



Sunset 2017 Review Summary Meeting 1 - Request for Public Comment Handling Substances §205.605(a) April 2015

Introduction

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2017. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the fall 2015 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the spring 2015 public meeting. These comments should be provided through www.regulations.gov by April 7, 2015 as explained in the meeting notice published in the [Federal Register](#).

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

Guidance on Submitting Your Comments

Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

For Comments That Support Substances Under Review:

If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

- (1) not harmful to human health or the environment;
- (2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
- (3) consistent with organic crop production.

For Comments That Do Not Support Substances Under Review:

If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

- (1) harmful to human health or the environment;
- (2) unnecessary because of the availability of alternatives; and
- (3) inconsistent with crop production.

For Comments Addressing the Availability of Alternatives:

Comments may present information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review. The following table can help you describe recommended alternatives in place of a current substance that you do not want to be continued.

For Comments on Nonorganic Agricultural Substances at Section 205.606.

For nonorganic agricultural substances on section 205.606, the NOSB Handling Subcommittee requests current industry information regarding availability of and history of unavailability of an organic form of the substance in the appropriate form, quality, or quantity of the substance. The NOSB Handling Subcommittee would like to know if there is a change in supply of organic forms of the substance or demand for the substance (i.e. is an allowance for the nonorganic form still needed), as well as any new information about alternative substances that the NOSB did not previously consider.

Written public comments will be accepted through April 7, 2015 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.



**Sunset 2017 Review Summary
Meeting 1 - Request for Public Comment
Handling Substances §205.605(a)
April 2015**

Reference: 7 CFR 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)).”

§205.605(a) Nonsynthetics allowed:

[Acid, Alginic](#)

[Acid, Citric](#)

[Acid, Lactic](#)

[Attapulgite](#)

[Bentonite](#)

[Calcium carbonate](#)

[Calcium chloride](#)

[Dairy cultures](#)

[Diatomaceous earth](#)

[Enzymes](#)

[Flavors](#)

[Kaolin](#)

[Magnesium sulfate](#)

[Nitrogen](#)

[Oxygen](#)

[Perlite](#)

[Potassium chloride](#)

[Potassium iodide](#)

[Sodium bicarbonate](#)

[Sodium carbonate](#)

[Waxes \(Carnauba\)](#)

[Waxes \(Wood rosin\)](#)

[Yeast](#)



Acid, Alginic

Reference: 205.605(a) Acids (Alginic; Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).

Technical Report: [02/2015 TR](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

1. Please bring forth any information regarding the effect of Alginic Acid and/or Alginates on human digestion.
2. Is Alginic acid in use in organic handling and should it have its own National List listing? What are the non-synthetic alternatives in specific handling uses?

Acid, Citric

Reference: 205.605(a) Acids (Alginic; Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).

Technical Report: [1995 TAP](#); [2015 TR](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

NONE

Acid, Lactic

Reference: 205.605(a) Acids (Alginic; Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).

Technical Report: [1995 TAP](#); [2015 TR](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)



Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

NONE

Attapulgit

Reference: 205.605(a) – as a processing aid in the handling of plant and animal oils.

Technical Report: [2010 TR](#)

Petition(s): [2009 Attapulgit](#)

Past NOSB Actions: [04/2011 NOSB recommendation](#)

Recent Regulatory Background: Added to National List effective 08/03/2012 [[77 FR 45903](#)]

Sunset Date: 08/03/17

Additional information requested by NOSB

NONE

Bentonite

Reference: 205.605(a)

Technical Report: [1995 Kaolin Clay and Bentonite](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)),

Sunset Date: 06/27/17

Additional information requested by NOSB

Are Bentonite and Kaolin essential in organic processing?

Calcium carbonate

Reference: 205.605(a)

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)



Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))
Sunset Date: 06/27/17

Additional information requested by NOSB
NONE

Calcium chloride

Reference: 205.605(a)
Technical Report: [1995 TAP](#)
Petition(s): N/A
Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)
Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))
Sunset Date: 10/21/17

Additional information requested by NOSB
NONE

Dairy cultures

Reference: 205.605(a)
Technical Report: [1995 TAP](#); 2015 TR for Ancillary Substances in development
Petition(s): N/A
Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)
Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))
Sunset Date: 10/21/17

Additional information requested by NOSB

The NOSB is considering removing dairy cultures from the national list since the broader listing of microorganisms may cover all currently allowed dairy cultures:

1. Is a separate listing for dairy cultures necessary or is the microorganisms listing sufficient to cover all materials used under the current dairy culture listing?
2. The following ancillary substances have been identified in dairy cultures:

Ancillary substances in dairy cultures by functional class:

Functional class	Substance name
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Anti-caking & anti-stick agents	magnesium stearate, calcium silicate, silicon dioxide
Carriers and fillers, agricultural or nonsynthetic	Lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, flour, milk, autolyzed yeast, inulin, cornstarch, sucrose.
Carriers and fillers, synthetic	Micro-crystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate.
Preservatives	sodium benzoate, potassium sorbate, ascorbic acid
Stabilizers	Maltodextrin
Cytoprotectants used to freeze-dry dairy cultures	liquid nitrogen, maltodextrin, magnesium sulfate, dimethyl sulfoxide, sodium aspartate, mannitol, sorbitol
Substrate that may remain in final product	milk, lactose

3. More information is sought about other ancillary substances that may be in use and not listed, ancillary substances that are listed here but are not in use in formulations approved for organic, and other functional classes of ancillary substances that are not in this chart.
4. Information is sought on specifically why any of the ancillary substances in dairy cultures do not meet the review criteria in the organic rule.

Diatomaceous earth

Reference: 205.605(a) - food filtering aid only

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

NONE



Enzymes

Reference: 205.605(a) - must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.

Technical Report: [1995 TAP](#); [1996 TAP](#); [2011 TR](#); 2015 TR for Ancillary Substances in development

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [04/2011 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

1. Below is a chart of ancillary substances that may be used in enzyme preparations. Please submit spec sheets or names of any ancillary substances that are not listed on the chart.

Ancillary Substances by Food Additive Functional Class¹	
Anti-caking & anti-stick agents	Magnesium stearate, calcium silicate, silicon dioxide
Carriers and fillers, agricultural or nonsynthetic	Lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, rice protein, grain (rice, wheat, corn, barley) flour, milk, autolyzed yeast, inulin, cornstarch, sucrose, glycerol, potassium chloride, ammonium sulfate
Carriers and fillers, synthetic	Micro-crystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate.
Preservatives	sodium benzoate, potassium sorbate, ascorbic acid
Stabilizers	maltodextrin

¹ this list does not include ancillary substances that are already on the National List. From the Technical Report and spec sheets

Flavors

Reference: 205.605(a), nonsynthetic sources only and must not be produced using synthetic solvents



and carrier systems or any artificial preservative.

Technical Report: [2005 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [04/2006 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

1. Supply: Organic flavors of various types are available in the marketplace (extracts, essential oils, compounded natural flavors, essences, distillates, etc.). Is the supply of some specific organic flavors sufficient to warrant the sunset of some specific natural (non-organic) flavors on 205.605 of the National List? If so which ones?
2. Commercial Availability: Given the availability of some organic flavors, do you think that commercial availability should apply to the use of natural flavors in organic products (i.e. use organic when commercially available in quantity, quality and form)?
3. Would it be appropriate to retain all natural flavors on the National List if organic flavors were required to be used when available? Please explain your reasoning and provide specific examples.
4. Essentiality: Are flavors essential to the continued success of the organic sector? Describe the effects to your operation should you no longer be allowed to use non-organic flavors. Specify which flavors you use.
5. Would certifiers and Material Review Organizations (MROs) find a standardized industry questionnaire to verify compliance a helpful document?

Kaolin

Reference: 205.605(a)

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

Are Bentonite and Kaolin essential in organic processing?



Magnesium sulfate

Reference: 205.605(a) - nonsynthetic sources only.

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

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [04/2011 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

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Additional information requested by NOSB

1. If you use this material please let us know what you use it for and why, and what would be the impact on your operation if it was removed from the list.
2. Could Material Review Organizations (MROs) and certifiers please clarify availability of non-synthetic magnesium sulfate.

Nitrogen

Reference: 205.605(a) - oil-free grades.

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

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Additional information requested by NOSB

NONE

Oxygen

Reference: 205.605(a) - oil-free grades.

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)



Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))
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Additional information requested by NOSB

NONE

Perlite

Reference: 205.605(a) -for use only as a filter aid in food processing.

Technical Report: [1996 TAP](#)

Petition(s): N/A

Past NOSB Actions: [NOSB minutes and vote 09/1996](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

NONE

Potassium chloride

Reference: (a) Nonsynthetics allowed:

Technical Report: [1995 TAP](#); 2015 TR

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

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Additional information requested by NOSB

NONE

Potassium iodide

Reference: 205.605(a)

Technical Report: [1995 TAP](#); [2011 TR](#); 2015 TR

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset](#)



[recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

NONE

Sodium bicarbonate

Reference: 205.605(a)

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

NONE

Sodium carbonate

Reference: 205.605(a)

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

NONE

Waxes (Carnauba)

Reference: 205.605(a) Waxes – nonsynthetic (Carnauba wax; and Wood resin).

Technical Report: [1996 TAP](#); [2014 TR - Carnauba Wax](#)

Petition(s): N/A



Past NOSB Actions: [NOSB minutes and vote 09/1996](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

1. Would changing this substance to an agricultural designation is a good idea? Comments are sought on this paragraph from the 2014 Technical Report: "However, it is possible that carnauba wax could be considered agricultural based on the definition of "agricultural product" at §205.2. It is derived from a plant, the carnauba palm, and does have intended uses for "human consumption." FDA regulations permit its use on food, and certified organic carnauba wax is available in the marketplace. There are seven operations in Germany, Brazil, and the U.S. that produce or handle organic carnauba wax according to the 2012 list of certified USDA organic operations (National Organic Program, 2012)." (TR page 7, lines 340-345)
2. Input is requested on ancillary substances that may be part of wax formulations. Note that all the nonsynthetic waxes are often used in combination with each other, but these are not considered ancillary to each other. Potential ancillaries identified in the TR include residues of processing aids such as sodium carbonate, emulsifiers, plasticizers, coloring and de-colorization agents, surfactants and preservatives. Potential ancillaries identified in the TR include emulsifiers (fatty acids such as oleic, linoleic, palmitic, myristic or lauric acid), basic counterions (hydroxides of sodium, potassium salts, or ammonium, morpholine), and anti-foam agents. Additional components in Table 3 of the TR (page 7) that may function as ancillaries include alkaline agents, emulsifiers, and protective colloids, as well as plant extracts and vegetable oils.

Waxes (Wood rosin) (sic. Resin)

Reference: (a) Nonsynthetics allowed: Waxes—nonsynthetic (Carnauba wax; and Wood resin).

Technical Report: [1996 TAP](#); [2014 TR - Wood Rosin](#)

Petition(s): N/A

Past NOSB Actions: [NOSB minutes and vote 09/1996](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

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Additional information requested by NOSB

1. Whether there will be any adverse impacts to the organic community from making a technical correction. See the TR for a detailed discussion of the identification of rosin.
2. It is not known if there are any wood rosin based waxes that are combined with substances on the National list available on the market. The public is requested to submit brand names and specification sheets for any such products. (TR lines 155-156, page 4).
3. Input is requested on ancillary substances that may be part of wax formulations. Note that all the nonsynthetic waxes are often used in combination with each other, but these are not considered



ancillary to each other. Potential ancillaries identified in the TR include coumarone indene resin (synthetic resins of low molecular weight), emulsifiers, plasticizers, anti-foam agents, surfactants and preservatives. Additional components in Table 3 of the TR (page 4) that may function as ancillaries include alkaline agents, emulsifiers, and protective colloids, as well as plant extracts and vegetable oils. Without knowing of any products in use, it is unknown whether any of these may have been reviewed by materials review organizations for use in organic handling.

Yeast

Listing: 205.605(a) - When used as food or a fermentation agent, yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when equivalent organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented.

Technical Report: [1995 TAP \(Smoked Yeast\)](#); [1995 TAP \(Baker's Yeast\)](#); [2014 TR](#)

Petition(s): [2006 Petition](#); [2010 Petition Supplement](#); [2010 Petition memo](#)

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

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Additional information requested by NOSB

1. Since the change to this listing in 2010, has organic yeast become available in all forms, including extracted ("autolysate") yeast?

The following ancillary substances have been identified in yeast so far from the TER:

Ancillary substances in yeast by functional class:

Functional class	Substance name
Antioxidants	butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), propyl gallate (PG).
Preservatives	ascorbic acid
Emulsifiers	soybean oil, cottonseed oil, sorbitan monostearate, sorbitan tristearate, sorbitan monolaurate, sorbitan monooleate, sorbitan monpalmitate, sorbitol.
Carriers	Malt Syrup
Defoaming agents	many in TR



Substrate that may remain in final product	food waste, microorganisms, molasses
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2. The Handling Subcommittee is seeking more information about others that may be in use, which of the many defoaming agents are used in formulations approved for organic, and other functional classes that are not in this chart.
3. The Handling Subcommittee is seeking more information on why, specifically, any of the ancillary substances in yeast do not meet the review criteria in the organic rule.