

**Sunset 2018 Review Summary**  
**NOSB Final Review**  
**Handling Substances §205.605(a), §205.605(b), §205.606**  
**November 2016**

As part of the National List Sunset Review process, the NOSB Handling Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic handling.

**Reference: 7 CFR 205.605(a)** Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

[Agar-agar](#)

[Animal enzymes](#)

[Calcium sulfate-mined](#)

[Carrageenan](#)

[Glucono delta-lactone](#)

[Tartaric acid](#)

**Reference: 7 CFR 205.605(b)** Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

[Cellulose](#)

[Potassium hydroxide](#)

[Silicon dioxide](#)

**Reference: 7 CFR §205.606** Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

(d) Colors derived from agricultural products - Must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(2) [Beta-carotene extract color](#)

## Agar-agar

**Reference:** §205.605(a)

**Technical Report:** [1995 TAP](#); [2011 TR](#)

**Petition(s):** NA

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

**Recent Regulatory Background:** National List amended 10/31/2003 ([68 FR 61987](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

**Sunset Date:** 11/03/2018

### [Subcommittee Review](#)

#### NOSB Review

There was strong public support for the continued use of agar agar. No new information was brought forward to show viable alternatives to use of agar agar or negative impacts on human health. The TR indicated limited evidence of effects on biodiversity; All marine materials on the National List, including agar agar, are currently being reviewed as a group by the Handling Subcommittee. Included in the review is the consideration of sustainable harvesting.

#### Vote

Motion to remove agar-agar from §205.605(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Lisa de Lima

Seconded by: Ashely Swaffar

Yes: 0 No: 14 Abstain: 0 Absent: 1 Recuse: 0

**Outcome:** Motion failed. NOSB completed its sunset review.

## Animal enzymes

**Reference:** §205.605(a) Animal enzymes - (Rennet - animals derived; Catalase - bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin).

**Technical Report:** [2000 TAP](#), [2011 TR](#), [2015 TR](#)

**Petition(s):** NA

**Past NOSB Actions:** [11/2000 meeting minutes and vote](#); [11/2007 recommendation](#); [12/2011 recommendation](#)

**Recent Regulatory Background:** National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

**Sunset Date:** 11/03/2018

### [Subcommittee Review](#)

#### NOSB Review

There was strong public support for the continued use of animal enzymes. Some commenters encouraged the industry to look for organic enzymes, which are not currently available to organic producers and handlers. Based on the Subcommittee review and public comment, the NOSB finds animal enzymes compliant with OFPA criteria.

#### **Vote**

Motion to remove animal enzymes - (Rennet - animals derived; Catalase - bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin) from §205.605(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Lisa de Lima

Seconded by: Ashley Swaffar

Yes: 0 No: 14 Abstain: 0 Absent: 1 Recuse: 0

**Outcome:** Motion failed. NOSB completed its sunset review.

## Calcium sulfate-mined

**Reference:** §205.605(a)

**Technical Report:** [1996 TAP](#), [2001 TAP](#)

**Petition(s):** [2000](#)

**Past NOSB Actions:** [09/1996 meeting minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

**Recent Regulatory Background:** National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

**Sunset Date:** 11/03/2018

#### **[Subcommittee Review](#)**

#### **NOSB Review**

There was strong public support for continued use of calcium sulfate-mined. Based on the Subcommittee review and public comment, the NOSB finds calcium sulfate-mined compliant with OFPA criteria, and does not recommend removal from the National List.

#### **Vote**

Motion to remove calcium sulfate-mined, from §205.605(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Tom Chapman

Seconded by: Ashley Swaffar

Yes: 0 No: 14 Abstain: 0 Absent: 1 Recuse: 0

**Outcome:** Motion failed. NOSB completed its sunset review.

## Carrageenan

**Reference:** §205.605(a)

**Technical Report:** [1995 TAP](#), [2011 TR](#); [2016 Limited Scope TR](#)

**Petition(s):** NA

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

**Recent Regulatory Background:** National List amended 10/31/2003 ([68 FR 61987 –misspelled as ‘carageenan’](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

**Sunset Date:** 11/03/2018

### [Subcommittee Review](#)

#### **NOSB Review**

Because there was intense scrutiny about carrageenan, each OFPA criteria was reviewed carefully and all public comment was acknowledged. Here are the results of that evaluation:

OFPA criteria at 7 CFR 6518(m)

- (1) The potential of such substances for detrimental chemical interactions with other materials used in organic farming systems; not applicable.
- (2) The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment; no concerns were found about the substance and its breakdown in the environment.
- (3) The probability of environmental contamination during manufacture, use, misuse, or disposal of such substance; there may be negative impacts on the environment from harvesting wild seaweed. Indications are that most of this species of seaweed is now farmed, and some farming methods are more sustainable and ecologically sound than others. It appears that it might be possible for the seaweed to be farmed organically, and this might improve the environmental footprint. Additionally, there are several ways to manufacture the carrageenan from seaweed. Some of these would result in a non-synthetic version, while at least one method might be considered a synthetic extraction.
- (4) The effect of the substance on human health; The research indicating that there may be negative health effects on all humans in terms of inflammation, glucose intolerance, or tumors does not seem to be replicated in the large body of scientific literature. There are many anecdotal reports of sensitivity to carrageenan in foods from individuals in public comments. These concerns have not been studied in the literature, however they are acknowledged. This was not seen as a primary reason to remove carrageenan since it is listed on the labels as a food ingredient.
- (5) The effects of the substance on biological and chemical interactions in the agroecosystem; No concerns noted except as above in (3).
- (6) The alternatives to using the substance in terms of practices or other available materials; an extensive list was prepared of all the food product categories in which carrageenan is used. In most of the product types there are versions that are currently being sold that do not contain carrageenan. These often contain other types of gums such as gellan, guar, or xanthan. Products for vegetarians where carrageenan is used in place of gelatin will be the most difficult to produce without it, but the majority of NOSB members were not concerned about this class of products being impacted.
- (7) Its compatibility with a system of sustainable agriculture; A majority of NOSB members believed that this ingredient is not compatible with sustainable agriculture because it is so controversial

and they wanted to invoke the Precautionary Principle. Also invoked were the NOSB Guidance on Compatibility from the Appendix of the NOSB Policy and Procedures Manual that poses this factor (out of 12) for consideration, “Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products”?

#### **Vote**

Motion to remove carrageenan from §205.605(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: OFPA 6518(m)(6) - availability of alternatives.

Motion by: Zea Sonnabend

Seconded by: Ashley Swaffar

Yes: 10 No: 3 Abstain: 1 Absent: 1 Recuse: 0

**Outcome:** Motion passed. The NOSB recommends removal of carrageenan from the National List.

## **Glucono delta-lactone**

**Reference:** §205.605(a) Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited.

**Technical Report:** [2002 TAP](#); [2016 TR](#)

**Petition(s):** [2002](#)

**Past NOSB Actions:** [09/2002 meeting minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

**Recent Regulatory Background:** National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

**Sunset Date:** 11/03/2018

#### **[Subcommittee Review](#)**

#### **NOSB Review**

Based on the Subcommittee review and strong support from public comment, the NOSB finds glucono delta-lactone compliant with OFPA criteria, and does not recommend removal from the National List.

#### **Vote**

Motion to remove glucono delta-lactone from §205.605(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Tom Chapman

Seconded by: Ashley Swaffar

Yes: 0 No: 13 Abstain: 1 Absent: 1 Recuse: 0

**Outcome:** Motion failed. NOSB completed its sunset review

## Tartaric acid

**Reference:** §205.605(a) Tartaric acid - made from grape wine.

**Technical Report:** [2011 TR](#)

**Petition(s):** [2011 Petition to remove from 205.605\(b\) - made from malic acid](#)

**Past NOSB Actions:** [NOSB meeting review 11/1995](#); [11/2005 recommendation](#); [12/2011 recommendation](#)

**Recent Regulatory Background:** National List amended 10/31/2003 ([68 FR 61987](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

**Sunset Date:** 11/03/2018

### [Subcommittee Review](#)

#### **NOSB Review**

There was strong public support for the continued use of tartaric acid. Based on the Subcommittee review and public comment, the NOSB finds Tartaric Acid compliant with OFPA criteria, and does not recommend removal from the National List

#### **Vote**

Motion to remove tartaric acid - made from grape wine, from §205.605(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None

Motion by: Ashley Swaffar

Seconded by: Zea Sonnabend

Yes: 0 No: 14 Abstain: 0 Absent: 1 Recuse: 0

**Outcome:** Motion failed. NOSB completed its sunset review. The NOSB finds tartaric acid to still be compliant with OFPA criteria and does not recommend removal from the National List.

## Cellulose

**Reference:** §205.605(b) Cellulose - for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.

**Technical Report:** [2016 TR](#)

**Petition(s):** [2001](#)

**Past NOSB Actions:** [10/2001 meeting minutes and vote](#); [11/2007 recommendation](#); [05/2012 recommendation](#)

**Recent Regulatory Background:** National List amended 11/03/2003 ([68 FR 62215](#)); Sunset renewal notice effective 11/03/13 ([78 FR 61154](#))

**Sunset Date:** 11/03/2018

### [Subcommittee Review](#)

## **NOSB Review**

Review of previous documents including the original recommendation, prior committee discussions, as well as information provided by the new Technical Evaluation Report (2/11/2016), public comments from both the spring and fall NOSB meetings via oral testimony (webinar and in-person) and written submitted comments, assisted the committee in this sunset review process. Comments submitted helped to provide the full Board with a detailed rationale as to why this material is still essential to organic handlers, even though some have found alternative processes to work for their specific needs. There was no information presented that made this committee feel this material should not be re-listed. This material is compliant with the organic principles of compatibility, and essentiality criteria under §205.600.

During the comment period, commenters, identified additional ancillary substances for cellulose, therefore, the NOSB Handling Subcommittee will develop a follow-up proposal to include the ancillaries.

## **Vote**

Motion to remove cellulose from §205.605(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None.

Motion by: Harold V. Austin IV

Seconded by: Lisa De Lima

Yes: 2 No: 11 Abstain: 0 Absent: 1 Recuse: 0

**Outcome:** Motion failed. NOSB completed its sunset review.

## **Potassium hydroxide**

**Reference:** §205.605(b) Potassium hydroxide - prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.

**Technical Report:** [2001 TAP](#); [2016 TR](#)

**Petition(s):** [2001 petition](#), [2011 petition to amend annotation](#)

**Past NOSB Actions:** [10/1995 meeting minutes and vote](#); [11/2005 recommendation](#); [12/2011 recommendation](#)

**Recent Regulatory Background:** Added to the National list 12/21/2000 ([65 FR 80548](#)); National List amended 11/03/2003 ([68 FR 62215](#)); National List amended 05/28/2013 ([78 FR 31815](#))

**Sunset Date:** 5/29/2018

## **[Subcommittee Review](#)**

### **NOSB Review**

There was strong public support for the continued use of potassium hydroxide. Based on the Subcommittee review and public comment, the NOSB finds potassium hydroxide compliant with OFPA criteria, and does not recommend removal from the National List.

### **Vote**

Motion to remove potassium hydroxide from §205.605(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: None

Motion by: Ashley Swaffar  
Seconded by: Scott Rice  
Yes: 0 No: 14 Abstain: 0 Absent: 1 Recuse: 0

**Outcome:** Motion failed. NOSB completed its sunset review

## Silicon dioxide

**Reference:** §205.605(b) Silicon dioxide - Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.

**Technical Report:** [1996 TAP](#), [2010 TR](#)

**Petition(s):** [2010 petition to remove](#)

**Past NOSB Actions:** [09/1996 minutes and vote](#); [11/2005 recommendation](#); [12/2011 recommendation](#)

**Recent Regulatory Background:** Added to NL 12/21/2000 ([65 FR 80548](#)); National list amended 05/28/2013 (effective 11/03/2013) ([78 FR 31815](#))

**Sunset Date:** 11/03/2018

### [Subcommittee Review](#)

#### **NOSB Review**

Based on the Subcommittee review and strong support from public comment, the NOSB finds silicon dioxide compliant with OFPA criteria, and does not recommend removal from the National List.

#### **Vote**

Motion to remove silicon dioxide from §205.605(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: none

Motion by: Lisa de Lima  
Seconded by: Tom Chapman  
Yes: 0 No: 14 Abstain: 0 Absent: 1 Recuse: 0

**Outcome:** Motion failed. NOSB completed its sunset review

## Colors: Beta-carotene extract

**Reference:** §205.606(d) Colors derived from agricultural products - Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(2) Beta-carotene extract color - derived from carrots or algae (pigment CAS# 7235-40-7).

**Technical Report:** [2011 TR](#)

**Petition(s):** [2007](#), [2009](#)

**Past NOSB Actions:** [04/2007 recommendation](#), [12/2011 recommendation](#)

**Recent Regulatory Background:** National List amended 06/27/2007 ([72 FR 35137](#)); National List amended 05/28/2013 ([78 FR 31815](#))

**Sunset Date:** 5/29/2018

## Subcommittee Review

### **NOSB Review**

Public comment regarding beta-carotene extract color was mixed. Producers were in support of keeping beta-carotene on the National List, some certifiers indicated that the material is not widely used, and consumer groups consider this color non-essential (205.600(b)(6)), and not compatible with sustainable agriculture.

### **Vote**

Motion to remove beta-carotene extract color - derived from carrots or algae (pigment CAS# 7235-40-7) from §205.606(d) based on the following criteria in the Organic Foods Production Act (OFPA) 6518 (m) (7) and 7 CFR 205.600(b) (1) and (4) and (7).

Motion by: Jean Richardson

Seconded by: Ashley Swaffar

Yes: 6 No: 8 Abstain: 0 Absent: 1 Recuse: 0

**Outcome:** Motion failed. NOSB completed its sunset review