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"Where a Member State considers that a product or substance should be added to, or withdrawn from the list referred to in paragraph 1, or that the specifications of use mentioned in subparagraph (a) should be amended, the Member State shall ensure that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
Carrageenan *Carraghénane*	Used as a Technical additive. This additive has 2 roles. The first was to modify the viscosity and improve the stability of the emulsions. The second role was to obtain a gel after cooking.

3. Status

Authorization in general agriculture or food processing

Historic use

Carrageenan is a family of polysaccharides that are obtained by extraction from some species of red algae.

Archaeologists estimate humans have been harvesting seaweed, like *Chondrus crispus*, for nearly 14,000 years. Evidence of red seaweed's medicinal benefits in China can be traced back to 600 BC, and it was originally used as a food source around 400 BC on the British Isles.

Stanford (1862) coined the name "carrageenin" for the gelatinous material extracted by water from Chondrus crispus. The present spelling, "carrageenan", has become accepted within the past 25 years, this being consonant with the use of the - an suffix for the names of polysaccharides. (FMC Corporation, Marine Colloids Division)

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) in OJ L 245, 12.09.1985, p. 10

4. Identification [1]

Common name Carrageenan
Name(s) of active substance Carrageenan
Other names N/A
Trade names N/A
CAS[2] No. 9000-07-1 11114-20-8 (κ) 9064-57-7 (λ) 9062-07-1 (ι)
IUPAC[3] Name Sulfate esters of polygalactose
E.C Additive Identification No E407, E407a
Other code(s) EINECS Number: 234-524-2 234-350-2(κ) 232-953-5(λ) 232-949-3(ι)

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 Carrageenan use in the EU organic Regulation, complete organic cat or dog food cannot be delivered to consumers anymore from 01/01/2021. Currently National standards authorize its use based on its technological essentiality.
Sectors affected

[1] To be filled in only when applicable

[2] Chemical Abstracts Systematic Names

[3] International Union of Pure & Applied Chemistry

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) According to FAO statistics, world carrageenan seaweed farming production increased from less than 1 million wet tonnes in 2000 to 5.6 million wet tonnes in 2010. Global available volumes are around 60.000 tons. Major carrageenan seaweed farming countries include Indonesia, the Philippines, the United Republic of Tanzania, Malaysia and China.
Aspects of international harmonization / market distortion Carrageenan is widely used in standard wet petfood to process. Its absence from the positive list of substances approved in organic feed will put organic manufacturers in a situation where they won't be able to produce wet organic products anymore.
A (possible) authorization leads to amendment(s) in the respective Annex[4] 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. Carrageenans 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

[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 …"

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
Concentration of active substance 100%
If preparation, other components Not applicable
Physical properties Yellowish or tan to white, coarse to fine powder that is practically odourless. Insoluble in ethanol; soluble in water at a temperature of about 80°C , forming a viscous clear or slightly opalescent solution that flows readily; disperses in water more readily if first moistened with alcohol, glycerol, or a saturated solution of glucose or sucrose in water.
Origin, inputs and production method of the active substance There are two different methods of producing carrageenan, based on different principles. In the original method - the only one used until the late 1970s-early 1980s - the carrageenan is extracted from the seaweed into an aqueous solution, the seaweed residue is removed by filtration and then the carrageenan is recovered from the solution, eventually as a dry solid containing little else than carrageenan. This recovery process is difficult and expensive relative to the costs of the second method. In the second method, the carrageenan is never actually extracted from the seaweed. Rather the principle is to wash everything out of the seaweed that will dissolve in alkali and water, leaving the carrageenan and other insoluble matter behind. This insoluble residue, consisting largely of carrageenan and cellulose, is then dried and sold as semi-refined carrageenan (SRC). Because the carrageenan does not need to be recovered from solution, the process is much shorter and cheaper. (FAO JECFA Monograph 16)
Method(s) of analysis Methods of analysis for identification, composition and purity are described by JECFA, (published in FNP Add 9 (2001)), the European Pharmacology.

[5] To be filled in only when applicable

7. Specification of use

Material/additive category Technological feed additives
Material/additive functional group Emulsifying and stabilizing agents, thickeners and gelling agents
Species groups Carrageenan [Pets and other non food producing animals (non-food fur animals)]
Minimum or maximum rate according to species group (if appropriate) Not applicable
Method of application

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 Carrageenans are used to gel, thicken, or suspend; therefore they are used in emulsion stabilization, for syneresis control, and for bodying, binding and dispersion.
What alternative solutions are currently authorised or possible? In wet petfood, Carrageenan is unique in its ability at very low concentration.
Is there any traditional use or precedents in organic production? In countries where a National standard exist, Carrageenan was authorized (e.g. French Cahier des Charges on organic petfood).

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 study in petfood
Human health The use of this additive in animal feed under the recommended conditions of use is not expected to present a risk for users and for consumers of food of animal origin.

Food quality and authenticity Carrageenan is not expected to affect food quality and authenticity.

11. Other aspects

Various aspects, further remarks Not applicable

12. Annexes

13. References

1. Re-evaluation of carrageenan (E 407) and processed Eucheuma seaweed (E407a) as a food additive EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). ADOPTED: 18 March 2018
2. FAO Fisheries and aquaculture technical paper. Social and economic dimensions of carrageenan seaweed farming. ISSN 2070-7010
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	No genetic modification has been used on the production strains.
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	Art. 3(b)	Yes	

quality			
Is it natural (not chemically synthesised)?	Art. 4(b) and (c) Art. 16(2)(e) (ii)	Yes	
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	
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)	No	
Is it produced organically?	Art. 14 (1) (d) (i) and (iv)	No	
Is it land-based/using natural internal resources?	Art. 4 (a) and (b) Art. 5 (g)	No	
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)	Yes	
The recycling of wastes and by-products of plant and animal origin as input in plant and livestock production	Art. 5 (c)		
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)	No	
Does it affect the permanent access to pasture ?	Art. 14 (1) (d) (iii)	No	
Does it restrict the use of additives and processing aids?	Art. 7 (b)	No	
Is it species appropriate?	Art. 16.2(e)(i)	No	
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)		
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	