



Sunset 2016 Review Summary Meeting 1: October 2014 Request for Public Comment Handling Substances

September 2014

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 handling which must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2016. 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 spring 2015 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the fall 2014 public meeting. These comments should be provided through www.regulations.gov by October 7, 2014 as explained in the meeting notice published in the [Federal Register](#) on September 8, 2014.

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 handling.

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 handling.

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 October 7, 2014 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.



**Sunset 2016 Review Summary
Meeting 1 - Request for Public Comment
Handling Substances
August 27, 2014**

SUNSET 2016: HANDLING SUBSTANCES

Egg white lysozyme

Nonsynthetic

Use - As a nonsynthetic, nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).

Listing: Egg white lysozyme (CAS # 9001–63–2)

Technical Report: [2011 TR: Enzymes](#), [2003 TAP: Enzymes, Plant and Fungal](#)

Petition(s): [Egg white lysozyme 06/05/02](#)

Past NOSB Actions: NOSB review and recommendation for addition to the National List [05/2003](#)
Recommendation to relist [11/05/2009](#)

Regulatory Background: Added to National List 09/11/06, [71 FR 53299](#)

Renewed 08/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/2016

Reference: 7 CFR 205.605(a)

Additional information requested by NOSB

No additional information is requested

L-Malic acid

Nonsynthetic

Use - As a nonsynthetic, nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).

Listing: L-Malic acid (CAS # 97-67-6)

Technical Report: [Malic Acid April 2003](#). New TR requested in 2014

Petition(s): [L-Malic Acid 11/01/02](#)

Past NOSB Actions: NOSB review and recommendation for addition to the National List [05/2003](#)
Recommendation to relist [11/05/2009](#)

Regulatory Background:

Added to National List 09/11/06 [71 FR 53299](#)

Renewed 08/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/16

Reference: 7 CFR 205.605(a)

Additional information requested by NOSB

The Handling subcommittee is interested in comments regarding the essentiality of this substance. We encourage current users of this substance to provide detailed comments describing the situations in which l-malic acid is the only appropriate substance for a given technical application.



Microorganisms

Nonsynthetic

Use - As a nonsynthetic, nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).

Listing: Microorganisms - any food grade bacteria, fungi, and other microorganism.

Technical Report: [2014 TR](#), [2003 TAP](#)

Petition(s): [Microorganisms 12/10/02](#)

Past NOSB Actions: NOSB review and recommendation for addition to the National List [05/2003](#)
Recommendation to relist [11/05/09](#)

Regulatory Background:

Added to National List with annotation 09/11/06 [71 FR 53299](#)

Renewed 08/03/2011 [76 FR 46595](#)

Sunset Date 9/12/2016

Reference: 7 CFR 205.605(a)

Additional information requested by NOSB

The Handling subcommittee is interested in comments regarding the following:

Microorganisms will be first major review of ancillary substances used with the listed substance and the HS is trying to follow the [Ancillary Substance Policy adopted by the Board in 2013](#).

The chart below lists all the ancillary substances by functional class that were identified in the Technical Report as well as those that have been turned in by Accredited Certifiers to make sure they are reviewed. The HS seeks additional public input on any other ancillary substances that may be in use in microorganism products that go into organic food.

Comment is also welcome in favor or against any particular ancillary substances with specific attention paid to alternative choices.

Ancillary Substances by Food Additive Functional Class¹	
Anti-caking & anti-stick agents	magnesium stearate, calcium silicate
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
Carriers and fillers, synthetic	micro-crystalline cellulose, propylene glycol, stearic acid
Preservatives	sodium benzoate, potassium sorbate
Stabilizers	maltodextrin

¹ this list does not include ancillary substances that are already on the National List. From the [2014 Technical Report](#) and spec sheets.



Cytoprotectants used to freeze-dry microorganisms	liquid nitrogen, maltodextrin, magnesium sulfate, dimethyl sulfoxide, sodium aspartate, mannitol, sorbitol
Substrate that may remain in final product	milk, lactose, grain (rice, barley, wheat) flour, brewed black tea and sugar, soy

Activated charcoal

Synthetic

Use - As a synthetic nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).

Listing: Activated charcoal (CAS #s 7440 - 44 - 0; 64365 - 11 - 3) - only from vegetative sources; for use only as a filtering aid.

Technical Report: [Activated Carbon 8/14/02](#)

Petition(s): [Charcoal/Activated Carbon 5/20/02](#)

Past NOSB Actions: NOSB review and recommendation for addition to the National List [9/2002](#)

Recommendation to relist [11/05/09](#)

Regulatory Background:

Added to National List with annotation 9/11/06 [71 FR 53299](#)

Renewed 8/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/2016

Reference: 7 CFR 205.605(b)

Additional information requested by NOSB

The Handling subcommittee is interested in comments regarding:

1. Is this substance still used as a filtering aid by organic handlers as part of their organic production process? Could either the handlers themselves or certifiers please confirm that this is still being used and thus there still exists a need for its continued listing?
2. Have the stakeholders that have relied upon this substance as part of their handling production process looked at other practices or alternatives as a possible replacement? If so could you give us examples of what other alternatives you have looked at and are they suitable replacements for activated charcoal?
3. Has the use of this substance increased or declined during the current sunset cycle? (This question would apply to Handlers- for your specific operation and for certifiers – for those operations that you certify and inspect on an annual basis).
4. Have the sources changed for where activated charcoal comes from, that might impact the need to continue its listing on the National List or not? (natural source versus synthetic source).



Peracetic acid

Synthetic

Use – As a synthetic nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).

Listing: Peracetic acid/Peroxyacetic acid (CAS # 79 -21- 0). For use as a sanitizer on food contact surfaces.

Technical Report: [11/3/2000 TAP \(for processing\)](#)

Petition(s): none

Past NOSB Actions: NOSB review and recommendation for addition to the National List [11/15/2000](#)
Recommendation to relist at [205.605\(b\) 11/5/09](#)

Regulatory Background:

Added to National List with annotation 9/11/06 [71 FR 53299](#)

Renewed: 8/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/16

Reference: 7 CFR 205.605(b)

Additional information requested by NOSB

No additional information is requested

Cyclohexylamine

Synthetic

Use – As a synthetic nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).

Listing: Cyclohexylamine (CAS # 108 - 91 - 8) for use only as a boiler water additive for packaging sterilization.

Technical Report: [02/2001](#)

Petition(s): [Cyclohexylamine 11/29/2000](#)

Past NOSB Actions: NOSB review and recommendation for addition to the National List [10/2001](#)
Recommendation to relist: [11/5/09](#)

Regulatory Background:

Added to National List: 09/11/06 [71 FR 53299](#)

Renewed 8/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/2016

Reference: 7 CFR 205.605(b)

Additional information requested by NOSB

The Handling subcommittee is interested in comments regarding:

1. How common is the use of this material in organic handling operations?
2. Are there alternative practices or materials that would make the use of this material obsolete?
3. Could ammonium hydroxide, if it were approved for use, serve as a possible substitute for this material?
4. Have there been any changes (increase or decline) in the use of this substance during the current sunset cycle?



Diethylaminoethanol

Synthetic

Use – As a synthetic nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).

Listing: Diethylaminoethanol (CAS # 100 -37- 8) for use only as a boiler water additive for packaging sterilization.

Technical Report: [2/2001 TAP](#)

Petition(s): Diethylaminoethanol [11/29/00](#)

Past NOSB Actions: NOSB review and recommendation for addition to the National List [5/2002](#)

Recommendation to relist: [11/5/09](#)

Regulatory Background:

Added to National List [09/11/06 71 FR 53299](#)

Renewed 8/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/2016

Reference: 7 CFR 205.605(b)

Additional information requested by NOSB

The Handling subcommittee is interested in comments regarding:

1. How common is the use of this material in organic handling operations?
2. Are there alternative practices or materials that would make the use of this material obsolete?
3. Could ammonium hydroxide, if it were approved for use, serve as a possible substitute for this material?
4. Have there been any changes (increase or decline) in the use of this substance during the current sunset cycle?

Octadecylamine

Synthetic

Use – As a synthetic nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).

Listing: Octadecylamine (CAS # 124–30–1) for use only as a boiler water additive for packaging sterilization.

Technical Report: [2/2001 TAP](#)

Petition(s): [Octadecylamine 11/29/00](#)

Past NOSB Actions: NOSB review and recommendation for addition to the National List [10/2001](#)

Recommendation to renew: [11/5/09](#)

Regulatory Background:

Added to National List: 09/11/06 [71 FR 53299](#)

Renewed 8/03/2011 [76 FR 46595](#)

Sunset Date: 9/11/2016

Reference: 7 CFR 205.605(b)

Additional information requested by NOSB

The Handling subcommittee is interested in comments regarding:



1. How common is the use of this material in organic handling operations?
2. Are there alternative practices or materials that would make the use of this material obsolete?
3. Could ammonium hydroxide, if it were approved for use, serve as a possible substitute for this material?
4. Have there been any changes (increase or decline) in the use of this substance during the current sunset cycle?

Sodium acid pyrophosphate

Synthetic

Use – As a synthetic nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).

Listing: Sodium acid pyrophosphate (CAS # 7758-16-9)

Technical Report: [9/2001 TAP](#) (report is for Sodium Phosphates as a group).

Petition(s): [Sodium acid pyrophosphate 10/31/02](#)

Past NOSB Actions: NOSB review and recommendation for addition to the National List [5/13/2003](#)
Recommendation to relist [11/5/09](#)

Regulatory Background:

Added to National List 09/12/06 [71 FR 53299](#)

Renewed 8/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/2016

Reference: 7 CFR 205.605(b)

Additional information requested by NOSB

The Handling subcommittee is interested in comments regarding the essentiality of this substance. We encourage current users of this substance to provide detailed comments describing the situations in which sodium acid pyrophosphate is the only appropriate leavening agent for a given technical application.

Tetrasodium pyrophosphate (TSPP)

Synthetic

Use – As a synthetic nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).

Listing: Tetrasodium pyrophosphate (CAS # 7722-88-5) - for use only in meat analog products.

Technical Report: [2014 Limited Scope TR](#), [2002 TAP](#)

Petition(s): [TSPP 12/10/2001](#)

Past NOSB Actions: NOSB review and recommendation for addition to the National List [9/17/2002](#)
Sunset Recommendation to relist: [11/5/09](#)

Regulatory Background:

Added to National List 09/12/06 [71 FR 53299](#)



Renewed 8/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/2016

Reference: 7 CFR 205.605(b)

Additional information requested by NOSB

The Handling subcommittee is interested in comments regarding the following:

The 2014 Technical Report elaborated on many alternatives to the use of this substance, both alternative vegetarian protein sources and alternative ways of processing this protein. The subcommittee would like public comment that is very specific about situations in which using TSPP would be the only viable choice and the reasons why.

The subcommittee has also raised the concern about the sole function of this input being to restore texture after complex processing and this runs counter to §205.600(4): "The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law". Input is sought on this subject.

Preliminary discussion among the Handling subcommittee is leading towards an inclination to remove this substance because of the concerns mentioned above.