

**Formal Recommendation by the
National Organic Standards Board (NOSB)
to the National Organic Program (NOP)**

Date: May 25, 2012

Subject: Carrageenan: Listing at § 205.605(a) for Sunset 2013

Chair: Barry Flamm

The NOSB hereby recommends to the NOP the following:

Rulemaking Action X
Guidance Statement
Other —

Statement of the Recommendation

The Board recommends the relisting of carrageenan on the National List under section 205.605(a) Nonagricultural (non-organic) substances allowed, as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" with the following annotations:

1. Only carrageenan with the following CAS numbers are permitted for use as a food processing ingredient (additive): 9000-07-1 (general), 9062-07-1 (iota), 11114-20-8 (kappa), and 9064-57-7 (lambda).
2. Carrageenan will not be allowed for use in infant formulas. Its use in foods for older infants (older than six months) and weaning foods for young children will be allowed.

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

It has been demonstrated that there is a continued need for carrageenan to be used in handling. There is still no organic substitute for some uses available at this time. While there have been concerns raised in some studies regarding adverse health effects caused by the use of carrageenan, most scientific reports tend to support the idea that the CAS numbers listed are for use as food ingredients and have been approved as such by the FDA. Carrageenan listed under other CAS numbers is not recommended for use in food production, as ingredients or otherwise.

The second annotation, regarding infants, is based on concerns that have been raised by the EU Scientific Committee on Food (SCF). Specifically the use of carrageenan in infant formulas for newborns. The SCF's concern is based on facts from the Pediatric Nutrition Handbook, which explains that in new born infants the neonatal intestine is uniquely capable of absorbing macromolecules via endocytosis. This is the basis for the recommendation by pediatricians to not feed infants solid foods until they are four to six months old, which also helps prevent food allergies. The SCF had no objections for its use for older infants or in weaning foods for young children. The Subcommittee feels that the addition of these two annotations to the recommendation addresses the concerns.

Committee Vote:

Moved: Harold Austin

Second: Jean Richardson

Yes: 10

No: 5

Abstain: 0

Absent: 0

Recusal: 0

Committee Backup Vote:

Moved: Harold Austin

Seconded: Zea Sonnabend

Yes: 11

No: 4

Abstain: 0

Absent: 0

Recusal: 0

**National Organic Standards Board
Handling Committee
Sunset 2013 Proposed Recommendation
Carrageenan on 205.605(a)
May 22, 2012**

List: 205.605 Nonagricultural (non-organic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group (s)).”

(a) Non-synthetics allowed

Subcommittee Summary:

The Federal register notice of the sunset of this material elicited several public comments both in favor and against its re-listing.

Review of the Technical Evaluation Report of October 3, 2011 showed that while new uses are being explored for Carrageenan in the food industry as protective coatings, the food uses of it have not changed substantially since the original TAP review was conducted in 1995.

Carrageenan is used as a food additive in the production of many processed foods. It can be used to help bind water, as a thickening agent, emulsifier, gelling agent, glazing agent, as a bulking agent, binder, etc.

The FDA states that Carrageenan may be safely used as a food additive for human consumption as long as its use is in accordance with 21 CFR 172.620. The regulation specifies that carrageenan should be prepared by aqueous extraction from any of the following eight species of Rhodophyceae seaweeds: *Chondrus crispus*, *Chondrus ocellatus*, *Eucheuma ocellatus*, *Eucheuma cottonii*, *Gigartina acicularis*, *Gigartina pistillata*, *Gigartina radula*, and *Gigartina stellata*. The following CAS numbers list the types of Carrageenan considered as, food safe: 9000-07-1 (general), 9062-07-1 (iota), 11114-20-8 (kappa), and 9064-57-7 (lambda).

While Carrageenan is a naturally occurring polysaccharide extracted from seaweed and considered non-synthetic, the extraction process used may in some instances alter it. There are differing points of view as to whether or not the extraction process actually changes the physical nature of the material to the point where it should be considered a synthetic or not.

During public comment there were several concerns raised regarding the possible health risks from the use of Carrageenan. We feel that those risks can be addressed by allowing only Carrageenan with one of the four CAS numbers mentioned above to be recommended for use as a food processing ingredient or additive.

Further concerns were raised about its potential risk to new born infants. The recommendation by the EU Scientific Committee on Food (SCF) suffices to cover this area of concern. The SCF's concern with Carrageenan and new born infants is based on facts from the Pediatric Nutrition Handbook that explains that in new born infants the neonatal intestine is uniquely capable of absorbing macromolecules via endocytosis. For this reason it is recommended by pediatricians to not feed infants solid foods until they are four to six months old, which helps prevent food allergies (as printed in the Pediatric Nutrition Handbook). The use of carrageenan in foods for older infants or weaning foods for young children does not appear to pose a concern, therefore uses in foods for older infants and young children should be ok.

The Handling Committee feels that that we have addressed the concerns that have been raised by adding annotations to the recommendation.

Based on public comment, carrageenan continues to be an important material used by the organic community and its stakeholders.

Recommendation:

At this time we would recommend the relisting of Carrageenan on the National List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group (s)).

We recommend relisting under 605 (a)

(a) Non-synthetics allowed

We would also include the following two annotations:

Annotations:

The first annotation: only carrageenan that is in one of the following four CAS Numbers will be allowed for use as a food additive – 9000-07-1 (general), 9062-07-1 (iota), 11114-20-8 (kappa), and 9064-57-7 (lambda). All other CAS numbers would not be recommended for use in food production, as an ingredient or otherwise.

The second annotation: carrageenan would not be allowed for use in infant formulas.

We also recommend that this listing be revisited once the NOP has finalized the Draft Guidance submitted by the NOSB on November 5, 2009. Re-evaluation of materials classification (agricultural, non-agricultural)(synthetic, non-synthetic) should be considered to ensure that the listed material has been properly classified and thus remove any further confusion from their status thus helping during future reviews.

Committee Vote:

6-Yes 0-No 0-Absent 0-Recused