

From:

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To:

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Dear Madam,

I am writing to inform you of the outcome of the request for authorisation to place a novel food ingredient, namely native guar gum, on the market, which was submitted in France in accordance with Articles 4 and 6 of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients.

On 24 July 2009, the company Danone submitted a request to the Directorate-General for Competition, Consumer Affairs and the Fight against Fraud (DGCCRF), for authorisation to place "native guar gum" on the market as a novel food ingredient. This request was transferred to the French Food Safety Agency (AFSSA) on 31 July 2009 for evaluation.

AFSSA issued its initial evaluation report (ref. 2009-SA-0214) on 11 February 2010. This concluded that native guar gum fulfils the acceptance criteria for a novel food defined in Article 3(1) of Regulation (EC) No 258/97, under certain conditions (detailed below). The report was the subject of a confidentiality request regarding certain of its elements, then was translated by AFSSA and sent by the DGCCRF to the Commission on 6 April 2010.

The Commission sent the initial evaluation report to all the European Union's Member States on 12 May 2010.

No reasoned objection regarding the placement of this product on the market has been presented by the Commission or the Member States within the sixty-day period specified in Article 6(4) of Regulation (EC) No 258/97.

On the basis of the initial evaluation report and in the absence of any objection, native guar gum may therefore be placed on the market, provided that the conditions of use

specified in the authorisation request are met and that the conclusions of the report (attached as an annex) are respected.

In addition, I would remind you that native guar gum is also a food additive (E412) and as such is subject to the following restrictions:

- It is prohibited in dehydrated foods, the rehydration of which occurs at the moment of ingestion, and in jelly mini-cups.
- Its use is restricted in jams, jellies and marmalades, children's foods and foods for infants and young children used for special medical purposes.

It should also be noted that this food ingredient and the foodstuffs which contain it must obey any other applicable laws, especially those relating to the provision of nutritional information or the setting forth of claims regarding nutrition or health.

Furthermore, given that guar gum is also a food additive, it would be appropriate to implement a system for monitoring the marketing and consumption of this novel food in order to track the global exposure of consumers to it. This could take the form of an annual report sent to France and the Commission, for example.

Finally, please find attached the observations and comments made by the Member States. I would be grateful if you would inform me how you intend to respond to them.

Yours faithfully.

Encl.:

ANNEX

Native guar gum may be placed on the market as a novel food ingredient under the following conditions:

A. The foodstuffs in which native guar gum may be used as a food ingredient and the conditions of said use are the following:

	Maximum Quantity
Fresh dairy products such as yogurts, fermented milks, fresh cheeses and other dairy-based desserts.	1.5g / 100g
Fruit or vegetable-based liquid foodstuffs (of the "smoothie" variety)	1.8g / 100g
Fruit or vegetable-based compotes	3.25g / 100g
Cereals accompanied by a dairy product, in packaging containing two compartments	10g / 100g in the cereals None in the accompanying dairy product 1g / 100g in the product when ready to eat

B. Native guar gum possesses the characteristics indicated below:

Definition: Native guar gum is the ground endosperm of seeds from natural strains of guar *Cyamopsis tetragonolobus* L. Taub. (Leguminosae family). It consists of a high molecular weight polysaccharide, primarily composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as a galactomannan (galactomannan content not less than 75%). In appearance it is a white to yellowish powder and practically odourless.

Molecular Weight: Between 50,000 and 8,000,000 Daltons

CAS Number: 9000-30-0

EINECS Number: 232-536-8

Purity Criteria: those specified for additive use (E412) as defined by Directive No 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners and by Regulation (EC) No 258/2010 imposing special conditions on the imports of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins, or by any possible subsequent instruments concerning the same subject and laying down new purity criteria.

Physico-chemical properties of guar gum in powder or flake form:

	POWDER	FLAKES
Useful life	2 years	1 year
Colour	White	White / off-white with absence or minimal presence of black spots
Odour	Light	Light
Average diameter of particles	60 to 70 µm	1 to 10 mm
Moisture	Max. 15%	Max. 15%
Viscosity at 1 hour*	/	Min. 3000 mPa.s
Viscosity at 2 hours*	Min. 3600 mPa.s	/
Viscosity at 24 hours*	Min. 4000 mPa.s	/
Solubility	Soluble in hot and cold water	Soluble in hot and cold water
pH for 10g / L, at 25°C	6 – 7.5	5 – 7.5

- C. The guar gum must respect the general labelling obligations regarding food ingredients and in particular must be mentioned on the label or in the list of ingredients of the foodstuffs containing it.
- D. A specific mention of the possible risks of digestive discomfort linked to the exposure of children aged under 8 to guar gum must be visible on the label of any foodstuffs containing it. This could, for example, be worded in the following way: "Une consommation excessive de ces produits peut entraîner un inconfort digestif, en particulier chez l'enfant de moins de 8 ans" / "Excessive consumption of these products may cause digestive discomfort, especially for children under 8 years of age."
- E. In the case of products with two compartments containing dairy and cereal products respectively, the instructions for use must clearly specify the need to mix the cereal and the dairy product before consumption, in order to take into account the potential risk of gastro-intestinal obstruction. These instructions could for instance be: "Mélanger les céréales et le produit laitier avant consommation" / "Mix the cereal with the dairy product before consumption".

* The measurements of viscosity are carried out under the following conditions: 1%, 25°C, 20 rpm