998 to cover also acacia gum from *Acacia seyal* (JECFA, 1998).

Acacia gum is a dried exudation obtained from the stems and branches of natural strains of *A. senegal* (L.) Willdenow or closely related species of *Acacia* (family Leguminosae) (JECFA, 2006).

Specifications for acacia gum (E 414) have been defined in Commission Regulation (EU) 231/2012. The Panel noted that according to the EC specifications it is not clear which are the closely related species of *Acacia*, while in the JECFA specifications (JECFA, 2006), it is indicated that gum arabic (acacia gum) can be obtained from *A. senegal* (L.) Willdenow or *A. seyal* (family Leguminosae). The Panel noted that the EC specifications do not limit the protein content which according to Phillips et al. (2008) can be between 0.13% and 10.4%. According to industry (Documentation provided to EFSA, n.5), contents of proteins were in a range from 0.99% to 2.70% as determined in three samples analysed in duplicate. The Panel agreed with the proposal by interested parties to include a limit for protein content of 3.5% in the EC specifications.

Because of both the botanical origin and the polysaccharidic nature of gums, they can be a substrate of microbiological contamination and of field and storage fungal development. The latter has been recently demonstrated by the mycotoxin contaminations of gums (Zhang et al., 2014). The Panel noted that the microbiological specifications for polysaccharidic thickening agents, such as gums, should be harmonised and that for acacia gum criteria for total aerobic microbial count (TAMC) and total combined yeasts and moulds count (TYMC) should be included into the EU specifications.

Regarding the possible presence of nanoparticles in the dry powder of acacia gum resulting from the manufacturing process, the Panel considered that the material used for toxicological testing would contain this nanofraction, if present. In addition, the Panel noted that contact of acacia gum with any liquids (in food or biological fluids) will result in an increase of the particle size.

The *in vitro* degradation and the *in vivo* digestibility of acacia gum have been investigated in animals and humans models and in a human study. The Panel considered that these data indicated that acacia gum would be not absorbed intact but fermented by enteric bacteria in humans. The rate of hydrolysis in the gastrointestinal tract in humans is unknown; however, the Panel considered that acacia gum is unlikely to be absorbed intact, and that the limited extent of its fermentation would lead to products such as short-chain fatty acids (SCFA) which were considered of no safety concern by the Panel.

Among other studies, the subchronic (13 weeks) oral toxicity of acacia gum was investigated by Anderson et al. (1982). The animals received acacia gum in their diet and the study was conducted in two consecutive experimental phases. In the first one, the rats were given doses ranging from 0 to about 5,000 mg acacia gum/kg body weight (bw) per day, and in the second phase, they received 0 or 14,000 mg acacia gum/kg bw per day. The Panel noted that these two studies were done independently and that merging their data may not be straightforward. The Panel considered that no toxicological effect was observed in these studies by Anderson et al. (1982). From the first study, no adverse effects have been identified up to 5,220 and 5,310 mg acacia gum/kg bw per day in male and female, respectively, the highest dose tested.

Overall, the short-term and subchronic 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.

Based on the data available, the Panel considered that there is no concern with respect to the genotoxicity of acacia gum.

No chronic toxicity studies according to OECD guidelines (452) or equivalent have been identified.

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 (NTP, 1982; Melnick et al., 1983). 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 (Collins et al., 1987), 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 (Morseth and Ihara (1989a), Huynh et al., 2000). In the identically performed prenatal developmental tests with acacia gum by gavage in mice, rats and hamsters (FDRL, 1972b), 1,600 mg/kg bw per day (the highest dose tested) showed no dose-related developmental effects.

No case reports on allergic reaction after oral exposure to acacia gum could be identified by the Panel.

In humans, the repeated oral daily intake of a large amount of acacia gum up to 30 g (approx. 430 mg acacia gum/kg bw per day) for up to 18 days was well tolerated and had only a minimum effect on stool weight and decrease in serum cholesterol. Some individuals experienced flatulence which was considered by the Panel as undesirable but not adverse.

Acacia (E 414) is authorised in a wide range of foods. The Panel did not identify brand loyalty to a specific food category, and therefore, the Panel considered that the non-brand-loyal scenario covering the general population was the more appropriate and realistic scenario for risk characterisation because it is assumed that the population would probably be exposed long-term to the food additive present at the mean reported use in processed food.

A refined estimated exposure assessment scenario taking into account the food for special medical purpose for infants and young children (FC 13.1.5.2 Dietary foods for babies and young children for special medical purposes as defined by Commission Directive 1999/22/EC) was also performed to estimate exposure for infants and toddlers who may be on a specific diet. Considering that this diet is required due to specific needs, it is assumed that consumers are loyal to the food brand, therefore only the refined brand-loyal estimated exposure scenario was performed.

A refined estimated exposure assessment scenario taking into account the consumption of food *supplements* for consumers only was also performed to estimate exposure for children, adolescents, adults and the elderly as exposure via food supplements may deviate largely from that via food, and the number of food supplement consumers may be low depending on populations and surveys.

The refined estimates are based on 31 out of 76 food categories in which acacia gum (E 414) is authorised. The Panel considered that the uncertainties identified would, in general, result in an overestimation of the exposure to acacia gum (E 414) as a food additive in European countries for the refined scenario if it is considered that the food additive may not be used in food categories for which no usage data have been provided. However, the Panel noted that given the information from the Mintel's Global New Products Database (GNPD), it may be assumed that acacia gum (E 414) is used in food categories for which no data have been provided by food industry.

The main food categories, in term of amount consumed, not taken into account were unflavoured fermented milk products, cheeses, breakfast cereals, foods for infants and young children (processed cereal-based foods and baby food, other foods for young children), snacks and some alcoholic beverages (cider and perry, spirit drinks, etc.). According to the Mintel GNPD (Appendix C), in the EU market, snacks and breakfast cereals are labelled with acacia gum (E 414), as well as few alcoholic drinks and nectars. Therefore, the Panel considered that if these uncertainties were confirmed, it would therefore result in an underestimation of the exposure.

The Panel noted that in Annex II of Regulation (EC) No 1333/2008, use levels of acacia gum (E 414) in food for infants under the age of 12 weeks are included in category 13.1.5.2. The Panel considered that these uses would require a specific risk assessment in line with the recommendations given by JECFA (1978) and the SCF (1998) and endorsed by the Panel (EFSA ANS

Panel, 2012). Therefore, the current re-evaluation of acacia gum (E 414) as a food additive is not considered to be applicable for infants under the age of 12 weeks and will be performed separately.

The Panel further noted that the exposure to acacia gum from its use according the Annex III (Part 1, 2, 3, 4 and 5) was not considered in the exposure assessment.

The Panel also noted that the refined exposure estimates are based on information provided on the reported level of use of acacia gum (E 414). If actual practice changes, this refined estimates may no longer be representative and should be updated.

According to the conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EU) No 257/2010 (EFSA ANS Panel, 2014) and given that:

- the safety assessment carried out by the Panel is limited to the use and use levels in 31 out of 76 food categories in which acacia gum (E 414) is authorised;
- an indicative high refined exposure assessment up to 719 mg/kg bw per day has been calculated in toddlers at the 95th percentile (non-brand loyal scenario) for the general population;
- an indicative high refined exposure assessment up to 626 mg/kg bw per day has been calculated in toddlers at the 95th percentile in the brand loyal scenario for the population consuming Foods for Special Medical Purposes (FSMPs);
- acacia gum is unlikely to be absorbed intact and is slightly fermented by intestinal microbiota;
- sufficient toxicity data were available;
- there is no concern with respect to the genotoxicity;
- no carcinogenic effects were reported in carcinogenicity studies in mice and rats at the doses up to 7,500 mg and 2,500 mg acacia gum/kg bw per day, respectively, the highest doses tested;
- oral daily intake of a large amount of acacia gum up to 30,000 mg acacia gum/person per day (approximately equivalent 430 mg acacia gum/kg bw per day) for up to 30 days was well tolerated in adults but some individuals experienced flatulence. A dose of 53,000 mg acacia gum/person per day (approximately equivalent 760 mg acacia gum/kg bw per day) induced mild flatulence, which was considered by the Panel as undesirable but not adverse,

the Panel concluded that there is no need for a numerical ADI for acacia gum (E 414), and that there is no safety concern at the refined exposure assessment for the reported uses of acacia gum (E 414) as a food additive.

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1. Introduction

The present opinion document deals with the re-evaluation of acacia gum (E 414) when used as a food additive. Acacia gum (E 414) is an authorised food additive in the European Union (EU) according to Annex II and Annex III of Regulation (EC) No 1333/2008[1].

1.1. Background and Terms of Reference as provided by the European Commission

1.1.1. Background as provided by the European Commission

Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives requires that food additives are subject to a safety evaluation by the European Food Safety Authority (EFSA) before they are permitted for use in the European Union (EU). In addition, it is foreseen that food additives must be kept under continuous observation and must be re-evaluated by EFSA.

For this purpose, a programme for the re-evaluation of food additives that were already permitted in the European Union before 20 January 2009 has been set up under the Regulation (EU) No 257/2010[2]. This Regulation also foresees that food additives are re-evaluated whenever necessary in light of changing conditions of use and new scientific information. For efficiency and practical purposes, the re-evaluation should, as far as possible, be conducted by group of food additives according to the main functional class to which they belong.

The order of priorities for the re-evaluation of the currently approved food additives should be set on the basis of the following criteria: the time since the last evaluation of a food additive by the Scientific Committee on Food (SCF) or by EFSA, the availability of new scientific evidence, the extent of use of a food additive in food and the human exposure to the food additive taking also into account the outcome of the Report from the Commission on Dietary Food Additive Intake in the EU of 2001. The report 'Food additives in Europe 2000' submitted by the Nordic Council of Ministers to the Commission, provides additional information for the prioritisation of additives for re-evaluation. As colours were among the first additives to be evaluated, these food additives should be re-evaluated with a highest priority.

In 2003, the Commission already requested EFSA to start a systematic re-evaluation of authorised food additives. However, as a result of adoption of Regulation (EU) 257/2010 the 2003 Terms of References are replaced by those below.

1.1.2. Terms of Reference as provided by the European Commission

1.1.2.1. Re-evaluation of acacia gum (E 414) as a food additive

The Commission asks EFSA to re-evaluate the safety of food additives already permitted in the Union before 2009 and to issue scientific opinions on these additives, taking especially into account the priorities, procedures and deadlines that are enshrined in the Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with the Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.

1.1.3. Interpretation of Terms of Reference

The Panel on Food Additives and Nutrient Sources added to Food (ANS) described its risk assessment paradigm in its Guidance for submission for food additive evaluations in 2012 (EFSA ANS Panel, 2012). This Guidance states, that in carrying out its risk assessments, the Panel sought to define a health-based guidance value, e.g. an acceptable daily intake (ADI) (IPCS, 2004) applicable to the general population. According to the definition above, the ADI as established for the general population does not apply to infants below 12 weeks of age (JECFA, 1978; SCF, 1998). In this context, the re-evaluation of the use of food additives, such as thickening agents and certain emulsifiers, in food for infants below 12 weeks represents a special case for which specific recommendations were

[1] 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. 16–33.

[2] Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 80, 26.3.2010, p. 19–27.

given by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1978, 1972) and by the SCF (1996; 1998). The Panel endorsed these recommendations.

In the current EU legislation (Annex III, part 5 section B of Regulation (EC) No 1333/2008), use of acacia gum in food for infants under the age of 12 weeks are authorised at the maximum level of 10 mg/kg carry over in final products included in categories 13.1. The Panel considers that these uses would require a specific risk assessment in line with the recommendations given by JECFA and the SCF and endorsed by the Panel in its current Guidance for submission for food additives evaluations (EFSA ANS Panel, 2012). Therefore, a risk assessment as for the general population is not considered to be applicable for infants under the age of 12 weeks and will be performed separately.

This re-evaluation refers exclusively to the uses of acacia gum (E 414) as a food additive in food, including food supplements and does not include a safety assessment of other uses of acacia gum.

1.2. Information on existing evaluations and authorisations

Acacia gum (E 414) is authorised as a food additive in the EU under Annex II of Regulation (EC) No 1333/2008 on food additives for use in foodstuffs. Specific purity criteria on acacia gum (E 414) have been defined in Commission Regulation (EU) No 231/2012.

In the EU, acacia gum has not been formally evaluated by the SCF and therefore no ADI has been allocated. However, it was accepted for use in weaning food (SCF, 1991). In 1999, the SCF considered 'that the use of acacia gum/gum arabic in coatings for nutrient preparations containing trace elements is acceptable provided carry-over levels in infant formulae, follow-on formulae or FSMP do not exceed 10 mg/kg' (SCF, 1999).

Acacia gum was evaluated by JECFA in 1982 and 1990 (JECFA, 1982, 1990). Based on the lack of adverse effects in the available toxicity studies, an ADI 'not specified' was allocated. It was stressed that the evaluation covered only acacia gum from *Acacia senegal* and closely related species; the specifications were amended in 1998 to cover also acacia gum from *Acacia seyal* (JECFA, 1998).

In 2010, the EFSA ANS Panel evaluated the use of gum acacia modified with octenyl succinic anhydride as a food additive (EFSA ANS Panel, 2010). Based on the results of the available studies, the information on gum acacia itself and on octenyl succinic anhydride modified starches, the Panel considered the use of octenyl succinic anhydride modified gum acacia as an emulsifier in foods at the proposed uses and use levels of no safety concern.

In 2010, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) prepared a scientific opinion on the substantiation of health claims related to acacia gum (EFSA NDA Panel, 2010). No cause and effect relationships could be established between the consumption of acacia gum and the reduction of post-prandial glycaemic responses or long-term maintenance of normal blood glucose concentrations.

Acacia gum is one of the food additives that composed jelly mini-cups which were suspended in 2004 by the European Commission to be placed on the market and import (Commission Decision 2004/37/EC), following the measures taken and information provided by different Member States. Jelly mini-cups are defined as 'jelly confectionery of a firm consistence, contained in semi rigid mini-cups or mini-capsules, intended to be ingested in a single bite by exerting pressure on the mini-cups or mini-capsule to project the confectionery into the mouth'.

In 2004, the EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) prepared a scientific opinion on a request from the European Commission related to the use of certain food additives derived from seaweed or non-seaweed origin, including acacia gum (E 414) in jelly mini-cups (EFSA AFC Panel, 2004). The AFC Panel concluded that any of these gel-forming additives or of any other type that gave rise to a confectionery product of a similar size, with similar physical and/or physicochemical properties and that could be ingested in the same way as the jelly mini-cups, would give rise to a risk for choking (EFSA AFC Panel, 2004). The use of these additives in jelly mini-cups is not authorised in the EU. The use of these additives in jelly mini-cups is not authorised in the EU.[3]

Acacia gum has also been reviewed by the Nordic Council of Ministers (TemaNord, 2002), who concluded that although the existing data do not point to any toxicological concern, the aspect of allergy/intolerance should be included in a future evaluation as well as the problem of marketing gums originating from acacia species not included in their evaluation.

[3] Annex II to Regulation (EC) No 1333/2008.

There is a monograph on acacia gum (named acacia) in the European Pharmacopoeia (2015). In this document, acacia gum is defined, and its solubility, identification and tests are indicated.

2. Data and methodologies

2.1. Data

The ANS Panel ANS was not provided with a newly submitted dossier. EFSA launched public calls for data,[4,5] to collect information from interested parties and, if relevant, contacted risk assessment bodies.

The Panel based its assessment on information submitted to EFSA following the public calls for data, information from previous evaluations and additional available literature up to 8 February 2017. Attempts were made at retrieving relevant original study reports on which previous evaluations or reviews were based; however, not always these were these available to the Panel.

The EFSA Comprehensive European Food Consumption Database (Comprehensive Database[6]) was used to estimate the dietary exposure.

The Mintel's Global New Products Database (GNPD) is an online resource listing food products and compulsory ingredient information that should be included in labelling. This database was used to verify the use of acacia gum (E 414) in food products.

2.2. Methodologies

This opinion was formulated following the principles described in the EFSA Guidance on transparency with regard to scientific aspects of risk assessment (EFSA Scientific Committee, 2009) and following the relevant existing guidance documents from the EFSA Scientific Committee.

The ANS Panel assessed the safety of acacia gum (E 414) as a food additive in line with the principles laid down in Regulation (EU) 257/2010 and in the relevant guidance documents: Guidance on submission for food additive evaluations by the Scientific Committee on Food (SCF, 2001) and taking into consideration the Guidance for submission for food additive evaluations in 2012 (EFSA ANS Panel, 2012).

When the test substance was administered in the feed or in the drinking water, but doses were not explicitly reported by the authors as mg/kg body weight (bw) per day based on actual feed or water consumption, the daily intake was calculated by the Panel using the relevant default values as indicated in the EFSA Scientific Committee Guidance document (EFSA Scientific Committee, 2012) for studies in rodents or, in the case of other animal species, by JECFA (2000). In these cases, the daily intake is expressed as equivalent. When in human studies in adults (aged above 18 years), the dose of the test substance administered was reported in mg/person per day, the dose in mg/kg bw per day was calculated by the Panel using a body weight of 70 kg as default for the adult population as described in the EFSA Scientific Committee Guidance document (EFSA Scientific Committee, 2012).

Dietary exposure to acacia gum (E 414) from its use as a food additive was estimated combining food consumption data available within the EFSA Comprehensive European Food Consumption Database with the maximum levels according to Annex II to Regulation (EC) No 1333/2008[7] and/or reported use levels and analytical data submitted to EFSA following a call for data. Different scenarios were used to calculate exposure (see Section 3.3.1). Uncertainties on the exposure assessment were identified and discussed.

In the context of this re-evaluation, the Panel followed the conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EC) No 257/2010 (EFSA ANS Panel, 2014).

[4] Call for scientific data on food additives permitted in the EU and belonging to the functional classes of emulsifiers, stabilisers and gelling agents. Published: 22 November 2009. Available from: http://www.efsa.europa.eu/en/dataclosed/call/ans091123

[5] Call for technical data on certain thickening agents permitted as food additives in the EU – Extended Deadline: 31 December 2015. Available online: http://www.efsa.europa.eu/it/data/call/141219

[6] Available online: http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm

[7] Commission 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.

3. Assessment

3.1. Technical data

3.1.1. Identity of the substance

Acacia gum is a dried exudation obtained from the stems and branches of natural strains of *A. senegal* (L.) Willdenow or closely related species of *Acacia* (family Leguminosae) (Commission Regulation (EU) No 231/2012[8]; JECFA, 2006). Acacia gum (E 414) has the CAS Registry Number 9000-01-5 and the EINECS number 232-519-5.

Several works on the chemical and physicochemical characterisation of acacia gum are available. The polysaccharidic fractions of acacia gum consist of monomeric units being D-galactose, L-arabinose, L-rhamnose, D-glucuronic acid and 4-*O*-methyl-D-glucuronic acid (Randall et al., 1988; Fenyo and Vandevelde, 1990; Islam et al., 1997; Idris et al., 1998; Goodrum et al., 2000; Bracher et al., 2005; Dror et al., 2006; Mahendran et al., 2008; Sanchez et al., 2008; Renard et al., 2012, 2014; Nie et al., 2013). An interested party (Documentation provided to EFSA, n.5) provided the following concentration range of neutral sugars and uronic acids for the two commercial samples of acacia gum analysed in duplicate: galactose (32.5–35.0 molar%), arabinose (31.7–53.1 molar%), rhamnose (2.7–16.3 molar%), glucuronic acid (5.3–14.0 molar%) and 4-*O*-methyl-glucuronic acid (0.8–5.2 molar%).

Carbohydrate analysis has indicated that the components of this gum from the different sources, corresponding to three UV absorbance peaks, all have a highly branched structure consisting of a β-1,3-linked D-galactose core with extensive branching through 3- and 6-linked galactose and 3-linked arabinose. The main component is the arabinogalactan (AG) fraction that represents around 90% of the gum, containing less than 1% protein and with a molecular weight ~ 2.5×10^6 g/mol. The study of Sanchez et al. (2008) has shown that after purification, this fraction has a disk-like structure with a diameter of ~ 20 nm and a thickness below 2 nm. The second major component (~ 10 wt% of the total) consists of a higher molecular weight (~ 1–2 × 10^6 g/mol) arabinogalactan–protein (AGP) fraction and contains ~ 10% protein. Recent studies on the AGP fraction have been carried out (Mahendran et al., 2008; Renard et al., 2012); the smallest component (~ 1% of the total) consists of a glycoprotein (GP) fraction with the highest protein content (~ 50 wt%). A recent study has identified that in solution, the structure of the GP fraction is a mixture of spheroidal monomers and more anisotropic oligomers (Renard et al., 2014).

From this data, the Panel noted that nanosized particles (with one or more dimensions below 100 nm) could be present in the dry powder of acacia gum when used as a food additive.

The proteinaceous component of the first two fractions had similar amino acid distributions (hydroxyproline and serine the most abundant), while the amino acid composition of the GP fraction is different, with aspartic acid being the most abundant (Renard et al., 2006).

The gums from *A. senegal* and *A. seyal* have the same amino acid compositions and the same sugar residues, although the content of some of the sugar residues varies and the average molecular mass of the gum from *A. senegal* is higher than from that of *A. seyal* (Williams and Phillips, 2009).

As regards the protein content, the Panel noted that the protein content of hydrolysates of samples derived from *A. senegal* trees ranged from ca 1.5% to 3%, dependent on the area of production (Anderson et al., 1985). For various gums of the *Acacia* species, a slightly broader range of protein content (0.13–10.4%) has been reported by Phillips et al. (2008). According to documentation provided to EFSA (n.5), the content of proteins were in a range of 0.99–2.70% as determined in three samples of commercial acacia gum analysed in duplicate using the Kjeldahl method.

According to the EC specifications (Commission Regulation (EU) No 231/2012), the molecular weight of acacia gum is approximately 3.5 x 10^5 g/mol.

Acacia gum has for synonyms arabic gum, gum arabic, gum acacia, acacia, Senegal gum and Indian gum, among others.

Regarding the term gum arabic, the Panel noted that although most internationally traded gum arabic comes from *A. senegal*, the term 'gum arabic' does not indicate a particular botanical source. In a few cases, so-called 'gum arabic' may not even have been collected from *Acacia* species, but may originate from *Combretum*, *Albizia* or some other genus (FAO, 1999).

[8] 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.

Unground acacia gum occurs as white or yellowish-white spheroidal tears of varying sizes or as angular fragments and is sometimes mixed with darker fragments. It is also available in the form of white to yellowish-white flakes, granules, powder or spray-dried material. One gram dissolves in 2 mL of cold water forming a solution, which flows readily. It is insoluble in ethanol (Commission Regulation (EU) No 231/2012). Solutions of food grades of acacia gum are practically odourless, colourless and tasteless (Klose and Glicksman, 1990).

3.1.2. Specifications

The specifications for acacia gum (E 414) as defined in the Commission Regulation (EU) No 231/2012 and by JECFA (2006) are listed in Table 1.

Table 1: Specifications for acacia gum (E 414) according to Commission Regulation (EU) No 231/2012 and JECFA (2006)

	Commission Regulation (EU) No 231/2012	**JECFA (2006)**
Definition	Acacia gum is a dried exudation obtained from the stems and branches of natural strains of *Acacia senegal* (L.) Willdenow or closely related species of *Acacia* (family Leguminosae). It consists mainly of high molecular weight polysaccharides and their calcium, magnesium and potassium salts, which on hydrolysis yield arabinose, galactose, rhamnose and glucuronic acid	Gum arabic is a dried exudate obtained from the stems and branches of *Acacia senegal* (L.) Willdenow or *Acacia seyal* (fam. Leguminosae). Gum arabic consists mainly of high-molecular weight polysaccharides and their calcium, magnesium and potassium salts, which on hydrolysis yield arabinose, galactose, rhamnose and glucuronic acid. Items of commerce may contain extraneous materials such as sand and pieces of bark, which must be removed before use in food
Molecular weight	Approximately 350,000	
Assay	–	–
Description	Unground acacia gum occurs as white or yellowish-white spheroidal tears of varying sizes or as angular fragments and is sometimes mixed with darker fragments. It is also available in the form of white to yellowish-white flakes, granules, powder or spray-dried material	Gum arabic (*A. senegal*) is a pale white to orange-brown solid, which breaks with a glassy fracture. The best grades are in the form of whole, spheroidal tears of varying size with a matt surface texture. When ground, the pieces are paler and have a glassy appearance. Gum arabic (*A. seyal*) is more brittle than the hard tears of gum arabic (*A. senegal*) Gum arabic is also available commercially in the form of white to yellowish-white flakes, granules, powder, roller dried or spray-dried material. An aqueous solution of 1 g in 2 mL flows readily and is acid to litmus
Identification		
Solubility	One gram dissolves in 2 mL of cold water forming a solution which flows readily and is acid to litmus, insoluble in ethanol	One gram dissolves in 2 mL of water; insoluble in ethanol
Gum constituents	–	Proceed as directed under Gum Constituents Identification (FNP 5) using the following as reference standards: arabinose, galactose, mannose, rhamnose, galacturonic acid, glucuronic acid and xylose. Arabinose, galactose, rhamnose and glucuronic acid should be present. Additional spots corresponding to mannose, xylose and galacturonic acid should be absent.

	Commission Regulation (EU) No 231/2012	JECFA (2006)
Optical rotation	–	Gum from *A. senegal*: aqueous solutions are levorotatory. Gum from *A. seyal*: aqueous solutions are dextrorotatory. Test a solution of 10 g of sample (dry basis) in 100 mL of water (if necessary, previously filtered through a No. 42 paper or a 0.8 μm Millipore filter) using a 200-mm tube
Purity		
Loss on drying	Not more than 17% (105°C, 5 h) for granular and not more than 10% (105°C, 4 h) for spray-dried material	Not more than 15% (105°, 5 h) for granular and not more than 10% (105°, 4 h) for spray-dried material
Total ash	Not more than 4%	Not more than 4%
Acid insoluble ash	Not more than 0.5%	Not more than 0.5%
Acid insoluble matter	Not more than 1%	Not more than 1%
Starch or dextrin	Boil a 1 in 50 solution of the gum and cool. To 5 mL add 1 drop of iodine solution. No bluish or reddish colours are produced	Boil a 1 in 50 solution of the sample, cool and add a few drops of Iodine TS. No bluish or reddish colour should be produced
Tannin	To 10 mL of a 1 in 50 solution add about 0.1 mL of ferric chloride solution (9 g $FeCl_3 \cdot 6H_2O$ made up to 100 mL with water). No blackish colouration or blackish precipitate is formed	To 10 mL of a 1 in 50 solution of the sample, add about 0.1 mL of ferric chloride TS. No blackish colouration or blackish precipitate should be formed
Arsenic	Not more than 3 mg/kg	–
Lead	Not more than 2 mg/kg	Not more than 2 mg/kg Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in Volume 4, 'Instrumental Methods'
Mercury	Not more than 1 mg/kg	–
Cadmium	Not more than 1 mg/kg	–
Hydrolysis products	Mannose, xylose and galacturonic acid are absent (determined by chromatography)	–
Microbiological criteria		
Salmonella spp.	Absent in 10 g	Negative per test
Escherichia coli	Absent in 5 g	Negative in 1 g

The Panel noted that the JECFA specifications contain additional identification tests for gum constituents and for optical rotation. The Panel also noted that the EC specifications do not limit the protein content. Reports (Anderson et al., 1985; Phillips, 2008) indicate that the protein content could be from 0.13% to 10.4%. According to Documentation provided to EFSA (n.5), contents of proteins were in a range from 0.99% to 2.70% as determined in three samples analysed in duplicate. The interested party proposes the inclusion of the limit for protein content of 3.5% in the EC specifications.

No data was provided from interested parties concerning the enzymatic activities in acacia gum.

In literature, it is reported that the protein part of acacia gum may contain oxidising enzymes, especially oxidases and peroxidases, which may interact with easily oxidisable substances and which may be inactivated by heating acacia gum at 100°C for a short time (Leung and Foster, 2003; Bracher et al., 2005; Martindale, 2016). Oxidation of amines and phenols (e.g. eugenol, tannins, thymol, vanillin) by peroxidase present in acacia gum may lead to formation of coloured compounds (Leung and Foster, 2003). According to Glicksman and Sand, the oxidising enzymes present in acacia gum, may destroy, for example, the active component of pharmaceutical or nutritional preparations as demonstrated for vitamin A in emulsions of cod liver oil stabilised by gum acacia (Glicksman and Sand, 1973). Further

investigations of oxidative enzymes in polysaccharide gums seem only to have been performed on polyphenol oxidase from acacia gum, for which two isoenzymes were isolated and characterised (Billaud et al., 1996).

The Panel noted publications recommending that the oxidases and peroxidases present in the gum should be destroyed by heating of acacia gum during the manufacturing process or before its use. The Panel further noted that limits and a test for residual enzymatic activities and for protein content may be required.

An interested party (Documentation provided to EFSA, n.5) provided results of analysis of five batches of acacia gum for side components expressed as: loss on drying (7.6–14.2%), total ash (2.9–3.6%) and acid-insoluble matter (0.3–< 0.5%). All obtained results comply with the EC specifications.

A literature research done by the Panel revealed a limited number of papers describing microbiological contamination of different polysaccharide thickening agents (Souw and Rehm, 1973, 1975a,b); Robbins and Ingledew, 1975) but none of the results presented, gave rise to a particular concern. According to microorganism analysis on four different batches of acacia gum provided (Documentation provided to EFSA, n.5), the total plate count was in the range of 60–34,000 cfu/g and yeast and mould in the range of < 10–8,800 cfu/g.

Because of both the botanical origin and the polysaccharidic nature of gums, they can be a substrate of microbiological contamination and of field and storage fungal development. The latter has been recently demonstrated by the mycotoxin contaminations of gums (Zhang et al., 2014). The Panel noted that the differences in the microbiological criteria for acacia gum between the specifications given by the EU Regulation and those given by JECFA are not decisive. The Panel also noted that the microbiological specifications for polysaccharidic thickening agents, such as gums, should be harmonised and that for acacia gum criteria for the absence of *Salmonella* spp. and *Escherichia coli*, for total aerobic microbial count (TAMC) and total combined yeasts and moulds count (TYMC) should be included into the EU specifications as it is the case for other polysaccharidic thickening agents (e.g. alginic acids and its salts (E 400–E 404), agar (E 406), carrageenan (E 407), processed eucheuma sea weed (E 407a), xanthan gum (E 415), gellan gum (E 418)).

In view of the botanical origin of acacia gum, furthermore limitations of possible contamination with pesticides should be considered. According to industry (Documentation provided to EFSA, n.4), contents of pesticides are below the maximum levels as set in Regulation 1881/2006[9] on certain contaminants in foodstuff, and in Regulation 396/2005[10] on maximum residue levels of pesticides in or on food and feed of plant animal origin. Following a call for data, an interested party (Documentation provided to EFSA, n.5) indicated that no pesticides have been found in six different batches of acacia gum. However, in view of the use of acacia gum in baby and children food, the Panel considered particularly necessary to pay attention on the compliance of acacia gum (E 414) raw material to existing EU regulation on pesticides.

Information has been provided (Documentation provided to EFSA, n.5) on the content of toxic and other elements in five different batches of acacia gum: lead (< 0.02–0.036 mg/kg), mercury (< 0.005 mg/kg), cadmium (< 0.005–< 0.01 mg/kg), arsenic (< 0.005–< 0.1 mg/kg), aluminium (3.71–14.74 mg/kg), copper (1.1–1.59 mg/kg), iron (3.2–16.54 mg/kg) and zinc (< 0.5–< 1 mg/kg).

The Panel noted that the levels of lead, mercury, cadmium and arsenic in the five batches analysed, were all far below the levels as defined in the Commission Regulation (EU) No 231/2012 (Documentation provided to EFSA, n. 5).

The Panel noted that, according to the EC specifications for acacia gum (E 414), impurities of the toxic elements lead, mercury, cadmium and arsenic are accepted up to concentrations of 2, 1, 1 and 3 mg/kg, respectively. The Panel also noted that aluminium is not included in the specifications. Aluminium from all sources in food should not lead to an exceedance of a tolerable weekly intake (TWI) of 1 mg aluminium/kg bw (EFSA ANS Panel, 2008). Contamination at those levels could have a significant impact on the exposure to these metals, for which the intake is already close to the health-based guidance values established by EFSA (EFSA CONTAM Panel, 2009a,b, 2010, 2012).

The European Pharmacopeia (European Pharmacopoeia, 2015) includes specifications for acacia gum and spray-dried acacia gum. Spray-dried acacia gum is obtained from a solution of acacia gum

[9] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. OJ L 364, 20.12.2006, p. 5.

[10] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1.

and has the lower content of water (loss on drying not more than 10%) than the not spray-dried acacia gum (loss on drying not more than 15%).

3.1.3. Manufacturing process

Acacia gum is obtained from trees of the genus *Acacia*, subfamily Mimosoideae, family Leguminosae. The substance is the result of a bacterial or a fungal infection. It is exuded only by unhealthy trees; heat, poor nutrition and drought stimulate its production. The infection takes place through wounds in the tree which may be accidental or purposely made to stimulate gum production. The gum is exuded through these wounds in the bark in the form of tears, or drops which rapidly harden due to evaporation. Most of the acacia gum production is from wild trees, but some is from cultivated gardens which are tapped and collected on a systematic basis. After gathering, it is taken to central collecting stations where it is auctioned, graded by hand and dried (Klose and Glicksman, 1990).

As described in Thevenet, 2010:

> 'Raw gum from the same botanical origin is a blend of gum nodules with different mesh sizes, containing vegetable and mineral impurities and fluctuating bacteriological contamination. Using dry purifications steps, such as kibbling, sieving and pulverisation, the level of impurities can be slightly reduced but bacteriological contamination cannot be improved. Most of the time, raw gum does not meet the specifications for acacia gum. Consequently, the dry methods of purification have been substituted by purification in aqueous solution which is much more efficient. The gum is fully dissolved in water and all the impurities removed by a cascade of filtration steps giving levels of insoluble matter in the finished product as low as 0.02%. Bacterial contamination is reduced by treatment in a plate heat exchanger and the gum syrup is concentrated and dried, giving a level of microbial contamination in the powder not more than $5 \cdot 10^2$ germs per gram' (cfu/g).

> 'During solubilisation and purification, the thermal conditions are critical. Acacia gum contains proteins which are important for the emulsifying properties but sensitive to heat denaturation. Different processes are used for recovering purified, powdered acacia gum from the syrup. Roller drying is used to produce a gum in powder form with good hydration properties, but it has reduced emulsifying properties due to drastic thermal treatment during the drying step. Spray drying is also used which gives the gum good physical qualities and functional properties. Recently, spray drying has been improved by using a multi-stage spray drying process where fine particles of gum produced during drying are recycled at the top of the dryer. Agglomerated gum particles are obtained, keeping the entire properties of the raw gum, but containing no dust or particles below 75 μm and giving unique hydration and dissolution properties, without any lump formation up to the maximum level of solubility in water of 45–50%'.

The Panel noted publications recommending that during the manufacturing process the oxidases and peroxidases present in acacia gum should be inactivated by heating to prevent the possible oxidative degradation of components in preparations to which acacia gum is added (Glicksman and Sand, 1973; Ternes et al., 2007).

3.1.4. Methods of analysis in food

Acacia gum contains proteins and soluble dietary fibre and consists of arabinogalactans and other carbohydrate moieties. It is virtually impossible to quantify the exact concentration of the acacia gum after it has been added to food, since similar compounds are almost invariably present in foods and will interfere with the analysis. Even after treatment with protease, glucosidase, amylase, etc. (AOAC, 1998), there is no existing validated method to separate fibre mixtures into their individual fibre components (EFSA ANS Panel, 2010).

The problems in gum analysis are mainly arising due to diversity of structures and frequent use of blends. Most commonly used procedures for determining the amount of hydrocolloid in food involve the use of colorimetric methods or hydrolysis and determination of the monosaccharide composition; the latter may be carried out using high-performance liquid chromatography (HPLC). Methods that depend on interaction of hydrocolloids with plant lectins or antibodies have also been described (O'Donnell and Baird, 1993). A further method for the analysis of monosaccharides (galactose, glucose, arabinose, xylose and rhamnose) by thin-layer chromatography (TLC) is described in European Pharmacopoeia (2015).

Pazur and Li (2004) developed a technique for the identification of acacia gum in food using antibodies, isolated from the serum of rabbits immunised with this gum. Agar diffusion was performed with several foods (ice cream, soup, candy, salad dressing and cottage cheese) and antibody combinations. This method is highly specific for acacia gum.

3.1.5. Stability of the substance, and reaction and fate in food

Limited information on reaction and fate of acacia gum in foods is available.

Acacia gum is stable in acid conditions. Although the gum has excellent heat stability, prolonged storage of acacia gum solutions at high temperatures can result in the loss of some of the functional properties (Ullmann's Encyclopedia of Industrial Chemistry, 2012). Acacia gum contains proteins which are important for the emulsifying properties but are denaturated by heat (Thevenet, 2010).

The viscosity of acacia gum solutions decreases on ageing due to bacterial action and consequent depolymerisation. Reduction in viscosity has also been reported on prolonged exposure of solutions of the gum to ultrasonic vibration or ultraviolet irradiation. This was attributed to depolymerisation, and could be due to glycosidic fission as well as to disruption of physical aggregates (Williams et al., 2006).

3.2. Authorised uses and use levels

Maximum levels of acacia gum (E 414) have been defined in Annex II to Regulation (EC) No 1333/2008[7] on food additives, as amended. In this document, these levels are named maximum permitted levels (MPLs).

Currently, acacia gum (E 414) is an authorised food additive in the EU at *quantum satis* (QS) in all food categories listed in Table 2 apart from food category 13.1 Foods for infants and young children. Acacia gum (E 414) is included in the Group I of food additives authorised at QS.

Table 2 summarises foods that are permitted to contain acacia gum (E 414) and the corresponding MPLs as set by Annex II to Regulation (EC) No 1333/2008.

Table 2: MPLs of acacia gum (E 414) in foods according to the Annex II to Regulation (EC) No 1333/2008

Food category number	Food category name	Restrictions/exceptions	E-number/ group	MPL (mg/L or mg/kg as appropriate)
01.3	Unflavoured fermented milk products, heat-treated after fermentation		Group I	QS
01.4	Flavoured fermented milk products including heat-treated products		Group I	QS
01.6.3	Other creams		Group I	QS
01.7.1	Unripened cheese excluding products falling in category 16	Except mozzarella	Group I	QS
01.7.5	Processed cheese		Group I	QS
01.7.6	Cheese products (excluding products falling in category 16)		Group I	QS
01.8	Dairy analogues, including beverage whiteners		Group I	QS
02.2.2	Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions		Group I	QS
02.3	Vegetable oil pan spray		Group I	QS
03	Edible ices		Group I	QS
04.2.1	Dried fruit and vegetables		Group I	QS
04.2.2	Fruit and vegetables in vinegar, oil, or brine		Group I	QS
04.2.4.1	Fruit and vegetable preparations excluding compote		Group I	QS

Food category number	Food category name	Restrictions/exceptions	E-number/ group	MPL (mg/L or mg/kg as appropriate)
04.2.5.4	Nut butters and nut spreads		Group I	QS
04.2.6	Processed potato products		Group I	QS
05.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC	As glazing agent only	E 414	QS
05.2	Other confectionery including breath refreshening microsweets	E 414 may not be used in jelly mini-cups, defined, for the purpose of this Regulation, as jelly confectionery of a firm consistence, contained in semi rigid mini-cups or mini-capsules, intended to be ingested in a single bite by exerting pressure on the mini-cups or mini-capsule to project the confectionery into the mouth	Group I	QS
05.3	Chewing gum		Group I	QS
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4		Group I	QS
06.2.2	Starches		Group I	QS
06.3	Breakfast cereals		Group I	QS
06.4.2	Dry pasta	Only gluten-free and/or pasta intended for hypoproteic diets in accordance with Directive 2009/39/EC	Group I	QS
06.4.4	Potato Gnocchi	Except fresh refrigerated potato gnocchi	Group I	QS
06.4.5	Fillings of stuffed pasta (ravioli and similar)		Group I	QS
06.5	Noodles		Group I	QS
06.6	Batters		Group I	QS
06.7	Precooked or processed cereals		Group I	QS
07.1.	Bread and rolls	Except products in 7.1.1 and 7.1.2	Group I	QS
07.2	Fine bakery wares		Group I	QS
08.3.1	Non-heat-treated meat products		Group I	QS
08.3.2	Heat-treated meat products	Except *foie gras, foie gras entier, blocs de foie gras, Libamáj, libamáj egészben, libamáj tömbben*	Group I	QS
08.3.3	Casings and coatings and decorations for meat		Group I	QS
09.2	Processed fish and fishery products including molluscs and crustaceans		Group I	QS
09.3	Fish roe	Only processed fish roe	Group I	QS
10.2	Processed eggs and egg products		Group I	QS
11.2	Other sugars and syrups		Group I	QS
11.4.1	Table Top Sweeteners in liquid form		E 414	QS
11.4.2	Table Top Sweeteners in powder form		E 414	QS

Food category number	Food category name	Restrictions/exceptions	E-number/ group	MPL (mg/L or mg/kg as appropriate)
11.4.3	Table Top Sweeteners in tablets		E 414	QS
12.1.2	Salt substitutes		Group I	QS
12.2.2	Seasonings and condiments		Group I	QS
12.3	Vinegars		Group I	QS
12.4	Mustard		Group I	QS
12.5	Soups and broths		Group I	QS
12.6	Sauces		Group I	QS
12.7	Salads and savoury based sandwich spreads		Group I	QS
12.8	Yeast and yeast products		Group I	QS
12.9	Protein products, excluding products covered in category 1.8		Group I	QS
13.1.3	Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC	Only processed cereal based foods and baby foods[(b)]	E 414	10,000
13.1.3	Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC	Only gluten-free cereal-based foods[(b)]	E 414	20,000
13.1.4	Other foods for young children	[(b)]	E 414	10,000
13.1.5.2	Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC	Only processed cereal based foods and baby foods[(b)]	E 414	10,000
13.1.5.2	Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC	Only gluten-free cereal-based foods[(b)]	E 414	20,000
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)		Group I	QS
13.3	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)		Group I	QS
13.4	Foods suitable for people intolerant to gluten as defined by Regulation (EC) No 41/2009	Including dry pasta	Group I	QS
14.1.2	Fruit juices as defined by Directive 2001/112/EC and vegetable juices	Only vegetable juices	Group I	QS
14.1.3	Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products	Only vegetable nectars	Group I	QS
14.1.4	Flavoured drinks		Group I	QS
14.1.5.2	Other	Excluding unflavoured leaf tea; including flavoured instant coffee	Group I	QS
14.2.1	Beer and malt beverages		E 414	QS
14.2.3	Cider and perry		Group I	QS
14.2.4	Fruit wine and made wine		Group I	QS
14.2.5	Mead		Group I	QS

Food category number	Food category name	Restrictions/exceptions	E-number/ group	MPL (mg/L or mg/kg as appropriate)
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	Except whisky or whiskey	Group I	QS
14.2.7.1	Aromatised wines		Group I	QS
14.2.7.2	Aromatised wine-based drinks		Group I	QS
14.2.7.3	Aromatised wine-product cocktails		Group I	QS
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% of alcohol		Group I	QS
15.1	Potato-, cereal-, flour- or starch-based snacks		Group I	QS
15.2	Processed nuts		Group I	QS
16	Desserts excluding products covered in category 1, 3 and 4		Group I	QS
17.1[(a)]	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms		Group I	QS
17.2[(a)]	Food supplements supplied in a liquid form		Group I	QS
17.3[(a)]	Food supplements supplied in a syrup-type or chewable form		Group I	QS
18	Processed foods not covered by categories 1–17, excluding foods for infants and young children		Group I	QS

MPL: Maximum permitted level; QS: *quantum satis*.
(a): FCS 17 refers to food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council excluding food supplements for infants and young children.
(b): E 410, E 412, E 414, E 415 and E 440 are authorised individually or in combination.

According to Annex III, Part 1 of Regulation (EC) No 1333/2008, acacia gum (E 414) is also authorised in all food additives as a carrier at QS.

According to Annex III, Part 2 of Regulation (EC) No 1333/2008, acacia gum (E 414) is also authorised in all food additives other than carriers in food additives at QS.

According to Annex III, Part 3 of Regulation (EC) No 1333/2008, acacia gum (E 414) is also authorised as a food additive in food enzymes with a maximum level in the products (beverages or not) at QS.

In addition, according to Annex III, Part 4 of Regulation (EC) No 1333/2008, acacia gum (E 414) is authorised in food additives including carriers in all food flavourings at QS.

Finally, according to Annex III, Part 5, Section A and B of Regulation (EC) No 1333/2008, acacia gum (E 414) is also authorised at QS in all nutrients, as well as in all nutrients intended to be used in foods for infants and young children listed in Point 13.1 of Part E of Annex II, at the maximum level of 150,000 mg/kg in the nutrient preparation and 10 mg/kg carry-over in final products.

3.3. Exposure data

3.3.1. Reported use levels or data on analytical levels of acacia gum (E 414)

Most food additives in the EU are authorised at a specific MPL. However, a food additive may be used at a lower level than the MPL. Therefore, information on actual use levels is required for performing a more realistic exposure assessment, especially for those food additives for which no MPL is set and which are authorised according to QS.

In the framework of Regulation (EC) No 1333/2008 on food additives and of Commission Regulation (EU) No 257/2010 regarding the re-evaluation of approved food additives, EFSA issued public calls,[11,12] for occurrence data (usage level and/or concentration data) on acacia gum (E 414). In response to these public calls, updated information on the actual use levels of acacia gum (E 414) in foods was made available to EFSA by industry (food industry and gum manufacturers). No analytical data on the concentration of acacia gum (E 414) in foods were made available by the Member States.

3.3.1.1. Summarised data on reported use levels in foods provided by industry

Updated information on the actual use levels (n = 287) of acacia gum (E 414) in foods was made available to EFSA by Association for international Promotion of Gums (AIPG), Associazione Industriali delle Carni e dei Salumi, Association of the European Self-Medication Industry (AESGP), DOMACO Dr. med. Aufdermaur AG, FoodDrinkEurope (FDE), Frutarom Industries Ltd, interested party providing Documentation n.11, F. Hunziker + Co AG, A.H. Meyer & Cie AG, International Chewing Gum Association (ICGA), Nathura, Specialised Nutrition Europe (SNE), CHEPLAPHARM Arzneimittel GmbH, Rudolf Wild GmbH & Co. KG and Stollwerck.

The Panel noted that some data providers (e.g. Association for international Promotion of Gums, Rudolf Wild GmbH & Co) are not food industry using gums in their food products but food additive producers. Usage levels reported by food additive producers should not be considered at the same level as those provided by food industry. Food additive producers might recommend usage levels to the food industry but the final levels might, ultimately, be different, unless food additive producers confirm that these levels are used by food industry. In all other cases, data from food additive producers will only be used in the MPL scenario in case of QS authorisation when no data are available from food industry in order to have the most complete exposure estimates.

Appendix A provides data on the use levels of acacia gum (E 414) in foods as reported by industry.

3.3.2. Summarised data extracted from the Mintel GNPD database

The Mintel's GNPD is an online database which monitors product introductions in consumer packaged goods markets worldwide. It contains information of over 2 million food and beverage products of which more than 900,000 are or have been available on the European food market. Mintel started covering EU's food markets in 1996, currently having 20 out of its 28 member countries and Norway presented in the GNPD.[13]

For the purpose of this Scientific Opinion, GNPD[14] was used for checking the labelling of products containing acacia gum (E 414) within the EU's food products as GNPD shows the compulsory ingredient information presented in the labelling of products.

In the 20 EU countries, acacia gum (E 414) is labelled on almost 13,000 foods and drinks with over 8,200 of them published between 2011 and 2016.

Appendix B presents the percentage of the food products labelled with acacia gum (E 414) between 2011 and 2016, out of the total number of food products per food subcategories according to the Mintel food classification.

3.3.3. Food consumption data used for exposure assessment

3.3.3.1. EFSA Comprehensive European Food Consumption Database

Since 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been populated with national data on food consumption at a detailed level. Competent authorities in the European countries provide EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a). New consumption surveys recently[15] added in the Comprehensive database were also taken into account in this assessment.[16]

[11] http://www.efsa.europa.eu/sites/default/files/consultation/ans091123.pdf
[12] http://www.efsa.europa.eu/sites/default/files/consultation/140310.pdf
[13] Missing Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Luxembourg, Malta and Slovenia.
[14] http://www.gnpd.com/sinatra/home/ accessed on 21/11/2016.
[15] Available online: http://www.efsa.europa.eu/en/press/news/150428.htm
[16] Available online: http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm

The food consumption data gathered by EFSA were collected by different methodologies and thus direct country-to-country comparisons should be interpreted with caution. Depending on the food category and the level of detail used for exposure calculations, uncertainties could be introduced owing to possible subjects' underreporting and/or misreporting of the consumption amounts. Nevertheless, the EFSA Comprehensive Database represents the best available source of food consumption data across Europe at present.

Food consumption data from the following population groups: infants, toddlers, children, adolescents, adults and the elderly were used for the exposure assessment. For the present assessment, food consumption data were available from 33 different dietary surveys carried out in 19 European countries (Table 3).

Table 3: Population groups considered for the exposure estimates of acacia gum (E 414)

Population	Age range	Countries with food consumption surveys covering more than 1 day
Infants	From more than 12 weeks up to and including 11 months of age	Bulgaria, Denmark, Finland, Germany, Italy, UK
Toddlers	From 12 months up to and including 35 months of age	Belgium, Bulgaria, Denmark, Finland, Germany, Italy, Netherlands, Spain, UK
Children[(a)]	From 36 months up to and including 9 years of age	Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Spain, Sweden, UK
Adolescents	From 10 years up to and including 17 years of age	Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Italy, Latvia, Spain, Sweden, UK
Adults	From 18 years up to and including 64 years of age	Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Romania, Spain, Sweden, UK
The elderly[(a)]	From 65 years of age and older	Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Romania, Sweden, UK

(a): The terms 'children' and 'the elderly' correspond, respectively, to 'other children' and the merge of 'elderly' and 'very elderly' in the Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a).

Consumption records were codified according to the FoodEx classification system (EFSA, 2011b). Nomenclature from the FoodEx classification system has been linked to the Food Classification System (FCS) as presented in Annex II of Regulation (EC) No 1333/2008, part D, to perform exposure estimates. In practice, FoodEx food codes were matched to the FCS food categories.

3.3.3.2. Food categories considered for the exposure assessment of acacia gum (E 414)

The food categories in which the use of acacia gum (E 414) is authorised were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx classification system), at the most detailed level possible (up to FoodEx Level 4) (EFSA, 2011b).

Some food categories or their restrictions/exceptions are not referenced in the EFSA Comprehensive Database and could therefore not be taken into account in the present estimate. This was the case for 10 food categories and may have resulted in an underestimation of the exposure. The food categories which were not taken into account are described below (in ascending order of the FCS codes):

- 01.6.3 Other creams;
- 02.3 Vegetable oil pan spray;
- 06.4.4 Potato gnocchi;
- 06.6 Batters;
- 06.7 Precooked or processed cereals, only precooked cereals;
- 08.3.3 Casings and coatings and decorations for meat;
- 12.1.2 Salts substitutes;
- 13.1.3 Processed cereal-based foods and baby foods for infants and young children as defined by Commission Directive 2006/125/EC, only gluten-free cereal-based foods;
- 13.1.5.2 Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC, only gluten-free cereal-based foods;

- 14.1.3 Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products, only vegetable nectars.

For the following food categories, the restrictions/exceptions which apply to the use of acacia gum (E 414) could not be taken into account, and therefore, the whole food category was considered in the exposure assessment. This applies to five food categories and may have resulted in an overestimation of the exposure:

- 05.1 Cocoa and Chocolate products as covered by Directive 2000/36/EC, as glazing agent only;
- 05.2 Other confectionery including breath refreshening microsweets, may not be used in jelly mini-cups;
- 07.1 Bread and rolls, except products in 7.1.1 and 7.1.2;
- 08.3.2 Heat-treated meat products, except *foie gras, foie gras entier, blocs de foie gras, Libamáj, libamáj egészben, libamáj tömbben*;
- 09.3 Fish roe, only processed fish roe.

For the maximum level exposure assessment scenario, one added food category was not taken into account because no concentration data were provided to EFSA. For the refined scenario, 31 added food categories were not taken into account because only concentration data provided by food additive manufacturers were made available to EFSA.

For the remaining food categories, the refinements considering the restrictions/exceptions as set in Annex II to Regulation No 1333/2008 were applied. Overall, for the maximum level exposure scenario, 61 food categories were included, while for the refined scenarios, 31 food categories were included in the present exposure assessment to acacia gum (E 414) (Appendix B).

3.4. Exposure estimates

3.4.1. Exposure to acacia gum (E 414) from its use as a food additive

The Panel estimated chronic exposure to acacia gum (E 414) for the following population groups: infants; toddlers, children, adolescents, adults and the elderly. Dietary exposure to acacia gum (E 414) was calculated by multiplying acacia gum (E 414) concentrations for each food category (Appendix C) with their respective consumption amount per kilogram of body weight for each individual in the Comprehensive Database. The exposure per food category was subsequently added to derive an individual total exposure per day. These exposure estimates were averaged over the number of survey days, resulting in an individual average exposure per day for the survey period. Dietary surveys with only 1 day per subject were excluded as they are considered as not adequate to assess repeated exposure.

This was carried out for all individuals per survey and per population group, resulting in distributions of individual exposure per survey and population group (Table 3). On the basis of these distributions, the mean and 95th percentile of exposure were calculated per survey and per population group. The 95th percentile of exposure was only calculated for those population groups where the sample size was sufficiently large to allow this calculation (EFSA, 2011a). Therefore, in the present assessment, the 95th percentile of exposure for infants from Italy and for toddlers from Belgium, Italy and Spain were not included.

It should be noted that, in a dietary surveys from Finland, namely DIPP_2001_2009 (EFSA, 2011a), the consumption of grain-based products including bread and fine bakery products was coded at the level of their ingredients (flour), which resulted in a very low exposure to locust bean gum in all Finnish populations compared with the other studies. Therefore, this study was excluded from the assessment.

Exposure assessment to acacia gum (E 414) was carried out by the ANS Panel based on (1) maximum levels of data provided to EFSA (defined as the *maximum level exposure assessment scenario*) and (2) reported use levels (defined as the *refined exposure assessment scenario*) as provided by industry. These two scenarios are discussed in detail below.

These scenarios do not consider the consumption of food supplements (FC 17.1, FC 17.2 and FC 17.3) nor the consumption of foods for special medical purposes (FSMP) which are covered in additional refined exposure scenarios detailed below (*food supplements consumers only scenario and food for special medical purposes consumer only scenario*).

As acacia gum (E 414) is also authorised in the food category 13.1.5.2, a refined estimated exposure assessment scenario taking into account this food category was performed to estimate the exposure of infants and toddlers who may eat and drink these FSMP. This scenario does not consider the consumption of food supplements.

The consumption of FSMP is not reported in the EFSA Comprehensive database. To consider the exposure to food additives via consumption of these foods, the Panel assumes that the amount consumed of FSMP in infants and toddlers resembles that of comparable foods in infants and toddlers from the general population. Thus, the consumption of FSMP categorised as food category 13.1.5 is assumed to equal that of formulae and food products categorised as food categories 13.1.1, 13.1.2, 13.1.3 and 13.1.4.

FSMP consumed in other population groups (children, adolescents, adults and the elderly) may be very diverse; they cannot be considered because of very limited information on consumption. Eating occasions belonging to the food categories 13.2, 13.3 and 13.4 were therefore reclassified under food categories in accordance to their main component.

Considering that the food category 18 (Processed foods not covered by categories 1–17, excluding foods for infants and young children) is extremely unspecific (e.g. composite foods), processed foods, prepared or composite dishes belonging to the food category 18 were reclassified under food categories in accordance to their main component. Therefore, food category 18 is not taken into account as contributor to the total exposure estimates.

Concerning the uses of acacia gum (E 414) as carriers, there might be food categories where acacia gum is used according to annex III and not to annex II. These food categories can only be addressed by analytical data or limits set in the Regulation No 1333/2008. According to Annex III, Part 5, Section B of Regulation (EC) No 1333/2008, acacia gum (E 414) is also authorised at QS in all nutrients intended to be used in foods for infants and young children listed in Point 13.1 of Part E of Annex II, at the maximum level of 150,000 mg/kg in the nutrient preparation and 10 mg/kg carry-over in final products. Therefore, this maximum level was taken into account in the MPL scenario. As a reported use levels was made available to EFSA for the FC 13.1.5.1, this food category was taken into in the refined exposure scenario.

3.4.1.1. Maximum level exposure assessment scenario

The regulatory maximum level exposure assessment scenario is based on the MPLs as set in Annex II to Regulation (EC) No 1333/2008. As acacia gum (E 414) is authorised according to QS in almost all food categories, a 'maximum level exposure assessment' scenario was estimated based on the maximum reported use levels provided by industry, as described in the EFSA Conceptual framework (EFSA ANS Panel, 2014).

The Panel considers the exposure estimates derived following this scenario as the most conservative as it is assumed that that the population group will be exposed to acacia gum (E 414) present in food at the maximum reported use levels over a longer period of time.

3.4.1.2. Refined exposure assessment scenario

The refined exposure assessment scenario is based on use levels reported by industry. This exposure scenario can consider only food categories for which the above data were available to the Panel.

Appendix C summarises the concentration levels of acacia gum (E 414) used in the refined exposure assessment scenario. Based on the available data set, the Panel calculated two refined exposure estimates based on different model populations:

- The brand-loyal consumer scenario: It was assumed that a consumer is exposed long-term to acacia gum (E 414) present at the maximum reported use for one food category. This exposure estimate is calculated as follows:
  - Combining food consumption with the maximum of the reported use levels for the main contributing food category at the individual level.
  - Using the mean of the typical reported use levels for the remaining food categories.
- The non-brand-loyal consumer scenario: It was assumed that a consumer is exposed long-term to acacia gum (E 414) present at the mean reported use in food. This exposure estimate is calculated using the mean of the typical reported use levels for all food categories.

As mentioned above, 2 specific scenarios were also performed:

- Food supplements consumers only scenario: This scenario was estimated as follows:
  - Consumers only of food supplements were assumed to be exposed to acacia gum (E 414) present at the maximum reported use level on a daily basis via consumption of food supplements. For the remaining food categories, the mean of the typical reported use levels was used.

As food category 17 does not consider food supplements for infants and toddlers as defined in the legislation, exposure to food additives from food supplements is not estimated for these two population groups.

- Food for special medical purposes consumers only scenario: This scenario was estimated as follows:
  - Consumers only of foods for special medical purposes were assumed to be exposed to acacia gum (E 414) present at the maximum reported use level on a daily basis via consumption of food category 13.1.5.2. For the remaining food categories, the mean of the typical reported use levels was used.

3.4.1.3. Dietary exposure to acacia gum (E 414)

Table 4 summarises the estimated exposure to acacia gum (E 414) from its use as a food additive in six population groups (Table 3) according to the different exposure scenarios (Section 3.4.1). Detailed results per population group and survey are presented in Appendix C.

Table 4: Summary of dietary exposure to acacia gum (E 414) from its use as a food additive in the maximum level exposure assessment scenario and in the refined exposure scenarios, in six population groups (minimum–maximum across the dietary surveys in mg/kg bw per day)

	Infants (12 weeks–11 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Maximum level exposure assessment scenario						
Mean	242.1–880.9	309.8–1,398.0	314.5–1,056.0	196.2–671.0	87.8–350.9	69.2–278.4
95th percentile	705.5–2,952.2	1,108.08–2,767.2	824.4–1,994.0	458.1–1,433.1	221.6–811.4	150.0–657.1
Refined estimated exposure assessment scenario						
Brand-loyal scenario						
Mean	24.0–135.1	116.8–820.3	198.2–667.9	101.1–423.9	50.8–201.9	40.6–119.8
95th percentile	141.1–444.5	579.2–1,735.6	529.9–1,546.4	290.0–1,055.3	124.9–566.5	91.0–249.1
Non-brand-loyal scenario						
Mean	4.8–43.7	64.5–317.7	86.9–276.3	35.0–146.0	15.0–65.2	16.7–43.9
95th percentile	59.0–160.4	215.7–719.2	231.5–615.1	88.6–419.1	43.7–175.9	40.7–105.4

From the *regulatory maximum level exposure assessment scenario*, mean exposure to acacia gum (E 414) from its use as a food additive ranged from 69.2 mg/kg bw per day for the elderly to 1,398 mg/kg bw per day in toddlers. The 95th percentile of exposure to acacia gum (E 414) ranged from 150 mg/kg bw per day for the elderly to 2,952.2 mg/kg bw per day in infants.

From the *refined estimated exposure scenario*, in the *brand-loyal scenario*, mean exposure to acacia gum (E 414) from its use as a food additive ranged from 24 mg/kg bw per day in infants to 820.3 mg/kg bw per day in toddlers. The high exposure to acacia gum (E 414) ranged from 91 mg/kg bw per day for the elderly to 1,735.6 mg/kg bw per day in toddlers. In the *non-brand-loyal scenario*, mean exposure to acacia gum (E 414) from its use as a food additive ranged from 4.8 mg/kg bw per day in infants to 317.7 mg/kg bw per day in toddlers. The 95th percentile of exposure to acacia gum (E 414) ranged from 40.7 mg/kg bw per day for the elderly to 719.2 mg/kg bw per day in toddlers.

From the *refined estimated exposure scenario taking into account the foods for special medical purposes*, consumers only, mean exposure to acacia gum (E 414) from its use as a food additive ranged for infants between 22 and 117 mg/kg bw per day and between 69 and 378 mg/kg bw per day for toddlers. The 95th percentile of exposure to acacia gum (E 414) ranged for infants between 89 and 317 mg/kg bw per day and for toddlers between 175 and 626 mg/kg bw per day. The food categories contributing the most at the mean exposure level are foods for infants and young children for infants and confectionary, foods for infants and young children and fine bakery wares for toddlers.

From the *refined estimated exposure scenario taking into account the consumption of food supplements*, consumers only, among children, adolescents, adults and the elderly, mean exposure to acacia gum (E 414) from its use as a food additive ranged between 18 and 424 mg/kg bw per day. The 95th percentile of exposure ranged between 83 and 521 mg/kg bw per day.

3.4.1.4. Main food categories contributing to exposure to acacia gum (E 414) using the maximum level exposure assessment scenario

The main contributing food categories to the mean exposure estimates for infants in this scenario were foods for infants and young children (FCS 13.1) and unflavoured fermented milk products; for toddlers, they were unflavoured fermented milk products, breakfast cereals and confectionary; for children, they were confectionary, flavoured drinks and unflavoured fermented milk products; confectionary and flavoured drinks were also the main contributing food categories for adolescents and adults. For the elderly, the main contributing food categories were breakfast cereals, coffee, tea, herbal and fruit infusions and bread and rolls (see Table 5 for more details).

3.4.1.5. Main food categories contributing to exposure to acacia gum (E 414) using the refined exposure assessment scenario

In the *brand-loyal scenario*, the main contributing food categories were bread and rolls for infants, confectionary for toddlers, children, adolescents; flavoured drinks for adults and coffee, tea, herbal and fruit infusions for the elderly In the *non-brand-loyal scenario*, the main contributing food categories were fine bakery wares for infants, fine bakery wares and confectionary for toddlers, confectionary for children and adolescents and fine bakery wares for adults and the elderly (see Tables 6 and 7 for more details).

Tables 5, 6 and 7 can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2017.4741

3.4.1.6. Uncertainty analysis

Uncertainties in the exposure assessment of acacia gum (E 414) have been discussed above. In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and summarised in Table 8.

Table 8: Qualitative evaluation of influence of uncertainties on the dietary exposure estimate

Sources of uncertainties	Direction[a]
Consumption data: different methodologies/representativeness/underreporting/misreporting/no portion size standard	+/–
Use of data from food consumption survey of a few days to estimate long-term (chronic) exposure for high percentiles (95th percentile)	+
Correspondence of reported use levels to the food items in the EFSA Comprehensive Food Consumption Database:	
• uncertainties to which types of food the levels refer to	+/–
• levels considered applicable for all items within the entire food category	+/–
Uncertainty in possible national differences in use levels of food categories	+/–
Concentration data:	
• levels considered applicable for all items within the entire food category,	+
• not fully representative of foods on the EU market	+/–
Range from 7% to 96% of the amount (g of foods by body weight) of food consumed taken into account in the refined exposure assessment scenarios out of all authorised food (n = 31/76 food categories)	–
Food categories selected for the exposure assessment:	
• exclusion of food categories due to missing FoodEx linkage (n = 10/76 food categories)	–
Food categories selected for the exposure assessment: inclusion of food categories without considering the restriction/exception (n = 5/76 food categories)	+

Sources of uncertainties	Direction[a]
Maximum level exposure assessment scenario:	
• exposure calculations based on the maximum reported use levels (reported use from industries)	+
• food categories which may contain acacia gum (E 414) due to carry-over not considered	–
• food categories authorised at MPL according to Annex II to Regulation (EC) No 1333/2008	+
• data not available for certain food categories which were excluded from the exposure estimates (n = 1/76 food categories)	–
Refined exposure assessment scenarios:	
• food categories which may contain acacia gum (E 414) due to carry-over not considered	–
• exposure calculations based on the maximum or mean levels (reported use from industries)	+/–
• data not available for certain food categories which were excluded from the exposure estimates (n = 31/76 food categories)	–

(a): +, uncertainty with potential to cause over-estimation of exposure; –, uncertainty with potential to cause underestimation of exposure.

Acacia gum (E 414) is authorised as a Group I food additive in 66 food categories and has a specific authorised uses in 10 other categories (Table 2). Since, the majority of food categories correspond to the general Group I food additives authorisation, acacia gum (E 414) may not necessarily be used in some of these food categories. This may explain why use levels reported by food industry for acacia gum (E 414) was not available for 31 food categories.

Furthermore, the Panel noted that information from the Mintel's GNPD (Appendix B) indicated that some of these 31 food categories were labelled with acacia gum (breakfast cereals, snacks, cheeses).

Overall, the Panel considered that the uncertainties identified would, in general, result in an overestimation of the exposure to acacia gum (E 414) as a food additive in European countries considered in the EFSA European database for the maximum level exposure scenario and for the refined scenario if it is considered that the food additive are not used in food categories for which no usage data have been provided.

However, the Panel noted that given the information from the Mintel's GNPD, it may be assumed that acacia gum (E 414) is used in food categories for which no data have been provided by food industry. If this was confirmed, it would therefore result in an underestimation of the exposure.

The Panel noted that food categories which may contain acacia gum (E 414) due to carry-over (Annex III, Part 1, 2, 3, 4 and 5 (sections A and B)) were not considered in the current exposure assessment.

Considering the exposure to acacia gum (E 414) for infants and young children eating FSMPs, the Panel considered that the uncertainties identified would, in general, result in an overestimation of the exposure in European countries considered in the EFSA European database for the brand-loyal refined scenario.

3.4.2. Exposure via other uses

Exposure to acacia gum due to the following uses were not considered in this opinion.

3.4.2.1. Acacia gum as an ingredient in food supplements and other foods

In literature, the use of acacia gum as 'soluble dietary fibre' in food is described (Cherbut et al., 2003).

3.4.2.2. Pharmaceutical uses

For acacia gum as an active ingredient, no authorised medicinal products exist within the EU (Documentation provided to EFSA, n.8).

Acacia gum is used in pharmaceutical products only as an excipient, e.g. as a suspending and emulsifying agent, as an adhesive and binder in tableting and demulcent syrups (Verbeken et al., 2003; Martindale, 2014).

3.5. Biological and Toxicological data

The biological properties of acacia gum (E 414) have been previously evaluated by JECFA in 1982 and 1990 (JECFA, 1982, 1990). The present opinion briefly reports the main studies evaluated in these reports. Additional information has been identified from literature (CIR, 2005) and from a new literature search. In most of the studies evaluated, the identity of the test material (acacia gum or gum arabic) was not specified.

The Panel noted that the toxicological database on acacia gum is mostly derived from its use as an emulsifying agent in studies of the toxicity of water-insoluble chemicals.

3.5.1. Absorption, distribution, metabolism and excretion

There is evidence that certain high molecular weight dietary polysaccharides, such as gums, could be partially broken down in the large intestine of man. In addition to intermediate metabolites, such as lactate, acrylate or fumarate, the main end products of this colonic anaerobic digestive process are short-chain fatty acids (SCFA), such as acetic, propionic and butyric acids, which are absorbed from the colon (Cummings and Englyst, 1987).

3.5.1.1. *In vitro* studies

A total of 188 strains from 11 species *Bacteroides* species found in the human colon were surveyed for their ability to ferment mucins and plant polysaccharides including gums (Salyers et al., 1977a). Many of the *Bacteroides* strains tested were able to ferment a variety of plant polysaccharides, including amylose, dextran, pectin and gums. The ability to utilise mucins and plant polysaccharides varied considerably among the *Bacteroides* species tested. By contrast to other gums (locust bean gum or gum tragacanth), none of the *Bacteroides* tested fermented acacia gum (origin, Meer Co).

A total of 154 strains from 22 species of *Bifidobacterium, Peptostreptococcus, Lactobacillus, Ruminococcus, Coprococcus, Eubacterium* and *Fusobacterium*, which are present in high concentrations in the human colon, were surveyed for their ability to ferment 21 different complex carbohydrates, including gums (Salyers et al., 1977b). Among them, acacia gum (origin, Meer Co) was fermented by some strains of *Bifidobacterium* species.

Adiotomre et al. (1990) investigated the effects of dietary fibres, including gums, on caecal fermentations by using fresh human microflora. Evolution of SCFAs and water-holding capacity after fermentation were also measured. Among other gums, acacia gum (E 414) yielded the largest amount of total SCFAs (74.0 vs 15.5 mmol/L for controls). The major SCFAs produced were acetic, propionic and butyric acids, with smaller amounts of isobutyric, valeric and isovaleric acids. By contrast, the amount of water held by 1 g of the fermented residue was low as compared to other fibres in case of acacia gum (2.05 vs 0.91 g/g for controls).

A total of 290 strains of 29 species of bifidobacteria of human and animal origin (mainly of faecal origin) were surveyed for their ability to ferment complex carbohydrates (Crociani et al., 1994). The substrates fermented by the largest number of species were D-galactosamine, D-glucosamine, amylose and amylopectin. Acacia gum (origin, Sigma Co) was shown to be mainly fermented by *Bifidobacterium longum* strains.

In another *in vitro* study, acacia gum (90.8% dry matter with 2.4% crude protein) was fermented using dog faeces as the source of inoculum (Sunvold et al., 1995a). Organic matter disappearance and SCFAs production was measured after 6, 12 or 24 h of incubation. Whatever the duration of incubation was, the organic matter disappearance, and acetate, propionate and butyrate productions were lower for acacia gum than for other gums. Identical conclusions were drawn from a similar study using the same substrates fermented by cat faecal microflora (Sunvold et al., 1995b).

Kishimoto et al. (2006) used enriched cultures of pig caecal bacteria to investigate the fermentation of a selected high molecular weight specific acacia gum (MW 1.77 x 10^6 g/mol, a specific gum arabic, namely *A. senegal* (L.) Willd. designated Acacia (sen) SUPER GUMTM EM2)). In this *in vitro* study, a *Prevotella ruminicola*-like bacterium was found as a predominant bacterium that is most likely to be responsible for fermentation of acacia gum to propionate.

3.5.1.2. *In vivo* studies

After fasting for 48 h, 20 young male rats (strain not specified, average weight 140 g) received orally 10 g of a mixture containing 34% acacia gum (white power, unspecified origin) in cocoa butter (Monke, 1941). Rats were killed 72 h later and their livers were removed and the glycogen levels

determined. The differences in liver glycogen levels between control and acacia gum-treated rats were not significant.

Groups of five rats (strain not specified) were pair-fed acacia gum (0.75 g/day in 5 g basal diet, (unspecified origin)). The digestibility of gum arabic was reported to be 71% (no further information was available) (in: Informatics Inc., 1972, referring to Booth et al., 1963).

Acacia gum (unspecified origin) was found to be highly digestible by guinea pigs (O'Dell et al., 1957) or by rats (Shue et al., 1962). However, the amounts of acacia gum in the diet or the exposure times were not specified. Therefore, these studies are of limited value for a final conclusion.

Later studies showed that acacia gum (unspecified origin) is partially digested by the rat (Booth et al., 1963). Weight gain and feed efficiency (gain/feed intake) was determined in six rats (strain and sex not specified, reported as albino rat, mean starting weight 37,500 mg, about 20 days old) fed 15% acacia gum for 62 days (equivalent[17] to 18,000 mg acacia gum/kg bw day). The feed efficiencies were identical in treated and control group but the rats given gum arabic had a mean weight gain of 224 g and the controls of 199 g, suggesting that gum arabic was utilised. Information regarding absorption is not reported in the publication.

The metabolism of acacia gum (conformed to the British Pharmacopoeia specification) was studied in male albino Wistar rats receiving acacia gum (form unspecified) incorporated into a high protein containing diet (Oxoid breeders) for 2 weeks (Ross et al., 1981, 1984). Animal numbers in treatment groups varied from 3 to 25 for the specific investigation. This diet was chosen for its high protein content in order to minimise the nutritional deficiency caused by the addition of large proportions of acacia gum (25,000, 50,000, 100,000 and 200,000 mg/kg diet, equivalent to 2,950, 5,900, 11,800 and 23,600 mg acacia gum/kg bw per day, respectively). An alternative method was to incorporate the acacia gum into a low-residue, nutritionally complete elemental diet up to 130,000 mg/kg (equivalent to 15,300 mg acacia gum/kg bw per day). It was observed, that acacia gum could be recovered from the small intestine, but not from the caecum, colon, rectum or faeces of the treated rats. By contrast, in rats where caecum was surgically removed with restoration of intestinal continuity, acacia gum was detected all along the gastrointestinal tract, from stomach to rectum and also in the faeces. The authors concluded that acacia gum is not significantly degraded in the upper gastrointestinal tract, but is rapidly decomposed by bacterial activity within the caecum, associated with increased breath methane excretion, increased volatile fatty acid concentrations and changes in the proportions of various volatile fatty acids in the faeces.

3.5.1.3. Human study

Five healthy male volunteers (33–55 years old) ingested daily doses of 25,000 mg acacia gum (approx. 350 mg acacia gum/kg bw per day, as a solution in 7% dextrose, conformed to the British Pharmacopoeia specification) for 21 days (Ross et al., 1983). Acacia gum was not recovered in faeces. According to the authors, the gum must have been digested during passage through the human colon. The dose was well tolerated. According to the authors, the absence of precipitable acacia gum in the faeces of the subjects and the marked increases in breath hydrogen production would indicate that the molecule is degraded during its passage through the human colon and that microflora is responsible for this.

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 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 (Den Besten et al., 2013; Topping and Clifton, 2001), the Panel considered that their potential formation as fermentation products from acacia gum does not raise a safety concern.

3.5.2. Acute toxicity

The acute oral toxicity of acacia gum (unspecified origin) was tested in mouse, rat, hamster and rabbit. The substance was given once by gavage as a 25% suspension in corn oil (FDRL, 1972a). The

[17] EFSA guidance on selected default values. EFSA Journal 2012;10(3):2579, 32 pp.

LD_{50} values were higher than 16,000, 18,000 and 16,000 mg/kg bw in mouse, rat and hamster, respectively. In rabbits, the LD_{50} was 8,000 mg/kg bw.

In another acute oral toxicity study in rabbits (weights and strain not stated), a LD_{50} of 80 000 mg/kg bw was reported for acacia gum (CIR, 2005).

3.5.3. Short-term and subchronic toxicity

Acacia gum tested in the following studies was not fully characterised.

Groups of six male Sprague–Dawley rats (3 weeks old) were fed a diet containing 50,000 mg acacia gum/kg diet (equivalent to 5,900 mg acacia gum/kg bw per day) for 4 weeks (Mallett et al., 1984). Treatment had no effect on body weight, but the weight of the caecal wall and of the caecal contents was significantly increased. In addition, concentration of caecal ammonia was increased. There was also a significant increase in the activity of bacterial enzymes such as azo reductase, nitroreductase and nitrate reductase as compared to controls.

In a study of Anderson et al. (1984), groups of three male Wistar rats (initial weight 140–160 g) were given diets containing 0% (control), 1%, 4% and 8% of acacia gum (conformed to the British Pharmacopoeia specification) for 28 days (equivalent to 1,180, 4,720 and 9,440 mg acacia gum/kg bw per day, respectively). At autopsy, all organs of all animals were examined microscopically and some material was retained for electron microscopy and for microsomal cytochrome P450 assays. There were no detectable abnormalities in any of the organelles in the heart and the liver specimens. All histological observations were normal. The data from the assays of the liver microsomal protein and cytochrome P450 gave no indication for an inductive effect of acacia gum.

Cook et al. (1992) evaluated the oral toxicity of gum arabic (*Acacia* species not stated) using 3-week-old Sprague–Dawley rats (16 males and 16 females). Three days before dosing, mean body weights were 122 g and 125 g for males and females, respectively. The animals were fed gum arabic (dose not stated) daily for 28 days. Blood samples were obtained for haematological examination and serum analysis the day before animals were killed. After microscopic examination of organs, including any tissues that appeared abnormal, histology was normal. No treatment-related behavioural effects were noted. All values for serum chemistry parameters were within the normal limits for laboratory rats. Mean red blood cell volume values were within the normal historical control for rats in this laboratory.

Wistar albino rats (99–120 g) were fed a diet containing 10% gum arabic (*Acacia senegal* gum, conformed to the British Pharmacopoeia specification) (equivalent to 11,800 mg acacia gum/kg bw per day) daily for 45 days (Anderson et al., 1986). The number of rats in the study was not reported. Portions of the jejunum, ileum and caecum were excised, and examined using transmission electron microscopy. No abnormalities in organelles were observed within cells of the jejunum, ileum or caecum of rats fed gum arabic. Additionally, neither inclusions nor other pathological changes were detected. The authors concluded that there were no ultrastructural differences between treated and control rats.

Subchronic effects of acacia gum (80.8–85.5% purity) were also determined in F344 rats (initial weight 78–85 g) and B6C3F1 mice (initial weight 17–21 g) fed diets containing 0%, 0.63%, 1.25%, 2.5%, 5% or 10% acacia gum (reported as 100,000 mg acacia gum/kg diet) for 13 weeks (NTP, 1982). The dietary doses were equivalent to 560, 1,120, 2,250, 4,500 or 9,000 mg acacia gum/kg bw per day in rats and 1.25, 2.5, 5, 10 or 20 g acacia gum/kg bw per day in mice. Ten animals of each sex and each species per dose were used and separate control groups of each sex and species were included. The investigations included clinical signs, body weights, feed consumption and histopathology of all major organs. Haematology, clinical chemistry and urine were not investigated. No compound-related effects were observed in rats and mice, except a reduction in feed consumption at the two highest doses in males rats and at all doses in females rats as compared with the control animals (NTP, 1982).

Two 90-day-toxicity studies of acacia gum (conformed to the British Pharmacopoeia specification) performed in Wistar rats were reported (Anderson et al., 1982). In the first study, groups of 15 male and 15 female rats (24–28 days old) were fed for 13 weeks (90 days) at dietary concentrations of 0%, and around 1%, 2%, 4% and 8% equal to 0, 530, 1,080, 2,550 and 5,220 mg acacia gum/kg bw per day in males, and 0, 500, 1,050, 2,600 and 5,310 mg acacia gum/kg bw per day in females, respectively. The investigations included clinical signs, body weights, feed consumption, haematology, clinical chemistry, urinalysis, liver and kidney weights, and histopathology of all major organs. There was no reduction in the growth rate of male or female rats. There were no significant haematological

and urinalysis changes, and histopathology revealed no alterations. The authors concluded that there was no adverse effect up to the highest dose tested (5,000 mg acacia gum/kg bw per day).

In the second study, 15 male and 15 female rats per group were given for 13 weeks a diet containing acacia gum at 0% (control), 18.6% for males and 18.1% for females, in order to achieve a constant daily intake of approximately 14,000 mg acacia gum/kg bw per day. The same protocol as described above was performed. No haematological changes were reported, the only significant differences in serum were a decrease in serum total CO_2 and an increase in serum urea for female animals that received 14,000 mg acacia gum/kg bw per day; they had also a small reduction in kidney weight and caecal enlargement. In male rats receiving 14,000 mg acacia gum/kg bw per day, feed and water consumption, body weight, liver and kidney weights were significantly decreased and caecal enlargement was observed.

The Panel noted that an increased caecum weight in animals fed high amounts of carbohydrates is considered a physiological response to an increased fermentation. Increased caecum weight has been observed in rats fed carbohydrates other that acacia gum (Leegwater et al., 1974; Licht et al., 2006). Animals fed diets containing potato starch, inulin or oligofructose had significantly higher caecum weights and lower pH values than the reference animal group (Licht et al., 2006). Different groups of animals fed modified diets containing increased concentration of potato starch, hydroxypropyl starch and hydroxypropyl distarch glycerol showed increases in the relative caecal weights, filled and emptied, with increasing concentrations of the various hydroxypropyl starches. These increases were accompanied by increased severities of diarrhoea that was related to an increased osmotic activity of the caecal fluid in the animals (Leegwater et al., 1974). The authors hypothesised that dietary components not completely digested and/or absorbed in the small intestine, and further fermented by the gut microflora, enhance the amounts of osmotically active material resulting in an increase in water retention and the animals drinking more water leading to the caecum distention to a size larger than normal.

The Panel noted that these two studies were done independently and that merging their data may not be straightforward. The Panel noted that the only significant adverse effect reported in the second study, i.e. a decreased body weight gain in male rats, was due to the fact that the control group had a body weight gain well above the one of the control group reported in the first study. In this second study, male rats treated with the highest dose had a weight gain similar to the one of males from the control group in the first study. In addition, in the second study, the Panel considered that the high amounts of acacia gum given through the diet could have lead to a nutritional imbalance; therefore, the Panel considered that no relevant toxicological effects were observed in the two studies by Anderson et al. (1982). From the first study, the Panel identified a no observed adverse effect level (NOAEL) of 5,220 and 5,310 mg acacia gum/kg bw per day in male and female, respectively, the highest dose tested.

Doi et al. (2006) performed a 90-day study, under good laboratory practice (GLP), on a polysaccharide exudate from gum acacia trees (*A. senegal*) (purity, 100%). The compound was administered for 90 days in the diet to F344 rats (10 rats/sex per group) at levels of 0% (control), 1.25%, 2.5% and 5.0% (equal to 3,100 and 3,300 mg/kg bw per day in male and female rats, respectively). During the study, the treatment had no effects on clinical signs, survival, body weights, and feed and water consumption, or on findings of urinalysis, ophthalmology, haematology or blood biochemistry. Gross pathology and histopathology exhibited no differences of toxicological significance between control and treated rats. Increased relative caecum (filled) weights, evident in both sexes in the 5.0% groups and females in the 1.25% and 2.5% groups, were considered to be a physiological adaptation. The authors concluded that the NOAEL from the present study was 5.0% (3,100 mg/kg bw per day for males and 3,300 mg/kg bw per day for females). The Panel agreed with this NOAEL, the highest dose tested.

Overall, the short-term and subchronic 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 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.

3.5.4. Genotoxicity

3.5.4.1. *In vitro*

In the study by Green (1977), acacia gum (unspecified origin) was assessed for its mutagenicity in the reverse mutation assay using *Salmonella* Typhimurium strains TA1530 and G-46 according to the method of Ames by the plate incorporation assay in the absence of rat liver S9 metabolism, and for mitotic recombination in *Saccharomyces cerevisiae* (strain D-3) in the absence of S9 metabolism only.

Negative results were reported for both mutagenic and mitotic recombination capabilities. However, the Panel noted that the study shows some shortcomings in the experimental design which include the use of a limited number of *S. typhimurium* strains, the absence of treatment in the presence of S9 metabolic activation and no indication of dose levels employed. On this basis, the Panel considered this study of limited value for risk assessment.

In the rec-assay employing the *Bacillus subtilis* strains M45 rec⁻, unable to repair DNA damage, and the wild-type strain H17 rec+ as control, acacia gum (unspecified origin) was assessed for its potential DNA-modifying effects at a single dose level of 10.3 mg/plate, both in the absence and presence of S9 metabolism. Negative results were obtained (Ishizaki and Ueno, 1987). The Panel noted that this mutagenicity assay is not frequently used and has not been validated.

In the study by Prival et al. (1991), acacia gum (origin Stein, Hall & Co.) was assessed for its mutagenicity in the reverse mutation assay using the *S. typhimurium* strains TA1535, TA1537, TA1538, TA98 and TA100, and the tryptophan-requiring *Escherichia coli* strain WP2, according to the method of Ames by the standard plate-incorporation assay both in the absence and presence of rat liver S9 metabolism up to dose levels of 10 mg/plate. Results obtained clearly indicated that acacia gum did not increase the number of revertant colonies both in the absence and presence of S9 metabolism. Furthermore, the Panel noted that the study complied with the current OECD Guideline 471.

Similarly, in the study by Zeiger et al. (1992), the mutagenicity of acacia gum (origin, Celanese Chemicals) was evaluated in the reverse mutation assay using the *S. typhimurium* strains TA 1535, TA1537, TA97, TA98 and TA100 according to the method of Ames by the pre-incubation protocol, both in the absence and presence of Aroclor 1254-induced rat and hamster S9 fractions at 10% and 30% up to dose level of 10 mg/plate. The outcome of the study clearly indicated that acacia gum was devoid of mutagenic activity under the reported experimental conditions. Furthermore, the Panel noted that the study complied with the current OECD Guideline 471 with the exception that tester strains TA102 or WP2uvrA bearing AT mutation were not used.

Newell and Maxwell (1972) and Maxwell and Newell (1974) assessed acacia gum (unspecified origin) for its ability to induce chromosomal aberrations in anaphase in the human embryonic lung cells (WI-38) at concentrations up to 1,000 μg/mL without S9 mix. Results reported by authors indicate slight increases in the frequency of cells bearing chromosomal aberrations particularly at the intermediate dose level used. However, the Panel noted that the observed increases were not dose-related and were accompanied by an elevated spontaneous level of chromosomal aberrations in the concurrent negative control (15.7%). In addition, the Panel noted that this assay did not receive further validation and is presently not used in genotoxicity testing.

Similarly, Green (1977) investigated the induction of chromosomal aberrations in anaphase by acacia gum (unspecified origin) in the human embryonic lung cells (WI-38) with questionable positive results, since no indication of dose levels employed and treatments performed only in the absence of S9 metabolic activation. However, the Panel noted that this assay did not receive further validation and is presently not used in genotoxicity testing.

3.5.4.2. *In vivo*

In the studies by Newell and Maxwell (1972) and Maxwell and Newell (1974), acacia gum (unspecified origin) was assessed for its genotoxicity in the following *in vivo* assays:

The host-mediated assay in Swiss Webster male mice administered once by oral gavage at 30, 2,500 and 5,000 mg/kg bw or for 5 consecutive days at the same dose levels employed in the single administration regime using the microbial systems *S. typhimurium* strains TA1530 and G-46 for mutagenicity and *S. cerevisiae* (strain D-3) for mitotic recombination.

Chromosomal aberrations in bone marrow cells of male albino rats administered by oral gavage once at 30, 2,500 and 5,000 mg/kg bw or for 5 consecutive days every 24 h at the same dose levels employed in the acute administration. In the acute treatment, sampling of bone marrow cells was performed at 6, 24 and 48 h after the last administration whereas, in the multiple administration study, sampling of bone marrow cells was only performed at 6 h from the last administration.

Dominant lethal assay in Sprague–Dawley rats following administration of the test compound by oral gavage once at 30, 2,500 and 5,000 mg/kg bw or for 5 consecutive days at the same dose levels employed in the single administration regime. Total implants (live fetuses plus early and late fetal deaths), total dead (early and late fetal deaths), dead implants per total implants and pre-implantation loss (calculated as the difference between the total corpora lutea and total implant counts) were evaluated.

The results reported indicated no effects for the host-mediated assay and dominant lethal assay, and 'slight positive findings' for the *in vivo* chromosomal aberration assay in bone marrow cells at the intermediate (5.3%) and high (5.2%) dose levels at the 6-h sampling time, compared with the concurrent negative control (0.7%). However, the Panel noted that increases in the number of aberrant cells observed at the 6-h sampling time at the intermediate and high dose levels were very similar to the incidence of aberrant cells observed in the negative control at the 24-h sampling time (4.0%) and were considered by the Panel to be of no biological significance. In addition, the Panel noted that the host-mediated assay did not receive further validation and is presently not used in genotoxicity testing.

In the study by Sheu et al. (1986), acacia gum (origin, Celanese Chemicals) was investigated for induction of chromosomal damage in rodent germ cells using the dominant lethal assay in male rats and dominant lethal and heritable translocation assays in mice. Acacia gum was incorporated into laboratory chow and fed to male rats and mice for 10 and 8 weeks, respectively. Three dose levels (500, 1,700 and 5,000 mg acacia gum/kg bw per day) were used. The treated male rats and mice were then tested for dominant lethal mutations evaluating the number of live and dead implants. The mice were also tested for induced heritable translocations. The authors reported negative results for both dominant lethal effects and heritable translocation in mice. Statistically significant increases for dominant lethal effects were instead observed in rats but considered to be of questionable biological significance by the authors. The Panel agreed with this conclusion and noted that increases of dead implants were small in absolute terms compared to the negative control values and were not dose-related.

Overall, the Panel noted that for the *in vivo* studies, acacia gum is not absorbed as such but appears, at the best, to be slightly fermented in the intestine to short chain fatty acids. On this basis the Panel considered the results of the *in vivo* studies of limited relevance for risk assessment.

In conclusion, the available *in vitro* and *in vivo* studies are generally limited or of limited relevance for different reasons. However, acacia gum was not mutagenic in *S. typhimurium* strains TA1535, TA1537, TA97, TA98, TA100 and TA 102 using the experimental method indicated by the OECD test guideline 471 (Prival et al. Zeiger et al., 1992) and did not show substantial evidence for the induction of chromosome mutations in mammalian cells *in vitro* in the anaphase chromosome aberration test, although this assay has not been validated and it is not currently employed for genotoxicity testing (Newell and Maxwell, 1972; Maxwell and Newell, 1974 and Green, 1977). Substantial negative results were also observed *in vivo* in the host-mediated assay in mice and the chromosomal aberration and dominant lethal assay in rats (Newell and Maxwell, 1972; Maxwell and Newell, 1974 and Sheu et al., 1986), although the relevance of these studies is limited due to the negligible absorption of the acacia gum.

Overall, based on the data available, the Panel concluded that there is no concern with respect to the genotoxicity of acacia gum.

3.5.5. Chronic toxicity and carcinogenicity

Mice and rats

No chronic toxicity studies were available.

A carcinogenicity study with acacia gum (80.8–85.5% purity) was conducted by feeding diets containing 25,000 mg/kg diet (2.5%) or 50,000 mg/kg diet (5%) of the test substance to 50 F344 rats and 50 B6C3F1 mice of each sex for 103 weeks. Groups of untreated rats and mice of each sex served as controls (NTP, 1982; Melnick et al., 1983). The dietary doses were 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. Throughout most of the study, mean body weights of dosed male and female mice and of dosed male rats were comparable with those of the controls; mean body weights of the dosed female rats were slightly lower than those of the controls. No other compound-related clinical signs or effects on survival were observed. Mean daily feed consumption of high-dosed rats and mice of either sex was 85–94% that of the controls.

According to NTP (1982), statistically significant ($p < 0.05$) increasing trends were observed for the number of female mice with hepatocellular carcinomas (1/49, 2/50, 6/50), and with total liver tumours (4/49, 2/50, 10/50). No statistically significant differences were obtained when comparing the control rates with those observed in the treated groups. These observations were not considered to be clearly associated with the dietary administration of acacia gum. Thus, no compound-related neoplastic or non-neoplastic lesions were found in rats or mice of either sex at doses up to 5% of acacia gum in the

diet, equivalent to 2.5 g acacia gum/kg bw per day in rats and 7.5 g acacia gum kg bw per day in mice. According to the authors, acacia gum was not carcinogenic in rat and mice. The Panel agreed with the conclusion of the authors and considered that acacia gum is not of concern with respect of carcinogenicity.

3.5.6. Reproductive and developmental toxicity

Reproductive and developmental toxicity of acacia gum was tested in different strains of mice and rats as well as in rabbits and hamsters.

3.5.6.1. Reproductive toxicity studies

In a combined fertility and developmental toxicity study of Collins et al. (1987) male and female Osborn–Mendel rats starting at 4 weeks of age. Body weights were recorded at regular intervals during the premating, mating and gestation period. Mating results were recorded by sperm detection. Pregnant (41–47) dams were observed daily for appearance and behaviour. The rats were treated from 13 weeks before mating, during gestation by specified acacia gum (A-12) added and blended with commercial diets. The rats were fed of 0%, 1%, 2%, 4%, 7.5 or 15% acacia gum in the diet (during gestation equal to 0, 683, 1,350, 2,836, 5,199 or 10,647 mg acacia gum/kg bw per day. At necropsy on gestation day (GD) 20, the numbers of implantation sites, resorption sites, live and dead fetuses, and body weights of live pups were recorded. All fetuses were examined grossly for external abnormalities, half for visceral examination and the other half only bone not cartilaginous stained and examined for skeletal defects). At doses up to 10,647 mg acacia gum/kg bw per day, there were no noticeable effects on pregnancy rate, implantation nor on maternal and fetal survival. The numbers of live or dead fetuses, resorptions, average implantations and fetal weights did not differ among the groups. The sex distribution of fetuses was not affected by the treatment. The number of abnormalities seen in either soft tissues or skeletons at fetal pathological examination of the acacia gum-treated groups did not differ from the number occurring spontaneously in vehicle-treated dams of the control group. There was no effect on female fertility. No adverse effects were mentioned about male fertility. The Panel identified from this study a NOAEL of for reproductive (fertility) effects of 10,647 mg acacia gum/kg bw per day, the highest dose tested.

Morseth and Ihara (1989a) evaluated the effect of a 5% solution of acacia gum (origin not specified) in water, on fertility and general reproductive performance using 30 male (6 weeks old, 181–226 g) and 30 female (10 weeks old, 210–309 g) Sprague–Dawley rats. The solution was administered by gavage once daily (5 mL/kg bw per day, equivalent to 250 mg acacia gum/kg bw per day) for 63 days prior to mating, throughout the mating period, and until the animals were killed. Male rats were killed after the females had littered. The oral dosing schedule for female rats was daily for 14 days prior to mating, throughout the mating period, and through GD 19 or 21 of lactation. Fifteen female rats were killed on day 20 of gestation, and the remaining females were allowed to raise their neonates to day 22 post-partum. No treatment–related abnormalities were observed in the oestrous cycles. Twenty-nine of the 30 females became pregnant; the male fertility index was 97%. Mean viability and mean weaning indices were 96% and 98%, respectively. No adverse effects were seen in this study at the only dose tested.

In a study to test the effects of another substance on fertility, 12 male Sprague-Dawley rats were fed 30% acacia gum (without further specifications; equivalent to 15,000 mg/kg bw per day) as vehicle controls (Huynh et al., 2000). Six males were killed after 82 days. During the last week, they could mate each two females. Following a period of up to 14 weeks, the remaining six males were killed and inspected. The following parameters were examined: fertility, including embryonic features in their mated females, hormone assays, blood and tissue examinations, epididymal sperm content and motility, sperm nuclear integrity and mitochondrial function. No effects were observed on mating behaviour and outcome, spermatogenesis, epididymal sperm function and fertility in male rats, at the end of the 82 days period and after the up to 14 weeks phase (Huynh et al., 2000). The Panel noted that in this fertility study acacia gum was used as control substance; the negative results cannot be used as a fertility assessment of acacia gum.

3.5.6.2. Developmental studies

In a study in mice receiving 5 oral doses of 0.5 mL of 1% and 10% (equivalent to 5 and 50 mg gum acacia gum/kg bw per day) solution of acacia gum (origin Merck AG) in water between day 11 and 15 of gestation, no embryotoxicity was observed (Frohberg et al., 1969).

Several developmental toxicity studies of acacia gum were conducted in Wistar rats, CD-1 mice, golden hamsters and Dutch belted rabbits (FDRL, 1972b). Animals were administered different doses of locust bean gum (not specified) suspended in anhydrous corn oil by gavage (1.0 mL/kg bw); the control groups were vehicle-treated. Body weights were recorded at regular intervals during gestation and all animals were observed daily for appearance and behaviour. All dams were subjected to caesarean section, and the numbers of implantation sites, resorption sites, live and dead fetuses, and body weight of live fetuses were recorded. All fetuses were examined grossly for external abnormalities, one-third underwent detailed visceral examinations and two-thirds were stained and examined for skeletal defects.

Mice

Pregnant CD-1 mice (19–21 animals/group) were treated by oral gavage once daily from GD 6 to 15 with doses of 0, 16, 75, 350 or 1,600 mg acacia gum/kg bw per day(no specification) in corn oil (20, 20, 21, 19 or 20 pregnant surviving females/group, respectively) (FDRL, 1972b). At necropsy on GD 17, the surviving dams appeared to be completely normal and the number of implantations, and live fetuses were comparable to the control group. Doses up to 1,600 mg acacia gum/kg bw per day had no noticeable effects on implantation nor on maternal and fetal survival. The numbers of live or dead fetuses, resorptions and the average implant sites, and also fetal weights did not differ among the groups. The sex distribution of fetuses was not affected by the treatment. The number of abnormalities seen in either soft tissues or skeletons at fetal pathological examination of the acacia gum-treated groups, did not differ from the number in vehicle-treated dams of the control group.

Rats

Pregnant Wistar rats (24 animals/group) were treated by oral gavage once daily from GD 6 to 15 with doses of 0, 16, 75, 350 or 1,600 mg acacia gum/kg bw per day in corn oil (23, 23, 22, 24 or 24 pregnant surviving females/group, respectively) (FDRL, 1972b). At necropsy on GD 20, doses up to 1,600 mg acacia gum/kg bw per day appeared to be completely normal and had no noticeable effects on implantation nor on maternal and fetal survival. The numbers of live or dead fetuses, resorptions, average implantations and fetal weights did not differ among the groups. The sex distribution of fetuses was not affected by the treatment. The number of abnormalities seen in either soft tissues or skeletons at fetal pathological examination of the acacia gum-treated groups did not differ from the number in vehicle-treated dams of the control group.

Hamsters

Pregnant Golden hamsters (20–22 animals/group) were treated by oral gavage once daily from GD 6 to 10 of gestation with doses of 0, 16, 75, 350 or 1,600 mg/kg bw per day of acacia gum in corn oil (20, 20, 19, 20 or 20 pregnant surviving females/group, respectively (FDRL, 1972b). At necropsy on GD 14, doses up to 1,600 mg acacia gum/kg bw per day appeared to be completely normal and showed no noticeable effects on implantation nor on maternal and fetal survival. The numbers of live or dead fetuses, resorptions, average implant sites or fetal weights did not differ among the groups. The sex distribution of fetuses was not affected by the treatment. The number of abnormalities seen in either soft tissues or skeletons at fetal pathological examination of the acacia gum-treated groups did not differ from the number in vehicle-treated dams of the control group.

Rabbits

Artificially inseminated Dutch-belted rabbits (15 animals/group) were treated by oral gavage once daily from GD 6 to 18 with doses of 0, 8, 37, 173 or 800 mg acacia gum/kg bw per day in corn oil (13, 11, 13, 9 or 8 pregnant surviving females/group, respectively) (FDRL, 1972b). The mortality in this test was 1, 2, 0, 3, 6 dams in the respective groups. Death was preceded by severe bloody diarrhoea, urinary incontinence and anorexia, 48–72 h before death, with, as pathological findings, haemorrhages in the mucosa of small intestines. At necropsy on GD 29, the surviving dams appeared normal throughout the observation period and had normal fetuses. No effect was observed on the number of implantations. The numbers of live or dead fetuses, resorptions, average implant sites or fetal weights did not differ among the groups. The sex distribution of fetuses was not affected by the treatment. The number of abnormalities seen in either soft tissues or skeletons at fetal pathological examination of the acacia gum-treated groups did not differ from the number in vehicle-treated dams of the control group. The higher maternal toxicity (lethality) observed in this study as compared to any of the other

species, can be caused by the difficulty of dosing rabbits by gavage with a viscous solution. Therefore, the Panel considered this study not suitable for the evaluation of risk assessment.

Male and female Osborne–Mendel rats were given diets containing 0% (control), 1%, 2%, 4%, 7.5% or 15% of acacia gum during premating, mating and throughout gestation (Collins et al., 1987). During gestation, the treated females consumed from 683 mg acacia gum/kg bw per day in the 1% group to 10,647 mg acacia gum/kg bw per day in the 15% group. The animals were killed on GD 20. There were no dose-related changes in maternal findings, number of fetuses, fetal viability or external, visceral or skeletal variations. The Panel identified from this study a NOAEL of for developmental effects of 10,647 mg acacia gum/kg bw per day, the highest dose tested.

Morseth and Ihara (1989b) investigated the developmental effects of a 5% solution of acacia gum in water using 37 female Crl:CDBR rats (9 months old, 207–314 g) for which mating had been confirmed. The solution was administered by gavage once daily (5 mL/kg per day, equivalent to 250 mg acacia gum/kg bw per day) from GD 6 to 17. Dams selected to study the developmental effects (24 females with caesarean section) were necropsied on day 20 of gestation. Fetuses were subjected to external (weight, examination of external abnormalities), visceral and skeletal (skull, long bones, vertebral column, rib cage, extremities, girdles) examinations. In females subjected to natural delivery (13 animals), one pup/sex per litter was subjected to behavioural evaluation, whereas the first male and female of each litter were used for breeding and measuring of reproductive ability. External, visceral or skeletal variations were not observed in any of the fetuses evaluated. There were no effects in the post-weaning behavioural evaluation or growth ratios. There were no treatment-related effects in F_1 reproductive indices and growth of F_2 pups.

Overall, in a dietary combined fertility and developmental toxicity study in rats (Collins et al., 1987) a 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 (Morseth and Ihara (1989a), Huynh et al., 2000). In the identically performed prenatal developmental tests with acacia gum by gavage in mice, rats and hamsters (FDRL, 1972b), 1,600 mg/kg bw per day (the highest doses tested) showed no dose-related developmental effects.

3.5.7. Hypersensitivity, allergenicity and food intolerance

The immunogenicity of acacia gum was compared to that of other gums in inbred mice (Strobel et al., 1982). The gums were dissolved in 0.15 M NaCl at a concentration of 4 mg/mL. Mice (6–8 per group, aged 6 weeks) were immunised with antigen emulsified in complete Freund's adjuvant. Twenty-one days after primary immunisation, the presence of delayed-type hypersensitivity was measured by a skin test and the specific cell-mediated immunity subsequently measured by a footpad swelling test. The immune response of acacia gum was comparable to that elicited by other common foodstuff components, e.g. hen's ovalbumin.

Serum immunoglobulin E (IgE) antibodies specific for the carbohydrate moiety of acacia gum and cross reactive with the carbohydrates found in pollens have been detected in a patient with strong respiratory allergy to acacia gum (Fötisch et al., 1998). In another study on one person occupationally exposed to acacia gum dust, the authors suggested that allergy to acacia gum was mediated preferentially by IgE antibodies directed to the polypeptide chains of acacia gum (Sander et al., 2006). Occupational sensitisation to acacia gum has been described after atmospheric exposure at work (Viinanen et al., 2011).

No case reports on allergic reaction after oral exposure to acacia gum could be identified by the Panel.

3.5.8. Other studies

3.5.8.1. Human data

Five healthy male volunteers (33–55 years old) ingested daily doses of 25 g acacia gum (approx. 350 mg acacia gum/kg bw per day, as a solution in 7% dextrose, conformed to the British Pharmacopoeia specification) for 21 days (Ross et al., 1983). The dose was well tolerated. Several haematological and biochemical parameters, glucose absorption and biological assays of components of urine and faeces were measured. Acacia gum had no effect on haematology and serum biochemistry after a 3-week daily administration. Only a minimum effect on glucose tolerance, stool weight and decreased serum cholesterol were observed. The Panel noted that there were no side effects in this study.

Sharma (1985) described a reduction of low-density lipoprotein (LDL) and very low-density lipoprotein (VLDL) cholesterol by approximately 10% when acacia gum was given to 2 × 15 g/person per day and to seven individuals for 30 days without having effects on high-density lipoprotein (HDL) cholesterol and triglycerides. In this report, from the seven individuals treated, a few experienced flatulence after ingestion of the gum.

In a study with 10 volunteers (4 men and 6 women, aged 22/33 years) treated for 10 days, dosages of 15,000 mg acacia gum/person per day increased water excretion with the stool and 10,000 mg acacia gum/person per day and 15,000 mg acacia gum/person per day increased the counts and proportion of bifidobacteria in human stools (Cherbut et al., 2003). In a second study by the same authors, 10 subjects (5 men and 5 women, aged 22/38 years) received 10–70 g of acacia gum per day (divided in two to six doses per day) in an escalation schedule lasting 18 days. The authors report that dosages below 30,000 mg acacia gum/person per day (approximately equivalent 430 mg acacia gum/kg bw per day) did not induce flatulence, while a dose of 53,000 mg acacia gum/person per day (approximately equivalent 760 mg acacia gum/kg bw per day) induced mild flatulence but did not provoke abdominal cramps or diarrhoea (Cherbut et al., 2003).

4. Discussion

Acacia gum is a dried exudation obtained from the stems and branches of natural strains of *A. senegal* (L.) Willdenow or closely related species of *Acacia* (family Leguminosae) (JECFA, 2006).

Specifications for acacia gum (E 414) have been defined in Commission Regulation (EU) 231/2012. The Panel noted that according to the EC specifications it is not clear which are the closely related species of acacia, while in the JECFA specifications (Documentation provided to EFSA, n.5), it is indicated that gum arabic (acacia gum) can be obtained from *A. senegal* (L.) Willdenow or *A. seyal* (family Leguminosae). The Panel noted that the EC specifications do not limit the protein content which according to Phillips et al. (2008) can be between 0.13% and 10.4%. According to industry (AIPG 2015), contents of proteins were in a range from 0.99% to 2.70% as determined in three samples analysed in duplicate. The Panel agreed with the proposal by interested parties to include a limit for protein content of 3.5% in the EC specifications.

Because of both the botanical origin and the polysaccharidic nature of gums, they can be a substrate of microbiological contamination and of field and storage fungal development. The latter has been recently demonstrated by the mycotoxin contaminations of gums (Zhang et al., 2014). The Panel noted that the microbiological specifications for polysaccharidic thickening agents, such as gums, should be harmonised and that for acacia gum criteria for TAMC and TYMC should be included into the EU specifications.

Regarding the possible presence of nanoparticles in the dry powder of acacia gum resulting from the manufacturing process, the Panel considered that the material used for toxicological testing would contain this nanofraction, if present. In addition, the Panel noted that contact of acacia gum with any liquids (in food or biological fluids) will result in an increase of the particle size.

The *in vitro* degradation and the *in vivo* digestibility of acacia gum have been investigated in animals and humans models and in a human study. The Panel considered that these data indicated that acacia gum would be not absorbed intact but fermented by enteric bacteria in humans. The rate of hydrolysis in the gastrointestinal tract in humans is unknown; however, the Panel considered that acacia gum is unlikely to be absorbed intact, and that the limited extent of its fermentation would lead to products such as SCFA which were considered of no safety concern by the Panel.

Acacia gum is regarded as having a low acute oral toxicity.

In a subacute toxicity study (Anderson et al., 1984), no histopathological changes were identified by electron microscopic examination of organs from rats fed diets containing 1–8% acacia gum daily (equivalent to 1,180–9,440 mg acacia gum/kg bw per day) for 28 days.

Among other studies, the subchronic (13 weeks) oral toxicity of acacia gum was investigated by Anderson et al. (1982). The animals received acacia gum in their diet and the study was conducted in two consecutive experimental phases. In the first one, the rats were given doses ranging from 0 to about 5,000 mg acacia gum/kg bw per day and in the second phase, they received 0 or 14,000 mg acacia gum/kg bw per day. The Panel noted that these two studies were done independently and that merging their data may not be straightforward. The Panel considered that no toxicological effect was observed in these studies by Anderson et al. (1982). From the first study, no adverse effects have been identified up to 5,220 and 5,310 mg acacia gum/kg bw per day in male and female, respectively, the highest dose tested.

Overall, the short-term and subchronic 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.

Based on the data available, the Panel considered that there is no concern with respect to the genotoxicity of acacia gum.

No chronic toxicity studies according to OECD guidelines (452) or equivalent have been identified.

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 (NTP, 1982; Melnick et al., 1983). 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 (Collins et al., 1987), a 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 (Morseth and Ihara (1989a), Huynh et al., 2000). In the identically performed prenatal developmental tests with acacia gum by gavage in mice, rats and hamsters (FDRL, 1972b), 1,600 mg/kg bw per day (the highest doses tested) showed no dose-related developmental effects.

No case reports on allergic reaction after oral exposure to acacia gum could be identified by the Panel.

In humans, the repeated oral daily intake of a large amount of acacia gum up to 30 g (approx. 430 mg acacia gum/kg bw per day) for up to 18 days was well tolerated and had only a minimum effect on stool weight and decrease in serum cholesterol. Some individuals experienced flatulence which was considered by the Panel as undesirable but not adverse.

To assess the dietary exposure to acacia gum (E 414) from its use as a food additive, the exposure was calculated based on (1) maximum levels of data provided to EFSA (defined as the *maximum level exposure assessment scenario*) and (2) reported use levels (defined as the *refined exposure assessment scenario, brand-loyal* and *non-brand-loyal consumer scenario*).

Acacia (E 414) is authorised in a wide range of foods. The Panel did not identify brand loyalty to a specific food category, and therefore, the Panel considered that the non-brand-loyal scenario covering the general population was the more appropriate and realistic scenario for risk characterisation because it is assumed that the population would probably be exposed long-term to the food additive present at the mean reported use in processed food.

A refined estimated exposure assessment scenario taking into account the FSMP for infants and young children (FC 13.1.5.2 Dietary foods for babies and young children for special medical purposes as defined by Commission Directive 1999/22/EC) was also performed to estimate exposure for infants and toddlers who may be on a specific diet. Considering that this diet is required due to specific needs, it is assumed that consumers are loyal to the food brand, therefore only the refined brand-loyal estimated exposure scenario was performed.

A refined estimated exposure assessment scenario taking into account the consumption of *food supplements* for consumers only was also performed to estimate exposure for children, adolescents, adults and the elderly as exposure via food supplements may deviate largely from that via food, and the number of food supplement consumers may be low depending on populations and surveys.

The refined estimates are based on 31 out of 76 food categories in which acacia gum (E 414) is authorised. The Panel considered that the uncertainties identified would, in general, result in an overestimation of the exposure to acacia gum (E 414) as a food additive in European countries for the refined scenario if it is considered that the food additive may not be used in food categories for which no usage data have been provided. However, the Panel noted that given the information from the Mintel's GNPD, it may be assumed that acacia gum (E 414) is used in food categories for which no data have been provided by food industry.

The main food categories, in term of amount consumed, not taken into account were unflavoured fermented milk products, cheeses, breakfast cereals, foods for infants and young children (processed cereal-based foods and baby food, other foods for young children), snacks and some alcoholic beverages (cider and perry, spirit drinks, etc.). According to the Mintel GNPD (Appendix C), in the EU market, snacks and breakfast cereals are labelled with acacia gum (E 414), as well as few alcoholic

drinks and nectars. Therefore, the Panel considered that if these uncertainties were confirmed, it would therefore result in an underestimation of the exposure.

The Panel noted that in Annex II of Regulation (EC) No 1333/2008, use levels of acacia gum (E 414) in food for infants under the age of 12 weeks are included in category 13.1.5.2. The Panel considered that these uses would require a specific risk assessment in line with the recommendations given by JECFA (1978) and the SCF (1998) and endorsed by the Panel (EFSA ANS Panel, 2012). Therefore, the current re-evaluation of acacia gum (E 414) as a food additive is not considered to be applicable for infants under the age of 12 weeks and will be performed separately.

The Panel further noted that the exposure to acacia gum from its use according the Annex III (Part 1, 2, 3, 4 and 5) was not considered in the exposure assessment.

The Panel also noted that the refined exposure estimates are based on information provided on the reported level of use of acacia gum (E 414). If actual practice changes, this refined estimates may no longer be representative and should be updated.

5. Conclusions

According to the conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EU) No 257/2010 (EFSA ANS Panel, 2014) and given that:

- the safety assessment carried out by the Panel is limited to the use and use levels in 31 out of 76 food categories in which acacia gum (E 414) is authorised (refined exposure assessment scenario);
- an indicative high refined exposure assessment up to 719 mg/kg bw per day has been calculated in toddlers at the 95th percentile (non-brand loyal scenario) for the general population;
- an indicative high refined exposure assessment up to 626 mg/kg bw per day has been calculated in toddlers at the 95th percentile in the brand loyal scenario for the population consuming FSMPs;
- acacia gum is unlikely to be absorbed intact and is slightly fermented by intestinal microbiota;
- sufficient toxicity data were available;
- there is no concern with respect to the genotoxicity;
- no carcinogenic effects were reported in carcinogenicity studies in mice and rats at the doses up to 7,500 mg and 2,500 mg acacia gum/kg bw per day, respectively, the highest doses tested;
- oral daily intake of a large amount of acacia gum up to 30,000 mg acacia gum/person per day (approximately equivalent 430 mg acacia gum/kg bw per day) for up to 18 days was well tolerated in adults but some individuals experienced flatulence. A dose of 53,000 mg acacia gum/person per day (equivalent to 760 mg acacia gum/kg bw per day) induced mild flatulence, which was considered by the Panel as undesirable but not adverse,

the Panel concluded that there is no need for a numerical ADI for acacia gum (E 414), and that there is no safety concern at the refined exposure assessment for the reported uses of acacia gum (E 414) as food additive.

6. Recommendations

The Panel noted that currently detected levels of these toxic elements (lead, cadmium, mercury and arsenic) were far below those defined in the EC specifications for acacia gum, and therefore, the current limits should be lowered in order to ensure that acacia gum (E 414) as a food additive will not be a significant source of exposure to those toxic elements in food, in particular for infants and children. The Panel also recommended that limits for aluminium should be included in the EC specifications.

The Panel recommended to harmonise the microbiological specifications for polysaccharidic thickening agents, such as gums, and to include criteria for TAMC and TYMC into the EU specifications of acacia gum.

The Panel recommended that the oxidases and peroxidases in acacia gum should be inactivated during the manufacturing process to avoid any oxidative degradation of components in preparations to which acacia gum is added. The Panel further recommended limits for residual enzymatic activities and for protein content in the EC specifications.

Due to the discrepancies observed between the data reported from industry and the Mintel database, where acacia gum (E 414) is labelled in more products than in food categories for which data were reported from industry, the Panel recommended collection of data of usage and use levels of acacia gum (E 414) in order to perform a more realistic exposure assessment.

Documentation provided to EFSA

1) MARS Chocolate UK. Data submitted to EFSA on 19 May 2010.
2) Pre-evaluation document prepared by Fraunhofer-Gesellschaft zur Förderung der angewandten Forschung e.V. October 2011.
3) Association for International Promotion of Gums (AIPG). Data submitted to EFSA on 4 March 2010.
4) Association for International Promotion of Gums (AIPG). Data submitted to EFSA on 24 April 2013.
5) Association for International Promotion of Gums (AIPG). Data submitted to EFSA on 22 December 2015.
6) Association for International Promotion of Gums (AIPG). Data submitted to EFSA on 16 February 2016.
7) Riemser Arzneimittel AG. E 414 Gummi arabicum. Data submitted 25 April 2013.
8) EMA (European Medicines Agency): communication to EFSA request in 4 May 2015, for information on a certain group of substances used as food additives, June 2014.
9) AIPG (Association for international Promotion of Gums), 2014. Data on usage levels of acacia gum (E 414) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 17 September 2014.
10) FDE (FoodDrinkEurope), 2013. Data on usage levels of acacia gum (E 414) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 29 November 2014.
11) Interested party 1, 2014. Data on usage levels of acacia gum (E 414) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 4 July 2014.
12) Stollwerck GMBH., 2014. Data on usage levels of acacia gum (E 414) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 28 August 2014.
13) DOMACO (DOMACO Dr. med. Aufdermaur AG), 2014. Data on usage levels of acacia gum (E 414) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 30 July 2014.
14) F. Hunziker & CO, 2014. Data on usage levels of acacia gum (E 414) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 4 September 2014.
15) A.H. Meyer & Cie AG, 2014. Data on usage levels of acacia gum (E 414) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 31 July 2014.
16) ICGA (International Chewing Gum Association), 2014. Data on usage levels of acacia gum (E 414) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 30 September 2014.
17) ASSICA (Associazione Industriali delle Carni e dei Salumi), 2014. Data on usage levels of acacia gum (E 414) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 25 September 2014.
18) SNE (Specialised Nutrition Europe), 2014. Data on usage levels of acacia gum (E 414) in foods in response to the EFSA call for food additives usage level and/or concentration data

in food and beverages intended for human consumption (2014). Submitted to EFSA on 30 September 2014.

19) CHEPLAPHARM Arzneimittel GmbH, 2014. Data on usage levels of acacia gum (E 414) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 21 August 2014.
20) Rudolf Wild GmbH & Co. KG, 2014. Data on usage levels of acacia gum (E 414) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 29 September 2014.
21) Frutarom Industries Ltd, 2014. Data on usage levels of acacia gum (E 414) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 26 September 2014.
22) Nathura, 2014. Data on usage levels of acacia gum (E 414) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 19 September 2014.
23) AESGP (Association of the European Self-Medication Industry), 2013. Data on usage levels of acacia gum (E 414) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 9 September 2013.

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Abbreviations

ADI	acceptable daily intake
AFC EFSA	Former Panel on Additives, Flavourings, Processing Aids and Materials in Contact with Food
AIPG	Association for International Promotion of Gums
ANS Panel	EFSA Panel on Food Additives and Nutrient Sources added to Food
AOAC	Association of Official Agricultural Chemists

CAS	Chemical Abstracts Service
CFU	colony-forming unit
EINECS	European Inventory of Existing Commercial Chemical Substances
EMA	European Medicines Agency
FCS	Food Classification System
FDA	Food and Drug Administration
FDE	Food Drink Europe
FDRL	Food and Drug Research Laboratories
FSMP	foods for special medical purposes
GD	gestation day
GLP	Good Laboratory Practice
GNPD	Global New Products Database
HDL	high-density lipoprotein
ICGA	International Chewing Gum Association
Ig	Immunoglobulin
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LD_{50}	lethal dose
LDL	low-density lipoprotein
LOQ	limit of quantification
MPL	maximum permitted level
NDA	EFSA Panel on Dietetic Products, Nutrition and Allergies
NOAEL	no-observed-adverse-effect-level
OECD	Organisation for Economic Co-operation and Development
QS	quantum satis
SCF	Scientific Committee for Food
SCFA	short-chain fatty acids
SNE	specialised Nutrition Europe
TAMC	total aerobic microbial count
TLC	thin-layer chromatography
TMDI	theoretical maximum daily intake
TYMC	total combined yeasts and moulds

Appendix A – Summary of the reported use levels (mg/kg or mg/L as appropriate) of acacia gum (E 414) provided by industry

Appendix A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2017.4741

Appendix B – Number and percentage of food products labelled with acacia gum (E 414) out of the total number of food products present in Mintel GNPD per food subcategory between 2011 and 2016

Mintel sub-category[a]	Total number of products	Products labelled with acacia	
		Number	%
Gum (chewing gum)	1,262	633	50.2
Sports Drinks	705	215	30.5
Standard & Power Mints	787	213	27.1
Non-Individually Wrapped Chocolate Pieces	4,687	960	20.5
Mixed Assortments	271	45	16.6
Liquorice	690	111	16.1
Pastilles, Gums, Jellies & Chews	3,346	315	9.4
Other Sugar Confectionery	950	84	8.8
Medicated Confectionery	891	76	8.5
Fruit/Flavoured Still Drinks	2,590	220	8.5
Energy Drinks	1,485	121	8.1
Meal Replacements & Other Drinks	990	69	7.0
Carbonated Soft Drinks	4,879	338	6.9
Snack Mixes	1,273	87	6.8
Seasonal Chocolate	4,962	305	6.1
Flavoured Alcoholic Beverages	1,800	105	5.8
Beverage Concentrates	2,097	119	5.7
Nuts	4,018	220	5.5
Marshmallows	431	19	4.4
Beverage Mixes	767	32	4.2
Spoonable Yogurt	8,752	329	3.8
Flavoured Water	1,164	37	3.2
Dairy-Based Frozen Products	7,001	201	2.9
Other Chocolate Confectionery	263	7	2.7
Lollipops	341	9	2.6
Baking Ingredients & Mixes	8,031	210	2.6
Individually Wrapped Chocolate Pieces	2,296	59	2.6
Cold Cereals	5,471	137	2.5
Boiled Sweets	858	20	2.3
Sticks, Liquids & Sprays	88	2	2.3
Snack/Cereal/Energy Bars	4,232	90	2.1
Other Frozen Desserts	1,678	35	2.1
Malt & Other Hot Beverages	921	19	2.1
Dessert Toppings	573	11	1.9
Chilled Desserts	5,584	107	1.9
Toffees, Caramels & Nougat	1,738	31	1.8
Other Snacks	117	2	1.7
Chocolate Spreads	979	16	1.6
Cakes, Pastries & Sweet Goods	11,611	186	1.6
Vegetable Snacks	511	7	1.4
Beer	7,035	94	1.3
Chocolate Tablets	7,344	91	1.2
Popcorn	981	12	1.2
Drinking Yogurt & Liquid Cultured Milk	2,886	35	1.2

Mintel sub-category[a]	Total number of products	Products labelled with acacia	
		Number	%
Other Sauces & Seasonings	851	10	1.2
Dips	1,282	15	1.2
Rice Snacks	352	4	1.1
Soft Cheese Desserts	1,364	15	1.1
Sweet Biscuits/Cookies	15,465	168	1.1
Chocolate Countlines	2,058	19	0.9
RTD (Iced) Tea	1,522	14	0.9
Shelf-Stable Desserts	2,950	25	0.8
Wheat & Other Grain-Based Snacks	1,664	14	0.8
Instant Rice	120	1	0.8
Cream	1,454	12	0.8
Fruit Snacks	2,892	23	0.8
Rice/Nut/Grain & Seed Based Drinks	954	7	0.7
Meal Kits	1,809	13	0.7
Dressings & Vinegar	3,035	19	0.6
Nectars	3,581	22	0.6
Meat Substitutes	1,908	11	0.6
Processed Cheese	1,875	9	0.5
Pizzas	3,886	18	0.5
Caramel & Cream Spreads	243	1	0.4
Sucrose	975	4	0.4
Artificial Sweeteners	269	1	0.4
Liqueur	1,467	5	0.3
Potato Snacks	4,388	13	0.3
Coffee	6,749	18	0.3
Syrups	408	1	0.2
Poultry Products	5,483	13	0.2
Baby Fruit Products, Desserts & Yogurts	1,405	3	0.2
Savoury Vegetable Pastes/Spreads	1,416	3	0.2
Fresh Cheese & Cream Cheese	2,457	5	0.2
Prepared Meals	9,894	20	0.2
Hot Cereals	1,021	2	0.2
Instant Pasta	549	1	0.2
Cooking Sauces	4,446	8	0.2
Sandwiches/Wraps	2,406	4	0.2
Soy Based Drinks	609	1	0.2
Confiture & Fruit Spreads	4,266	7	0.2
Stocks	1,233	2	0.2
Nut Spreads	645	1	0.2
Corn-Based Snacks	1,955	3	0.2
Meat Pastes & Pates	2,776	4	0.1
Hors d'oeuvres/Canapes	3,631	5	0.1
Dry Soup	1,466	2	0.1
RTD (Iced) Coffee	768	1	0.1
Salads	2,337	3	0.1
Mayonnaise	802	1	0.1
Cider	837	1	0.1

Mintel sub-category[a]	Total number of products	Products labelled with acacia	
		Number	%
Pastry Dishes	1,721	2	0.1
Margarine & Other Blends	889	1	0.1
Wine	3,590	4	0.1
Sandwich Fillers/Spreads	901	1	0.1
Rice	2,932	3	0.1
Fish Products	10,920	11	0.1
Instant Noodles	995	1	0.1
Stuffing, Polenta & Other Side Dishes	1,999	2	0.1
Water-Based Frozen Desserts	1,072	1	0.1
Vegetables	9,286	8	0.1
Fruit	2,448	2	0.1
Meat Products	13,984	11	0.1
Flavoured Milk	1,272	1	0.1
Bread & Bread Products	8,946	7	0.1
Tea	7,889	6	0.1
Table Sauces	5,376	4	0.1
Savoury Biscuits/Crackers	4,219	3	0.1
Soft Cheese & Semi-Soft Cheese	4,995	3	0.1
Pasta Sauces	3,398	2	0.1
Wet Soup	3,751	2	0.1
Seasonings	8,423	3	0.0
Potato Products	2,870	1	0.0
Pasta	8,872	1	0.0
Total sample	**384,088**	**6,666**	**1.7(b)**

(a): According to the Mintel GNPD food categorisation.
(b): In total, around 1.7% of the foods available on the Mintel GNPD are labelled with acacia gum (E 414) between 2011 and 2016.

Appendix C – Concentration levels of acacia gum (E 414) used in the refined exposure scenarios (mg/kg or mL/kg as appropriate)

Appendix C can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2017.4741

Appendix D – Summary of total estimated exposure of acacia gum (E 414) from their use as food additives for the maximum level exposure scenario and the refined exposure assessment scenarios per population group and survey: mean and high level (mg/kg bw per day)

Appendix D can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2017.4741