Thickening agents used in foods for infants below 16 weeks of age

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efsa
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THICKENING AGENTS IN FOOD FOR INFANTS < 16 WEEKS OF AGE

Category 13.1.1: Infant formulae	E 412 Guar gum E 414 Acacia gum* E 1450 Starch sodium octenyl succinate*
Category 13.1.5.1: Dietary foods for infants for special medical purposes and special formulae for infants	E 407 Carrageenan E 410 Locust bean gum E 412 Guar gum E 414 Acacia gum* E 415 Xanthan gum E 440 Pectins E 466 Sodium carboxy methyl cellulose E 1450 Starch sodium octenyl succinate

* No direct use, carry over from FA use in nutrients

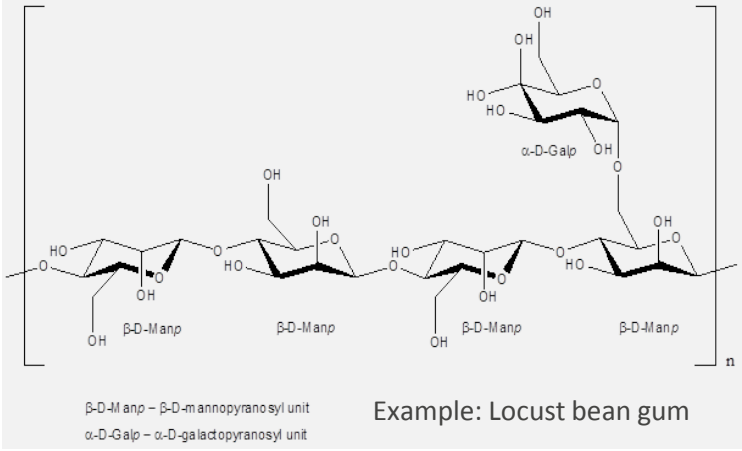
Physicochemical characteristics of thickening FA

Identity

- high molecular weight, long chain, **hydrocolloidal polysaccharides**

Relevant impurities

- **proteins** (possible source of hypersensitivity reactions)
- **microbial contamination** (due to microbial or botanical origin and polysaccharidic nature)
- **toxic elements** (Pb, Hg, As, Cd)



β-D-Manp – β-D-mannopyranosyl unit
α-D-Galp – α-D-galactopyranosyl unit

Example: Locust bean gum

Properties in water

- form **viscous dispersions** or **gels**, which may be **adhesive**
- may **rapidly swell** and **largely increase volume**
- may show **synergistic** increase in **viscosity** and **gel formation** when mixed (e.g. mixture of xanthan gum and locust bean gum)

Toxicological characteristics of thickening FA

Kinetics

- **not absorbed** intact,
- significantly **fermented by the intestinal microbiota** (exception: enzymatic hydrolysis of modified starches before fermentation; no fermentation of modified celluloses).

Dynamics

- in most **subchronic** and **chronic** rodent toxicity studies, **no adverse effects at the highest dose** tested (**caecal enlargement** observed in some studies was considered a **physiological response** to an increase in fermentation due to high intake of polysaccharides),
- **no concerns** with respect to **genotoxicity, carcinogenicity** or **reproductive and developmental toxicity,**
- in **studies in adults** after intake of large amounts of certain gums (e.g. 15 g guar gum/adult per day), some individuals experienced **abdominal discomfort**, considered by the ANS as undesirable but not adverse.
- Some **studies in infants** suggest that intake of **thickened formulae (e.g. antiregurgitation formulae)** could lead to **gastrointestinal symptoms, including diarrhoea,** in part of the exposed subjects.

Human case reports from food and medicinal uses

After oral intake of gums in the form of

- **jelly mini-cups** or
- **pills or granules** (e.g. weight reduction products containing guar gum) **without enough liquid**,

few cases of severe adverse effects, such as **asphyxiation** or **oesophageal or small bowel obstructions** have been reported. - Nowadays, these risks are accounted for by restrictions in the Regulation (EC) No. 1333/2008.

Cases of partly fatal **necrotising enterocolitis** (NEC) in newborns (mostly premature) have been associated with the use of the thickeners **xanthan gum** or **locust bean gum** (concentrations in milk/formulae not known) in the treatment of **gastro-oesophageal reflux**. - The available information does not allow conclusions on causal relationships.

Conclusions on the safety of Locust bean gum (LBG)(ANS, 2017)

(I) General population:

The Panel considered

- **the available toxicological data**
- **the highest refined exposure estimates, based on the reported data from food industry** (up to 765 mg LBG/kg bw per day for infants 12 weeks – 11 months)

On this basis the Panel concluded that there are

- **no needs for a numerical ADI**
- **no safety concerns for the reported uses as a food additive.**

Conclusions on the safety of Locust bean gum (LBG) (ANS, 2017)

(II) Infants and young children consuming FSMP and special formulae:

The Panel considered that

- they may show a **higher susceptibility** to the **GIT effects** than their healthy counterparts,
- **no adequate clinical data** addressing the safety of these uses were available,
- case reports indicated **undesirable GIT symptoms** in infants taking **food products for reduction of gastro-oesophageal reflux**,
- these products are authorised to contain LBG 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 LBG in infants and young children consuming these foods.

Technical data requirements: Locust bean gum (LBG)

(I) Uses in food for all population groups:

To enable an **adequate definition of maximum limits** in the specifications according to **recent recommendations** (ANS, 2017), information is sought on

- current **analytical data** on **toxic elements** (Pb, Hg, Cd, As) in commercial samples (and the lowest technologically achievable levels),
- current **levels of residual proteins** in clarified and unclarified LBG (and the lowest technologically achievable levels),
- the **possibility to use clarified LBG** to cover all technological needs,
- data demonstrating the **absence of *Salmonella* spp. and *Escherichia coli*** and on the **lowest** reachable **TAMC** (total aerobic microbial count) and **TYMC** (total combined yeast and mould count).

Technical data requirements: Locust bean gum (LBG)

(II) Uses in FSMP and special formulae for infants below 16 weeks:

Information is sought on

- the **usage levels** of LBG alone or in combination with other thickening food additives,
- the **fate** and the **reaction products** of LBG in the formulae,
- **particular specification requirements** for identity and purity,
- data demonstrating the **absence of *Cronobacter sakazakii*** in the food additive.

Toxicological data requirements: Locust bean gum (LBG)

Uses in FSMP for infants of all ages and young children:

With reference to the **EFSA Guidance on substances in food for infants below 16 weeks of age (SC, 2017)** and to the recommendations of the recent **EFSA Opinion on LBG** (ANS, 2017), the following information is required:

- a **repeated dose study** with **direct oral administration** of LBG **to neonatal animals** (piglets, unless justification for another species is given), which includes **gross and histopathological examination of the GIT** and data on possible influences on the **microbiota** and the **bioavailability of nutrients**,
- **clinical data** focusing on **GIT effects** to assess the safety of LBG, when used in FSMP (FC 13.1.5.1) in infants below 16 weeks of age,
- **post-marketing surveillance reports** on undesired and adverse reactions,
- **published and unpublished case reports** on undesired and adverse effects.

Thank you for your attention