



## Sunset 2016 Review Summary Meeting 2 - Subcommittee Review Handling Substances February 25, 2015

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.

**§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)).”**  
**(a) Nonsynthetics allowed:**

### Egg white lysozyme

**Reference:** 7 CFR 205.605(a) Egg white lysozyme (CAS # 9001–63–2)

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

**Petition(s):** [06/2002](#)

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

**Regulatory Background:** Added to National List effective 09/12/06 [71 FR 53299](#); Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

**Sunset Date:** 9/12/2016

#### Subcommittee Review

Egg White Lysozyme (EWL) is a purified enzyme preparation extracted from chicken egg whites using an inert polymer resin. Following extraction, EWL is stripped from the resin, concentrated, purified and dried. The material is commonly used as an antimicrobial in cheese and wine making. EWL has several other applications, including health and wellness products. Egg white lysozyme is an antimicrobial protein (i.e., a protein with the ability to inhibit or kill microorganisms) comprised of 129 amino acid residues.

Egg white lysozyme controls the proliferation of bacteria during fermentation or food processing and has been shown to possess antimicrobial properties especially in relation to *Clostridium tyrobutyricum* (Kewpie Corporation, 2010; FDA, 2000). Therefore, it is used to improve the shelf life of chilled foods and confectionary products and has been used to preserve fresh fruits and vegetables, tofu bean curd, seafood, meats and sausages, potato salad, cooked burdock with soy sauce, and varieties of semi-hard cheeses such as Edam, Gouda, and some Italian cheeses (Cunningham et al., 1991). Egg white lysozyme is also incorporated into casings for frankfurters and in cooked meat and poultry products that are sold as ready-to-eat (FDA, 2000). Unlike other enzymes, egg white lysozyme does not inhibit the lactic acid bacteria that are critical for cheese fermentation. (TR, lines 161-169)

All international organic standards allow the use of egg white lysozyme in organic production. (TR, lines 406-435)

To manufacture egg white lysozyme, the lysozyme is extracted from fresh egg white by mixing in an inert polymer resin that binds to the lysozyme. The resin carrying the lysozyme is separated from the egg white. The lysozyme is then removed from the resin through the addition of salts. The lysozyme is then concentrated, purified, and dried. Although the resulting purified protein, on a dry basis is almost 100 percent

lysozyme, small amounts of other egg white proteins may be present (FDA, 2000). (TR, lines 483-488)

Because egg white lysozyme does not undergo a chemical change during the manufacturing process, the material is considered non-synthetic. Egg white lysozyme was included as part of the tentative final rule (21 CFR 184) on direct food substances affirmed as GRAS in 1998. In 2000, a GRAS petition was submitted to FDA for egg white lysozyme. FDA follow up was identified; however, it is unknown if a conclusion was made on the GRAS status of egg white lysozyme (FDA, 2000). Egg white lysozyme does act as a preservative because it inhibits the growth of deleterious organisms, prolonging the shelf life of food products. Egg white lysozyme is an important preservative in cheese manufacturing and minimizes the process called 'late blowing,' which is caused by the fermentation of butyric acid.

Egg white lysozyme is commonly used in food processing to decrease the loss of nutritional quality caused by thermal processing. The enzyme acts as an antimicrobial agent and is considered to be thermally stable. The use of egg white lysozyme may reduce the amount of thermal processing (including pasteurization and heat sterilization) needed during food manufacture, which also minimizes the loss of nutritional quality (Rahman, 2007). (TR, lines 688-692)

EWL was first added to the National List in 2006 and went through its first Sunset review in 2009. A 2003 TAP review concluded the material posed no significant risk to human health or the environment during its manufacture, had been used in the organic industry since the inception of organic processed foods, and was used as an alternative to harsher preservatives.

This is the second 2016 Sunset presentation of Egg White Lysozyme for public comment. During the first round, public comments were received regarding the fact that EWL is made from conventionally raised eggs and the question was brought forward as to whether the material could be made with organic eggs. At the time of 2003 TAP review, it was possible the newly emerging organic egg market did not have sufficient capacity to allow for manufacture of EWL using organic eggs, and no mention was made of the use of organic egg whites.

#### **Request for Public Comments**

1. The NOSB Handling Subcommittee seeks input from the public and industry as to whether there currently exist EWL manufacturers using organic egg whites to make this material.
2. At present, it appears as though the material is essentially pure, without any remaining ancillary substances. The Handling Subcommittee seeks input regarding the presence of ancillary substances in EWL following the extraction, concentration and purification processes.

#### **Motion to Remove:**

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Consistency with Organic Production.

**The Handling Subcommittee found no concerns regarding the continued listing of Egg white lysozyme on the National List. The justification of this motion is that the whole NOSB needs to consider and vote on each**



**material, rather than just the individual Subcommittee, to fulfill its' responsibility of Sunset Review.**

Motion to remove Egg white lysozyme (CAS # 9001-63-2) from 205.605(a)

Motion by: Tracy Favre

Seconded by: Jean Richardson

Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 3

## L-Malic Acid

**Reference:** 7 CFR 205.605(a) L-Malic acid (CAS # 97-67-6)

**Technical Report:** [04/2003](#)

**Petition(s):** [11/2002](#)

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

**Regulatory Background:** Added to National List effective 09/12/06 [71 FR 53299](#); Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

**Sunset Date:** 9/12/16

### Subcommittee Review

L-Malic acid (CAS #97-67-6) was added to the National List (Federal Register Vol. 71, No. 175) §205.605(a) on September 11, 2006. This addition was based on a review of L-malic acid by the NOSB at their May 13-14, 2003 meeting. This material underwent its first sunset review at the Fall 2009 NOSB meeting, and was relisted. L-Malic acid is used as a flavor enhancer, flavoring agent and adjuvant, and for pH control agent in a variety of foods.

In the first meeting posting, the HS requested input on the essentiality and current use patterns of L-Malic acid. We received public comment from one certifier with 7 current clients using L-Malic acid in the wine, juice and bottled tea sectors. Another large producer gave comment confirming their current use and need for this substance. Two other commenters expressed concern that the [original TAP review](#) evaluated DL-malic acid, the synthetic form, rather than L-malic acid, the non-synthetic form currently listed. However, a review of the 2003 TAP shows that the reviewers very clearly accounted for the fact that there are two forms of this substance, very clearly recommended that the synthetic form not be listed, and that L-malic acid be listed on 605(a).

This substance is used in handling, and does not include any ancillary substances.

The Subcommittee review indicated that there are no ancillary substances. There have been no ancillary substances declared by stakeholders during the public comment periods (both oral and written). Therefore, no ancillary substances will be allowed, unless otherwise petitioned and reviewed by the NOSB and the appropriate Subcommittee. This completes the ancillary substance review.

### Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of L-Malic Acid from the National List based on the



following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Availability of non-synthetic alternative protein sources [§ 205.600(b)(1)], alternative substances in use [§6518(m)(6)], lack of essentiality for handling organic products [§205.600(b)(6)], inconsistent with organic handling [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]

**The Handling Subcommittee found no concerns regarding the continued listing of L-Malic on the National List. The justification of this motion is that the whole NOSB needs to consider and vote on each material, rather than just the individual Subcommittee, to fulfill its' responsibility of Sunset Review.**

Motion to remove L-Malic acid (CAS # 97-67-6) from section 205.605(a)

Motion by Joe Dickson

Seconded Tracy Favre

Yes: 0 No: 5 Abstain: Recuse: Absent: 3

## Microorganisms

**Reference:** **7 CFR 205.605(a)** Microorganisms - any food grade bacteria, fungi, and other microorganism.

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

**Petition(s):** [12/2002](#)

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

**Regulatory Background:** Added to National List with annotation, effective 09/12/06 [71 FR 53299](#), Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

**Sunset Date:** 9/12/16

### Subcommittee Review

The Listing for "Microorganisms" refers to living organisms added to food. There is some overlap with other National List entries such as Dairy Cultures and Yeasts, which are also living organisms. This listing is not meant to include either dead microorganisms or substances derived or extracted from microorganisms. Each of these latter groups must have separate listings and reviews.

These living organisms consist of bacteria, bacteriophages, fungi, and viruses. The specific types within these groups are covered in the 2014 Technical Report (TR) on pages 2 through 5. Algae were not covered by the TR and are not considered to be part of this listing.

Microorganisms are used to create desired "biogenic effects" through fermentation (such as in vinegar or miso) or to have a "probiotic effect" by interacting directly with the digestive system (such as yogurt with *L. bulgaricus*). (2014 TR page 5) They may also be used to improve palatability or nutritional value of food. Bacteriophages may be used as antimicrobial agents to control bacteria during the production or processing of foods. (2014 TR pages 5 and 10) They provide a non-synthetic alternative to cleaning agents, sanitizers, and antimicrobial products that are not allowed for use in organic food processing and handling.

Evaluation Question #1 (page 17) in the TR describes the fermentation processes for probiotics, starter cultures, and bacteriophages. The Subcommittee believes this assessment of fermentation processes to be complete enough to enable Materials Review Organizations (MROs) to determine compliance with this listing as non-synthetic substances under the existing Materials Classification guidance.

Fermentation is a naturally occurring biological process and as such does not need additional criteria under the organic law. MROs can evaluate the starting feedstocks, non-GMO affidavits, ancillary substances, and purification/ media removal steps without further guidance.

At the first posting for Microorganisms there was a call made for public comment to provide input on a chart of existing ancillary substances and to identify additional ancillary substances that may be used in formulations of microorganisms. While some public comments stated the list was incomplete, the only additional ones suggested were a few mentioned in the text of the TR. No public comments were received with evidence of compatibility issues that would lead to removal of any ancillary substances. Therefore a secondary motion and review form for ancillary substances is provided as a separate proposal. It contains the same list as the first posting with the addition of 2 more substances from the text of the TR

Ancillary substances were requested to be identified and reviewed by the TR contractor. In addition, dozens of spec sheets on products that were turned in by certifiers were looked at to gather ancillary substances for the table presented. The following were reviewed:

<b>Ancillary Substances by Food Additive Functional Class</b>	
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.
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 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

The public comment came from a few companies and certifiers in favor of continued allowance and a few groups opposed to moving this forward until the list was complete and they were reviewed further. A point raised in the comments noted that the materials that are already on the National List are listed by specific use, and therefore should be listed in the table provided for this additional use. The Subcommittee agrees with this point and the National List substances are now in the table.

The review in the TR included the following statements:

"There is no literature to suggest preservatives used in microbial preparations as ancillary substances exert any technical or functional preservative effect in the final fermented product. Typically, Good Manufacturing Practices (GMP) dictate that preservatives are added at a maximum level of 0.1% by



weight of the finished product to exert the desired effect (FDA 2013b)." (2014 TR page 23)

"There is no literature to suggest that the manufacture or use of microbial preparations with ancillary substances is harmful to the environment or biodiversity." (2014 TR page 26)

There is no literature to suggest that microbial preparations with ancillary substances have negative effects on human health. (2014 TR page 28)

For microbial preparations with ancillary substances, there are alternative practices to using nonorganic carriers and/or growth substrates for cultures. Specifically, nonorganic carriers can be replaced with organic carriers and growth substrates. Certification agencies differ in whether growth substrates and carriers are required to be organic. (2014 TR page 28)

The latter statement was discussed by the Subcommittee. The NOSB has made several recommendations in the past that commercial availability of organic sources should apply to everything on the National List. The Handling Subcommittee would like to re-affirm this position in regards to the ancillary substances used for Microorganisms and is making a motion on this in conjunction with the ancillary substance proposal.

**Motion to Remove:**

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable): [OFPA criteria at 7 U.S.C. 6158(m), (7) its compatibility with a system of sustainable agriculture.

**The Subcommittee found no concerns regarding the continued listing of Microorganisms. The justification for this motion is that the whole NOSB needs to consider and vote on each material, rather than just a Subcommittee.**

**Motion to remove** Microorganisms from 205.605(b)

Motion by: Zea Sonnabend

Seconded by: Jean Richardson

Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2



**§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)).”**  
(b) Synthetics allowed:

### Activated charcoal

**Reference:** **7 CFR 205.605(b)** Activated charcoal (CAS #s 7440 - 44 - 0; 64365 - 11 - 3) only from vegetative sources; for use only as a filtering aid.

**Technical Report:** [08/2002 Activated Carbon](#)

**Petition(s):** [05/2002 Charcoal/Activated Carbon](#)

**Past NOSB Actions:** [9/2002](#) - NOSB review and recommendation for addition to the National List;  
[11/2009](#) - Recommendation to relist

**Regulatory Background:** Added to National List with annotation, effective 09/12/06 [71 FR 53299](#); Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

**Sunset Date:** 9/12/16

#### Subcommittee Review

Activated charcoal is an important filtering aid used in organic handling. It is widely used to filter water and a variety of other substances that are used in organic handling such as refined oils, grape juice, clear liquid products, and used in many distilleries.

Activated charcoal (carbon) was added to the National List on September 12, 2006, with the annotation, “only from vegetative sources: for use only as a filtering aid. (It is also on the National List under: §205.603 for use in Livestock). The Handling Subcommittee has reviewed this material in accordance with the required Sunset review process as stated by the September 2013 NOP notice to the NOSB and also the required ancillary substance review as requested in the February 3, 2014 Memorandum to the National Organic Standards Board from the NOP.

The first of two required postings for public comment was done prior to the October 2014 Fall NOSB Meetings. The second and final posting for this sunset review cycle is scheduled for the April 2015 Spring NOSB meeting. During the first round of public comments there were 11 written public comments on activated charcoal. Of those comments 7 were in support of relisting, 3 were in support of relisting only with an annotation to limit use to filtering water (as suggested by one of the reviewers in the original 2002 TAP) and require steam activation as the source of the material, and 1 commenter taking a neutral position because a new TR had not been requested to provide information updates. (It should be noted that an annotation may not be made to a material that is under Sunset Review as the Rule currently is listed).

There was no new evidence provided that identified any unacceptable risks to the environment, human or animal health resulting from the use or manufacture of activated charcoal as annotated. One concern raised was pertaining to the spent material and that was answered during oral comment period that the spent material was reconditioned by the manufacturer of the material and that was subject to review as part of the annual certification renewal process. There was no new information presented to the Handling Sub-committee or the NOSB that would call this material into question and prompt a more extensive review.

Activated charcoal use has increased during this past sunset cycle, as stated from responses provided during public comment. There are advances in alternatives such as: steam activated coal, as a source (it is uncertain what the actual availability of this source of material is at this time) – which OMRI considers to be a non-synthetic. While it appears that activated charcoal as currently listed is still needed by organic handlers, progress has been made in looking for alternatives to the current listed material. The NOSB would like to encourage stakeholders to continue to pursue these organic alternatives if available and whenever possible.

This substance is used in handling, and does not include any ancillary substances. The Subcommittee review indicated that there are no ancillary substances in this material. There have been no ancillary substances declared by stakeholders during the public comment periods (both oral and written). Therefore, no ancillary substances will be allowed, unless otherwise petitioned and reviewed by the NOSB and the appropriate Subcommittee. This completes the ancillary substance review.

**Motion to Remove:**

This proposal to remove will be considered by the NOSB at its public meeting. The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA) criteria 7 U.S.C. 6518(m)(6) the alternatives to using the substance in terms of practices or other available materials: and (7) its compatibility with a system of sustainable agriculture.

**The Handling Subcommittee found no concerns regarding the continued listing of Activated Charcoal on the National List. The justification of this motion is that the whole NOSB needs to consider and vote on each material, rather than just the individual Subcommittee, to fulfill its' responsibility of Sunset Review.**

Motion to remove activated charcoal (CAS #s 7440–44–0; 64365–11–3) from §205.605(b).

Motion by: Harold Austin

Seconded by: Tracy Favre

Yes: 0 No: 5 Abstain: 0 Absent: 3 Recuse: 0

## Peracetic acid

**Reference: 7 CFR 205.605(b)** Peracetic acid/Peroxyacetic acid (CAS # 79 -21- 0). Peracetic acid/Peroxyacetic acid (CAS # 79-21-0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.

**Technical Report:** [2000 TAP \(for processing\)](#)

**Petition(s):** [2008 Peracetic Acid](#)

**Past NOSB Actions:** [11/2000](#) - NOSB review and recommendation for addition to the National List (Note: alternate name as periacetic in meeting notes). [11/5/09](#) - Recommendation to renew



**Regulatory Background:** Added to National List, effective 09/12/06 [71 FR 53299](#). Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

**Sunset Date:** 9/12/16

### **Subcommittee Review**

Peracetic acid/Peroxyacetic acid is an important sanitizer used in organic handling. It is widely used as a sanitizer on food contact surfaces and as a disinfectant for fruits and vegetables. Peracetic acid/Peroxyacetic acid was added to the National List on September 12, 2006, with the annotation, “for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.” (It is also list on the National List under: §205.601 and §205.603 for use in Crops and Livestock respectively). The Handling Subcommittee has reviewed this material in accordance with the required sunset review process as stated by the September 2013 NOP notice to the NOSB and the required ancillary substance review as requested in the February 3, 2014 Memorandum to the National Organic Standards Board from the NOP.

The first of two required postings for public comment was done prior to the October 2014 Fall NOSB Meeting. The second and final posting for this sunset review cycle is scheduled for the April 2015 Spring NOSB meeting. During the first round of public comments there were 22 written and verbal public comments on Peracetic acid/Peroxyacetic acid. Of those comments 9 were from industry, 3 from individuals, 2 from non-profit organizations, 2 from manufacturers of the substances, 2 from certifiers, 1 from a trade association, and 1 from a USDA research scientist (2 comment were redundant verbal/written). 21 commenters were in support of relisting, 1 commenter was neutral. 1 commenter noted the TR was old and should be updated but still supported relisting. Another commenter noted the need for a more robust public discussion but still supported relisting. One comment noted the potential presence of ancillary substances.

There was no new evidence provided about unacceptable adverse impacts on human health or the environment. Commenters noted Peracetic acid/Peroxyacetic acid had less adverse impact than allowed alternatives. There was no new evidence presented that refuted the substance’s essentiality for organic production. Several industry members noted the ongoing essentiality of the substance, particularly in the dairy, beverage, fresh and cut fruit/vegetable industries. Two certifiers commented on the wide use of this substance by their clients. Several commenters noted its criticality to ensuring food safety. There was no new evidence provided about the substances incompatibility with organic production practices. Several commenters noted its compatibility given the substance breaks down to relatively benign complement (acetic acid [same acid found in vinegar] and hydrogen peroxide [which in turn breakdown to water and hydrogen]). There was no new information presented to the Handling Subcommittee or the NOSB that would call this material into question and prompt a more extensive review.

This substance is used in handling, and does not include any ancillary substances.

The Subcommittee review indicated that there are no ancillary substances. There have been no ancillary substances declared by stakeholders during the public comment periods (both oral and written). Therefore, no ancillary substances will be allowed, unless otherwise petitioned and reviewed by the NOSB and the appropriate Subcommittee. This completes the ancillary substance review for peracetic acid.

The 2000 TR notes that “Stock commercial preparations usually contain a synthetic stabilizer such as 1-

hydroxyethylidene-1,1-diphosphonic acid (HEDP) or 2,6-pyridinedicarboxylic (dipicolinic) acid to slow the rate of oxidation or decomposition.” No ancillary substances were identified during public comment however one commenter noted this section of the TR. Since Peracetic acid/Peroxyacetic acid needs to be registered with the EPA when used as an antimicrobial these substances are considered inert and are not subject to review under the ancillary substance review. Furthermore, the annotation currently states “for use in wash and/or rinse water according to FDA limitation”, which define the permitted stabilizers.

**Motion to Remove:**

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA) criteria 7 U.S.C. 6518(m)(6) the alternatives to using the substance in terms of practices or other available materials: and (7) its compatibility with a system of sustainable agriculture.

**The Handling Subcommittee found no concerns regarding the continued listing of Peracetic acid/Peroxyacetic acid on the National List. The justification of this motion is that the whole NOSB needs to consider and vote on each material, rather than just the individual Subcommittee, to fulfill its’ responsibility of Sunset Review.**

Motion to remove Peracetic Acid (CAS # 79–21–0), from §205.605b

Motion by: Tom Chapman

Seconded by: Zea Sonnabend

Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

## Cyclohexylamine

**Reference:** 7 CFR 205.605(b) Cyclohexylamine (CAS # 108 - 91 - 8) for use only as a boiler water additive for packaging sterilization.

**Technical Report:** [02/2001](#)

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

**Past NOSB Actions:** [10/2001](#) - NOSB review and recommendation for addition to the National List; [11/2009](#) - Recommendation to relist

**Regulatory Background:** Added to National List 09/12/06 [71 FR 53299](#), Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

**Sunset Date:** 9/12/16

### Subcommittee Review

Cyclohexylamine, a volatile amine, is a boiler water additive used to prevent corrosion in boilers and boiler distribution lines.

The material can pose serious risks to human health and the environment, and is an irritant and should be handled as such. Cyclohexylamine is often used in conjunction with other volatile amines.

Volatile amines are characterized by their high solubility in water and reactivity. These very chemical properties that make them effective as boiler water additives make them extremely difficult to remove from the steam, NOSB TAP Review Compiled by OMRI, 2001. Given this characteristic, it makes it possible that Cyclohexylamine could come into contact with food items. For this reason, its use has been limited to use only for packaging sterilization.

In August 2014, the NOSB put forth a request for information regarding the continued use of this material in boiler systems and received limited information regarding its continued use in organic processing. Some information received by the NOSB suggests that most manufacturers have already begun a move away from this material. This information, in conjunction with the potential for harm to human health and the environment, is the reason the Handling Subcommittee is recommending removal from the National List.

This substance is used in handling, and does not include any ancillary substances.

### Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the Subcommittee's review, the Subcommittee proposes removal of Cyclohexylamine from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): lack of essentiality for handling organic products [§205.600(b)(6)], inconsistent with organic handling [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]

Motion to remove the boiler amines, Cyclohexylamine (CAS # 108 -91-8), Diethylaminoethanol (CAS # 100-37-8), and Octadecylamine (CAS # 124-30-1), all three with the annotation "for use only as a boiler water additive for packaging sterilization", from section 205.605(b)

Motion by: Tracy Favre

Seconded: Jean Richardson

Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 3

## Diethylaminoethanol

**Reference: 7 CFR 205.605(b)** Diethylaminoethanol (CAS # 100 -37- 8) for use only as a boiler water additive for packaging sterilization.

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

**Petition(s):** [11/2000](#)

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



11/5/09 - Recommendation to relist

**Regulatory Background:** Added to National List, effective 09/12/06 71 FR 53299, Sunset renewal notice published 08/03/2011 76 FR 46595

**Sunset Date:** 9/12/2016

### **Subcommittee Review**

Diethylaminoethanol (DEAE), a volatile amine, is a boiler water additive used to prevent corrosion in boilers and boiler distribution lines. It neutralizes carbonic acid the boiler lines by scavenging free oxygen.

The material can pose serious risks to human health and the environment, and is an irritant and should be handled as such. Diethylaminoethanol is poisonous when ingested. DEAE is often used in conjunction with other volatile amines.

Volatile amines are characterized by their high solubility in water and reactivity. These very chemical properties that make them effective as boiler water additives make them extremely difficult to remove from the steam, NOSB TAP Review Compiled by OMRI, 2001. Given this characteristic, it makes it possible that Diethylaminoethanol could come into contact with food items. For this reason, its used has been limited to use only for packaging sterilization.

In August 2014, the NOSB put forth a request for information regarding the continued use of this material in boiler systems and received limited information regarding its continued use in organic processing. Some information received by the NOSB suggests that most manufacturers have already begun a move away from DEAE. This information, in conjunction with the potential for harm to human health and the environment is the reason the Handling Subcommittee is recommending removal from the National List.

This substance is used in handling, and does not include any ancillary substances.

### **Motion to Remove:**

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of Diethylaminoethanol from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): lack of essentiality for handling organic products [§205.600(b)(6)], inconsistent with organic handling [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]

Motion to remove the boiler amines, Cyclohexylamine (CAS # 108 -91-8), Diethylaminoethanol (CAS # 100-37-8), and Octadecylamine (CAS # 124-30-1), all three with the annotation "for use only as a boiler water additive for packaging sterilization", from section 205.605(b)

Motion by Tracy Favre

Seconded Jean Richardson

Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 3

## Octadecylamine

**Reference:** 7 CFR 205.605(b) Octadecylamine (CAS # 124–30–1) for use only as a boiler water additive for packaging sterilization.

**Technical Report:** [02/2001 TAP](#)

**Petition(s):** [11/2000](#)

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

**Regulatory Background:** Added to National List, effective 09/12/06 [71 FR 53299](#), Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

**Sunset Date:** 9/12/2016

### Subcommittee Review

Octadecylamine, a volatile amine, is a boiler water additive used to prevent corrosion in boilers and boiler distribution lines. It forms a thin film on the inside of boiler water lines and prevents the formation of carboic acid from carbon dioxide contained in the boiler water.

The material can pose serious risks to human health and the environment, and is an irritant and should be handled as such. Octadecylamine is poisonous when ingested. Octadecylamine is often used in conjunction with other volatile amines.

Volatile amines are characterized by their high solubility in water and reactivity. These very chemical properties that make them effective as boiler water additives make them extremely difficult to remove from the steam, NOSB TAP Review Compiled by OMRI, 2001. Given this characteristic, it makes it possible that Octadecylamine could come into contact with food items. For this reason, its use has been limited to use only for packaging sterilization.

In August 2014, the NOSB put forth a request for information regarding the continued use of this material in boiler systems and received limited information regarding its continued use in organic processing. Some information received by the NOSB suggests that most manufacturers have already begun a move away from Octadecylamine. This information, in conjunction with the potential for harm to human health and the environment is the reason the Handling Subcommittee is recommending removal from the National List.

This substance is used in handling, and does not include any ancillary substances.

### Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of Octadecylamine from the National List



based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): lack of essentiality for handling organic products [§205.600(b)(6)], inconsistent with organic handling [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]

Motion to remove the boiler amines, Cyclohexylamine (CAS # 108 -91-8), Diethylaminoethanol (CAS # 100-37-8), and Octadecylamine (CAS # 124-30-1), all three with the annotation “for use only as a boiler water additive for packaging sterilization”, from section 205.605(b)

Motion by Tracy Favre

Seconded Jean Richardson

Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 3

## Sodium acid pyrophosphate

**Reference:** **7 CFR 205.605(b)** Sodium acid pyrophosphate (CAS # 7758-16-9) - for use only as a leavening agent.

**Technical Report:** [09/2001 TAP](#) (report is for Sodium Phosphates as a group).

**Petition(s):** [10/2002](#); [06/2009 petition for expanded use](#)

**Past NOSB Actions:** [05/2003](#) - NOSB review and recommendation for addition to the National List; [11/2009](#) - recommendation to relist; [04/2011](#) - recommendation on expanded use

**Regulatory Background:** Added to National List, effective 09/12/06 [71 FR 53299](#), Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

**Sunset Date:** 9/12/2016

### Subcommittee Review

Sodium Acid Pyrophosphate (SAPP) was first petitioned on 10/31/02 and added to the National List §205.605(b) effective on September 12, 2006 by Final Rule TM-04-01FR based on the NOSB recommendation of May 2003. It most recently underwent sunset review at the Fall 2009 meeting, and was relisted by the NOSB.

Sodium acid pyrophosphate (CAS # 7758-16-9) was originally petitioned for use as a leavening acid in baked goods, and was given the annotation “for use only as a leavening agent” when originally recommended for listing by the NOSB. It is a relatively common food additive with USDA and FDA approval for many functions in conventional foods. In this intended use, it is used as an acid to react with sodium bicarbonate (baking soda) to produce a controlled release of the CO<sub>2</sub> that leavens the baked good. SAPP is prepared by partial neutralization of phosphoric acid with sodium hydroxide or sodium carbonate to form monosodium phosphate, which is followed by molecular dehydration of that substance under controlled conditions at 250 degrees C to form SAPP. Environmental impact from manufacture and use is minimal, and it is not considered toxic to humans.

In the first meeting posting, the HS requested input on the essentiality and current use patterns of SAPP. We received comment from one certifier who noted that this substance is in current use by six clients, and is used in five of the six baking powder formulas it has reviewed. A trade organization, the International Food Additives Council (IFAC), supported its continued listing, noted that it is widely used



and essential in baked good. IFAC also noted that “Delisting SAPP would significantly limit the quality, variety and availability of organic bakery products, negatively impacting organic consumers who currently purchase organic bakery items.” One large processor commented that they currently widely use SAPP in a variety of products.

Two other comments commented in opposition to relisting SAPP, on the grounds that the TAP review was focused on the use of sodium phosphates in non-dairy milk, rather than as a leavening agent. However, the HS believes that the technical information contained in the [original TAP](#), along with the additional detail contained in the SAPP [petition](#), the [2010 TR](#) prepared for the evaluation of SAPP for use in produce, independent research, public comment and the food science expertise contained within this and past Handling Subcommittees is sufficient for a thorough review of this substance and that a new TR is not needed.

This substance is used in handling, and does not include any ancillary substances.

The Subcommittee review indicated that there are no ancillary substances. There have been no ancillary substances declared by stakeholders during the public comment periods (both oral and written).

Therefore, no ancillary substances will be allowed, unless otherwise petitioned and reviewed by the NOSB and the appropriate Subcommittee. This completes the ancillary substance review for Sodium Acid Pyrophosphate (SAPP).

#### **Motion to Remove:**

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of Sodium Acid pyrophosphate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) criteria 7 U.S.C. 6518(m)(6) the alternatives to using the substance in terms of practices or other available materials: and (7) its compatibility with a system of sustainable agriculture.

**The Handling Subcommittee found no concerns regarding the continued listing of SAPP on the National List. The justification of this motion is that the whole NOSB needs to consider and vote on each material, rather than just the individual sub-committee, to fulfill its’ responsibility of Sunset Review.**

Motion to remove Sodium acid pyrophosphate (SAPP) (CAS # 7758-16-9) -for use only as a leavening agent, from 205.605(b)

Motion by: Joe Dickson

Seconded by: Tracy Favre

Additional discussion: none

Yes: 0 No: 5 Abstain: 0 Absent: 3 Recuse: 0



## Tetrasodium pyrophosphate (TSPP)

**Reference:** 7 CFR 205.605(b) Tetrasodium pyrophosphate (CAS # 7722–88–5) - for use only in meat analog products.

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

**Petition(s):** [12/2001](#)

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

**Regulatory Background:** Added to National List with annotation, effective 09/12/06 [71 FR 53299](#), Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

**Sunset Date:** 9/12/2016

### Subcommittee Review

Tetrasodium Pyrophosphate (TSPP) is a processing aid that is used to make certain types of meat analogs. As a processing aid it does not appear on a food label and does not contain any ancillary substances.

In reviewing the historical background for Tetrasodium Pyrophosphate (TSPP), the Handling Subcommittee (HS) had concerns that this substance was put on the list by the former NOSB in spite of the fact that the majority of the 2002 TAP reviewers were against it, it was marked on the checklist as failing the criteria, and the information about which products it was used in (and therefore why it was specifically necessary for those products) was proprietary. Therefore a new TR was commissioned to try to further evaluate the alternatives.

In the first meeting posting the HS requested public comment on the specific uses of the substance and experience with alternatives, as well as the issue of whether TSPP was primarily used to restore texture after complex (and possibly excessive) processing of vegetable protein.

Very little public comment was received for this substance. No users of TSPP came forward and no certifiers stated that their clients used this material. One industry association wrote in favor of this as well as the other food additives in sunset, but gave no specifics on uses or alternatives. Several groups opposed this material along with many other synthetics on the National List, but none gave specific information that was unique to this substance.

The HS has determined from the 2014 TR and lack of clear input from the organic community that there are ample alternatives to the use of TSPP and some of the other criteria in the rule are not sufficiently met. Therefore a checklist is presented to go into some of the specific issues. A motion is being put forward to remove TSPP from the National List.

This substance is used in handling, and does not include any ancillary substances.

### Supplemental Review Information

#### **Motion to Remove:**

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to





remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of Tetrasodium Pyrophosphate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Availability of non-synthetic alternative protein sources [§ 205.600(b)(1)], alternative substances in use [§6518(m)(6)], lack of essentiality for handling organic products [§205.600(b)(6)], inconsistent with organic handling [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]

Motion to remove Tetrasodium Pyrophosphate (CAS # 7722–88–5) - for use only in meat analog products, from 205.605(b).

Motion by: Zea Sonnabend

Seconded by: Tracy Favre

Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 2

**Approved by Harold Austin, Subcommittee Chair, to transmit to NOSB February 25, 2015**