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Re-evaluation of locust bean gum (E 410) as a food additive

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Abstract

Following a request from European Commission, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) provides a scientific opinion re-evaluating the safety of locust bean gum (E 410) as a food additive. Locust bean gum (E 410) is an authorised food additive in the EU. Locust bean gum (E 410) as specified in the Commission Regulation (EU) No 231/2012 is derived from the ground endosperm of the seeds of the strains of carob tree, *Ceratonia siliqua* (L.) Taub. (Family Leguminosae). An acceptable daily intake (ADI) 'not specified' was allocated by the Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives (JECFA) in 1981. Although not evaluated by the Scientific Committee for Food (SCF), it was accepted by the SCF in 1991 for use in weaning food, and in 1994, in infant formulae for special medical purposes. Locust bean gum is practically undigested, not absorbed intact, but significantly fermented by enteric bacteria in humans. No adverse effects were reported in 90-day toxicity and carcinogenicity studies in rodents at the highest doses tested and there was no concern with respect to the genotoxicity and to reproductive and developmental toxicity of locust bean gum (E 410). The Panel concluded that there is no need for a numerical ADI for locust bean gum (E 410), and that there is no safety concern for the general population at the refined exposure assessment for its reported uses as a food additive. However, infants and young children consuming foods for special medical purposes may show a higher susceptibility to gastrointestinal effects of locust bean gum due to their underlying medical condition. The Panel concluded that the available data do not allow an adequate assessment of the safety of locust bean gum (E 410) in these foods for infants and young children.

Keywords: locust bean gum (E 410), carob bean gum, food additive, CAS Registry number 9000-40-2

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Summary

Following a request from the European Commission (EC), the Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to deliver a scientific opinion re-evaluating the safety of locust bean gum (E 410) when used as a food additive.

Locust bean gum is the ground endosperm of the seeds of the strains of carob tree, *Ceratonia siliqua* (L.) Taub. (Family Leguminosae). The substance has the CAS Registry Number 9000-40-2 and the EINECS number 232-541-5.

Purity criteria on locust bean gum (E 410) have been defined in Commission Regulation (EU) No 231/2012 and by the Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives (JECFA, 2008a,b). As indicated by the JECFA specifications, locust bean gum (E 410) is also produced in a purified form as clarified locust bean gum. According to industry the 'Carob Bean Gum is also produced in purified form as "Carob Bean Gum (Clarified)" INS No. E-410. It is however not being used as replacement of "Carob Bean Gum"' (Documentation provided to EFSA, number 5).

According to the recent JECFA evaluation (summary of JECFA, 2016), a limit of 0.5 mg/kg for lead was introduced for locust bean gum and locust bean gum (clarified) for use in infant formula.

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 therefore for locust bean gum criteria for the absence of *Salmonella* spp. and *Escherichia coli*, for total aerobic microbial count (TAMC) and for total combined yeasts moulds count (TYMC) should be included into the EU specifications.

The Panel noted that special requirements for specifications of locust bean gum (E 410) to be used in formulae or food for infants, toddlers and other young children (food category 13.1) might be prudent.

The Panel noted that when locust bean gum (E 410), was added to food in combination with other gums, such as xanthan gum (E 415), agar (E 406) or carrageenan (E 407), there was a greater than additive increase in viscosity or gel strength which may have implications for the safety of the product.

The *in vitro* degradation by human gastrointestinal fluids and *in vivo* digestibility of locust bean gum in animals have been investigated. Despite the absence of an *in vivo* study in humans, the Panel considered that these data indicated that locust bean gum would be not absorbed intact but significantly fermented by the intestinal microflora.

Locust bean gum is regarded as not acutely toxic, based on the results of acute oral toxicity studies.

Three subacute toxicity studies (Ershoff and Wells, 1962; Vohra et al., 1979; Mallett et al., 1984) have been described in rats.

In a subchronic toxicity study in rats by Til et al. (1974), no adverse effects were reported at doses up to 4,500 mg of locust bean gum/kg body weight (bw) per day. In the NTP (1982) study, no adverse effects were reported in mice and rats receiving doses up to 20,000 and 9,000 mg of locust bean gum/kg bw per day, respectively. The Panel noted that NTP study did not include haematology, urinalysis and clinical chemistry.

The available *in vitro* and *in vivo* data for genotoxicity were limited. However, no genotoxic activity was observed for locust bean gum. In addition, considering the chemical structure of locust bean gum and its negligible absorption, the Panel concluded that there is no concern with respect to the genotoxicity of locust bean gum (E 410).

Locust bean gum was tested for carcinogenicity in mice and rats receiving doses up to 7,500 mg of locust bean gum/kg bw per day up to 2,500 mg of locust bean gum/kg bw per day, respectively, for 103 weeks (Carlson and Domanski, 1980 as reported by JECFA; NTP, 1982; Melnick et al., 1983). The Panel noted that in these studies, locust bean gum was not carcinogenic.

The Panel considered that no adverse effects were reported in a three-generation reproductive toxicity study receiving doses up to 5% locust bean gum in the diet (equivalent to 4,500 mg of locust bean gum/kg bw per day), the highest dose tested. In the prenatal developmental toxicity studies in rats and hamsters, no maternal and developmental effects were observed up to the highest dose (1,300 and 1,000 mg locust bean gum/kg bw per day) (FDRL, 1972).

In human adults, there are few case reports of allergy to locust bean gum after oral ingestion. However, most of the reports described rhinitis and asthma that were essentially caused by occupational contact with locust bean gum. The Panel recognised the possible potential allergenicity of

locust bean gum; however, it considered that the specification and origin of the gum are lacking in these studies. Case reports of hypersensitivity reactions associated with locust bean gum included the case of a 5-month-old infant; the Panel considered that this hypersensitivity might be due to the locust bean gum proteins and therefore their content should be reduced as much as possible.

The Panel further noted that in a group of 28 hypercholesterolaemic or normal adolescents and adults treated with locust bean gum for 8 weeks, doses up to 500 mg/kg bw per day were well tolerated without side effects.

The present re-evaluation includes the use of locust bean gum (E 410) in foods for infants from 12 weeks of age onwards and for young children.

Concerning uses of locust bean gum in food for infants and young children, the Panel concurs with the SCF (SCF 2003) '… the SCF reaffirmed its earlier view that it is not persuaded that it is necessary to give thickened infant formulae to infants in good health, and that the information available on the potential effects on the bioavailability of dietary nutrients and growth in young infants is not conclusive (SCF, 1999). It is therefore recommended that the use of locust bean gums should not be acceptable for use in infant formulae' and 'The SCF recommended maintaining the current maximum level of the use of locust bean gums in follow-on formulae of 1 g/L. The Committee further recommended maintaining the concept that if more than one of the three substances locust bean gum, guar gum or carrageenan are added to a follow-on formula, the maximum level established for each of those substances is lowered with that relative part as is present of the other substances together' and 'The SCF accepted that there is a case of need for use of locust bean gums in dietary foods for special medical purposes for therapeutic use in a small number of infants with gastro-oesophageal reflux disease under medical supervision, and the Committee considered its use in these products up to a maximum level of 10 g/L acceptable'. The Panel endorsed the conclusions of the SCF which are reflected in the current regulation for food category 13.1.2. The Panel acknowledged that consumption of the concerned food categories would be short and noted that it is prudent to keep the number of additives used in foods for infants and young children to the minimum necessary and that there should be strong evidence of need as well as safety before additives can be regarded as acceptable for use in infant formulae and foods for infants and young children.

The Panel noted reports suggesting a putative effect of locust bean gum to decrease the bioavailability of certain nutrients; however, a human study did not confirm this effect. For the specific group of infants of more than 12 weeks of age,[1] the Panel considered a case of sensitivity and reports on undesirable gastrointestinal effects, such as diarrhoea, frequent loose stools and flatulence, associated with the use of locust bean gum in products for reduction in gastro-oesophageal reflux (GOR).

Furthermore, the Panel noted that no specific clinical data addressing the safety of use of locust bean gum (E 410) in 'dietary foods for infants for special medical purposes and special formulae for infants' (food category 13.1.5.1) and in 'dietary foods for baby and young children for special medical purposes as defined in Directive 1999/21/EC' (food category 13.1.5.2) considering the defined maximum use levels were available to the Panel.

The Panel also noted that infants and young children consuming these foods may be exposed to a greater extent to locust bean gum (E 410) than their healthy counterparts because the permitted levels of locust bean gum (E 410) in products for special medical purposes to reduce GOR are 10-fold higher than in follow-on formulae for healthy individuals. The Panel further noted that, given their medical condition, infants and young children consuming foods belonging to these food categories may show a higher susceptibility to the gastrointestinal effects of locust bean gum than their healthy counterparts. Thus, monitoring of any adverse effects including those in the gastrointestinal system in infants and young children consuming these foods under medical supervision could be helpful to reduce this uncertainty.

From the *refined estimated exposure scenario*, considering only food categories for which direct addition of locust bean gum (E 410) to food is authorised, in the *brand-loyal scenario*, mean exposure to locust bean gum (E 410) ranged from 35.7 mg/kg bw per day in adults to 368.9 mg/kg bw per day in infants. The 95th percentile of exposure ranged from 74 mg/kg bw per day for adults to 765.2 mg/kg bw per day in infants. In the *non-brand-loyal scenario*, mean exposure to locust bean gum (E 410) from its use as a food additive ranged from 20.7 mg/kg bw per day for adults to 204.3 mg/kg bw per day in infants. The 95th percentile of exposure ranged from 38.8 mg/kg bw per day for the elderly to

[1] In some reports individual age was not indicated (< or ≥ 12 weeks).

415.4 mg/kg bw per day in infants. The main contributing food categories for all population groups were foods for infants and young children and bread and rolls in both scenarios.

A refined estimated exposure assessment scenario taking into account the food for special medical purpose for infants and young children (FCS 13.1.5. 'Dietary foods for infants and young children for special medical purposes as defined by Commission Directive 1999/22/EC and special formulae for infants') 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.

From this refined brand-loyal estimated exposure scenario taking into account the foods for special medical purposes, mean exposure to locust bean gum (E 410) from its use as a food additive ranged for infants between 179 and 553 mg/kg bw per day and between 135 and 245 mg/kg bw per day for toddlers. The 95th percentile of exposure ranged for infants between 435 and 1,555 mg/kg bw per day and for toddlers between 262 and 578 mg/kg bw per day.

The Panel considered that the uncertainties identified would, in general, result in an overestimation of the exposure to locust bean gum (E 410) as a food additive according to Annex II in European countries for all scenarios.

For the general population following the conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EU) No 257/2010 (EFSA ANS Panel, 2014), the Panel concluded that there is no need for a numerical ADI for locust bean gum (E 410), and that there is no safety concern for the general population at the refined exposure assessment for the reported uses of locust bean gum (E 410) as a food additive.

Concerning the use of locust bean gum (E 410) in 'dietary foods for special medical purposes and special formulae for infants' (Food category 13.1.5.1) and in 'dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC' (Food category 13.1.5.2), the Panel concluded that the available data do not allow an adequate assessment of the safety of locust bean gum (E 410) in these foods for special medical purposes for infants and young children.

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1. Introduction

The present opinion document deals with the re-evaluation of the safety of locust bean gum (E 410) when used as a food additive.

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 EU 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 the 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, also taking 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

The Commission asked 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 ANS Panel 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 given by the Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) (JECFA, 1972, 1978) and by the SCF (SCF, 1996, 1998). The Panel endorsed these recommendations.

In the current EU legislation (Annex II to Regulation (EC) No 1333/2008)[1], use levels of additives authorised in food for infants under the age of 12 weeks in categories 13.1.1 and 13.1.5 (Annex II)

[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.

and uses of food additives in nutrient preparations for use in food for infants under the age of 12 weeks and maximum levels for the carry-over from these uses (Annex III, Part 5, section B) are included. 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 locust bean gum (E 416) as a food additive in food, including food supplements and does not include a safety assessment of other uses of locust bean gum.

1.2. Information on existing evaluations and authorisations

Locust bean gum (E 410) is authorised as a food additive in the EU according to Annexes II and III to Regulation (EC) No 1333/2008[3] and specific purity criteria on locust bean gum (E 410) have been defined in Commission Regulation (EU) No 231/2012[4].

In the EU, locust bean gum has not been formally evaluated by the SCF. However, it was accepted for use in weaning food (SCF, 1991), and in infant formulae, for special medical purposes (SCF, 1994), but not for infant food in general (SCF, 1994, 1999).

In 2003, the SCF re-evaluated locust bean gum in the revision of the essential requirements of infant formulae and follow-on formulae intended for the feeding of infants and young children (SCF, 2003).

- 'The Committee reaffirmed its earlier view that it is not persuaded that it is necessary to give thickened infant formulae to infants in good health, and that the information available on the potential effects on the bioavailability of dietary nutrients and growth in young infants is not conclusive (SCF, 1999). It is therefore recommended that the use of locust bean gums should not be acceptable for use in infant formulae.
- The Committee recommends maintaining the current maximum level of the use of locust bean gums in follow-on formulae of 1 g/L. The Committee further recommends maintaining the concept that if more than one of the three substances locust bean gum, guar gum or carrageenan are added to a follow-on formula, the maximum level established for each of those substances is lowered with that relative part as is present of the other substances together.
- The Committee accepts that there is a case of need for use of locust bean gums in dietary foods for special medical purposes for therapeutic use in a small number of infants with gastro-oesophageal reflux disease under medical supervision, and the Committee considers its use in these products up to a maximum level of 10 g/L acceptable'.

Locust bean gum was evaluated by JECFA in 1975, 1980 and 1981 (JECFA, 1975a,b, 1980a,b, 1981a,b). Based on the lack of adverse effects in the available toxicity studies, an ADI 'not specified' was allocated. In 2008, JECFA updated the specifications of carob (locust) bean gum (JECFA, 2008a,b).

In 2016, the Committee discussed the safety of use of locust bean gum in infant formula and concluded that the available studies are not sufficient for the evaluation of locust bean gum for use in infant formula at the proposed use level (10,000 mg/L). The Committee requested toxicological data from studies in neonatal animals, adequate to evaluate the safety for use in infant formula, to complete the evaluation (summary of JECFA, 2016).

In 2004, the EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (EFSA AFC Panel, 2004) 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 locust bean gum (E 410) in jelly minicups. 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 minicups, would give rise to a risk for choking (EFSA, 2004). The use of these additives in jelly

[3] 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.

[4] 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.

minicups is not authorised in the EU.[5] Furthermore, locust bean gum (E 410) belongs to those food additives of Group I for which the EU Regulation[5] in general indicates that they may not be used to produce dehydrated foods intended to rehydrate on ingestion.

2. Data and methodologies

2.1. Data

The Panel on Food Additives and Nutrient Sources added to Food (ANS) was not provided with a newly submitted dossier. EFSA launched public calls for data,[6,7] and, if relevant, contacted risk assessment bodies to collect information from interested parties.

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 the date of the last Working Group (WG) meeting before the adoption of the opinion on 12 October 2016. Attempts were made at retrieving relevant original study reports on which previous evaluations or reviews were based; however, these were not always available to the Panel.

The EFSA Comprehensive European Food Consumption Database (Comprehensive Database[8]) 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 locust bean gum (E 410) 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 locust bean gum (E 410) 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 locust bean gum (E 410) 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[9] 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).

[5] Annex II to Regulation (EC) No 1333/2008.
[6] 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 online: http://www.efsa.europa.eu/en/dataclosed/call/ans091123
[7] 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
[8] Available online: http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm
[9] 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

According to Commission Regulation (EU) No 231/2012, locust bean gum (E 410) is the ground endosperm of the seeds of the strains of carob tree, *Ceratonia siliqua* (L.) Taub. (Family Leguminosae). The substance has the CAS Registry number 9000-40-2 and the EINECS number 232-541-5. The molecular weight of locust bean gum varies over a wide range and is reported to be approximately 50,000–3,000,000 g/mol (Commission Regulation (EU) No 231/2012).

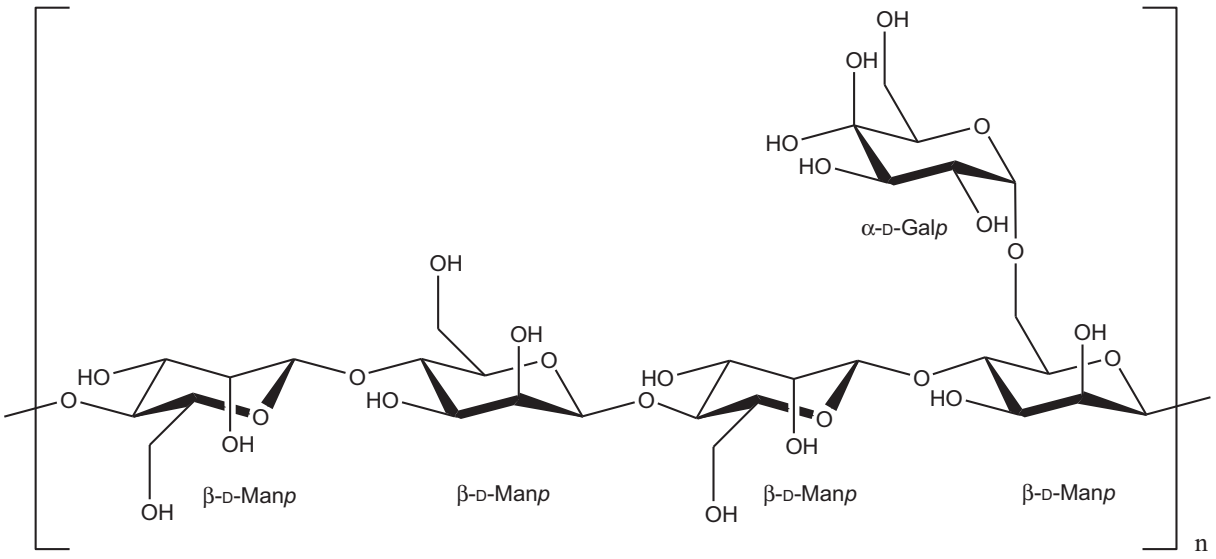
According to the information (Documentation provided to EFSA, document 5), locust bean gum consists of 87–88% (on dry basis) high molecular weight polysaccharides composed of mannose and galactose units (galactomannans) in approximate ratio 4:1. The remaining 12–13% consists mainly of protein and fibrous matter such as residues from the germ, seed coat and cell wall material. Locust bean gum galactomannans are composed of linear chains of (1→4)-linked β-D-mannopyranosyl units with varying amounts of single (1→6)-linked α-D-galactopyranosyl residues as side chains (Wielinga, 2009; Documentation provided to EFSA, document 5).

According to industry, the content of protein (N × 6.25) in the food additive is less than 7% (Documentation provided to EFSA, document 1; Documentation provided to EFSA, document 5).

Locust bean gum is also produced in purified form as 'Carob Bean Gum (Clarified)' INS No 410. According to the JECFA specifications, clarified locust bean gum does not contain cell wall materials and the content of protein is less than 1% (JECFA, 2008a). An interested party (Documentation provided to EFSA, document 4) confirmed that according to the results for purity testing refined locust bean gum complies with the requirements for clarified locust bean gum from JECFA specifications.

Locust bean gum has as synonyms algarroba gum, carob gum, carob bean gum, St. John's bread, Johannisbrotmehl among others.

The structural formula of polysaccharide units of locust bean gum is presented in Figure 1.



β-D-Man*p* – β-D-mannopyranosyl unit

α-D-Gal*p* – α-D-galactopyranosyl unit

Figure 1: Structural formula of polysaccharide units of locust bean gum

Locust bean gum is a white to yellowish-white, nearly odourless powder. It is soluble in hot water and insoluble in ethanol (Commission Regulation (EU) No 231/2012). The substance is insoluble in organic solvents (Lewis, 2007). When the degree of galactose substitution on mannose chain increases (e.g. in tara gum and guar gum), the galactomannans become more soluble in water (Barak and Mudgil, 2014). Locust bean gum swells in cold water, but heating is necessary for maximum solubility. Solutions are

cloudy with a white opacity due to the presence of insoluble impurities such as proteins and cellulose. According to industry (Documentation provided to EFSA, document 1), the solubility varies with the molecular weight, solubility declines with increasing molecular weight and increasing concentration.

Solutions of 1% w/w are highly viscous (2,000–6,000 mPa s); 2–5% w/w swollen dispersions show gel-like behaviour (Ullmann, 2007). A slight increase in viscosity on ageing is exhibited. Viscosity is little affected over pH range 3–11 (Klose and Glicksman, 1990). When heated to decomposition, locust bean gum emits acrid smoke and irritating fumes (Lewis, 2004).

The viscosity profiles are similar to those of guar gum solutions: a drastic increase in viscosity is seen for fully hydrated gums above a concentration of 1% (at 25°C, viscosity of 1% solution amounts to 150 mPa s and of a 2% solution over 2,000 mPa s). A 3% solution of locust bean gum has sufficient viscosity that the solution has the appearance of gelling. Generally, solutions of locust bean gum have no gelling properties under normal conditions, although upon freeze-thaw treatment or in the presence of borate (pH $\geq$ 7) or of a large amount of saccharose, gels are obtained (Meister, 2000; Barak and Mudgil, 2014). Locust bean gum shows physicochemical synergistic interaction with other hydrocolloids, such as carrageenan, xanthan gum and agar, namely resulting in a high-degree increase in viscosity or gel strength and leading to the ability to impart a desirable elastic character and to retard syneresis in these gels (Klose and Glicksman, 1990; Copetti et al., 1997; Meister, 2000; Barak and Mudgil, 2014). The synergistic effects occurring when combining locust bean gum with carrageenan, agar or xanthan gum are technologically utilised in food production (Wielinga, 2010).

The infrared (IR) spectrum of locust bean gum has been provided by Guiliano et al. (2002). The Panel noted that ultraviolet–visible, nuclear magnetic resonance or mass spectra were not available in the literature.

Upon request of the Panel for information on the particle size distribution, data were provided by industry (Documentation provided to EFSA, document 7) regarding locust bean gum when used as a food additive. According to the submitted results of batch analysis by laser diffraction in dry dispersion, the average size of the particles was 66.4 μm. According to Documentation provided to EFSA, document 7, 'although the method used does not detect finer particles than 0.1 μm, the data shows that the majority of particles are of sizes larger than 1 μm and not in the nanoscale'.

3.1.2. Specifications

The specifications for locust bean gum (E 410) as defined in Commission Regulation (EU) No 231/2012 and for carob (locust) bean gum and carob (locust) bean gum (clarified) by the JECFA (2008a,b) are listed in Table 1.

Table 1: Specifications for locust bean gum (E 410) according to Commission Regulation (EU) No 231/2012, and for carob (locust) bean gum and carob (locust) bean gum (clarified) by the Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives (JECFA, 2008a,b)

	Commission Regulation (EU) No 231/2012 on locust bean gum	**JECFA (2008a) on carob (locust) bean gum**	**JECFA (2008b) on carob (locust) bean gum (clarified)**
Definition	Locust bean gum is the ground endosperm of the seeds of the strains of carob tree, *Ceratonia siliqua* (L.) Taub. (Family *Leguminosae*). Consists mainly of a high molecular weight hydrocolloidal polysaccharide, composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as galactomannan	Primarily the ground endosperm of the seeds from *Ceratonia siliqua* (L.) Taub. (Family Leguminosae) mainly consisting of high molecular weight (approximately 50,000–3,000,000) polysaccharides composed of galactomannans; the mannose:galactose ratio is about 4:1. The seeds are dehusked by treating the kernels with dilute sulfuric acid or with thermal mechanical treatments, elimination of the germ followed by milling and screening of the endosperm to obtain native carob bean gum. The gum may be washed with ethanol or isopropanol to control the microbiological load (washed carob bean gum)	Primarily the ground endosperm of the seeds from *Ceratonia siliqua* (L.) Taub. (Family Leguminosae) mainly consisting of high molecular weight (approximately 50,000–3,000,000) polysaccharides composed of galactomannans; the mannose:galactose ratio is about 4:1. The seeds are dehusked by treating the kernels with dilute sulfuric acid or with thermal mechanical treatments, elimination of the germ, followed by milling and screening of the endosperm to obtain native carob bean gum. The gum is clarified by dispersing in hot water, filtration and precipitation with ethanol or isopropanol, filtering, drying and milling. The clarified carob bean gum does not contain cell wall materials. Clarified carob bean gum in the market is normally standardised with sugars for viscosity and reactivity
Molecular weight	50,000–3,000,000	–	–
Assay	Galactomannan content not less than 75%	–	
Description	White to yellowish-white, nearly odourless powder		
Identification			
Tests for galactose	Passes test	–	–
Tests for mannose	Passes test	–	–
Microscopic examination	Place some ground sample in an aqueous solution containing 0.5% iodine and 1% potassium iodide on a glass slide and examine under microscope. Locust bean gum contains long stretched tubiform cells, separated or slightly interspaced. Their brown contents are much less regularly formed in guar gum. Guar gum shows close groups of round to pear shaped cells. Their contents are yellow to brown	Disperse a sample of the gum in an aqueous solution containing 0.5% iodine and 1% potassium iodide on a glass slide and examine under a microscope. Carob bean gum contains long stretched tubiform cells, separated or slightly interspaced. Their brown contents are much less regularly formed than in Guar gum	–
Solubility	Soluble in hot water, insoluble in ethanol	Insoluble in ethanol	Insoluble in ethanol
Gel formation	–	Add small amounts of sodium borate TS to an aqueous dispersion of the sample; a gel is formed	Add small amounts of sodium borate TS to an aqueous dispersion of the sample; a gel is formed

	Commission Regulation (EU) No 231/2012 on locust bean gum	JECFA (2008a) on carob (locust) bean gum	JECFA (2008b) on carob (locust) bean gum (clarified)
Viscosity	–	Transfer 2 g of the sample into a 400-mL beaker and moisten thoroughly with about 4 mL of isopropanol. Add 200 mL of water with vigorous stirring until the gum is completely and uniformly dispersed. An opalescent, slightly viscous solution is formed. Transfer 100 mL of this solution into another 400-mL beaker. Heat the mixture in a boiling water bath for about 10 min and cool to room temperature. There is an appreciable increase in viscosity (differentiating carob bean gums from guar gums)	Transfer 2 g of the sample into a 400-mL beaker and moisten thoroughly with about 4 mL of isopropanol. Add 200 mL of water with vigorous stirring until the gum is completely and uniformly dissolved. An opalescent, slightly viscous solution is formed. Transfer 100 mL of this solution into another 400-mL beaker. Heat the mixture in a boiling water bath for about 10 min and cool to room temperature. There is an appreciable increase in viscosity (differentiating carob bean gums from guar gums)
Gum constituents	–	Proceed as directed under Gum Constituents Identification using 100 mg of the sample instead of 200 mg and 1–10 µL of the hydrolysate instead of 1–5 µL. Use galactose and mannose as reference standards. These constituents should be present	Proceed as directed under Gum Constituents Identification using 100 mg of the sample instead of 200 mg and 1–10 µL of the hydrolysate instead of 1–5 µL. Use galactose and mannose as reference standards. These constituents should be present
Purity			
Loss on drying	Not more than 15% (105°C, 5 h)	Not more than 14% (105°, 5 h)	Not more than 14% (105°, 5 h)
Ash	Not more than 1.2% determined at 800°C	Not more than 1.5% Not more than 1.2% (800°C, 3–4 h)	Not more than 1.2% (800°, 3–4 h)
Acid insoluble matter	Not more than 4%	Not more than 4.0%	Not more than 3.5%
Protein (N × 6.25)	Not more than 7%	Not more than 7.0% Proceed as directed under nitrogen determination (Kjeldahl method) in Volume 4 (under 'General Methods, Inorganic components'). The percentage of nitrogen determined multiplied by 6.25 gives the percentage of protein in the sample	Not more than 1.0% Proceed as directed under nitrogen determination (Kjeldahl method) in Volume 4 (under 'General Methods, Inorganic components'). The percentage of nitrogen determined multiplied by 6.25 gives the percentage of protein in the sample
Starch	Not detectable by the following method: to a 1 in 10 solution of the sample add a few drops of iodine solution. No blue colour is produced	To a 1 in 10 dispersion of the sample add a few drops of iodine TS; no blue colour is produced	To a 1 in 10 solution of the sample add a few drops of iodine TS; no blue colour is produced
Residual solvents	–	Not more than 1% of ethanol or isopropanol, singly or in combination See description under TESTS	Not more than 1% of ethanol or isopropanol, singly or in combination See description under TESTS
Arsenic	Not more than 3 mg/kg	(a)	(a)
Lead	Not more than 2 mg/kg	Not more than 2 mg/kg Determine using an AAS/ICP-AES technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the methods described in Volume 4 (under 'General Methods, Metallic Impurities')(b)	Not more than 2 mg/kg Determine using an AAS/ICP-AES technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the methods described in Volume 4 (under 'General Methods, Metallic Impurities')(b)
Mercury	Not more than 1 mg/kg	–	–
Cadmium	Not more than 1 mg/kg	–	–
Ethanol and Propane-2-ol	Not more than 1%, single or in combination	–	–

	Commission Regulation (EU) No 231/2012 on locust bean gum	JECFA (2008a) on carob (locust) bean gum	JECFA (2008b) on carob (locust) bean gum (clarified)
Microbiological criteria	–	Initially prepare a 10-1 dilution by adding a 50 g sample to 450 mL of Butterfield's phosphate-buffered dilution water and homogenising the mixture in a high-speed blender. Total (aerobic) plate count: Not more than 5,000 CFU/g E. coli: Negative in 1 g *Salmonella*: Negative in 25 g yeasts and moulds: Not more than 500 CFU/g	Initially prepare a 10-1 dilution by adding a 50 g sample to 450 mL of Butterfield's phosphate-buffered dilution water and homogenising the mixture in a high-speed blender. Total (aerobic) plate count: Not more than 5,000 CFU/g E. coli: Negative in 1 g *Salmonella*: Negative in 25 g yeasts and moulds: Not more than 500 CFU/g

AAS: atomic absorption spectrophotometry; ICP-AES: inductively coupled plasma atomic emission spectroscopy; CFU: colony-forming units.
(a): According to the recent JECFA evaluation, there were insufficient data to set a limit for arsenic for locust bean gum and locust bean gum (clarified) (summary of JECFA, 2016).
(b): According to the recent JECFA evaluation, a limit for lead of 0.5 mg/kg for use in infant formula was introduced for locust bean gum and locust bean gum (clarified). The lead limits for general use (2 mg/kg) were maintained. The method descriptions for the determination of lead and sample preparation for residual solvents were updated (summary of JECFA, 2016).

Industry provided screening data for contamination of locust bean gum by microorganisms and derived toxins (aflatoxins B1, B2, G1, G2, deoxynivalenol, HT-2 Toxin, T-2 Toxin, ochratoxin A and patuline) (Documentation provided to EFSA, document 1). New results provided by the industry on analysis of aflatoxins B1, B2, G1, G2 in two samples of locust bean gum (non-refined and refined) were all below the limit of quantification (LOQ) of 0.1 μg/kg, (Documentation provided to EFSA, document 4).

In contrast to the JECFA specifications, the EU specifications do not define limits for microbiological contaminations of locust bean gum (E 410). 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, different from other gums, no microbiological criteria were defined for locust bean gum by the EU Regulation. The Panel also noted that the microbiological specifications for polysaccharidic thickening agents, such as gums, should be harmonised and that for locust bean gum criteria for the absence of *Salmonella* spp. and *Escherichia coli*, for total aerobic microbial count (TAMC) and for total combined yeasts 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 seaweed (E 407a), xanthan gum (E 415), gellan gum (E 418)).

The proteins in the final product originate from the germ which is removed during the processing of carob kernels (Documentation provided to EFSA, document 5). Using a modified Osborne extraction procedure, carob germ flour proteins were found to contain ~ 32% albumin and globulin and ~ 68% glutelin with no prolamins detected (Smith et al., 2010).

During the processing of carob kernels traces of seed coat, germ and cell wall material end up in the final product and are determined as 'Acid insoluble matter' (Documentation provided to EFSA, document 5).

An interested party (Documentation provided to EFSA, document 4) provided the results for purity testing of three randomly selected lots of refined locust bean gum which demonstrated that tested samples comply with the requirements for clarified locust bean gum from the JECFA specifications.

According to the industry, depending on the manufacturing process (sulphuric acid or thermal treatment), there might be residual enzymatic activity (amylase, galactosidase, mannosidase). Probably, the main part is inactivated but it is not excluded that there is some residual activity in locust bean product. Their assumption is that it will be inactivated during dissolution and heating before its use, as locust bean gum is cold water-insoluble (Documentation provided to EFSA, document 5).

The Panel noted some case reports of hypersensitivity reactions including the case of a 5-month-old infant associated with locust bean gum (Section 3.5.7.2). The Panel considered that these hypersensitivity reactions might be due to the locust bean gum proteins. The Panel noted that locust bean gum (E 410) is also produced in a purified form as clarified locust bean gum. According to industry the 'Carob Bean Gum is also produced in purified form as "Carob Bean Gum (Clarified)"

INS No. E-410. It is however not being used as replacement of "Carob Bean Gum"' (Documentation provided to EFSA, number 5).

In view of the botanical origin of locust bean gum furthermore limitations of possible contamination with pesticides should be considered. According to an interested party (Documentation provided to EFSA, document 1), no pesticides are present. Pesticides analysis for different locust bean products produced in different countries were provided showing that the level of pesticides (27 analysed) were below the limit of detection. Documentation provided to EFSA (document 5), informed that industry is annually analysing pesticides residues in locust bean gum from kernels of different origin. The result is regularly in compliance with the regulation for pesticides in food (no analytical data provided). New results provided by the industry (Documentation provided to EFSA, document 4) on analysis of pesticides in two samples of locust bean gum (clarified and non-clarified) failed to detect organochlorine, organophosphorus and organonitrogen pesticides and pyrethroids (limit of detection (LOD) not indicated). However, in view of the use of locust bean gum in food for infant and young children, the Panel considered it particularly necessary to pay attention on the compliance of locust bean gum raw material to the existing EU regulation on pesticides.

Information on the levels of heavy metals, including arsenic, lead, mercury, cadmium, as requested in the EFSA call for data[7] was not provided by interested parties. But JECFA recently reported, that based on the data submitted, the Committee was reassured that for locust bean gum the lead level of 0.5 mg/kg for use in infant formula was achievable (summary of JECFA, 2016). The Panel noted that, according to the European Commission specifications for locust bean gum (E 410), impurities of the toxic elements arsenic, cadmium, lead and mercury are accepted up concentrations of 3, 1, 2 and 1 mg/kg, respectively. 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 Panel noted that since a roasting process is used as one of the manufacturing processes, information on the possible presence of polycyclic aromatic hydrocarbons may be relevant for the specifications.

According to an interested party (Documentation provided to EFSA, document 5), there are no special requirements for specifications of locust bean gum (E 410) to be used in formulae or food for infants, toddlers and other young children.

3.1.3. Manufacturing process

According to an interested party (Documentation provided to EFSA, document 1), the endosperm of the carob fruit seeds is ground to a fine powder and is commercially available in this form as locust bean gum. The carob seeds are difficult to process, since the seed coat is very tough and hard. By special processes the seeds are pealed without damaging the endosperm and the germ. The following procedures are applied:

- In the acid process, the seeds are heated with sulfuric acid to carbonise the seed coat. The remaining fragments of the seed coat are removed from the clean endosperm 'sandwich' in an efficient washing and brushing process. The sandwiches are dried and cracked and the more friable germs get crushed. The germ parts can be sifted off from the unbroken endosperm halves.
- In the roasting process, the seeds are roasted in a rotating furnace where the seed coat drops off the rest. The germ and the endosperm halves are recovered as mentioned above. This process yields a product of slightly darker colour. The advantage is that no sulfuric acid as processing aid is necessary, and therefore, no effluent originates from the production process (Ullmann, 2007; Documentation provided to EFSA, document 1).

The clarified gum is obtained by dissolution in hot water and then recovery by precipitation in ethanol or isopropanol (JECFA, 2008b, Barak and Mudgil, 2014). Locust bean gum processing flowchart is presented in Figure 2.

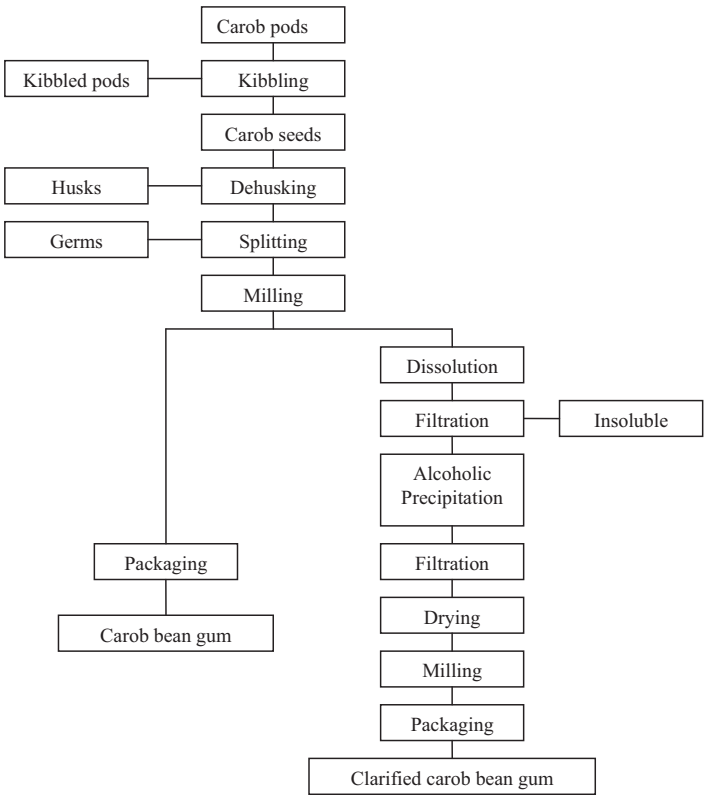


Figure 2: Flowchart for manufacturing of locust bean gum (Kawamura and Carob, 2004)

3.1.4. Methods of analysis in food

Methods identified in the literature for the quantitative chemical analysis of locust bean gum in foods are based on the determination of the degradation products after hydrolysis. Koswig et al. (1997) reported a high-performance anion-exchange-pulsed amperometric detection method for determination of hydrolytic degradation monosaccharides of seven thickening agents, including locust bean gum, in fruit preparations. Eberendu et al. (2005) described quantitative determination of saccharides from plant-derived hydrocolloids, including locust bean gum, in food supplements by anion-exchange liquid chromatography with integrated pulsed amperometric detection. For galactose, the limits of detection and limit of quantification were 1.67 and 5.57 μg/kg, respectively, and for mannose, they were 4.64 and 15.48 μg/kg, respectively.

Analytical methods for commercial locust bean preparations are reported. Commercial galactomannan preparations still may contain remnants of germs and hull that are rich in protein and fibre, and reduce the galactomannan content. The galactomannan content is therefore an important factor in quality. The presence of galactomannans can be demonstrated by various precipitation reactions (e.g. gelation with borax). For determination of the mannose: galactose ratio, the preparation is hydrolysed and the sugar moieties are analysed using gas chromatography (Ullmann, 2007).

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

According to industry, stability is tested by the increase in viscosity because this is directly related to the amount of galactomannan. Shelf life tests performed by an interested party in a ring-test with six samples from different manufacturers at 20° and 40°C for 12 months resulted in the following decrease in viscosity: < 5% (storage at 20°C) and < 10% (storage at 40°C) (Documentation provided to EFSA, document 1). No information on degradation products was provided.

3.1.6. Technological function

Locust bean gum is generally used as a food additive due to its thickening and stabilising properties. In the food industry, it is used as thickener and stabiliser in ice cream, sauce, beverages,

and in the bakery and meat industries (Barak and Mudgil, 2014). Its technological functions in food include improving shelf life by binding water, controlling the texture, influencing crystallisation, preventing creaming or settling, improving the freeze–thaw behaviour, preventing syneresis, preventing the retrogradation of starch products, maintaining turbidity in soft drinks and juices, and stabilising foam. The rate of addition in food products varies from below 0.1–2.0%, depending on the application. It is used as clouding agents at less than 0.1% and in gum drops and jelly candies up to 2.0%. The most common rate of addition lies between 0.2% and 0.5%. The functional properties of locust bean gum, blended with carrageenan and/or other biopolymers, are extensively utilised in dairy products, including ice cream. Synergistic interactions with xanthan gum or agar on viscosity are used in a variety of different foods, for example to improve the texture of sauces and dressings (Wielinga, 2010).

Apart from its technological function it is used as an active ingredient as a source of soluble fibre in food supplements and dietetic products, e.g. in dietary fibre enriched products (Barak and Mudgil, 2014).

3.2. Authorised uses and use levels

Maximum levels of locust bean gum (E 410) have been defined in Annex II to Regulation (EC) No 1333/2008[9] on food additives, as amended. In this document, these levels are named maximum permitted levels (MPLs).

Currently, locust bean gum (E 410) is an authorised food additive in the EU at *quantum satis* (QS) in most foods apart from jam, jellies and similar fruit or vegetables and foods for infants and young children. Locust bean gum (E 410) is included in the Group I of food additives authorised at QS. E 410 may not be used to produce dehydrated foods intended to rehydrate on ingestion.

Table 2 summarises foods that are permitted to contain locust bean gum (E 410) and the corresponding MPLs as set by Annex II to Regulation (EC) No 1333/2008.

Table 2: MPLs of locust bean gum (E 410) in foods according to the Annex II to Regulation (EC) No 1333/2008

Food category number	Food category name	E number/ group	Restrictions/exceptions	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
01.6.2	Unflavoured live fermented cream products and substitute products with a fat content of less than 20%	E 410		QS
01.6.3	Other creams	Group I		QS
01.7.1	Unripened cheese, excluding products falling in category 16	Group I	Except mozzarella	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

Food category number	Food category name	E number/ group	Restrictions/exceptions	MPL (mg/L or mg/kg as appropriate)
04.2.1	Dried fruit and vegetables	Group I	E 410 may not be used to produce dehydrated foods intended to rehydrate on ingestion	QS
04.2.2	Fruit and vegetables in vinegar, oil or brine	Group I		QS
04.2.3	Canned or bottled fruit and vegetables	E 410	Only chestnuts in liquid	QS
04.2.4.1	Fruit and vegetable preparations, excluding compote	Group I		QS
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EC	E 410	(a)	10,000
04.2.5.3	Other similar fruit or vegetable spreads	E 410	(a)	10,000
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	Group I	Only energy-reduced or with no added sugar	QS
05.2	Other confectionery, including breath refreshening microsweets	Group I	E 410 may not be used in jelly minicups, defined, for the purpose of this Regulation, as jelly confectionery of a firm consistence, contained in semi rigid minicups or minicapsules, intended to be ingested in a single bite by exerting pressure on the minicups or minicapsule to project the confectionery into the mouth; E 410 may not be used to produce dehydrated foodstuffs intended to rehydrate on ingestion	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	Group I	Only gluten-free and/or pasta intended for hypoproteic diets in accordance with Directive 2009/39/EC	QS
06.4.4	Potato Gnocchi	Group I	Except fresh refrigerated potato gnocchi	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	Group I	Except products in 7.1.1 and 7.1.2	QS
07.2	Fine bakery wares	Group I		QS

Food category number	Food category name	E number/ group	Restrictions/exceptions	MPL (mg/L or mg/kg as appropriate)
08.2	Meat preparations as defined by Regulation (EC) No 853/2004	E 410	Only preparations in which ingredients have been injected; meat preparations composed of meat parts that have been handled differently: minced, sliced or processed and that are combined together. Except *bifteki, soutzoukaki, kebap, gyros and souvlaki*	QS
08.3.1	Non-heat-treated meat products	Group I		QS
08.3.2	Heat-treated meat products	Group I	Except *foie gras, foie gras entier, blocs de foie gras, Libamáj, libamáj egészben, libamáj tömbben*	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	Group I	Only processed fish roe	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 410		QS
11.4.2	Table top sweeteners in powder form	E 410		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
13.1.2	Follow-on formulae as defined by Directive 2006/141/EC	E 410	(b)	1,000
13.1.3	Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC	E 410	Only gluten-free cereal-based foods(c)	20,000
13.1.3	Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC	E 410	Only processed cereal-based foods and baby foods(c)	10,000
13.1.4	Other foods for young children	E 410	(c)	10,000
13.1.5.1	Dietary foods for infants for special medical purposes and special formulae for infants	E 410	From birth onwards in products for reduction in gastro-oesophageal reflux	10,000
13.1.5.1	Dietary foods for infants for special medical purposes and special formulae for infants	E 410	(b)	1,000

Food category number	Food category name	E number/ group	Restrictions/exceptions	MPL (mg/L or mg/kg as appropriate)
13.1.5.2	Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC	E 410	Only gluten-free cereal-based foods[(c)]	20,000
13.1.5.2	Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC	E 410	Only processed cereal-based foods and baby foods[(c)]	10,000
13.1.5.2	Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC	E 410	From birth onwards in products for reduction in gastro-oesophageal reflux	10,000
13.1.5.2	Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC	E 410	[(b)]	1,000
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	Group I	Including dry pasta	QS
14.1.2	Fruit juices as defined by Directive 2001/112/EC and vegetable juices	Group I	Only vegetable juices	QS
14.1.3	Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products	Group I	Only vegetable nectars	QS
14.1.4	Flavoured drinks	Group I		QS
14.1.5.2	Other	Group I	Excluding unflavoured leaf tea; including flavoured instant coffee	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
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	Group I	Except whisky or whiskey	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

Food category number	Food category name	E number/ group	Restrictions/exceptions	MPL (mg/L or mg/kg as appropriate)
16	Desserts, excluding products covered in category 1, 3 and 4	Group I		QS
17.1(d)	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms	Group I	E 410 may not be used to produce dehydrated foods intended to rehydrate on ingestion	QS
17.2(d)	Food supplements supplied in a liquid form	Group I		QS
17.3(d)	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): Maximum individually or in combination with E 400–404, E 406, E 407, E 410, E 412, E 415 and E 418.
(b): If more than one of the substances E 407, E 410 and E 412 is added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substances together in that foodstuff.
(c): E 410, E 412, E 414, E 415 and E 440 are authorised individually or in combination.
(d): 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.

According to Annex III, Part 1, to Regulation (EC) No 1333/2008, locust bean gum (E 410) is also authorised as a carrier in all food additives at QS.

According to Annex III, Part 2, to Regulation (EC) No 1333/2008, locust bean gum (E 410) is also authorised as a food additive other than carriers in all foods additives at QS.

In addition, according to Annex III, Part 3, to Regulation (EC) No 1333/2008, locust bean gum (E 410) is authorised as a food additive including as a carrier, in food enzymes with a maximum level in enzyme preparation and in final food (beverages or not) at QS.

According to Annex III, Part 4, to Regulation (EC) No 1333/2008, locust bean gum (E 410) is also authorised as a food additive including carriers in all foods flavourings at QS.

Finally, according to Annex III, Part 5, Section A, to Regulation (EC) No 1333/2008, locust bean gum (E 410) is authorised as a food additive in all nutrients (except nutrients intended to be used in foodstuffs for infants and young children listed in point 13.1 of Part E to Annex II) at QS.

Regulation (EC) No 1333/2008 stipulates that locust bean gum (E 410), as a food additive, belonging to group I, is not authorised for the use in jelly minicups and may not be used to produce dehydrated foods intended to rehydrate on ingestion.

The Panel noted that these restrictions have to be seen against the background of human cases on severe adverse effects, such as oesophageal obstruction or asphyxiation, after oral intake of other gums/hydrocolloids with similar physicochemical properties as locust bean gum in the form of granules or pills without enough liquid (e.g. guar gum: Ranft and Imhof, 1983; Morse and Malloy, 1990; Opper et al., 1990; Seidner et al., 1990; Lewis, 1992; Halama and Mauldin, 1992; Taylor et al., 1998; FDA, 2015) or in the form of jelly minicups (konjac gum/glucomannan: EFSA, 2004).

The Panel noted further that apart from the food additive uses in the food categories mentioned in Regulation (EC) No 1333/2008 (see Table 2), there is direct use of locust bean gum (E 410) as a food additive by the consumer in form of special powders to thicken foods (soup, sauce, cream, dessert, pap for children). Inappropriate preparation of the thickened food could lead to insufficient hydration of the locust bean gum particles associated with the possible risks of oesophageal obstruction. Thus, labelling including instructions for adequate preparation of the thickened food with sufficient liquid is deemed to be necessary.

Furthermore, Regulation (EC) No 1333/2008 defines that for combined uses of locust bean gum with certain other gums/hydrocolloids, the individual maximum levels are reduced in certain food categories.

However, the Panel noted that for food category 13.1.4 carrageenan (E 407) is excluded from this combined approach, thus allowing parallel use of locust bean gum (E 410) and carrageenan (E 407) at

unreduced individual maximum levels even though synergistic effects on viscosity and gelling have to be expected.

3.3. Exposure data

3.3.1. Reported use levels or data on analytical levels of locust bean gum (E 410)

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,[10,11] for occurrence data (usage level and/or concentration data) on locust bean gum (E 410). In response to these public calls, updated information on the actual use levels of locust bean gum (E 410) in foods was made available to EFSA by the food industry and also by gums producers. No analytical data on the concentration of locust bean gum (E 410) in foods were made available by the Member States.

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

Industry provided EFSA with data on use levels (n = 375) of locust bean gum (E 410) in foods for 64 out of the 84 food categories in which locust bean gum (E 410) is authorised.

Updated information on the actual use levels of locust bean gum (E 410) in foods was made available to EFSA by BABBI Confectionary Industry, Biovegan GmbH, Danisco, EMCESA, Eurogums A/S, FoodDrinkEurope (FDE), Mars, Specialised Nutrition Europe (SNE) and Rudolf Wild GmbH & Co.

The Panel noted that some data providers (e.g. Danisco, Eurogums A/S, 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.

For instance, for Eurogum A/S, all the submitted data are theoretical amounts suggested or recommended; they are based on their own technical know-how regarding adequate/recommended levels of use in different food applications. Eurogums A/S provided three identical levels on meat products not in line with levels from other data providers. These levels were not considered in the current estimates.

Data made available by Danisco and Mars were provided in 2010. More recent data were received for the same food categories and these data were not used in the present exposure estimates.

Appendix A provides data on the use levels of locust bean gum (E 410) in foods as reported by industry (food industry and gum producers).

3.3.2. Summarised data extracted from the Mintel GNPD database

The Mintel's Global New Products Database (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 the European Union's food markets in 1996, currently having 20 out of its 28 member countries and Norway presented in the GNPD.[12]

For the purpose of this Scientific Opinion, the GNPD[13] was used for checking the labelling of products containing locust bean gum (E 410) within the EU's food products as the GNPD shows the compulsory ingredient information presented in the labelling of products.

[10] http://www.efsa.europa.eu/sites/default/files/consultation/140310.pdf
[11] http://www.efsa.europa.eu/sites/default/files/consultation/ans091123.pdf
[12] Missing Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Luxembourg, Malta and Slovenia.
[13] http://www.gnpd.com/sinatra/home/(accessed on 28/10/2016).

According to the Mintel GNPD, locust bean gum (E 410) was labelled on more than 24,000 food, drink and supplement products with over 15,500 of them published between 2011 and 2016.

The Panel noted that information from Mintel's GNPD (Appendix B) indicated that approximately 95 out of the 118 food subcategories, categorised according to the Mintel nomenclature, in which locust bean gum (E 410) was labelled, were included by the Panel in the current exposure estimates. These 95 food subcategories represented approximately 95% of the food products items labelled with locust bean gum (E 410) in the database. In the remaining 23 food subcategories, in which locust bean gum (E 410) was labelled but which were not included in the exposure assessment, locust bean gum (E 410) was authorised in approximately 20 food subcategories.

Appendix B presents the percentage of the food products labelled with locust bean gum (E 410) 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 the 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. The 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, 2011b). New consumption surveys recently[14] added in the Comprehensive Database were also taken into account in this assessment.[15]

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 locust bean gum (E 410)

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).

[14] Available online: http://www.efsa.europa.eu/en/press/news/150428.htm
[15] Available online: http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm

Consumption records were codified according to the FoodEx classification system (EFSA, 2011b). The nomenclature from the FoodEx classification system has been linked to the food categorisation 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 locust bean gum (E 410)

The food categories in which the use of locust bean gum (E 410) 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 13 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):

- 01.7.6 Cheese products (excluding products falling in category 16);
- 02.3 Vegetable oil pan spray;
- 04.2.3 Canned or bottled fruit and vegetables, only chestnuts in liquid;
- 06.4.4 Potato gnocchi;
- 06.6 Batters;
- 06.7 Precooked or processed cereals;
- 08.3.3 Casings and coatings and decorations for meat;
- 12.1.2 Salt substitutes;
- 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;
- 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;
- 14.2.4 Fruit wine and made wine;
- 14.2.5 Mead;

For the following food categories, the restrictions/exceptions which apply to the use of locust bean gum (E 410) could not be taken into account, and therefore, the whole food category was considered in the exposure assessment. This applies to six 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, only energy-reduced or with no added sugar;
- 05.2 Other confectionery, including breath refreshening microsweets, may not be used in jelly minicups and to produce dehydrated foodstuffs intended to rehydrate on ingestion;
- 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;
- 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.

Additionally, food category 4.2 (Processed fruits and vegetables) was further refined to take into calculation only the FoodEx levels which were presented in data provided for EFSA by the industry. This left the subcategory 4.2.5.3 (Other similar fruit or vegetable spreads) to be ignored during the exposure assessment.

For the following food categories, the differences between subgroups could not be taken into account, and therefore, the whole category was considered in the exposure assessment. This may result in an overestimation of the exposure:

- 01.6 Cream
  - 01.6.2 Unflavoured live fermented cream products and substitute products with a fat content of less than 20%;
  - 01.6.3 Other creams.

- 08.3 Meat products
  - 08.3.1 Non-heat-treated processed meat;
  - 08.3.2 Heat-treated processed meat.
- 11.4 Table top sweeteners
  - 11.4.1 Table top sweeteners in liquid form;
  - 11.4.2 Table top sweeteners in powder form.

Considering that the food category 18 (Processed foods not covered by categories 1–17, excluding foods for infants and young children) being by definition unspecific (e.g. composite foods), processed foods, prepared or composite dishes belonging to the food category 18 were reclassified under their main component food categories. Therefore, no food products remain under the food category 18 and the food category as such will not appear as a food contributor of the total exposure estimates.

Otherwise, for 16 food categories, no concentration data were provided 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, 59 food categories out of 84 were included in the present exposure assessment to locust bean gum (E 410) (Appendix C).

3.4. Exposure estimates

3.4.1. Exposure to locust bean gum (E 410) from its use as a food additive

The Panel estimated chronic exposure to locust bean gum (E 410) for the following population groups: infants, toddlers, children, adolescents, adults and the elderly. Dietary exposure to locust bean gum (E 410) was calculated by multiplying locust bean gum (E 410) 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 two dietary surveys from Finland, namely DIPP_2001_2009 and NWSSP07-08 (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, these two studies were excluded from the assessment.

The exposure assessment to locust bean gum (E 410) 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.

As locust bean gum (E 410) is also authorised in the food categories 13.1.5.1 and 13.1.5.2, a refined estimated exposure assessment scenario taking into account these two food categories was performed to estimate the exposure of infants and toddlers who may eat and drink these foods for special medical purposes (FSMP).

Considering that these specific foods are not reported in the EFSA Comprehensive database, but that foods for infants and young children in good health are, the Panel assumed that the amount consumed of FSMP in infants and toddlers is similar to the consumption of comparable foods in infants and toddlers from the general population. Thus, the consumption of FSMP under the food category 13.1.5 was assumed to be the same amount as the formulae and food products of food categories

13.1.1, 13.1.2, 13.1.3 and 13.1.4 (e.g. the consumption of 'special' infant formulae for medical purposes was assumed to be the same amount than the infant formulae of the FC 13.1.1).

Concerning the uses of locust bean gum (E 410) as carriers, there might be food categories where locust bean 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 that were not available to the Panel. Therefore, a possible additional exposure from the use of locust bean gum (E 410) as a food additive in Annex III to Regulation (EC) No 1333/2008 was not considered in any of the exposure assessment scenarios.

Another dietary exposure to locust bean gum (E 410) as a food additive could also be from its use directly by the consumer in adding special powder to thicken foods (soup, sauce, cream, dessert, pap for children). This was not considered in any of the exposure assessment scenarios.

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 locust bean gum (E 410) 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) (Appendix C).

The Panel considers the exposure estimates derived following this scenario as the most conservative as it is assumed that the population group will be exposed to locust bean gum (E 410) present in food at 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 locust bean gum (E 410) 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 locust bean gum (E 410) 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 locust bean gum (E 410) present at the mean reported use levels in food. This exposure estimate is calculated using the mean of the typical reported use levels for all food categories.

For the scenario taking into account the FSMP, considering that it is very specific diet it is assumed that consumers are brand-loyal and only the results of the brand-loyal scenario were presented.

3.4.1.3. Dietary exposure to locust bean gum (E 410)

Table 4 summarises the estimated exposure to locust bean gum (E 410) from its use as a food additive in six population groups (Table 3) according to the different exposure scenario's. Detailed results per population group and survey are presented in Appendix D.

Table 4: Summary of exposure to locust bean gum (E 410) 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)
Scenarios for the general population (i.e. not taking into account the food categories 13.1.5)						
Maximum level exposure assessment scenario						
Mean	175.9–436.7	218.5–402.6	159.8–325.8	87.5–164.5	51.6–113.0	54.9–105.3
95th percentile	372.3–886.4	378.4–645.4	313.8–554.4	168.9–329.7	100.8–209.1	108.7–176.3
Refined estimated exposure assessment scenario						
Brand-loyal scenario						
Mean	128.9–368.9	127.4–236.7	108.1–188.4	58.1–97.2	35.7–68.8	40.3–65.1
95th percentile	268.4–765.2	226.0–434.9	202.8–346.7	107.3–196.5	74.0–136.4	74.4–109.0
Non-brand-loyal scenario						
Mean	76.0–204.3	70.8–137.0	55.6–106.4	32.2–55.7	20.7–39.2	22.0–36.4
95th percentile	150.6–415.4	126.5–208.8	102.5–189.8	61.0–111.8	41.1–76.5	38.8–59.8

Considering the general population, from the *maximum level exposure assessment scenario*, the mean exposure to locust bean gum (E 410) from its use as a food additive ranged from 51.6 mg/kg bw per day for adults to 436.7 mg/kg bw per day in infants. The 95th percentile of exposure to locust bean gum (E 410) ranged from 100.8 mg/kg bw per day for adults to 886.4 mg/kg bw per day in infants. From the *refined estimated exposure scenario*, in the *brand-loyal scenario*, the mean exposure to locust bean gum (E 410) from its use as a food additive ranged from 35.7 mg/kg bw per day in adults to 368.9 mg/kg bw per day in infants. The 95th percentile of exposure to locust bean gum (E 410) ranged from 74 mg/kg bw per day for adults to 765.2 mg/kg bw per day in infants. In the *non-brand-loyal scenario*, the mean exposure to locust bean gum (E 410) from its use as a food additive ranged from 20.7 mg/kg bw per day for adults to 204.3 mg/kg bw per day in infants. The 95th percentile of exposure locust bean gum (E 410) ranged from 38.8 mg/kg bw per day for the elderly to 415.4 mg/kg bw per day in infants.

From the *refined estimated exposure scenario taking into account the foods for special medical purposes*, in the *brand-loyal scenario*, the mean exposure to locust bean gum (E 410) from its use as a food additive ranged for infants between 179 and 553 mg/kg bw per day and between 135 and 245 mg/kg bw per day for toddlers. The 95th percentile of exposure to locust bean gum (E 410) ranged for infants between 435 and 1,555 mg/kg bw per day and for toddlers between 262 and 578 mg/kg bw per day.

3.4.1.4. Main food categories contributing to exposure for the general population (i.e. not taking into account FCS 13.1.5)

3.4.1.5. Main food categories contributing to exposure to locust bean gum (E 410) using the maximum level exposure assessment scenario (Table 5)

Table 5: Main food categories contributing to exposure to locust bean gum (E 410) using maximum usage levels (> 5% to the total mean exposure) and number of surveys in which each food category is contributing

Food category number	Food category name	Infants	Toddlers	Children	Adolescents	Adults	The elderly
		Range of % contribution to the total exposure (number of surveys)[a]					
01.2	Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation	7.8–45.1 (2)	5.6–37.5 (4)	5.1–22.5 (7)	5.2–7.1 (3)	5.3–9.1 (9)	5.5–14.5 (8)
01.4	Flavoured fermented milk products, including heat-treated products	11.2 (1)	5.5–20.6 (7)	5.0–20.7 (10)	5.3–9.8 (6)	6.0–10.0 (4)	5.2–7.3 (4)
01.7.1	Unripened cheese, excluding products falling in category 16	7.7 (1)	5.2–7.2 (2)	–	–	–	–
02.2	Fat and oil emulsions mainly of type water-in-oil	–	–	–	–	–	6.2 (1)
04.2	Processed fruit and vegetables	–	–	8.6 (1)	7.9–8.3 (2)	7.1 (1)	7.6 (1)
05.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC		5.5–18.4 (6)	5.2–20.7 (15)	5.6–22.2 (16)	5.2–14.2 (15)	5.1–8.9 (4)
07.1	Bread and rolls	6.7–35.0 (4)	16.4–48.8 (9)	14.4–48.8 (17)	21.4–49.2 (16)	21.9–58.3 (17)	20.1–63.9 (14)
07.1	Fine bakery wares	7.7 (1)	10.7–22.4 (8)	11.3–34.2 (16)	10.9–29.9 (15)	5.7–25.2 (15)	5.1–25 (14)
08.3	Meat products		5.2–8.5 (4)	5.9–8.8 (10)	5.9–10.9 (13)	5.7–13.5 (14)	6.0–13.9 (11)
12.5	Soups and broths	6.0 (1)	8.7 (1)	7.1–13.5 (2)	6.7–11.0 (2)	5.1–12.0 (5)	5.0–15.3 (6)
12.6	Sauces	–	–	–	5.6–6.2 (2)	5.1–5.7 (3)	–
12.7	Salads and savoury-based sandwich spreads	–	–	5.1 (1)	5.5 (1)	7.7–9.2 (2)	5.4–7.3 (2)
12.9	Protein products, excluding products covered in category 1.8	–	7.2 (1)	–	–	–	–
13.1	Foods for infants and young children	31.3–83.6 (5)	6.3–26.3 (5)	–	–	–	–
16	Desserts, excluding products covered in category 1, 3 and 4	–	5.5–7.9 (3)	5.0–6.6 (4)	–	–	5.1 (1)

(a): The total number of surveys may be greater than the total number of countries as listed in Table 3 because some countries submitted more than one survey for a specific population.

3.4.1.6. Main food categories contributing to exposure to locust bean gum (E 410) using the refined exposure assessment scenario (Tables 6 and 7)

Table 6: Main food categories contributing to exposure to locust bean gum (E 410) using the brand-loyal refined exposure scenario (> 5% to the total mean exposure) and number of surveys in which each food category is contributing

Food category number	Food category name	Infants	Toddlers	Children	Adolescents	Adults	The elderly
		Range of % contribution to the total exposure (number of surveys)[a]					
01.2	Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation	6.7–52.3 (2)	5.6–45.5 (3)	5.1–21.1 (2)	–	5.7–10.2 (6)	5.1–16.7 (5)

Food category number	Food category name	Infants	Toddlers	Children	Adolescents	Adults	The elderly
		Range of % contribution to the total exposure (number of surveys)[a]					
01.4	Flavoured fermented milk products, including heat-treated products	10.0 (1)	5–28.6 (6)	7.5–28.6 (7)	6.7–11.1 (3)	5.9–9.2 (3)	6.6 (1)
02.2	Fat and oil emulsions mainly of type water-in-oil						5.6 (1)
04.2	Processed fruit and vegetables		5.1 (1)	5.9–10.0 (2)	9.8–10.9 (2)	7.6 (1)	7.4 (1)
05.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC		5.4–22.1 (6)	5.4–25.3 (13)	7.9–25.0 (15)	5.1–12.3 (15)	5.1–6.8 (5)
07.1	Bread and rolls	7.7–41.9 (3)	18.8–69.8 (9)	16.6–70.6 (17)	27.6–67.0 (16)	29.6–77.6 (17)	24.9–82.2 (14)
07.1	Fine bakery wares		7.4–23.7 (7)	6.6–44.7 (16)	6.4–35.4 (15)	10.6–27.9 (14)	8.3–31.2 (11)
08.3	Meat products		5.2 (1)	5.1–5.4 (3)	5.3–6.6 (4)	5.3–9.7 (6)	6.1–8.3 (4)
12.5	Soups and broths			7.3 (1)	6.3 (1)	6.7–7.1 (2)	5.5–10.2 (2)
12.7	Salads and savoury-based sandwich spreads				5.2 (1)	7.4–10.0 (2)	7.3 (1)
12.9	Protein products, excluding products covered in category 1.8		11.7 (1)				
13.1	Foods for infants and young children	35.1–93.1 (5)	8.7–35.4 (5)				
16	Desserts, excluding products covered in category 1, 3 and 4		5.9 (1)				

(a): The total number of surveys may be greater than the total number of countries as listed in Table 3 because some countries submitted more than one survey for a specific population.

Table 7: Main food categories contributing to exposure to locust bean gum (E 410) using the non-brand-loyal refined exposure scenario (> 5% to the total mean exposure) and number of surveys in which each food category is contributing

Food category number	Food category name	Infants	Toddlers	Children	Adolescents	Adults	The elderly
		Range of % contribution to the total exposure (number of surveys)[a]					
01.3	Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation	5.1–34.9 (2)	8.5–32 (2)	5.0–18.8 (4)	5.0–5.6 (2)	6.0–7.5 (6)	6.0–11.8 (5)
01.4	Flavoured fermented milk products, including heat-treated products	7.2 (1)	5.6–17.4 (6)	5.5–17.9 (8)	5.0–8.2 (5)	5.5–8.2 (3)	5.9 (1)
01.7.1	Unripened cheese, excluding products falling in category 16	5.1 (1)	5.6 (1)				
02.2	Fat and oil emulsions mainly of type water-in-oil					5.0–5.8 (3)	5.6–9.4 (5)
04.2	Processed fruit and vegetables			7.1–13.7 (2)	12.2–12.8 (2)	10.4 (1)	10.3 (1)
05.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC	–	5.8–21.5 (7)	5.1–24.9 (17)	6.4–23.4 (16)	6.7–14.3 (15)	5.0–8.9 (7)
07.1	Bread and rolls	7.2–40.5 (4)	22.8–60.7 (9)	22.0–59.1 (17)	31.6–62.1 (16)	32.9–71.8 (17)	32.0–79.2 (14)
07.2	Fine bakery wares		6.0–10.6 (7)	6.5–17.3 (15)	6.8–14.6 (14)	6.4–11.8 (14)	6.0–12 (11)
08.3	Meat products		5–8.4 (3)	5.4–8.9 (10)	5.4–11.2 (13)	5.1–12.3 (14)	5.4–12.2 (11)
12.5	Soups and broths			8.1 (1)	6.3 (1)	5.2–6.6 (2)	8.5 (1)

Food category number	Food category name	Infants	Toddlers	Children	Adolescents	Adults	The elderly
		Range of % contribution to the total exposure (number of surveys)[a]					
12.7	Salads and savoury-based sandwich spreads			5.5–8.0 (2)	8.1 (1)	6.2–13.7 (3)	7.9–11.6 (2)
12.9	Protein products, excluding products covered in category 1.8		10.6 (1)				
13.1	Foods for infants and young children	37.2–89.2 (5)	5.0–34.6 (6)				

(a): The total number of surveys may be greater than the total number of countries as listed in Table 3 because some countries submitted more than one survey for a specific population.

3.4.1.7. Main food categories contributing to refined estimated exposure assessment scenario taking into account FCS 13.1.5. Dietary foods for infants and young children for special medical purposes as defined by Commission Directive 1999/22/EC and special formulae for infants to locust bean gum (E 410) using the refined exposure assessment scenario

Main food categories contributing to exposure to locust bean gum (E 410) using the refined exposure assessment scenario is shown in Table 8.

Table 8: Main food categories contributing to exposure to locust bean gum (E 410) using the brand-loyal refined exposure scenario (> 5% to the total mean exposure) and number of surveys in which each food category is contributing

Food category number	Food category name	Infants	Toddlers
		Range of % contribution to the total exposure (number of surveys)[a]	
01.2	Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation	26.1 (1)	5.5–43.0 (3)
01.4	Flavoured fermented milk products, including heat-treated products	6.6 (1)	7.2–28.0 (5)
05.1	Cocoa and chocolate products as covered by Directive 2000/36/EC		6.1–22.1 (4)
07.1	Bread and rolls	28.1 (1)	18.3–67.6 (9)
07.2	Fine bakery wares		7.1–22.1 (7)
12.9	Protein products, excluding products covered in category 1.8		11.3 (1)
13.1	Foods for infants and young children	56.3–97.2 (5)	7.6–55.3 (7)
16	Desserts, excluding products covered in category 1, 3 and 4		5.8 (1)

(a): The total number of surveys may be greater than the total number of countries as listed in Table 3 because some countries submitted more than one survey for a specific population.

3.4.1.8. Uncertainty analysis

Uncertainties in the exposure assessment of locust bean gum (E 410) 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 9.

Table 9: 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)	+

Sources of uncertainties	Direction[a]
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 foods within the entire food category	+/–
Food categories excluded from the exposure assessment due to missing FoodEx linkage (n = 13/84 food categories)	–
Food categories selected for the exposure assessment: inclusion of food categories without considering the restriction/exception (n = 6/79 food categories)	+
Food categories included in the exposure assessment: data not available for certain food categories which were excluded from the exposure estimates (n = 16/84 food categories)	–
Maximum level exposure assessment scenario: • food categories which may contain locust bean gum (E 410) due to carry-over not considered • exposure calculations based on the maximum reported use levels (reported use from industries)	– +
Refined exposure assessment scenarios: • food categories which may contain locust bean gum (E 410) due to carry-over not considered • exposure calculations based on the maximum or mean levels (reported use from industries)	– +/–
Uncertainty in possible national differences in use levels of food categories	+/–

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

Overall, the Panel considered that the uncertainties identified would, in general, result in an overestimation of the exposure to locust bean gum (E 410) as a food additive according to Annex II in European countries for the maximum level exposure scenario and 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. The Panel noted that food categories which may contain locust bean gum (E 410) due to carry-over (Annex III, Part 1, 2, 3, 4, 5, Section A) were not considered in the current exposure assessment.

Considering the exposure to locust bean gum (E 410) for infants and young children eating foods for special medical purposes, the Panel considered that the uncertainties identified would, in general, result in an overestimation of the exposure in European countries for the brand-loyal refined scenario.

3.4.2. Exposure via other uses

The exposure to locust bean gum due to the following uses was not considered in this opinion.

3.4.2.1. Locust bean gum as ingredient in slimming products and other foods

According to the literature, locust bean gum is used as a bulk-forming agent or 'soluble fibre' in energy-reduced slimming products and other foods taken under conditions of nutritional disorders (Teuscher et al., 2004; Gruenwald et al., 2007; Haensel and Sticher, 2007). Preparations containing locust bean gum are also offered for all age groups including infants to be used as a food for special medical purpose in the management of vomiting and rumination (Teuscher et al., 2004; Gruenwald et al., 2007).

3.4.2.2. Pharmaceutical use

Locust bean gum can be used as a thickening agent and stabiliser in medicinal products (Martindale, 2014).

3.5. Biological and toxicological data

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 (SCFAs), such as acetic, propionic and butyric acids, which are absorbed from the colon (Cummings and Englyst, 1987).

3.5.1.1. *In vitro* studies

The following *in vitro* data on microbial fermentation of locust bean gum were available:

Solutions or suspensions of locust bean gum were incubated with human gastric juice, duodenal juice plus bile, pancreatic juice and succus entericus with or without added rabbit small gut membrane enzymes. Hydrolysis of locust bean gum was not observed in any of the test systems (Semenza, 1975; as reported in JECFA, 1981b).

A total of 188 strains from 11 species of *Bacteroides* 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. Locust bean gum (origin, Meer Co) was shown to be mainly fermented by *Bacteroides 0061-9* strains.

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. Among them, locust bean gum (origin, Meer Co) was fermented by some strains of *Bifidobacterium,* and *Ruminococcus* species (Salyers et al., 1977b).

A total of 290 strains of 29 species of bifidobacteria from human and animal origin (mainly from 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. Locust bean gum (origin, Sigma Co.) was shown to be mainly fermented by *Bifidobacterium dentium* strains.

In another *in vitro* study, locust bean gum (90.9% dry matter, 5.9% crude protein) was fermented using dog faeces as the source of inoculum (Sunvold et al., 1995a). Organic matter disappearance and SCFAs production were measured after 6, 12 or 24 h of incubation. Regardless of the duration of incubation, the disappearance of organic matter, and the production of acetate, propionate and butyrate, were higher in the case of locust bean gum than for other gums such as acacia gum and particularly karaya or xanthan gum. Identical conclusions were drawn from a similar study using the same substrates fermented by cat faecal microflora (Sunvold et al., 1995b).

3.5.1.2. *In vivo* studies

Rats were fed with locust bean gum for 21 days. Thereafter, the large gut microflora of these conditioned rats partially hydrolysed locust bean gum *in vitro* (Towle and Schranz, 1975; as reported in JECFA, 1981b).

A digestibility study in groups of five male and five female rats (Purdue strain) on a mannose-free diet showed that 85–100% of mannose fed as 1% locust bean gum (unspecified origin) in the diet for 18 h was excreted in the faeces over a total of 30 h (Tsay and Whistler, 1975 as reported in JECFA, 1981b). Some decrease in chain length of galactomannan may have occurred, probably through the action of the microflora. Liberation of galactose units was not determined. The Panel noted that no further information was available.

The effect of locust bean gum (unspecified origin) on protein digestibility and nitrogen balance was tested in male Sprague–Dawley rats (Harmuth-Hoene and Schwerdtfeger, 1979 as reported in JECFA, 1981b). A total of 12 rats received a basal diet plus 10% locust bean gum (equivalent to 12 g of locust bean gum/kg bw per day). A total of 12 control rats were fed only basal diet. Following a 3-day adaption period, feed remnants, urine and faeces were collected during an 8-day balance period. In the treated group, dry matter digestibility, apparent protein digestibility and urinary nitrogen excretion were significantly decreased. The latter compensated for increased faecal nitrogen loss by these rats.

Although the faecal dry matter excretion was significantly increased in treated animals, it was considerably lower than could be expected if the ingested polysaccharide would be excreted unchanged. From these data, the authors assumed that 70–80% of locust bean gum was degraded by the intestinal microflora and made available to the host organism.

3.5.1.3. Human study

The behaviour of locust bean gum (unspecified origin) in the gastrointestinal tract of man was described by Holbrook (1951). According to the authors, both X-ray-studies and stool examination showed that the colloidal gel resulting from the disintegration of the locust bean gum preparation permeated the faecal mass in the colon and mixed thoroughly with it. The greatest effect on the faeces is the alteration in consistency (described as soft, gelatinous and homogeneous); the stool weight is only slightly increased. Locust bean gum did not disintegrate until reaching the large bowel and there is no interference with normal digestion (Holbrook, 1951).

Overall, data on *in vitro* degradation by human gastrointestinal fluids and on *in vivo* digestibility of locust bean gum in animals demonstrated that this compound would not be absorbed intact or hydrolysed by digestive enzymes. However, locust bean gum would be fermented with production of SCFAs, such as acetic, propionic and butyric acids, during its passage through the large intestine by strains of bacteria found in the human colon. Based on the available knowledge on the role of SCFA as end products of the fermentation of dietary fibres by the anaerobic intestinal microflora (Topping and Clifton, 2001; den Besten et al., 2013), the Panel considered that their potential formation as fermentation products from locust bean gum does not raise any concern. Despite the absence of convincing *in vivo* study in humans, the Panel considered that these data indicate that locust bean gum would most probably not be absorbed intact but significantly fermented by enteric bacteria in humans.

3.5.2. Acute toxicity

The reported oral lethal dose (LD_{50}) values in all tested species exceed 5,000 mg of locust bean gum/kg bw (Table 10). The Panel noted that information about strain, sex, weights and effects was, in most cases, not available.

Table 10: Acute oral toxicity of locust bean gum reported in the Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives evaluation (JECFA, 1981b)

Species	LD_{50} (mg/kg bw)	Reference
Mouse	13,100 ± 650[(a)]	Maxwell and Newell (1970)[(d)]
Rat	13,100 ± 750[(a)]	Food and Drug Res. Lab. Inc. (1976)[(a)]
Rat (5 male Sprague–Dawley)	> 10,000[(b)]	Maxwell and Newell (1972)
Rat	5,000[(c)]	Maxwell and Newell (1970)[(d)]
Hamster	10,300 ± 490	Maxwell and Newell (1970)[(d)]
Rabbit	9,100 ± 390	Maxwell and Newell (1970)[(d)]

bw: body weight.
(a): Cited in NTP (1982) as 13,000 mg/kg bw (Bailey and Morgareidge, 1976).
(b): Transient depression for a few hours after dosing was observed.
(c): Cited in WHO (1980) as > 5,000 mg/kg bw (Maxwell and Newell, 1972); this is the 5-day exposure study; see below.
(d): Cited as in WHO (1981); however, the reference section of WHO (1981) does not include this specific reference.

In addition, Covington and Burling (1993) reported the oral LD_{50} values for locust bean gum as 'more than 8,000 mg of locust bean gum/kg in rats, mice, rabbits and hamsters'.

van Nevel et al. (2005) investigated the influence of various galactomannans on bacteriological and morphological aspects of the gastrointestinal tract in weanling pigs. Four groups of five newly weaned piglets received one of the following diets for 11 or 12 days: control feed (control group), control feed supplemented with guar gum (1%), locust bean gum (1%) or 10% of carob tree seeds meal as a source of locust bean gum (corresponding to about 250 mg gum/kg bw per day or 2,500 mg seeds/kg bw per day). The animals were euthanised after 11 or 12 days and digesta were sampled in the stomach, jejunum and caecum. On these samples, bacteriological, biochemical and morphological determinations were carried out. Only with the carob tree seeds diet the viscosity of jejunal contents was increased. According to the authors, the effects of the addition of 1% of pure guar gum or locust

bean gum (250 mg/kg bw per day) to the diet were inconsistent, whereas only supplementation with 10% of carob tree seeds to the diet influenced the intestinal characteristics at the bacteriological and morphological levels. The Panel noted that this study was inconclusive when considered in the assessment of locust bean gum used as a food additive in humans.

3.5.3. Short-term and subchronic toxicity

Holtzman rats (eight males/group, age not specified) received basic diet (control), basic diet plus 1% cholesterol, basic diet plus 1% cholesterol and 10% locust bean gum (unspecified origin, equivalent to 12,000 mg of locust bean gum/kg bw per day) for 28 days (Ershoff and Wells, 1962 as reported in JECFA, 1981b). There were no statistically significant differences in weight gain among the groups. No adverse effects were reported.

Sprague–Dawley rats (six males/group, 3-weeks old) were fed a diet containing 50,000 mg of locust bean gum/kg diet (equivalent to 6,000 mg of locust bean 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. There was also a significant increase in the activity of bacterial enzymes azo reductase, glucosidase, nitroreductase, nitrate reductase and urease compared to controls.

The effect of 2% locust bean gum in the diet (unspecified origin, equivalent to 2,400 mg of locust bean gum/kg bw per day) on digestibility and growth was tested in newly weaned Sprague–Dawley rats (10 males/group) for 36 days (Vohra et al., 1979; JECFA, 1981b). The dietary intake was measured every day during the last week of the treatment period. The digestibility of the diet was calculated from dry weights of the feed and excreta (digestibility % = diet intake/excreta). The digestibility of the diet and the growth rate were not influenced by locust bean gum.

Rats (10 males and 10 females Wistar/group) were given doses of 0%, 1%, 2% and 5% locust bean gum (origin Cesalpinia, Bergamo) in the diet for 90 days (Til et al., 1974). The dietary doses were equivalent to 0, 900, 1,800 or 4,500 mg of locust bean gum/kg bw per day. The animals were observed daily and weighed on the first day of treatment, weekly thereafter. Urine samples collected at weeks 5 and 13, were tested for pH, protein, glucose, ketones, blood and microscopic examination. Blood samples were obtained at weeks 4 and 12 of treatment and were examined for haemoglobin concentration, red and white blood cell counts, and haematocrit. Serum concentrations of glucose, blood urea nitrogen and activities of alanine transaminase (ALAT), aspartate transaminase (ASAT) and alkaline phosphatase (ALP) were determined. At autopsy, following visual examination of all organs, the following organs were removed and weighed: the heart, kidneys, liver, spleen, brain, testicles or ovaries, thymus, thyroid, adrenals and caecum (filled and empty). Detailed histopathological examination was performed on 10 males and 10 females of the highest dose group and of the control group. Examinations were performed in the weighed organs and also in the lung, prostate, epididymis, urinary bladder, salivary glands, axillary and mesenteric lymph nodes, gastrointestinal tract (six levels) and pancreas. No treatment-related differences between the control and treated groups were observed in general condition, behaviour, survival, growth, feed intake, haematology, blood biochemistry and urinalysis. The serum glucose level determined in the highest dose group was slightly increased. Since this increase was within the normal range for the strain of rats used, this change was not ascribed by the authors to the feeding of the gum. At any dietary level of locust bean gum, gross and microscopic examinations did not reveal any pathological changes attributable to the test substance. The increase in the relative weight of the caecum observed only in groups receiving the highest dose was considered to be of no toxicological relevance by the authors. The authors concluded that the feeding of the locust bean gum at levels up to 5% in the diet of rats for 3 months did not cause any distinct adverse effects. The Panel agreed with this conclusion and identified a NOAEL of 4,500 mg of locust bean gum/kg bw per day, the highest dose tested.

The Panel noted that an increased caecum weight in animals fed high amounts of carbohydrates is considered a physiological response to an increased fermentation due to a carbohydrate-induced modification on the composition of the intestinal microbiota. Increased caecum weight has been observed in rats fed carbohydrates other that guar 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.

A 90-day study was performed in F344 rats (initial weight 69–89 g) and B6C3F1 mice (initial weight 16–21 g) fed diets containing 0%, 0.63%, 1.25%, 2.5%, 5%, and 10% locust bean gum (food grade material, 77–88% galactomannans) (NTP, 1982). The dietary doses were equivalent to 0, 560, 1,120, 2,250, 4,500 and 9,000 mg of locust bean gum/kg bw per day in rats and 1,250, 2,500, 5,000, 10,000 and 20,000 mg of locust bean gum/kg bw per day in mice. Ten animals of each sex and each species per dose were used and separate control groups of 10 animals for 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. One female rat of the 2,250 mg of locust bean gum/kg bw per day group died. The weight gain depression in rats was $\leq$ 10% in all dosed groups and no compound-related toxic effects were observed. Two male mice (one from the 5,000 mg of locust bean gum/kg bw per day group and one from the control group) and two female mice (one from the 2,500 mg of locust bean gum/kg bw per day and one from the 5,000 mg of locust bean gum/kg bw per day group) died from accidental causes. No weight gain changes were reported in mice (NTP, 1982). The Panel noted that no adverse effects were reported in this study.

Overall, the subacute or subchronic administration of oral doses as high as 9,000 mg of locust bean gum/kg bw per day to rats did not induce any adverse effect. The only side effect observed was the caecal enlargement. 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 due to a carbohydrate-induced modification on the composition of the intestinal microbiota.

3.5.4. Genotoxicity

3.5.4.1. *In vitro*

Negative results for locust bean gum (unspecified origin) were reported when assayed for gene mutation in the Ames test with *Salmonella* Typhimurium, tester strains TA1535, TA1537, and TA1538 and for gene conversion with *Saccharomyces cerevisiae,* tester strain D4, both in the absence and presence of exogenous mouse, rat and monkey liver S9 metabolism. Dose levels of 0.45%, 0.90% and 1.80% (equivalent to 4.5, 9.0 and 18.0 mg/mL) for the Ames test and dose levels of 0.55%, 1.1% and 2.2% (equivalent to 5.5, 11 and 22 mg/mL) for the gene conversion assay were used (Litton Bionetics, 1975). However, the Panel noted that the results from both studies are limited due to the inadequate number of tester strains used in the bacteria gene mutation assay and that the gene conversion assay with *S. cerevisiae* has not been validated and it is no longer employed for risk assessment.

In the spore rec-assay employing the *Bacillus subtilis* strains M45 rec^-, unable to repair DNA damage, and the wild-type strain H17 rec^+ as a control, locust bean gum (unspecified origin) was assessed for its potential DNA-modifying effects at single dose level of 2.5 mg/plate both in the absence and presence of S9 metabolism. Negative results were obtained. The Panel noted that this mutagenicity assay is not frequently used and has not been validated (Ishizaki and Ueno, 1987).

In the studies by Ashby and Tennant (1988) and Zeiger et al. (1992), the mutagenicity of locust bean gum (unspecified origin) 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 a dose level of 10 mg/plate. The outcome of the study clearly indicated that locust bean gum was devoid of mutagenic activity under the reported experimental conditions. The Panel noted that the study complies with the current OECD Guideline 471 with the exception that tester strains TA102 or WP2*uvr*A bearing AT mutation were not used.

Locust bean gum (unspecified origin) was assessed for its capability to induce chromosomal aberrations in anaphase in human embryonic lung cells (WI-38) at dose levels up to 1,000 μg/mL without S9 mix. No cytogenetic effects were reported by authors. However, the Panel noted that this assay has not been validated and it is no longer employed for risk assessment (Maxwell and Newell, 1972, 1974).

3.5.4.2. *In vivo*

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

1) Host-mediated assay in Swiss Webster male mice administered once by oral gavage at 30, 2,500, 5,000 mg/kg bw or for five consecutive days at the same dose levels employed in the single administration regime using the *S.* Typhimurium tester strains TA 1530 and G-46 for mutagenicity and *S. cerevisiae* (strain D3) for mitotic recombination.
2) Chromosomal aberrations in bone marrow cells of male albino rats administered by oral gavage once at 30, 2,500, 5,000 mg/kg bw or for five consecutive days at the same dose levels employed in the single administration regime. In the acute treatment, sampling of bone marrow cells was performed at 6, 24 and 48 h from the administration of test compound, whereas, in the multiple administration study, sampling of bone marrow cells was only performed at 6 h from the last administration.
3) Dominant lethal assay in Sprague–Dawley rats following administration of test compound by oral gavage once at 30, 2,500, 5,000 mg/kg bw or for five consecutive days at the same dose levels employed in the single administration regime. Negative and positive control animal groups were also included. Following treatment, the males were sequentially mated to two females per week for 8 weeks (7 weeks in the subacute study) and housed separately until sacrifice.

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.

No genotoxic effects were observed in any of the assay performed. The Panel noted that the host-mediated assay system has not received further validation and it is presently considered to be obsolete. For chromosomal aberration, no significant reduction in mitotic indices in the locust bean-treated groups compared to the concurrent vehicle control groups were observed indicating no target tissue exposure. However, this is in line with the evidence that locust bean gum is not absorbed as such but appears, to be slightly fermented in the intestine to SCFAs.

Overall, although the available *in vitro* and *in vivo* studies are generally limited or not relevant for the reasons listed above, no genotoxic activity has been observed for locust bean gum. On this base and considering the chemical structure of locust bean gum and its negligible absorption, the Panel concluded that there is no concern with respect to the genotoxicity of locust bean gum (E 410).

3.5.5. Chronic toxicity and carcinogenicity

JECFA (1981b) reported an unpublished study from Carlson and Domanski (1980). In this study, groups of 50 male and 50 female Charles River albino rats were given diets containing 2% and 5% locust bean gum (unspecified origin, equivalent to 1,000 and 2,500 mg of locust bean gum/kg bw per day) for 24 months. Rats (10/sex per dose) were sacrificed at 12 months. Significantly greater body weights were observed in the females of the 2% group at week 11, as well as weeks 94–100, and in the females of the 5% group at week 13. The following changes in haematological parameters were noted: decrease in reticulocyte count in females of the 5% group at 6 months; decrease in haemoglobin concentration in females of the 2% group at 6 months; increase in segmented neutrophils; and decrease in lymphocytes in males of the 2% group at 6 months. At the interim sacrifice, a statistically significant reduction in the absolute thyroid weight was observed in males of both treated groups and, at final sacrifice, a significant reduction in the absolute brain weight in females of the 5% group was reported. Significant treatment-related effects on gross or microscopic pathology were not seen. The study report was not available to the Panel, and therefore, the relevance of the reported effects cannot be fully evaluated. However, the Panel considered that the effects reported in the JECFA evaluation did not show any consistency (no dose-effect relationship, no consistency in time, no histopathological findings in these organs) and therefore their adversity does not seem to be demonstrated. In addition, JECFA did not consider these effects in its conclusion on this study. The authors of the study concluded that under the conditions of this bioassay, locust bean gum was not carcinogenic for male or female F344 rats. The Panel agreed with this conclusion.

A carcinogenicity study was performed in F344 rats and B6C3F1 mice fed diets containing 2.5% and 5% locust bean gum (food grade material, 77–88% galactomannans) for 103 weeks (NTP, 1982; Melnick et al., 1983). The investigations included clinical signs, body weights, feed consumption and

histopathology of all major organs. Haematology, clinical chemistry and urine analysis were not performed. In mice, the dietary doses were equivalent 3,750 and 7,500 mg of locust bean gum/kg bw per day. A total of 50 animals of each sex per dose were used and separate control groups of each sex and species were included. Although alveolar/bronchiolar adenomas occurred in low-dose male mice at a significantly ($p = 0.017$) higher incidence than that in the controls (7/50, 17/50 and 11/50), no significant statistical results were obtained when the combined incidence of animals with either alveolar/bronchiolar adenomas or carcinomas was analysed (14/50, 21/50 and 14/50). In rats, the dietary doses were equivalent to 1,250 and 2,500 mg of locust bean gum/kg bw per day. A total of 50 animals of each sex per dose were used and separate control groups of each sex and species were included. Cortical adenomas in the adrenal gland of female rats occurred with a statistically significant ($p < 0.05$) positive trend (1/50, 4/50 and 6/50), but comparisons between test groups and the control group were not statistically different. From these data in mice and rats, the authors concluded that under the conditions of this bioassay, locust bean gum was not carcinogenic for male or female F344 rats or B6C3F1 mice. By considering the absence of a dose-related effect of these findings, the Panel agreed with the conclusion of the authors and noted that no adverse effects were reported in rats at the highest dose tested of 2,500 mg locust bean gum/kg bw per day.

Overall, the Panel considered that locust bean gum is not of concern with respect to carcinogenicity.

3.5.6. Reproductive and developmental toxicity

3.5.6.1. Reproductive toxicity studies

As reported by JECFA 1981b, 'A three-generation reproduction study was carried out in CD strain Charles River albino rats (Domanski et al., 1980). Groups of 10 male and 20 female animals were fed a rat chow diet containing 2% or 5% locust bean gum (equivalent to 1,800 and 4,500 mg LBG/kg bw/day) or 5% alpha cellulose (control). The same doses and animal numbers were used throughout the study. In each generation the parental animals received the test diet for 11 weeks prior to mating and then through mating, gestation and weaning. Two or three litters were raised per generation and the second litter was used to produce the following generation. Ten males and 10 females from each treatment group of the F_{3b} generation were selected for histopathological examination of 12 major organs and tissues and organ weight analysis. All other animals were subject to gross necropsy only. There were statistically significant decreases in premating body weight gain in the F_0 females fed 2% LBG and in final body weight in the females fed 5% LBG. There were the following significant differences in organ weight ratios in the F_{3b} 5% LBG group as compared to the controls: smaller spleen to brain weight, absolute liver weight, liver to brain weight and larger brain to body weight. These differences were ascribed to the highly variable values for these parameters in young rats and the fact that all the animals may not have been at the same age at sacrifice. This factor could have had an effect on organ weight ratios in young animals. There were no significant treatment-related effects on reproductive indices or gross or microscopic pathology'.

The Panel noted that the original study report was not available. According to JECFA, no reproductive, including fertility, maternal or developmental toxic effects were seen in a three-generation study with rats at the doses tested up to 5% locust bean.

The Panel considered that the NOAEL (according to JECFA1981b) for reproductive toxicity was 5% (equivalent to 4,500 mg of locust bean gum/kg bw per day), the highest dose tested.

3.5.6.2. Developmental toxicity studies

Several developmental toxicity studies of locust bean gum were conducted in CD-1 mice Wistar, rats, golden hamsters and Dutch-belted rabbits (FDRL, 1972). Animals were administered different doses of locust bean gum (unspecified origin) 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 (20–21/group) were treated by oral gavage once daily from gestation day (GD) 6–15 with doses of 0, 13, 60, 280, 1,300 mg/kg bw per day of locust bean in corn oil (20, 18, 19, 20 and 16 pregnant surviving females/group, respectively, and 0, 2, 2, 1 and 5 dead females, respectively) (Morgareidge, 1972). At necropsy on GD 17, the surviving dams appeared to be completely normal and the number of implantations and live fetuses was comparable to the control group. Doses up to 1,300 mg of locust bean/kg bw per day had no effects on implantation nor on maternal and fetal survival (with the exception of five of 21 female deaths in the highest dose group). The numbers of live or dead fetuses, resorptions and 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 locust bean-treated groups did not differ from the number in vehicle-treated dams of the control group.

Rats

Pregnant Wistar rats (24/group) were treated by oral gavage once daily from GD 6–15 with doses of 0, 13, 60, 280 or 1,300 mg/kg bw per day of locust bean in corn oil (23, 23, 21, 24, 22 pregnant surviving females/group, respectively) (Morgareidge, 1972). At necropsy on GD 20, doses up to 1,300 mg of locust bean/kg bw per day appeared to be completely normal and had no effects on implantation or 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 locust bean-treated groups did not differ from the number in vehicle-treated dams of the control group.

Hamsters

Pregnant golden hamsters (20 animals/group) were treated by oral gavage once daily from GD 6–10 of gestation with doses of 0, 10, 45, 220 or 1,000 mg/kg bw per day of locust bean in corn oil (20, 20, 19, 20, 19 pregnant surviving females/group, respectively (Morgareidge, 1972). At necropsy on GD 14, doses up to 1,000 mg locust bean/kg bw per day appeared to be completely normal and showed no effects on implantation or 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 locust bean-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 6–18 with doses of 0, 9, 42, 196 or 910 mg/kg bw per day of locust bean in corn oil (13, 11, 12, 11 and 6 pregnant surviving females/group, respectively) (Morgareidge, 1972). The mortality in this test was 1, 0, 0, 2 and 7 dams in the respective groups. Maternal death was preceded by severe bloody diarrhoea and urinary incontinence, and anorexia was observed 48–72 h before death with pathological findings of haemorrhages in the mucosa of small intestines. At necropsy on GD 29, the surviving does 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 locust bean-treated groups did not differ from the number in vehicle-treated dams of the control group.

The Panel noted that the mortality observed in mice at 1,300 mg/kg bw per day and in rabbits at 910 mg/kg bw per day is not in line with the findings from acute toxicity studies (Maxwell and Newell, 1972). The higher maternal toxicity observed in these studies as to compared to other species can be caused by the difficulty of dosing mice and rabbits with a viscous solution. Therefore, the Panel considered these studies not suitable for the evaluation of risk assessment.

Overall, the Panel considered that the NOAEL for reproductive toxicity was 5% in the diet (equivalent to 4,500 mg of locust bean gum/kg bw per day), the highest dose tested (Domanski et al., 1980). Furthermore, the Panel considered the prenatal developmental toxicity studies in mice and

rabbits not suitable for the evaluation of risk assessment due to high maternal toxicity (mortality). In the prenatal developmental toxicity studies in rats and hamsters no maternal and developmental effects were observed up to the highest dose tested (1,300 and 1,000 mg locust bean gum/kg bw per day) (FDRL, 1972).

3.5.7. Other studies including hypersensitivity, allergenicity and food intolerance

3.5.7.1. Animal studies

As reported by Covington and Burling (1993), an unpublished animal study was conducted by the oral administration of locust bean gum (unspecified origin) to male B6C3FI mice at a dose of 2,500 mg of locust bean gum/kg bw per day (considered by the authors as 50% maximum tolerated dose) daily for 11 days (no further information available). The animals were sensitised to sheep red blood cells (SRBC) by intraperitoneal injections on the third day of test material administration. On the 12th day following the initiation, no suppression of the anti-SRBC primary immune response was observed among locust bean gum-treated mice even at the high dose level administered.

The effect of polysaccharides, including locust bean gum, fed at the 10% level in a semisynthetic diet on absorption of Ca, Fe, Zn, Cu, Cr and Co, on weight gain and on faecal dry matter excretion was studied over a period of 8 days in five groups of 12 weanling male rats each and compared to a control group (Harmuth-Hoene and Schelenz, 1980). Locust bean gum reduced significantly the absorption of Zn, Cr, Cu and Co. A considerable portion of locust bean gum was metabolised, presumably due to the action of intestinal bacteria.

The Panel noted that JECFA recently requested toxicological data from studies in neonatal animals, adequate to evaluate the safety for use in infant formulae (JECFA, 2016). This study is not yet available and its results may be also relevant for the risk assessment of the additive use in food for other age groups than infants up to 12 weeks of age which is excluded from this evaluation.

3.5.7.2. Human data

Adults

Few case reports on allergic reactions in humans are available in the literature. Occupational rhinitis and asthma due to locust bean gum (unspecified origin) have been described in a chemist (Mechaneck, 1954), in a jam factory worker (van der Brempt et al., 1992) and in an ice cream manufacturer (Scoditti et al., 1996).

Fiocchi et al. (1999) reported that 'carob'-specific sensitisation, apparent both *in vitro* and in skin prick tests, can be concordant with peanut allergy and that heat-processing deactivates carob protein allergenicity.

Immediate hypersensitivity to locust bean pods resulting in burning sensations, discomfort in the throat and chest tightness when chewing locust bean pods was reported. Prick tests showed positive results for locust bean gum and were confirmed by detection of specific immunoglobulin E (IgE) to locust bean gum (Komericki and Kränke, 2009).

In a case of urticaria and angioedema in a woman after ingestion of a crème caramel containing locust bean gum (unspecified origin), allergy to locust bean gum was proven by prick testing and detection of IgE specific. Skin prick tests were positive for locust bean gum and high titres of serum IgE specific to locust bean gum demonstrated an IgE-mediated mechanism (Alarcon et al., 2011).

Various studies investigated the effect of locust bean gum on plasma lipids. In the study of Zavoral et al. (1983), 17 adults and 11 adolescents, a group of 18 familial hypercholesterolaemic (FHC) and 10 normal subjects, were fed for 8 weeks diets with and without locust bean gum (10–20 and 10–35 g/day in children and adults, respectively; corresponding to 200–500 mg/kg bw per day) to assess the hypolipidemic effect of the gum. Identical food products with and without locust bean gum were consumed by two groups (A and B) of arbitrarily assigned patients using a cross-over design. Plasma cholesterol, low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), very LDL-C and triglycerides were measured at 2-week intervals and compared to control feeding periods. According to the authors, locust bean gum food products provided a safe, effective means to lower serum lipids in hypercholesterolaemic and normal adults and children over a 3-month feeding study. In FHC patients, serum cholesterol was lowered 10–17%, LDL-C was lowered from 11 to 19%, and HDL/LDL ratios were unchanged. The locust bean gum food products were consumed without significant side effects and were well accepted.

Behall et al. (1984) considered 12 men consuming a basal diet for 20 weeks. Four refined fibres including locust bean gum were added to the basal diet individually for 4 week each at levels ranging from 19.1 to 27.0 g/day of fibre source (corresponding to 270–380 mg locust bean gum/kg bw per day). Locust bean gum added to the diet decreased significantly total serum cholesterol and plasma low-density lipoproteins, whereas no change was observed in triglyceride, very LDL or HDL cholesterol levels. In this study, no side effects of locust bean gum were described.

Infants and children

Locust bean gum is described to be frequently added to infant formulae in the treatment of non-complicated gastro-oesophageal reflux (GOR) (Meunier et al., 2014). The efficacy of thickening agents depends on their ability to increase gastric retention time, avoiding a return to the oesophagus during the first digestion phase (Corvaglia et al., 2013). These types of products are commercialised under the name of antireflux or antiregurgitation infant formulae (AR formulae), and are promoted with the claim that they benefit infants who have GOR or who spit up regularly. The North American and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN and ESPGHAN, respectively) commented on the use of AR formulae in physiological GOR and gastro-oesophageal reflux disease (GORD)[16] and reported that it may decrease visible regurgitation but does not result in a measurable decrease in the frequency of oesophageal reflux episodes. However, long-term use would require additional studies (Vandenplas and Rudolph, 2009). Authors of a systematic review concluded that there was no evidence from randomised controlled trials to support or refute the efficacy of feed thickeners in newborn infants with GOR (Huang et al., 2002).

Locust bean gum as ingredient for AR formulae, is legally allowed in Europe.[17] Locust bean gum may be added up to a maximum level of 10 g/L from birth onwards (see Section 3.2).

As previously mentioned, locust bean gum was considered by the SCF as acceptable for its use up to 1 g/100 mL (10 g/L) in Foods for Special Medical Purposes when prescribed under medical supervision to treat GORD (SCF, 2003) (see section 1.2).

- ***Paediatric case reports***

Few cases of severe adverse effects or fatality in premature or low birth weight infants with GORD receiving infant formulae thickened with locust bean gum were reported in the open literature. The origin of such effects could be related to the very immature state of their gastrointestinal tract. Sievers and Schaub (2003) reported a study in which six premature infants (age not specified) were fed 0.2–0.5 g/100 mL of locust bean gum formula to reduce vomiting. This treatment resulted in an increased frequency of defaecation, metabolic acidosis and hypokalaemia as long as the exposure continued. Clarke and Robinson (2003) reported fatal necrotising enterocolitis observed on days 26 and 30, in two extremely low birth weight premature infants fed locust bean gum thickened milk (dose unspecified). According to the authors, thickened milk may have led to a bowel obstruction resulting in a necrotising enterocolitis; however, the pathophysiology of these two cases was not investigated because no post-mortem examination was done.

A study was conducted in 166 bottle-fed infants under 4 months of age, who were presented with frequent regurgitation/vomiting due to uncomplicated GOR at the outpatient clinics of six paediatric centres (Iacono et al., 2002). Patients were divided into two groups. Group 1 comprised 82 infants (45 males, 37 females; median age 1.5 months) who were treated with an AR formula available on the Italian market thickened with locust bean gum (the concentration is not given, but is expected to not exceed MPLs according to the EU food legislation). Group 2 consisted of 84 patients (43 males, 41 females; median age 1.5 months) treated with a common, adapted formula without any thickening component. No differences between the two groups in regurgitation scores were recorded either at baseline, after 4 and 8 weeks of treatment. But in 14 patients[18] in the group receiving the formula thickened with locust bean gum, treatment was suspended due to the onset of diarrhoea during the first 2 weeks of the study. The authors concluded that the use of the thickened formula could cause diarrhoea.

[16] GOR is a normal physiological process occurring several times per day in healthy infants, children and adults, in the post-prandial period, and causes few or no symptoms. In contrast, GORD is present when the reflux of gastric contents causes troublesome symptoms and/or complications with possible pathophysiological causes underlying (Vandenplas and Rudolph, 2009).

[17] European Parliament and Council Directive 2006/141/EC on infant formulae and follow-on formulae and European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners.

[18] Individual age not known (< or ≥ 12 weeks).

Considering the specific group of infants of more than 12 weeks of age, a case of hypersensitivity and cases of gastrointestinal discomfort have been associated with the use of locust bean gum in infant formulae to treat GOR and are described in the following.

An immediate hypersensitivity to locust bean gum after oral ingestion has been reported in an infant (Savino et al., 1999). The report described a 5-month-old girl, suffering from GOR who developed recurrent vomiting, urticaria and flushing after ingestion of a milk formula containing locust bean gum as a thickening agent. Diagnosis was based only on a case history but no specific tests were performed.

Vivatvakin and Buachum (2003) described the effect of a locust bean gum milk formula (unspecified concentration) on gastric emptying and on regurgitation in 20 Thai infants (4–24 weeks old). Statistically significant improvements in symptoms of vomiting and in weight gain per week where observed in infants consuming the locust bean gum formula for 2–4 weeks. However, there was no significant difference in gastric emptying half time. The only side effect was a significantly increased flatus observed in one infant.

Miyazawa et al. (2006) investigated the effects of milk-based formulae thickened with two different concentrations of locust bean gum (0.4 and 0.5 g/100 mL, formulae HL-350 and HL-450, respectively) on gastric emptying in 27 infants (18–19 weeks old) with recurrent regurgitation episodes. The thickened formula containing the higher concentration of locust bean gum (0.5 g/100 mL) slowed gastric emptying in infants with GOR. In this study, the mothers of two subjects fed with HL-350 and one subject fed with HL-450 reported an increase in bowel movements, but none of these infants had severe diarrhoea. The Panel noted that the highest applied dose reported was only half of the MPL of locust bean gum in formulae for special medical purposes (categories 13.1.5.1 and 13.1.5.2).

Carré described that in the management of GOR of infants, carob seed (locust bean) preparations added to bottle feeds in the proportion of 1 g to 115 mL were given. The author indicated that the treatment could cause frequent loose gelatinous stools which might occasionally necessitate the temporary withdrawal of the treatment (Carré, 1985).

The Panel noted from the above-mentioned studies, that hypersensitivity and undesirable gastrointestinal effects occurred when locust bean gum was used to treat GOR in infants and young children. However, the evidence on these effects was limited. Nevertheless, the Panel noted that the Committee on Nutrition of the European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) concluded 'The effects of thickening agents in infant feeds on the bioavailability of nutrients; on mucosal, metabolic, and endocrine responses; and on infant growth have not been clarified sufficiently. The frequency of allergic reactions to various thickening agents in infancy also is unknown. In view of the limited information available, the Committee recommends that thickening agents and infant diets containing thickening agents should not be used indiscriminately in healthy, thriving infants who spit up. Until better information is available, thickening agents and infant diets containing thickening agents should be used only in selected infants with failure to thrive caused by excessive nutrient losses associated with regurgitation, and used only in conjunction with appropriate medical treatment and supervision. The current practice of indiscriminately offering thickened infant diets to the general public in retail stores, with claims that these products benefit infants who spit up, results in their frequent overuse and misuse, and should be discontinued' (Aggett et al., 2002). Furthermore, the ESPGHAN/NAPGHAN concluded that 'The impact of thickened formula on the natural history of physiologic GOR or GORD has not been studied. The allergenicity of commercial thickening agents is uncertain, and the possible nutritional risks of long-term use require additional study' (Vandenplas and Rudolph, 2009).

Overall, the Panel considered that these conclusions were in line with the one by SCF regarding the use of the locust beam gum in the revision of the essential requirements of infant formulae and follow-on formulae intended for the feeding of infants and young children (SCF, 2003) (see Section 1.2).

Possible effects of locust bean gum on the bioavailability of nutrients

Several authors have indicated the need to explore further the effect of thickening agents on the nutrition and health of infants as some studies in *in vitro* model have suggested that the bioavailability of calcium, iron and zinc may be affected by these compounds (Bosscher et al., 2000, 2003a,b; Vandenplas et al., 2011; González-Bermúdez et al., 2014). However, one *in vivo* human study (Behall et al., 1987) did not support this hypothesis.

3.6. Discussion

Locust bean gum is the ground endosperm of the seeds of the strains of carob tree, *Ceratonia siliqua* (L.) Taub. (family Leguminosae). The substance has the CAS Registry Number 9000-40-2 and the EINECS number 232-541-5.

Purity criteria on locust bean gum (E 410) have been defined in Commission Regulation (EU) No 231/2012 and by JECFA (JECFA, 2008a,b). As indicated by the JECFA specifications, locust bean gum (E 410) is also produced in a purified form as clarified locust bean gum. According to industry the 'Carob Bean Gum is also produced in purified form as "Carob Bean Gum (Clarified)" INS No. E-410. It is however not being used as replacement of "Carob Bean Gum"' (Documentation provided to EFSA, number 5).

According to the recent JECFA evaluation (summary of JECFA, 2016), a limit of 0.5 mg/kg for lead was introduced for locust bean gum and locust bean gum (clarified) for use in infant formula.

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 therefore for locust bean gum criteria for the absence of *Salmonella* spp. and *E. coli*, for TAMC and for TYMC should be included into the EU specifications.

The Panel noted that special requirements for specifications of locust bean gum (E 410) to be used in formulae or food for infants, toddlers and other young children (food category 13.1) might be prudent.

The Panel noted that when locust bean gum (E 410), was added to food in combination with other gums, such as xanthan gum (E 415), agar (E 406) or carrageenan (E 407), there was a greater than additive increase in viscosity or gel strength which may have implications for the safety of the product.

The *in vitro* degradation by human gastrointestinal fluids and *in vivo* digestibility of locust bean gum in animals have been investigated. Despite the absence of an *in vivo* study in humans, the Panel considered that these data indicated that locust bean gum would be not absorbed intact but significantly fermented by the intestinal microflora.

Locust bean gum is regarded as not acutely toxic, based on the results of acute oral toxicity studies.

Three subacute toxicity studies (Ershoff and Wells, 1962; Vohra et al., 1979; Mallett et al., 1984) have been described in rats.

In a subchronic toxicity study in rats by Til et al. (1974), no adverse effects were reported at doses up to 4,500 mg of locust bean gum/kg bw per day. In the NTP (1982), no adverse effects were reported in mice and rats receiving doses up to 20,000 and 9,000 mg of locust bean gum/kg bw per day, respectively. The Panel noted that the NTP study did not include haematology, urinalysis and clinical chemistry.

The available *in vitro* and *in vivo* data for genotoxicity were limited. However, no genotoxic activity was observed for locust bean gum. In addition, considering the chemical structure of locust bean gum and its negligible absorption the Panel concluded that there is no concern with respect to the genotoxicity of locust bean gum (E 410).

Locust bean gum was tested for carcinogenicity in mice and rats receiving doses up to 7,500 mg of locust bean gum/kg bw per day up to 2,500 mg of locust bean gum/kg bw per day, respectively, for 103 weeks (Carlson and Domanski, 1980 as reported by JECFA; NTP, 1982; Melnick et al., 1983). The Panel noted that in these studies, locust bean gum was not carcinogenic.

The Panel considered that no adverse effects were reported in a three-generation reproductive toxicity study receiving doses up to 5% locust bean gum in the diet (equivalent to 4,500 mg of locust bean gum/kg bw per day), the highest dose tested. In the prenatal developmental toxicity studies in rats and hamsters, no maternal and developmental effects were observed up to the highest dose (1,300 and 1,000 mg locust bean gum/kg bw per day) (FDRL, 1972).

In human adults, there are few case reports of allergy to locust bean gum after oral ingestion. However, most of the reports described rhinitis and asthma that were essentially caused by occupational contact with locust bean gum. The Panel recognised the possible potential allergenicity of locust bean gum; however, it considered that the specification and origin of the gum are lacking in these studies. Case reports of hypersensitivity reactions associated with locust bean gum included the case of a 5-month-old infant, the Panel considered that this hypersensitivity might be due to the locust bean gum proteins and therefore their content should be reduced as much as possible.

The Panel further noted that in a group of 28 hypercholesterolaemic or normal adolescents and adults treated with locust bean gum for 8 weeks, doses up to 500 mg/kg bw per day were well tolerated without side effects.

The present re-evaluation includes the use of locust bean gum (E 410) in foods for infants from 12 weeks of age onwards and for young children.

Concerning uses of locust bean gum in food for infants and young children the Panel concurs with the SCF (SCF 2003) '... the SCF reaffirmed its earlier view that it is not persuaded that it is necessary to give thickened infant formulae to infants in good health, and that the information available on the potential effects on the bioavailability of dietary nutrients and growth in young infants is not conclusive (SCF, 1999). It is therefore recommended that the use of locust bean gums should not be acceptable for use in infant formulae' and 'The SCF recommended maintaining the current maximum level of the use of locust bean gums in follow-on formulae of 1 g/L. The Committee further recommended maintaining the concept that if more than one of the three substances locust bean gum, guar gum or carrageenan are added to a follow-on formula, the maximum level established for each of those substances is lowered with that relative part as is present of the other substances together' and 'The SCF accepted that there is a case of need for use of locust bean gums in dietary foods for special medical purposes for therapeutic use in a small number of infants with gastro-oesophageal reflux disease under medical supervision, and the Committee considered its use in these products up to a maximum level of 10 g/L acceptable'. The Panel endorsed the conclusions of the SCF which are reflected in the current regulation for food category 13.1.2. The Panel acknowledged that consumption of the concerned food categories would be short and noted that it is prudent to keep the number of additives used in foods for infants and young children to the minimum necessary and that there should be strong evidence of need as well as safety before additives can be regarded as acceptable for use in infant formulae and foods for infants and young children.

The Panel noted reports suggesting a putative effect of locust bean gum to decrease the bioavailability of certain nutrients; however, a human study did not confirm this effect. For the specific group of infants of more than 12 weeks of age,[1] the Panel considered a case of sensitivity and reports on undesirable gastrointestinal effects, such as diarrhoea, frequent loose stools and flatulence, associated with the use of locust bean gum in products for reduction in GOR.

Furthermore, the Panel noted that no specific clinical data addressing the safety of use of locust bean gum (E 410) in 'dietary foods for infants for special medical purposes and special formulae for infants' (food category 13.1.5.1) and in 'dietary foods for baby and young children for special medical purposes as defined in Directive 1999/21/EC' (food category 13.1.5.2) considering the defined maximum use levels were available to the Panel.

The Panel also noted that infants and young children consuming these foods may be exposed to a greater extent to locust bean gum (E 410) than their healthy counterparts because the permitted levels of locust bean gum (E 410) in products for special medical purposes to reduce GOR are 10-fold higher than in follow-on formulae for healthy individuals. The Panel further noted that, given their medical condition, infants and young children consuming foods belonging to these food categories may show a higher susceptibility to the gastrointestinal effects of locust bean gum than their healthy counterparts. Thus, monitoring of any adverse effects including those in the gastrointestinal system in infants and young children consuming these foods under medical supervision could be helpful to reduce this uncertainty.

According to the conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EU) No 257/2010 (EFSA, 2014), the Panel considered that sufficient toxicity data were available in animals showing no adverse effects at highest doses tested up to 7,500 mg/kg bw per day. Therefore, the Panel considered that there is no need to allocate a numerical ADI for locust bean gum (E 410).

To assess the dietary exposure to locust bean gum (E 410) 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*).

Based on the available data set, the Panel calculated two refined exposure estimates based on different assumptions: a *brand-loyal consumer scenario*, where it is assumed that the population is exposed over a long period of time to the food additive present at the maximum reported use for one food category and to a mean reported use for the remaining food categories; and a *non-brand-loyal scenario*, where it is assumed that the population is exposed over a long period of time to the food additive present at the mean reported use in all relevant food categories. The Panel considered that

the refined exposure assessment approach resulted in more realistic long-term exposure estimates compared to the *maximum level exposure assessment scenario* as it is based on the range of data made available to EFSA by food industry.

The exposure estimates in the *maximum level exposure assessment scenario*, at the mean level exposure to locust bean gum (E 410) from its use as a food additive ranged from 51.6 mg/kg bw per day for the adults to 436.7 mg/kg bw per day in infants. The 95th percentile of exposure to locust bean gum (E 410) ranged from 100.8 mg/kg bw per day for adults to 886.4 mg/kg bw per day in infants (Table 4). The main contributing food categories to the mean exposure estimates for infants and toddlers in this scenario were foods for infants and young children (FCS 13.1), and bread and rolls. For the other population groups, the main contributing food categories were bread and rolls, and fine bakery wares. The Panel noted that the estimated long-term exposures based on this scenario are very likely conservative as this scenario assumes that all foods and beverages listed under the annex II to Regulation No 1333/2008 contain locust bean gum (E 410) as a food additive at the maximum reported use level.

From the *refined estimated exposure scenario* considering only food categories for which direct addition of locust bean gum (E 410) to food is authorised, in the *brand-loyal scenario*, the mean exposure to locust bean gum (E 410) ranged from 35.7 mg/kg bw per day in adults to 368.9 mg/kg bw per day in infants. The 95th percentile of exposure ranged from 74 mg/kg bw per day for adults to 765.2 mg/kg bw per day in infants. In the *non-brand-loyal scenario*, the mean exposure to locust bean gum (E 410) from its use as a food additive ranged from 20.7 mg/kg bw per day for adults to 204.3 mg/kg bw per day in infants. The 95th percentile of exposure ranged from 38.8 mg/kg bw per day for the elderly to 415.4 mg/kg bw per day in infants. The main contributing food categories for all population groups were foods for infants and young children and bread and rolls in both scenarios.

A refined estimated exposure assessment scenario taking into account the food for special medical purpose for infants and young children (FCS 13.1.5. 'Dietary foods for infants and young children for special medical purposes as defined by Commission Directive 1999/22/EC and special formulae for infants') 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.

From this refined brand-loyal estimated exposure scenario taking into account the foods for special medical purposes, the mean exposure to locust bean gum (E 410) from its use as a food additive ranged for infants between 179 and 553 mg/kg bw per day and between 135 and 245 mg/kg bw per day for toddlers. The 95th percentile of exposure ranged for infants between 435 and 1,555 mg/kg bw per day and for toddlers between 262 and 578 mg/kg bw per day.

These estimates are based on 59 out of 84 food categories in which locust bean gum (E 410) is authorised. The main food categories, in term of amount consumed, not taken into account were breakfast cereals, gluten-free dietary foods for infants and young children, snacks and some alcoholic beverages (cider and perry, spirit drinks …). However, based on the information in the Mintel GNPD (Appendix C), in the EU market, no breakfast cereals are labelled with locust bean gum (E 410), and few alcoholic drinks are labelled with the additive. Therefore, the Panel considered that the uncertainties identified would, in general, result in an overestimation of the exposure to locust bean gum (E 410) as a food additive according to Annex II in European countries for all scenarios.

Locust bean gum (E 410) is used as a thickener and stabiliser in a wide range of foods. In specific populations, consuming foods for special medical purposes and special formulae and in infants and young children consuming follow-on formulae brand-loyalty may be relevant. Because these food groups are main contributors to mean exposure, the Panel therefore selected the brand-loyal refined scenario as the most relevant exposure scenario for this additive in these specific situations.

The Panel noted that in Annex II of Regulation (EC) No 1333/2008 use levels of locust bean gum (E 410) in food for infants under the age of 12 weeks are included in categories 13.1.1, 13.1.5.1 and 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 locust bean gum (E 410) as a food additive(s) is not considered to be applicable for infants under the age of 12 weeks and will be performed separately.

4. Conclusion

4.1. General population

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

- adequate exposure data were available; in the general population, the highest refined exposure estimates based on the reported data from food industry were for infants (12 weeks–11 months) up to 765 mg/kg bw per day (brand-loyal scenario) while these estimates were lower than 435 mg/kg bw per day in the other groups of population;
- locust bean gum is practically undigested, not absorbed intact, but significantly fermented by enteric bacteria in humans;
- adequate toxicity data were available;
- no adverse effects were reported in 90-day toxicity studies in rodents at the highest doses tested (20,000 mg locust bean gum/kg bw per day in mice, and 4,500 or 9,000 mg locust bean gum/kg bw per day in rats);
- there is no concern with respect to the genotoxicity of locust bean gum;
- no carcinogenic effects were reported in carcinogenicity studies in rodents at the highest dose tested, up to 7,500 mg locust bean gum/kg bw per day in mice and 2,500 mg locust bean gum/kg bw per day in rats;
- oral intake of locust bean gum at doses in doses amounting up to 500 mg/kg bw per day for 8 weeks was tolerated in adolescents and adults without significant side effects. Although no information was available for higher doses in humans, no effects were observed in animals at doses up to 10-fold higher,

the Panel concluded that there is no need for a numerical ADI for locust bean gum (E 410), and that there is no safety concern for the general population at the refined exposure assessment for the reported uses of locust bean gum (E 410) as a food additive.

4.2. Infants and young children consuming foods for special medical purposes and special formulae

Concerning the use of locust bean gum (E 410) in 'dietary foods for special medical purposes and special formulae for infants' (Food category 13.1.5.1) and in 'dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC' (Food category 13.1.5.2), and given that:

- for populations consuming foods for special medical purposes and special formulae, the 95th percentile of refined exposure assessments calculated based on the reported data from food industry are for infants (12 weeks – 11 months) up to 1,555 mg/kg bw per day (brand-loyal scenario);
- infants and young children consuming foods belonging to these food categories may show a higher susceptibility to the gastrointestinal effects of locust bean gum than their healthy counterparts due to their underlying medical condition;
- no adequate clinical data addressing the safety of these uses of locust bean gum (E 410) in this population under certain medical conditions were available; however, there are case reports indicating undesirable gastrointestinal symptoms in infants taking food products for reduction in GOR which are authorised to contain locust bean gum up to 10-fold higher levels than in follow-on formulae for healthy infants;
- no relevant animal studies were available;

the Panel concluded that the available data do not allow an adequate assessment of the safety of locust bean gum (E 410) in infants and young children consuming these foods for special medical purposes.

5. Recommendations

The Panel recommended that the maximum limits for the impurities of toxic elements (lead, mercury and arsenic) in the EU specification for locust bean gum (E 410) should be revised in order to

ensure that locust bean gum (E 410) 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 recommended to give separate specifications in the EU regulation for locust bean gum and clarified locust bean gum differing significantly in the protein content.

The Panel noted some case reports of hypersensitivity reactions associated with locust bean gum (E 410). The Panel considered that this hypersensitivity might be due to the locust bean gum proteins, and therefore, the Panel recommended that their content should be reduced as much as possible.

The Panel recommended to harmonise the microbiological specifications in the EU Regulation for polysaccharidic thickening agents, such as gums, and to include criteria for the absence of *Salmonella* spp. and *E. coli*, for TAMC and for TYMC into the EU specifications of locust bean gum (E 410).

In view of the synergistic effects on viscosity and gelling with mixtures of locust bean gum (E 410) and carrageenan (E 407), the Panel recommended to include carrageenan (E 407) in the footnote for food category 13.1.4 regulating the combined use of the gums.

Concerning the direct use of locust bean gum (E 410) by the consumer in the form of a powder to thicken food, the Panel recommended labelling, including instructions for adequate preparation of the thickened food with sufficient liquid to avoid the risk of possible oesophageal obstruction due to insufficient hydration of the locust bean gum.

The Panel recommended that additional data should be generated to assess the potential health effects of locust bean gum (E 410) when used in 'dietary foods for infants for special medical purposes and special formulae for infants' (Food category 13.1.5.1) and in 'dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC' (Food category 13.1.5.2).

Documentation provided to the EFSA

1) Danisco. Dossier. Locust Bean Gum. Section II: Identity, characterisation and conditions of use of the additive; methods of analysis. Submitted to EFSA by Danisco. Submitted November 2010.
2) Mars. Submission of data on emulsifiers, stabilisers and gelling agents in response to the EFSA call for scientific data for the re-evaluation of food additives. Submitted May 2010.
3) EINEC (Association of Carob Bean Gum). Submission of data on emulsifiers, stabilisers and gelling agents in response to the EFSA call for scientific data for the re-evaluation of food additives. Submitted May, 2010.
4) CP Kelco. Submission of data for LBG (E 410), EFSA Call for technical data on certain thickening agents permitted as food additives in the EU. Submitted December, 2015.
5) INEC. Association of Producers of Carob Bean Gum, INEC response regarding carob bean gum (E 410), EFSA Call for technical data on certain thickening agents permitted as food additives in the EU. Submitted December, 2015.
6) European Medicines Agency (EMA) communication following EFSA request on 4 May 2015, for information on a certain group of substances used as food additives. Submitted June 2015.
7) INEC. Data on Carob bean gum. Submitted to EFSA. January 2016.
8) FDE (FoodDrinkEurope), 2014. Data on usage levels of locust bean gum (E 410) 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. Submitted September 2014.
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Abbreviations

AAS	atomic absorption spectrophotometry
ADI	acceptable daily intake
ALAT	alanine transaminase
ALP	alkaline phosphatase
ANS Panel	EFSA Panel on Food Additives and Nutrient Sources added to Food
AR	antiregurgitation
ASAT	aspartate transaminase
bw	body weight
CFU	colony-forming units
ESPGHAN	European Society for Pediatric Gastroenterology, Hepatology, and Nutrition
FAO	Food and Agriculture Organization

FCS	Food Classification System
FDA	Food and Drug Administration
FDE	Food and Drink Europe
FHC	familial hypercholesterolaemic
FSMP	foods for special medical purposes
GD	gestation day
GNPD	Global New Products Database
GOR	gastro-oesophageal reflux
GORD	gastro-oesophageal reflux disease
GRAS	Generally Recognised As Safe
HDL-C	high-density lipoprotein cholesterol
ICP-AES	inductively coupled plasma atomic emission spectroscopy
IgE	immunoglobulin E
IR	infrared
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LD_{50}	lethal dose
LDL-C	low-density lipoprotein cholesterol
LOD	limit of detection
LOQ	limit of quantification
MPL	maximum permitted level
NASPGHAN	North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition
NTP	National Toxicology Program
QS	*quantum satis*
SCF	Scientific Committee for Food
SCFA	short-chain fatty acids
SNE	Specialised Nutrition Europe
SRBC	sheep red blood cell
TAMC	total aerobic microbial count
TYMC	total combined yeasts moulds count
WG	Working Group
WHO	World Health Organization

Appendix A – Summary of reported use levels of locust bean gum (E 410) provided by industry (mg/L or mg/kg as appropriate)

Food category number	Food category name	MPL	Restrictions	Provider name	N	Typical levels		Maximum levels	Comments
						Mean	Min–Max		
01.3	Unflavoured fermented milk products, heat-treated after fermentation	QS		FDE Food and Drink Europe	2	2,800	600–5,000	10,000	
01.4	Flavoured fermented milk products, including heat-treated products	QS		FDE Food and Drink Europe	2	2,800	600–5,000	10,000	
01.4	Flavoured fermented milk products, including heat-treated products	QS		Rudolf Wild GmbH & Co. KG	1	400	–	3,000	
01.6.2	Unflavoured live fermented cream products and substitute products with a fat content of less than 20%	QS		Danisco	1	500	–	4,500	2010 call for data
01.6.2	Unflavoured live fermented cream products and substitute products with a fat content of less than 20%	QS		FDE Food and Drink Europe	4	2,900	600–5,000	10,000	
01.6.3	Other creams	QS		FDE Food and Drink Europe	10	1,002	190–2,250	4,000	
01.7.1	Unripened cheese excluding products falling in category 16	QS	Except mozzarella	FDE Food and Drink Europe	12	2,262	1,000–3,414	8,000	
01.7.5	Processed cheese	QS		FDE Food and Drink Europe	11	2,979	1,000–5,000	10,000	
01.7.5	Processed cheese	QS		Rudolf Wild GmbH & Co. KG	1	530	–	1,000	
01.7.6	Cheese products (excluding products falling in category 16)	QS		FDE Food and Drink Europe	2	3,500	2,000–5,000	10,000	
01.8	Dairy analogues, including beverage whiteners	QS		FDE Food and Drink Europe	8	2,438	700–5,000	10,000	

Food category number	Food category name	MPL	Restrictions	Provider name	N	Typical levels		Maximum levels	Comments
						Mean	Min–Max		
02.2.2	Other fat and oil emulsions, including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions	QS		FDE Food and Drink Europe	1	8,000	–	15,000	
03	Edible ices	QS		BABBI Confectionary Industry	1	600	–	820	
03	Edible ices	QS		Danisco	1	500	–	3,000	2010 call for data
03	Edible ices	QS		FDE Food and Drink Europe	86	1,506	585–3,766.7	8,000	
03	Edible ices	QS		Mars	1	500	–	1,150	2010 call for data
03	Edible ices	QS		Rudolf Wild GmbH & Co. KG	1	1,690	–	9,000	
04.2.2	Fruit and vegetables in vinegar, oil or brine	QS		FDE Food and Drink Europe	1	3,000	–	5,000	
04.2.3	Canned or bottled fruit and vegetables	QS	Only chestnuts in liquid	FDE Food and Drink Europe	1	3,000	–	5,000	
04.2.4.1	Fruit and vegetable preparations, excluding compote	QS		FDE Food and Drink Europe	8	1,900	1,200–2,700	8,000	
04.2.5.2	Jam, jellies and marmalades, and sweetened chestnut puree as defined by Directive 2001/113/EC	10,000		FDE Food and Drink Europe	5*	3,200	2,000–5,000	10,000	
04.2.5.3	Other similar fruit or vegetable spreads	10,000		FDE Food and Drink Europe	1	2,000	–	5,000	
04.2.6	Processed potato products	QS		FDE Food and Drink Europe	2	20,000	2,000–38,000	38,000	
05	Confectionery			Rudolf Wild GmbH & Co. KG	1	750	–	1,380	
05.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC	QS	Only energy-reduced or with no added sugar	FDE Food and Drink Europe	1	30,562	–	72,768	

Food category number	Food category name	MPL	Restrictions	Provider name	N	Typical levels		Maximum levels	Comments
						Mean	Min–Max		
05.2	Other confectionery, including breath refreshening microsweets	QS	E 410 may not be used in jelly minicups, defined, for the purpose of this Regulation, as jelly confectionery of a firm consistence, contained in semirigid minicups or minicapsules, intended to be ingested in a single bite by exerting pressure on the minicups or minicapsule to project the confectionery into the mouth; E 410 may not be used to produce dehydrated foods intended to rehydrate on ingestion	FDE Food and Drink Europe	4	1,536.5	146–2,000	10,000	
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	QS		FDE Food and Drink Europe	9	1,521	26–5,000	16,000	
06.2.2	Starches	QS		FDE Food and Drink Europe	1	76	–	119	
06.4.2	Dry pasta	QS	Only gluten-free and/or pasta intended for hypoproteic diets in accordance with Directive 2009/39/EC	FDE Food and Drink Europe	1	2,000	–	5,000	
06.4.4	Potato Gnocchi	QS	Except fresh refrigerated potato gnocchi	FDE Food and Drink Europe	2	1,500	1,000–2,000	5,000	
06.4.5	Fillings of stuffed pasta (ravioli and similar)	QS		FDE Food and Drink Europe	2	2,000	1,000–3,000	5,000	
06.5	Noodles	QS		FDE Food and Drink Europe	1	2,000	–	5,000	
06.6	Batters	QS		FDE Food and Drink Europe	2	1,500	1,000–2,000	5,000	
06.7	Precooked or processed cereals	QS		FDE Food and Drink Europe	1	5,000	–	10,000	

Food category number	Food category name	MPL	Restrictions	Provider name	N	Typical levels		Maximum levels	Comments
						Mean	Min–Max		
07.1	Bread and rolls	QS	Except products in 7.1.1 and 7.1.2	FDE Food and Drink Europe	1	10,000	–	20,000	
07.2	Fine bakery wares	QS		FDE Food and Drink Europe	10 (1 NP)*	3,885.1	152–10,000	20,000	
07.2	Fine bakery wares	QS		Rudolf Wild GmbH & Co. KG	1	1,110	–	4,000	
08.2	Meat preparations as defined by Regulation (EC) No 853/2004	QS	Only preparations in which ingredients have been injected; meat preparations composed of meat parts that have been handled differently: minced, sliced or processed and that are combined together. Except *bifteki, soutzoukaki, kebap, gyros and souvlaki*	EUROGUM A/S	1	5,000	–	20,000	
08.3.1	Non-heat-treated meat products	QS		EMCESA Fabricante Embutidos del centro SA (España)	2	2	–	2	Representative for Spain
08.3.1	Non-heat-treated meat products	QS		FDE Food and Drink Europe	1	3,000	–	6,000	
08.3.2	Heat-treated meat products	QS	Except *foie gras, foie gras entier, blocs de foie gras, Libamáj, libamáj egészben, libamáj tömbben*	EMCESA Fabricante Embutidos del centro SA (España)	9	5	4–6	6	Representative for Spain
08.3.2	Heat-treated meat products	QS	Except *foie gras, foie gras entier, blocs de foie gras, Libamáj, libamáj egészben, libamáj tömbben*	EUROGUM A/S	2	5,000	5,000–5,000	20,000	
08.3.2	Heat-treated meat products	QS	Except *foie gras, foie gras entier, blocs de foie gras, Libamáj, libamáj egészben, libamáj tömbben*	FDE Food and Drink Europe	8*	1,618	346–3,000	6,000	

Food category number	Food category name	MPL	Restrictions	Provider name	N	Typical levels		Maximum levels	Comments
						Mean	Min–Max		
08.3.3	Casings and coatings and decorations for meat	QS		FDE Food and Drink Europe	4	2,500	1,000–6,000	15,000	
09.2	Processed fish and fishery products including molluscs and crustaceans	QS		FDE Food and Drink Europe	2	2,000	1,000–3,000	6,000	
09.3	Fish roe	QS	Only processed fish roe	FDE Food and Drink Europe	1	3,000	–	6,000	
10.2	Processed eggs and egg products	QS		FDE Food and Drink Europe	2*	3,500	2,000–5,000	10,000	
11.2	Other sugars and syrups	QS		FDE Food and Drink Europe	1	2,000	–	3,000	
11.4.1	Table top sweeteners in liquid form	QS		FDE Food and Drink Europe	1	4,000	–	10,000	
11.4.2	Table top sweeteners in powder form	QS		FDE Food and Drink Europe	1	20,000	–	40,000	
12.2.2	Seasonings and condiments	QS		FDE Food and Drink Europe	1	2,000	–	5,000	
12.4	Mustard	QS		FDE Food and Drink Europe	2	2,500	2,000–3,000	5,000	
12.5	Soups and broths	QS		FDE Food and Drink Europe	8*	1,117	67.3–2,667	7,000	
12.6	Sauces	QS		Danisco	2	2,000	2,000–2,000	5,000	2010 call for data
12.6	Sauces	QS		FDE Food and Drink Europe	26* (7 NP)	1,647	25.3–5,000	10,000	
12.7	Salads and savoury-based sandwich spreads	QS		FDE Food and Drink Europe	3	5,000	5,000–5,000	10,000	
12.9	Protein products, excluding products covered in category 1.8	QS		FDE Food and Drink Europe	1	5,000	–	10,000	
12.9	Protein products, excluding products covered in category 1.8	QS		Rudolf Wild GmbH & Co. KG	1	1,110	–	1,320	
13.1.2	Follow-on formulae as defined by Directive 2006/141/EC	1,000	(c)	FDE Food and Drink Europe	4 (1 NP)	675	500–1,000	1,000	

Food category number	Food category name	MPL	Restrictions	Provider name	N	Typical levels		Maximum levels	Comments
						Mean	Min–Max		
13.1.3	Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC	20,000	Only gluten-free cereal-based foods[(d)]	FDE Food and Drink Europe	1	15,000		20,000	
13.1.3	Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC	10,000	Only processed cereal-based foods and baby foods[(d)]	FDE Food and Drink Europe	2	3,800	1,600–6,000	7,000	
13.1.4	Other foods for young children	10,000	[(d)]	FDE Food and Drink Europe	1	5,000	–	10,000	
13.1.4	Other foods for young children	10,000	[(d)]	SNE Specialised Nutrition Europe	1	4,000	–	5,000	
13.1.5.1	Dietary foods for infants for special medical purposes and special formulae for infants	10,000	From birth onwards in products for reduction in gastro-oesophageal reflux	FDE Food and Drink Europe	2	6,500	5,000–8,000	10,000	
13.1.5.1	Dietary foods for infants for special medical purposes and special formulae for infants	10,000	From birth onwards in products for reduction in gastro-oesophageal reflux	SNE Specialised Nutrition Europe	3 (1 NP)	6,033	2,700–10,000	10,000	
13.1.5.1	Dietary foods for infants for special medical purposes and special formulae for infants	1,000	[(b)]						
13.1.5.2	Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC	10,000	Only processed cereal-based foods and baby foods	FDE Food and Drink Europe	2	6,500	5,000–8,000	10,000	
13.1.5.2	Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC	10,000	From birth onwards in products for reduction in gastro-oesophageal reflux	SNE Specialised Nutrition Europe	5 (2 NP)	5,338	250–10,000	10,000	
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	QS		FDE Food and Drink Europe	2	1,000	1,000–1,000	10,000	

Food category number	Food category name	MPL	Restrictions	Provider name	N	Typical levels		Maximum levels	Comments
						Mean	Min–Max		
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	QS		SNE Specialised Nutrition Europe	2	1,502	900–2,104	2,104	
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)	QS		FDE Food and Drink Europe	3	1,667	1,000–3,000	10,000	
13.4	Foods suitable for people intolerant to gluten as defined by Regulation (EC) No 41/2009	QS	Including dry pasta	FDE Food and Drink Europe	2	7,000	4,000–10,000	20,000	
13.4	Foods suitable for people intolerant to gluten as defined by Regulation (EC) No 41/2009	QS	Including dry pasta	SNE Specialised Nutrition Europe	2	1,761	722–2,800	2,800	
14.1.2	Fruit juices as defined by Directive 2001/112/EC and vegetable juices	QS	Only vegetable juices	FDE Food and Drink Europe	2	1,000	1–2,000	4,000	
14.1.3	Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products	QS	Only vegetable nectars	FDE Food and Drink Europe	2	1,500	1,000–2,000	4,000	
14.1.4	Flavoured drinks	QS		FDE Food and Drink Europe	16	304	12–2,000	4,000	
14.1.4	Flavoured drinks	QS		Rudolf Wild GmbH & Co. KG	7	1,263	30–6,600	46,000[(a)]	[(a)]On a sport drink, flavoured
14.1.5.2	Other	QS	Excluding unflavoured leaf tea; including flavoured instant coffee	FDE Food and Drink Europe	1	2,000	–	4,000	
14.2.7.3	Aromatised wine-product cocktails	QS		FDE Food and Drink Europe	1	200	–	500	
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% of alcohol	QS		FDE Food and Drink Europe	4	69	25–200	500	

Food category number	Food category name	MPL	Restrictions	Provider name	N	Typical levels		Maximum levels	Comments
						Mean	Min–Max		
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% of alcohol	QS		Rudolf Wild GmbH & Co. KG	2	45	30–60	20,400[(a)]	
16	Desserts, excluding products covered in category 1, 3 and 4	QS		FDE Food and Drink Europe	14	1,939	270–7,000	10,000	
16	Desserts, excluding products covered in category 1, 3 and 4	QS		Rudolf Wild GmbH & Co. KG	1	590		1,500	
17	Food supplements	QS		FDE Food and Drink Europe	4	2,250	1,000–4,000	10,000	
18	Processed foods not covered by categories 1–17, excluding foods for infants and young children	QS		FDE Food and Drink Europe	2	3,035	3,000–3,070	8,000	
–				Biovegan GmbH	4 NP	0.33	0.1–1	1	Levels as 'thickener' or 'pure locust bean gum'
–				FDE Food and Drink Europe	3	2,310	360–4,071	33,330	Gum blend, emulsifier gel

MPL: maximum permitted level; NP: niche products; QS: *quantum satis*.
*: Of which some not representative of EU but of only one country.
(a): On a beer mix.

Appendix B – Number and percentage of food products labelled with locust bean gum (E 410) out of the total number of food products present in the Mintel GNPD per food subcategory between 2011 and 2016

Mintel subcategory[a]	Total number of products	Products labelled with locust bean gum (E 410)	
		Number	%
Dairy-Based Frozen Products	8,351	5,614	67.2
Soy-Based Frozen Products	83	50	60.2
Water-Based Frozen Desserts	1,287	662	51.4
Fresh Cheese & Cream Cheese	2,875	752	26.2
Soy Yogurt	451	89	19.7
Soft Cheese Desserts	1,621	272	16.8
Other Frozen Desserts	1,696	265	15.6
Chilled Desserts	6,625	953	14.4
Sandwich Fillers/Spreads	1,099	124	11.3
Rice/Nut/Grain & Seed Based Drinks	1,305	128	9.8
Processed Cheese	2,238	219	9.8
Meat Substitutes	2,551	234	9.2
Salads	2,804	234	8.3
Spoonable Yogurt	10,467	855	8.2
Shelf-Stable Desserts	3,213	252	7.8
Cream	1,719	128	7.4
Savoury Vegetable Pastes/Spreads	1,868	109	5.8
Fruit/Flavoured Still Drinks	3,058	170	5.6
Stocks	1,454	79	5.4
Carbonated Soft Drinks	6,027	321	5.3
Sandwiches/Wraps	2,777	147	5.3
Curd & Quark	1,075	55	5.1
Meat Pastes & Pates	3,188	162	5.1
Baby Fruit Products, Desserts & Yogurts	1,710	86	5.0
Dessert Toppings	674	32	4.7
Sports Drinks	850	40	4.7
Liquid Dairy Other	136	6	4.4
Eggs & Egg Products	1,628	71	4.4
Hors d'oeuvres/Canapes	4,276	185	4.3
Baby Formula (0–6 months)	280	12	4.3
Drinking Yogurt & Liquid Cultured Milk	3,347	132	3.9
Meal Kits	2,215	86	3.9
Mayonnaise	964	37	3.8
Dips	1,592	47	3.0
Table Sauces	6,345	185	2.9
Energy Drinks	1,782	51	2.9
Cakes, Pastries & Sweet Goods	14,053	401	2.9
Other Snacks	150	4	2.7
Potato Products	3,335	88	2.6
Meat Snacks	1,079	25	2.3
Dressings & Vinegar	3,460	74	2.1
Confiture & Fruit Spreads	5,027	105	2.1
Pizzas	4,632	96	2.1
Prepared Meals	11,658	195	1.7

Mintel subcategory[a]	Total number of products	Products labelled with locust bean gum (E 410)	
		Number	%
Pastry Dishes	2,033	33	1.6
Fish Products	13,424	206	1.5
Beer	8,749	132	1.5
Poultry Products	6,992	104	1.5
Wet Soup	4,358	64	1.5
Soy-Based Drinks	693	10	1.4
Cooking Sauces	5,267	76	1.4
Soft Cheese & Semisoft Cheese	6,079	83	1.4
Baby Cereals	725	9	1.2
Flavoured Alcoholic Beverages	2,108	26	1.2
Nectars	4,306	48	1.1
Nut Spreads	844	9	1.1
Meat Products	17,292	180	1.0
Flavoured Milk	1,514	15	1.0
RTD (Iced) Coffee	938	9	1.0
Pasta Sauces	4,033	38	0.9
Other Baby Food	113	1	0.9
Instant Pasta	617	5	0.8
Baking Ingredients & Mixes	9,621	73	0.8
Chocolate Spreads	1,232	9	0.7
Instant Rice	140	1	0.7
Baby Formula (6–12 months)	282	2	0.7
Bread & Bread Products	10,759	72	0.7
Beverage Concentrates	2,460	16	0.7
Meal Replacements & Other Drinks	1,388	9	0.6
Malt & Other Hot Beverages	1,084	7	0.6
Cassava & Other Root-Based Snacks	332	2	0.6
RTD (Iced) Tea	1,829	11	0.6
Mixed Assortments	333	2	0.6
Stuffing, Polenta & Other Side Dishes	2,671	16	0.6
Flavoured Water	1,405	8	0.6
Pastilles, Gums, Jellies & Chews	4,040	23	0.6
Margarine & Other Blends	1,063	6	0.6
Fruit	2,964	16	0.5
Liquorice	823	4	0.5
Creamers	206	1	0.5
Butter	1,513	7	0.5
White Rum	217	1	0.5
Wheat & Other Grain-Based Snacks	2,092	9	0.4
Sweet Biscuits/Cookies	18,664	76	0.4
Other Sauces & Seasonings	989	4	0.4
Bean-Based Snacks	251	1	0.4
Potato Snacks	5,340	21	0.4
Hot Cereals	1,312	5	0.4
Dry Soup	1,723	6	0.3
Corn-Based Snacks	2,390	8	0.3
Popcorn	1,226	4	0.3

Mintel subcategory[a]	Total number of products	Products labelled with locust bean gum (E 410)	
		Number	%
Savoury Biscuits/Crackers	5,061	15	0.3
Vegetable Snacks	714	2	0.3
Baby Juices & Drinks	380	1	0.3
Fruit Snacks	3,807	10	0.3
Individually Wrapped Chocolate Pieces	2,696	7	0.3
Snack/Cereal/Energy Bars	5,446	14	0.3
Other Sugar Confectionery	1,170	3	0.3
Sucrose	1,173	3	0.3
Toffees, Caramels & Nougat	2,001	5	0.2
Rice Snacks	428	1	0.2
Seasonal Chocolate	5,813	12	0.2
Chocolate Tablets	8,922	18	0.2
Rice	3,498	6	0.2
Vegetables	11,290	19	0.2
Cold Cereals	6,756	11	0.2
Seasonings	10,070	16	0.2
Pasta	10,787	17	0.2
Non-Individually Wrapped Chocolate Pieces	5,551	8	0.1
Snack Mixes	1,584	2	0.1
Hard Cheese & Semihard Cheese	7,300	8	0.1
Medicated Confectionery	1,099	1	0.1
Tea	9,416	7	0.1
Pickled Condiments	5,896	4	0.1
Wine	4,190	2	0.0
Juice	8,570	2	0.0
Oils	4,821	1	0.0
Nuts	5,014	1	0.0
Total sample	**464,224**	**15,496**	**3.3**[b]

(a): According to the Mintel food categorisation.
(b): In total, between 2011 and 2016, in the food categories where food products can be labelled with locust bean gum (E 410), around 3.3% of the products available on the Mintel GNPD are labelled with locust bean gum (E 410).

Appendix C – Concentration levels of locust bean gum (E 410) used in the refined exposure scenarios (mg/kg or mL/kg as appropriate)

Food category number	Food category name	Restrictions/exceptions	MPL	Levels used in the refined exposure assessment		Comments
				Mean	Max	
01.3	Unflavoured fermented milk products, heat-treated after fermentation		QS	2,800	10,000	
01.4	Flavoured fermented milk products including heat-treated products		QS	2,800	10,000	
01.6.2	Unflavoured live fermented cream products and substitute products with a fat content of less than 20%		QS	1,550	10,000	
01.6.3	Other creams		QS			
01.7.1	Unripened cheese, excluding products falling in category 16	Except mozzarella	QS	2,260	8,000	
01.7.5	Processed cheese		QS	2,980	10,000	
01.7.6	Cheese products (excluding products falling in category 16)		QS	–	–	Not taken into account (not in FoodEx)
01.8	Dairy analogues, including beverage whiteners		QS	2,440	10,000	
02.2.2	Other fat and oil emulsions, including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions		QS	8,000	15,000	
02.3	Vegetable oil pan spray		QS	–	–	Not taken into account (not in FoodEx and no concentration data)
3	Edible ices		QS	1,500	8,000	
04.2.1	Dried fruit and vegetables	E 410 may not be used to produce dehydrated foods intended to rehydrate on ingestion	QS	–	–	Not taken into account (no concentration data)
04.2.2	Fruit and vegetables in vinegar, oil, or brine		QS	3,000	5,000	
04.2.3	Canned or bottled fruit and vegetables	Only chestnuts in liquid	QS	–	–	Not taken into account (not in FoodEx)

Food category number	Food category name	Restrictions/exceptions	MPL	Levels used in the refined exposure assessment		Comments
				Mean	Max	
04.2.4.1	Fruit and vegetable preparations, excluding compote		QS	1,900	5,000	
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EC	(a)	10,000	2,000	5,000	
04.2.5.3	Other similar fruit or vegetable spreads	(a)	10,000	2,000	5,000	
04.2.5.4	Nut butters and nut spreads		QS	–	–	Not taken into account (no concentration data)
04.2.6	Processed potato products		QS	20,000	38,000	
05.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC	Only energy-reduced or with no added sugar	QS	30,560	72,770	
05.2	Other confectionery, including breath refreshening microsweets	E 410 may not be used in jelly minicups, defined, for the purpose of this Regulation, as jelly confectionery of a firm consistence, contained in semirigid minicups or minicapsules, intended to be ingested in a single bite by exerting pressure on the minicups or minicapsule to project the confectionery into the mouth; E 410 may not be used to produce dehydrated foodstuffs intended to rehydrate on ingestion	QS	1,540	10,000	
05.3	Chewing gum		QS	–	–	Not taken into account (no concentration data)
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4		QS	–	–	Not taken into account (not in FoodEx)
06.2.2	Starches		QS	80	120	
06.3	Breakfast cereals		QS	–	–	Not taken into account (no concentration data)
06.4.2	Dry pasta	Only gluten-free and/or pasta intended for hypoproteic diets in accordance with Directive 2009/39/EC	QS	2,000	5,000	
06.4.4	Potato Gnocchi	Except fresh refrigerated potato gnocchi	QS	–	–	Not taken into account (not in FoodEx)

Food category number	Food category name	Restrictions/exceptions	MPL	Levels used in the refined exposure assessment		Comments
				Mean	Max	
06.4.5	Fillings of stuffed pasta (ravioli and similar)		QS	2,000	5,000	
06.5	Noodles		QS	2,000	5,000	
06.6	Batters		QS	–	–	Not taken into account (not in FoodEx)
06.7	Precooked or processed cereals		QS	–	–	Not taken into account (not in FoodEx)
07.1	Bread and rolls	Except products in 7.1.1 and 7.1.2	QS	10,000	20,000	
07.2	Fine bakery wares		QS	2,750	20,000	
08.2	Meat preparations as defined by Regulation (EC) No 853/2004	Only preparations in which ingredients have been injected; meat preparations composed of meat parts that have been handled differently: minced, sliced or processed and that are combined together. Except *bifteki, soutzoukaki, kebap, gyros* and *souvlaki*	QS	1,920	6,000	
08.3.1	Non-heat-treated meat products		QS			
08.3.2	Heat-treated meat products	Except *foie gras, foie gras entier, blocs de foie gras, Libamáj, libamáj egészben, libamáj tömbben*	QS			
08.3.3	Casings and coatings and decorations for meat		QS	–	–	Not taken into account (not in FoodEx)
09.2	Processed fish and fishery products, including molluscs and crustaceans		QS	2,000	6,000	
09.3	Fish roe	Only processed fish roe	QS	3,000	6,000	
10.2	Processed eggs and egg products		QS	5,000	10,000	
11.2	Other sugars and syrups		QS	2,000	3,000	
11.4.1	Table top sweeteners in liquid form		QS	12,000	40,000	
11.4.2	Table top sweeteners in powder form		QS			
12.1.2	Salt substitutes		QS	–	–	Not taken into account (not in FoodEx and no concentration data)
12.2.2	Seasonings and condiments		QS	2,000	5,000	

Food category number	Food category name	Restrictions/exceptions	MPL	Levels used in the refined exposure assessment		Comments
				Mean	Max	
12.3	Vinegars		QS	–	–	Not taken into account (no concentration data)
12.4	Mustard		QS	2,500	5,000	
12.5	Soups and broths		QS	990	7,000	
12.6	Sauces		QS	1,825	10,000	
12.7	Salads and savoury-based sandwich spreads		QS	5,000	10,000	
12.8	Yeast and yeast products		QS	–	–	Not taken into account (no concentration data)
12.9	Protein products, excluding products covered in category 1.8		QS	5,000	10,000	
13.1.2	Follow-on formulae as defined by Directive 2006/141/EC	(b)	1,000	670	1,000	
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(c)	20,000	–	–	Not taken into account (not in FoodEx)
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(c)	10,000	3,800	7,000	
13.1.4	Other foods for young children	(c)	10,000	4,500	10,000	
13.1.5.1	Dietary foods for infants for special medical purposes and special formulae for infants	(b)	10,000/ 1,000	6,250	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(c)	20,000	–	–	Not taken into account (not in FoodEx and no concentration data)
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(c)	10,000	5,700	10,000	
13.1.5.2	Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC	From birth onwards in products for reduction in gastro-oesophageal reflux(c)	10,000			

Food category number	Food category name	Restrictions/exceptions	MPL	Levels used in the refined exposure assessment		Comments
				Mean	Max	
13.1.5.2	Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC	(c)	1,000	4,500	10,000	
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)		QS	1,250	10,000	
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)		QS	1,670	10,000	
13.4	Foods suitable for people intolerant to gluten as defined by Regulation (EC) No 41/2009	Including dry pasta	QS	4,380	20,000	
14.1.2	Fruit juices as defined by Directive 2001/112/EC and vegetable juices	Only vegetable juices	QS	1,000	4,000	
14.1.3	Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products	Only vegetable nectars	QS			Not taken into account (not in FoodEx)
14.1.4	Flavoured drinks		QS	300	4,000	
14.1.5.2	Other	Excluding unflavoured leaf tea; including flavoured instant coffee	QS	2,000	4,000	
14.2.3	Cider and perry		QS	–	–	Not taken into account (no concentration data)
14.2.4	Fruit wine and made wine		QS	–	–	Not taken into account (not in FoodEx and no concentration data)
14.2.5	Mead		QS	–	–	Not taken into account (not in FoodEx and no concentration data)
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	Except whisky or whiskey	QS	–	–	Not taken into account (no concentration data)

Food category number	Food category name	Restrictions/exceptions	MPL	Levels used in the refined exposure assessment		Comments
				Mean	Max	
14.2.7.1	Aromatised wines		QS	200	500	
14.2.7.2	Aromatised wine-based drinks		QS			
14.2.7.3	Aromatised wine-product cocktails		QS			
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% of alcohol		QS	70	500	
15.1	Potato-, cereal-, flour- or starch-based snacks		QS	–	–	Not taken into account (no concentration data)
15.2	Processed nuts		QS	–	–	Not taken into account (no concentration data)
16	Desserts, excluding products covered in category 1, 3 and 4		QS	1,940	10,000	
17.1	Food supplements supplied in a solid form, including capsules and tablets and similar forms, excluding chewable forms	E 410 may not be used to produce dehydrated foods intended to rehydrate on ingestion	QS	2,250	10,000	
17.2	Food supplements supplied in a liquid form		QS			
17.3	Food supplements supplied in a syrup-type or chewable form		QS			
18	Processed foods not covered by categories 1–17, excluding foods for infants and young children		QS	3,035	3,035	

MPL: maximum permitted levels; QS: *quantum satis*.
(a): Maximum individually or in combination with E 400–404, E 406, E 407, E 410, E 412, E 415 and E 418.
(b): If more than one of the substances E 407, E 410 and E 412 is added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substances together in that foodstuff.
(c): E 410, E 412, E 414, E 415 and E 440 are authorised individually or in combination.

Appendix D – Summary of total estimated exposure of locust bean gum (E 410) from their use as food additive for the maximum level exposure scenario and the refined exposure assessment scenarios per population group and survey: mean and 95th percentile (mg/kg bw per day)

	Number of subjects	Maximum scenario		Brand-Loyal scenario		Non-Brand-Loyal scenario	
		Mean	p95	Mean	p95	Mean	p95
Infants							
Bulgaria (NUTRICHILD)	659	344.2	879.7	283.2	765.2	124.4	297.2
Germany (VELS)	159	436.7	886.4	368.9	741.3	204.3	415.4
Denmark (IAT 2006 07)	826	175.9	372.3	128.9	268.4	76.0	150.6
United Kingdom (DNSIYC 2011)	1,369	229.8	507.0	173.6	435.3	98.5	225.8
Italy (INRAN SCAI 2005 06)	12	234.3	–	203.2	–	106.6	–
Toddlers							
Belgium (Regional Flanders)	36	402.6	–	236.7	–	137.0	–
Bulgaria (NUTRICHILD)	428	336.9	613.3	231.1	434.9	110.5	197.0
Germany (VELS)	348	290.2	506.4	171.8	340.8	104.8	205.6
Denmark (IAT 2006 07)	917	255.4	421.0	170.8	278.0	102.6	163.1
Spain (enKid)	17	261.5	–	164.4	–	94.1	–
United Kingdom (NDNS-RollingProgrammeYears1-3)	185	218.5	378.4	127.4	226.0	70.8	126.5
United Kingdom (DNSIYC 2011)	1,314	242.1	459.9	151.4	314.7	88.8	180.5
Italy (INRAN SCAI 2005 06)	36	223.2	–	149.7	–	82.3	–
Netherlands (VCP kids)	322	368.4	645.4	221.9	415.4	121.6	208.8
Children							
Austria (ASNS Children)	128	222.8	410.7	139.6	264.1	77.9	128.1
Belgium (Regional Flanders)	625	325.8	544.3	187.9	346.7	106.4	189.8
Bulgaria (NUTRICHILD)	433	280.3	489.1	182.9	332.2	93.9	171.1
Czech Republic (SISP04)	389	222.3	416.8	137.2	274.7	77.6	158.6
Germany (EsKiMo)	835	189.9	323.0	114.8	203.4	70.8	127.3
Germany (VELS)	293	253.0	407.3	144.7	239.4	86.6	144.5
Denmark (DANSDA 2005-08)	298	210.5	356.5	140.5	247.7	86.9	148.0
Spain (enKid)	156	225.6	413.9	138.2	256.6	78.6	147.5
Spain (NUT INK05)	399	238.9	384.4	133.9	220.5	81.1	133.5
France (INCA2)	482	265.4	478.5	148.2	269.3	86.7	160.6
United Kingdom (NDNS-RollingProgrammeYears1-3)	651	189.0	313.8	111.3	202.8	60.3	106.9
Greece (Regional Crete)	838	196.3	321.6	122.5	223.7	59.4	102.5
Italy (INRAN SCAI 2005 06)	193	159.8	344.6	108.1	223.2	55.6	115.0
Latvia (EFSA TEST)	187	216.4	434.9	128.2	285.2	69.6	150.9
Netherlands (VCP kids)	957	322.2	554.4	188.4	343.0	104.7	175.4
Netherlands (VCPBasis AVL2007 2010)	447	260.6	435.5	149.2	262.3	86.0	152.2
Sweden (NFA)	1,473	231.9	403.4	129.5	226.5	74.4	134.9
Adolescents							
Austria (ASNS Children)	237	123.3	245.7	80.9	156.4	44.9	91.8
Belgium (Diet National 2004)	576	107.0	200.7	65.1	117.5	36.1	68.4
Cyprus (Childhealth)	303	87.5	169.2	58.1	107.3	32.5	63.3
Czech Republic (SISP04)	298	152.6	293.8	97.2	196.5	54.1	110.0
Germany (National Nutrition Survey II)	1,011	101.5	207.1	66.2	137.2	36.2	75.0
Germany (EsKiMo)	393	143.9	253.3	90.0	165.5	54.9	96.9

	Number of subjects	Maximum scenario		Brand-Loyal scenario		Non-Brand-Loyal scenario	
		Mean	p95	Mean	p95	Mean	p95
Denmark (DANSDA 2005-08)	377	108.2	207.1	74.9	140.5	45.3	86.5
Spain (AESAN FIAB)	86	92.3	168.9	58.4	113.7	32.8	63.4
Spain (enKid)	209	138.5	252.4	87.0	172.7	49.8	100.1
Spain (NUT INK05)	651	141.7	236.5	83.3	139.6	50.1	87.0
France (INCA2)	973	140.2	266.9	81.3	155.2	47.5	91.7
United Kingdom (NDNS-RollingProgrammeYears1-3)	666	102.5	192.9	62.1	117.4	32.2	61.0
Italy (INRAN SCAI 2005 06)	247	94.7	194.7	64.5	134.3	33.2	67.7
Latvia (EFSA TEST)	453	164.5	329.7	97.0	189.5	55.7	111.8
Netherlands (VCPBasis AVL2007 2010)	1,142	161.5	292.3	92.1	168.2	53.8	100.7
Sweden (NFA)	1,018	155.4	269.0	90.3	157.2	52.5	98.6
Adults							
Austria (ASNS Adults)	308	113.0	208.1	68.8	135.9	38.0	69.6
Belgium (Diet National 2004)	1,292	92.4	170.0	56.7	107.5	32.2	63.5
Czech Republic (SISP04)	1,666	87.7	166.0	60.4	115.6	33.2	64.1
Germany (National Nutrition Survey II)	10,419	91.9	175.0	57.7	111.2	32.1	61.6
Denmark (DANSDA 2005-08)	1,739	72.7	130.0	51.1	89.8	30.4	53.5
Spain (AESAN)	410	73.4	141.2	47.7	89.4	26.4	50.5
Spain (AESAN FIAB)	981	68.5	135.8	44.1	91.5	24.9	51.0
Finland (FINDIET2012)	1,295	83.4	154.6	51.4	101.0	28.5	54.4
France (INCA2)	2,276	95.1	167.9	56.0	105.0	33.6	63.3
United Kingdom (NDNS-RollingProgrammeYears1-3)	1,266	69.1	126.1	41.5	77.0	22.6	41.1
Hungary (National Repr Surv)	1,074	73.2	132.2	54.0	98.1	31.5	56.0
Ireland (NANS 2012)	1,274	77.3	133.2	48.7	85.9	28.5	50.4
Italy (INRAN SCAI 2005 06)	2,313	57.8	115.1	42.0	84.8	21.9	45.0
Latvia (EFSA TEST)	1,271	111.3	209.1	67.3	136.4	39.2	76.5
Netherlands (VCPBasis AVL2007 2010)	2,057	106.3	196.1	62.0	113.5	36.4	66.8
Romania (Dieta Pilot Adults)	1,254	51.6	100.8	35.7	74.0	20.7	41.7
Sweden (Riksmaten 2010)	1,430	97.3	170.0	54.9	101.6	32.4	56.0
The elderly							
Austria (ASNS Adults)	92	105.3	163.8	65.1	109.0	36.4	56.9
Belgium (Diet National 2004)	1,215	93.1	166.3	55.2	98.0	32.6	59.8
Germany (National Nutrition Survey II)	2,496	90.9	163.0	57.1	103.8	31.9	56.2
Denmark (DANSDA 2005-08)	286	67.8	121.3	48.9	86.0	28.5	48.5
Finland (FINDIET2012)	413	77.7	162.1	49.6	107.5	26.6	55.5
France (INCA2)	348	87.2	152.3	54.4	102.3	32.9	57.7
United Kingdom (NDNS-RollingProgrammeYears1-3)	305	68.3	116.4	40.3	74.4	22.0	38.8
Hungary (National Repr Surv)	286	65.9	114.4	49.4	83.3	28.1	47.3
Ireland (NANS 2012)	226	72.7	129.1	45.5	78.8	26.5	49.1
Italy (INRAN SCAI 2005 06)	518	54.9	108.7	42.2	86.8	22.1	45.8
Netherlands (VCPBasis AVL2007 2010)	173	101.7	176.3	58.5	100.6	33.9	54.7
Netherlands (VCP-Elderly)	739	100.9	164.7	56.8	93.4	34.8	57.8
Romania (Dieta Pilot Adults)	128	56.7	112.5	42.4	99.9	23.8	52.5
Sweden (Riksmaten 2010)	367	92.5	163.9	52.3	91.5	29.1	51.1

p95: 95th percentile; bw: body weight; – : p95 of exposure was only calculated for those population groups where the sample size was sufficiently large to allow this calculation (EFSA, 2011a).

Appendix E – Summary of total estimated exposure of locust bean gum (E 410) from their use as food additive taking into account foods for special medical purposes at the brand-loyal refined exposure assessment scenarios for infants and toddlers per survey: mean and 95th percentile (mg/kg bw per day)

	Number of subjects	Maximum scenario		Brand-Loyal scenario	
		Mean	p95	Mean	p95
Infants					
Bulgaria (NUTRICHILD)	659	619.6	1,572.2	553.4	1,554.7
Germany (VELS)	159	562.8	1,133.4	494.3	1,051.7
Denmark (IAT 2006 07)	826	230.1	533.6	178.6	434.8
United Kingdom (DNSIYC 2011)	1,369	390.4	994.8	332.1	918.3
Italy (INRAN SCAI 2005 06)	12	528.9	–	497.8	–
Toddlers					
Belgium (Regional Flanders)	36	415.8	–	245.3	–
Bulgaria (NUTRICHILD)	428	350.9	666.1	241.6	533.2
Germany (VELS)	348	312.1	603.8	191.5	418.8
Denmark (IAT 2006 07)	917	260.9	443.2	174.9	299.0
Spain (enKid)	17	261.5	–	164.4	–
United Kingdom (NDNS-RollingProgrammeYears1-3)	185	226.9	398.8	134.6	262.4
United Kingdom (DNSIYC 2011)	1,314	303.0	693.9	208.9	577.7
Italy (INRAN SCAI 2005 06)	36	237.6		161.8	
Netherlands (VCP kids)	322	375.1	658.8	226.5	418.5

p95: 95th percentile; bw: body weight; – : p95 of exposure was only calculated for those population groups where the sample size was sufficiently large to allow this calculation (EFSA, 2011a).