DOSSIER CONCERNING THE REQUEST TO AMEND ANNEXES V and VI concerning feed materials, additives/processing aids and certain substances used in animal nutrition of Commission Regulation (EC) No 889/2008

Articles 16.3 b of Council Regulation (EC) No 834/2007.

"Where a Member State considers that a product or substance should be added to, or withdrawn from the list referred to in paragraph 1, or that the specifications of use mentioned in subparagraph (a) should be amended, the Member State shall ensure that a dossier giving the reasons for the inclusion, withdrawal or amendments is sent officially to the Commission and to the Member States."

1. General information on the request

Nature of the request	X Inclusion ☐ Deletion ☐ Change of disposition
Request introduced by	[Member State] Contact e-mail:
Date	

Please indicate if the material provided is confidential

2. Requested inclusion/deletion/amendment

Name of additive / substance	Primary use/conditions
Locust bean gum (carob gum)	Used as a technological additive (gelling agent) in wet cat and dog recipes.

3. Status

Authorization in general agriculture or food processing

Historic use Locust bean gum is widely used in the petfood industry for its water-binding and thickening properties, as a stabiliser, to reduce syneresis, and to improve the gel properties of other hydrocolloids. In ambient stable water jellies it is normally used in combination with carrageenan or xanthan gum to give the desired texture and stability over the shelf life. 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. Locust bean gum (E 410) is authorised as a feed additive in the EU according to Regulation (EU) No 231/2012. Accordingly, it is listed in the European Union Register of Feed Additives pursuant to Regulation (EC) No 1831/2003. It is currently under reauthorisation.

Regulatory status (EU, national, others) (including expiry dates of authorisation if applicable) COMMISSION DIRECTIVE of 8 July 1985 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs (85/429/EEC) COMMISSION REGULATION (EU) No 231/2012 of 9 March 2012

4. Identification [1]

Common name Locust bean gum
Name(s) of active substance Carob gum
Other names Carob bean gum, Algaroba gum
Trade names N/A
CAS[2] No. 9000-40-2
IUPAC[3] Name Locust bean gum
E.C Additive Identification No E410
Other code(s) EINECS number 232-541-5

5. Aspects related to the relevance and priority of the request

Geographical relevance (Member States, regions, …) Relevant in all member states
Socio-economic relevance (acreage, turnover, number of stakeholders affected, …) Without authorization of Carob gum use in the EU organic Regulation, wet organic cat and dog food cannot be delivered to consumers anymore from 01/01/2021.

[1] To be filled in only when applicable

[2] Chemical Abstracts Systematic Names

[3] International Union of Pure & Applied Chemistry

Sectors affected Wet Cat and dog Organic petfood.
Stakeholder engagement/consultation in dossier preparation Submission of this dossier is the result of a joint effort from French petfood manufacturers with the support of French Trade association and endorsement of European trade association (FEDIAF).
Market presence: availability (quantity / quality) and origin (local / imported) The global volumes are 15.000 tons globally per year, coming from Europe.
Aspects of international harmonization / market distortion Carob gum is widely used in standard wet petfood as a technologic aid. Its texturizing properties help to design wet product such as chunks in jelly, chunks in gravy and mousses. The absence of carob gum from the positive list of substances approved in organic feed put organic manufacturers in a situation that will prevent them to compete on the petfood market with manufacturers that don't produce organic products.
A (possible) authorization leads to amendment(s) in the respective Annex[4]

[4] It should be carefully analysed whether the specific use of a substance is already (impicitly) authorized or not. This is to avoid the following conclusion: "The Group considers that the use of … is in line with the objectives, criteria and principles of the organic regulation. There is no need for amendment of the specific conditions of Annex …"

Yes
Other aspects justifying high priority, such as • relevance for the development of a new organic production sector, • addressing of a newly upcoming problem in production or a quarantine organism, • addressing a recent development in agricultural policies, • addressing a new trend in consumer preferences/nutritional habits or new developments in food technology, • addressing a declared goal of organic farming. Carob gum authorization in Organic is key for the development of wet petfood and Organic petfood sector. Many consumers, especially cat owners, are feeding their animal with a mix of dry and wet products. The inability for manufacturers to produce organic wet products because of a lack of authorized gelling agents would prevent consumers buying organic petfood for their animal to offer them textures variety (dry + wet). Knowing the importance of feeding wet products on the maintenance of a healthy urinary tract in felines, it is also a question of maintaining good health in cats fed with organic products. Wet organic products are already existing on the French market as gelling agents are approved in the French Organic standard. A lack of authorization at EU level will damage the current growing market of Organic petfood in France and in Europe.

6. Characterisation [5]

Chemical formula/composition of active substance 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
Concentration of active substance Galactomannan content not less than 75%
If preparation, other components N/A
Physical properties Its molecular weight is 50 000-3 000 000. It is a white to yellowish-white, nearly odourless powder. Locust bean gum consists of a (1–4)-linked β-D-mannopyranose backbone with branch points from the 6-positions linked to α-D-galactose (that is, 1-6-linked α-D-galactopyranose). Locust

[5] To be filled in only when applicable

bean gum has an average molecular weight of about 300 kDa and a mannose:galactose ratio of 4:1 c.f. 2:1 in guar. Locust bean gum has many similar properties to guar but, due to a lower level of galactose side groups, it is not as soluble in cold water and requires heating to about 80 °C to fully solubilise. It forms less viscous solutions than guar (viscosity at 1% ~ 3000 mPa.S at 25 °C compared to 5000 mPa.S for guar) but is also cloudy and freeze-thaw stable. Like guar, it is frequently used in combination with xanthan to produce elastic gels.
Origin, inputs and production method of the active substance. 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. The clarified gum is obtained by dissolution in hot water and then recovery by precipitation in ethanol or isopropanol.
Method(s) of analysis 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.

7. Specification of use

Material/additive category Technological additive
Material/additive functional group Emulsifying and stabilizing agents, thickeners and gelling agents
Species groups Cat and Dog
Minimum or maximum rate according to species group (if appropriate) None (Quantum satis)
Method of application Added as such in a pet food product

8. Reasons for the inclusion, withdrawal or amendments,

Specifiy in which Annex the inclusion , withdrawal or amendments is requested

V ☐ VI X

Explain the need for the proposed feed material or additive change Carob gum is necessary to formulate wet pet food as its gelling properties is key in the manufacturing of jellies, gravies or mousses
What alternative solutions are currently authorised or possible? Non organic gelling agents are currently not authorized in organic feed. Organic locust bean gum exist on the market but the volume available represents only 1-5% of the total global annual volumes for locust bean gum. These volumes are too small to supply the whole feed and food organic sector demands.
Is there any traditional use or precedents in organic production? In countries where a National standard exist, the use of gelling agents and thickeners is authorized (e.g. French Cahier des Charges on organic petfood). Current organic wet pet food products on the market are using additives such as Carob gum.

9. Consistency with objectives and principles of organic production

Please use the check list in Annex A to this dossier to indicate consistency with objectives and principles of organic production, as well as criteria and general rules, laid down in Council Regulation (EC) 834/2007 Title II and Title III as applicable.

10. Impact

Environment
Animal health and welfare 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 Acceptable Daily Intake 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.
Human health Used widely in human food (baked goods and baking mixes, non-alcoholic beverages and beverages bases, cheeses, gelatins, puddings, jams and jellies, gravies, frozen dairy desserts). Locust bean gum is generally regarded as an essentially noncarcinogenic, nontoxic and nonirritant material.
Food quality and authenticity Processing aid to obtain an adequate texture or cosmetic in wet products using mousse, chunks in gravy or chunks in jelly technologies. It doesn't compromise the nutritional value of the

products but offers a variety of textures that improve product appeal and adequate palatability of products to promote a sufficient food intake in order to fulfill pets nutritional needs.

Availability of wet products is key in managing feline lower urinary tract health as they help to naturally hydrate cats and dilute their urine so that the risk to form calculus in their bladder is reduced.

11. Other aspects

Various aspects, further remarks

12. Annexes

13. References

1. EFSA Scientific Opinion - Re-evaluation of locust bean gum (E 410) as a food additive. 10.2903/j.efsa.2017.4646
2. FAO 2016 CAROB BEAN GUM Chemical and Technical Assessment (CTA). Y. Kawamura, J. Smith, M. Rao, - 82nd JECFA
3. Cahier des Charges "Aliments pour animaux de compagnie" à base de matières premières issues du mode de production biologique » - JORF 25/02/04

Annex A

CHECKLIST FOR CONSISTENCY

with objectives and principles of organic production with reference to specific articles in the organic regulations

Criterion	**Specific articles in Reg. 834/2007**	**Yes/No/ Not applicable**	**Brief qualification**
Exclude the use of GMOs and products produced from or by GMOs	Art. 9 Art. 4(a)(iii)	Yes	
Is it a synthetic amino acid ?	Art. 14 (1) (d) (v)	No	
Is it a growth promoter?	Art. 14 (1) (d) (v)	No	
Aim at producing a wide variety of foods and other agricultural products……goods produced by the uses of processes that do not harm the environment, human health, plant health or animal health and welfare.	Art 3 (c)	Yes	
Aim at producing products of high quality	Art. 3(b)	Yes	Wet petfood

Is it natural (not chemically synthesised)?	Art. 4(b) and (c) Art. 16(2)(e) (ii)	No	
Their use is necessary for sustained production and essential for its intended use, and general and specific criteria has been evaluated	Art. 16(2)(a)(e)	Yes	Essential to produce wet product textures
Does it have nutritional value?	Art 14(1)(d)(ii)	No	
Is it a natural milk replacer?	Art. 14 (1) (d) (vi)	No	
Is it of agricultural origin?	Art. 5 (k) Art. 14 (1) (d) (iv)	Yes	
Is it produced organically?	Art. 14 (1) (d) (i) and (iv)	Can be	
Is it land-based/using natural internal resources?	Art. 4 (a) and (b) Art. 5 (g)	Yes	
Is it aquaculture which complies with the principle of sustainable fisheries/using natural internal resources?	Art. 5 (o) Art. 4 (a) (b) and Art. 5 (g)	No	
The recycling of wastes and by-products of plant and animal origin as input in plant and livestock production	Art. 5 (c)	N/A	
Is it produced internally (primarily from the holding where animals are kept or from other holding in the same region?	Art. 14(1) (d) (i)	N/A	
Does it affect the permanent access to pasture ?	Art. 14 (1) (d) (iii)	N/A	
Does it restrict the use of additives and processing aids?	Art. 7 (b)	No	
Is it species appropriate?	Art. 16.2(e)(i)	N/A	
Does it have negative environmental impacts?	Art. 3 (a) (i) and Art. 4 (c) (iii)		
Does it have negative animal health/welfare impacts?	Art. 5 (h) and art. 14 (e) (i)	No	
Does it have negative human health impacts?	Art. 3 (b) and (c)	No	
Does it involve 'misleading' substances/processes?	Art. 7 (c) and Art. 18 (4)	No	
Products and substances to be withdrawn or their use amended/ limited	Art .21 (2)	N/A	
Others: please specify		N/A	