Sunset 2023
Meeting 1 - Request for Public Comment
Crops Substances § 205.601 & § 205.602
April 2021

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 which must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, annotation, 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 2021 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2021 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov on or before April 5, 2021, 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 (see 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: (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 clearly indicate the commentor's position on the allowance or prohibition of substances on the National List and explain the reasons for the position. Public comments should focus on providing relevant 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 (*e.g.*, scientific, environmental, manufacturing, industry impact information, etc.). Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

For Comments that Support the Continued Use of § 205.601 Substances in Organic Production:

If you provide comments supporting the allowance of a substance at § 205.601, 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 the Continued Use of § 205.601 Substances in Organic Production:

If you provide comments that do not support a substance at § 205.601, you should provide reasons why the use of the substance should no longer be allowed in organic production. 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/or
3. inconsistent with organic crop production.

For Comments that Support the Continued Prohibition of § 205.602 Substances in Organic Production:
If you provide comments supporting the prohibition of a substance on the §205.602 section of the National List, you should provide information demonstrating that the substance is:

1. harmful to human health or the environment; and
2. inconsistent with organic crop production.

For Comments that Do Not Support the Continued Prohibition of § 205.602 Substances in Organic Production:
If you provide comments that do not support the prohibition of a substance at § 205.602, you should provide reasons why the use of the substance should no longer be prohibited in organic production. Specifically, comments that support the removal of a substance from the § 205.602 section of the National List should provide new information since its last NOSB review to demonstrate that the substance is:

1. not harmful to human health or the environment; and/or
2. consistent with organic crop production.

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

- Alternative management practices or natural substances that would eliminate the need for the specific substance;
- Other substances that are on the National List that are better alternatives, which could eliminate the need for this specific substance; and/or
- 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 organic operations 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.

Written public comments will be accepted through April 5, 2021, via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

§205.601 Sunsets: Synthetic substances allowed for use in organic crop production:

- Copper sulfate (§205.601(a)(3) & §205.601(e)(4))
- Ozone gas
- Peracetic acid (§205.601(a)(6) & §205.601(i)(8))
- EPA List 3 - Inerts of unknown toxicity
- Chlorine materials
    - (i) Calcium hypochlorite
    - (ii) Chlorine dioxide
    - (iii) Hypochlorous acid - generated from electrolyzed water
    - (iv) Sodium hypochlorite
- Magnesium oxide

§205.602 Sunsets: Nonsynthetic substances prohibited for use in organic crop production:

- Calcium chloride
- Rotenone (CAS # 83-79-4)

Copper sulfate

Reference: §205.601(a)(3) Copper sulfate - for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent; and,
§205.601(e)(4) Copper sulfate—for use as tadpole shrimp control in aquatic rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.
Technical Report: 1995 TAP (Copper Sulfate and Other Coppers); 2001 TAP; 2011 TR
Petition(s): 2001
Past NOSB Actions: 10/2001 meeting minutes and vote; 11/2007 recommendation; 04/2011 recommendation; 10/2016 sunset recommendation; 11/2017 sunset recommendation
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 11/03/2013; Sunset renewal notice effective 5/29/2018 (83 FR 14347)
Sunset Date: 5/29/2023

Subcommittee Review

Use

Copper sulfate is used as an algicide for rice crops, as the growth of algal matting in flooded fields can dislodge young seedlings. It is broadcast aerially into the flooded rice fields by plane. Rice farmers also spray copper sulfate to control a freshwater invertebrate, *Triops longicaudatus*, otherwise known as tadpole shrimp. Tadpole shrimp are also only detrimental to very young seedlings, as their burrowing activities can disrupt the seedling roots and the first emerging leaves.

Manufacture

Copper sulfate is manufactured by treating copper metal with hot concentrated sulfuric acid. Copper oxides can be treated with a more dilute sulfuric acid to produce copper sulfate. Copper sulfate is also known as copper vitriol.

International Acceptance

While the majority of rice is grown in Asian countries, the top ten countries that contribute to global organic rice production include Italy and the USA, as shown in the table below.

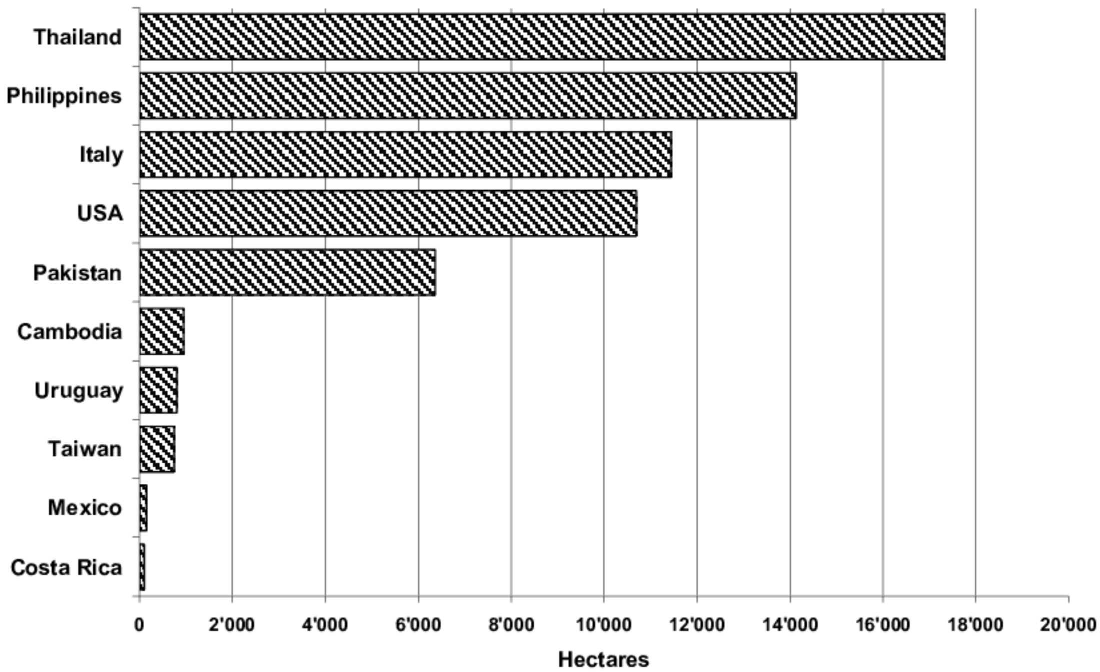

Figure 1. Top producers of organic rice globally (Willer and Yuseffi 2007).

Canadian General Standards Board Permitted Substances [List]

- Permitted for use as a wood preservative, fungicide on fruit and vegetables or for disease control.
- Shall be used with caution to prevent excessive copper accumulation in the soil. Copper buildup in soil may prohibit future use.
- Visible residue of copper products on harvested crops is prohibited.

There is very little rice grown in Canada, but the organic rice grown in Abbottsford is farmed without copper sulfate and using the seedling transplanting method that eliminates the need for copper sulfate.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008. European Chemicals Agency (ECHA)
The EU does not permit copper sulfate for use in organic rice production.

ECHA states copper sulfate "is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects, may cause cancer, may damage fertility or the unborn child, is harmful if swallowed, causes serious eye damage, may cause damage to organs through prolonged or repeated exposure, causes skin irritation and may cause an allergic skin reaction."

Japan Agricultural Standard (JAS) for Organic Production
Copper sulfate is only permitted in organic agriculture as a fungicidal spray, not for use in rice fields.

Environmental Issues
Copper is readily dissolved and suspended in the water and is lethal to fish and other aquatic organisms at fairly low concentrations. In amphibians, increasing concentrations of copper can alter behavior, reduce growth rates and final size, and at higher concentrations result in death. Copper also has algicidal effects and can disrupt the food chain in aquatic environments. For this reason, its direct introduction into flooded rice fields is contentious, particularly since rice fields serve as replacement wetlands for many flora and

fauna in agricultural areas like Northern California. Previous comments to the NOSB have highlighted specific concerns that the application rates in organic rice fields in California are several times higher than the amounts documented to kill the native amphibian species.

In the soil, it tends to concentrate heavily in the topsoil and leads to copper resistant fungal strains over time, as well as altering the soil microbiota and killing soil-dwelling animals such as earthworms. Copper toxicity in the soil can reduce the growth and nutrient value of crop plants, as well as damage the integrity of root systems (Van Assche and Clijsters, 1990). Because it accumulates in the soil over time and eventually results in poor plant outcomes, its use as a sustainable practice must be questioned.

Copper sulfate has been shown to be toxic to bees, particularly in tropical environments. At sub-lethal levels, the heavy metal also changes behavior and movement ability (Rodrigues et al, 2016). Despite this, there are multiples statements on the National Pesticide Information Center (NPIC) and in US Environmental Protection Agency Office of Pesticide Programs documents stating that copper sulfate is virtually non-toxic to bees. This is an important point to clarify. The role that bees play in the pollination of commercial crops globally should make this a concern to farmers and the general public alike.

Copper sulfate has been classified as a human carcinogen by the European Chemicals Agency (ECHA), with specific concern for renal cancers (Buzio et al, 2002). Chronic exposure to fungicidal sprays elevated the risk of renal cancers by almost 3 times. While copper binds to soils readily, copper contamination of drinking water sources would also be a concern.

Discussion

Copper sulfate is a difficult substance to evaluate, as there appears to be broad consensus throughout the US, EU, and Canada that it is hazardous to both human health and the environment. Despite this, it has repeatedly had its use period extended in all three jurisdictions, as there isn't yet a viable organic alternative for copper in certain applications. The EU, Canada and Japan all exclude copper sulfate for organic rice production but allow it as a fungicidal spray in organic orchards and vineyards.

In terms of the copper sulfate use in rice paddies to control tadpole shrimp, it appears that there are ways to circumvent the need for chemical control. The tadpole shrimp emerge from eggs and most hatch within 1-3 days of flooding. Tadpole shrimp primarily cause injury to the rice through chewing young roots and shoots and disrupting the roots with burrowing activities (Tindall and Fothergill, 2012). The shrimp do not injure older seedlings once they have reached the water surface and roots are well established in the soil. In fact, at this later stage in seedling development, the tadpole shrimp can be beneficial to the crop by controlling algae and mosquitos.

Transplanting in older seedings eliminates any threat from algal mats to the delicate young seedling stage, as do practices such as dry seeding the rice or ensuring that the rice is seeded directly at the time of flooding. Interestingly, transplanting seedlings has been the preferred method of rice production throughout most of human rice cultivation. In Asian rice cultivation, the tadpole shrimp are often deliberately introduced as a means of controlling algae and mosquitos. The current approach of flooding the fields and then direct wet-seeding didn't gain popularity until broad chemical use was implemented, and has been demonstrated to marginally reduce costs and increase yields.

In conclusion, it may be time to reconsider copper sulfate as an algicide and means of controlling tadpole shrimp. It appears there is sufficient evidence to conclude that:

1) use of copper sulfate in rice fields is environmentally detrimental,

2) alternative seeding practices could eliminate the need for the chemical as both algae and tadpole shrimp cease to be problematic once seedlings are established and
3) international standards do not allow for spraying of copper sulfate for organic rice production.

Questions to our Stakeholders

1. What are the roadblocks to transitioning to a dry-seeding or transplanting of rice seedlings in US rice production?

2. Are there viable practices that can be used to offset the toxic build-up of copper in the soil and water (i.e. crop rotation, phytoremediation with plants that draw copper from the soil)?

References

Buzio L, Tondel M, De Palma G, et al. (2002) Occupational risk factors for renal cell cancer. An Italian case-control study. La Medicina del Lavoro. 93(4):303-309.

Rodrigues C, Krüger A, Barbosa W, Guedes R (2016) Leaf fertilizers affect survival and behavior of the Neotropical Stingless Bee *Friesella schrottkyi* (Meliponini: Apidae: Hymenoptera) , *Journal of Economic Entomology*, 109(3):1001–1008.

Tindall K, Fothergill K (2012) Review of a new pest of rice, Tadpole Shrimp (Notostraca: Triopsidae), in the midsouthern United States and a winter scouting method of rice fields for preplanting detection. Journal of Integrated Pest Management 3 (3):B1–B5.

Van Assche F, Clijsters H (1990) Effects of metals on enzyme activity in plants. Plant Cell Environ. 13:195-206.

Willer, Helga & Yussefi, Minou. (2007). The World of Organic Agriculture - Statistics and Emerging Trends 2007.

Ozone gas

Reference: §205.601(a)(5) Ozone gas—for use as an irrigation system cleaner only.
Technical Report: 2002 TAP; 2021 TR Pending
Petition(s): 2001
Past NOSB Actions: 09/2002 meeting minutes and vote; 11/2007 recommendation; 12/2011 recommendation; 10/2016 sunset recommendation
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987); Sunset renewal notice effective 11/03/2013 (78 FR 61154); Sunset renewal notice effective 5/29/2018 (83 FR 14347)
Sunset Date: 5/29/2023

Subcommittee Review

Use

Ozone is a strong oxidant and works by oxidizing plant tissue and bacterial membranes. It is used as an antimicrobial agent to clean irrigation lines. It has been used in Europe for more than 100 years to treat drinking water and it has been used in the United States to also disinfect water and to oxidize color and taste contaminants in water. It is found in nature at levels of 0.05 ppm but in levels of 0.5 ppm in cities with smog. Ozone is approved by the US Food and Drug Administration for use on food.

Manufacture
Ozone is usually formed by combining an oxygen molecule with an oxygen atom in an endothermic reaction. Because ozone is unstable it is generated at the point of use. It can be generated by irradiating oxygen-containing gas with UV light and other technologies, but the primary industrial method is by corona discharge. There are generally four system components to an ozone generating process: a power source or ozone generator; a gas source; an ozone delivery system; and an off-gas destruction system. The gas source may be air, high purity oxygen, or a combination of the two.

International acceptance
Canadian General Standards Board Permitted Substances List
The 2002 Technical Advisory Panel (TAP) review of ozone noted that ozone was not specifically listed.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
The 2002 Technical Advisory Panel (TAP) review of ozone noted that ozone was not specifically listed.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
The 2002 Technical Advisory Panel (TAP) review of ozone noted that ozone was not specifically listed.

International Federation of Organic Agriculture Movements (IFOAM) Norms
The 2002 Technical Advisory Panel (TAP) review of ozone noted that ozone was not specifically listed.

Japan Agricultural Standard (JAS) for Organic Production
The 2002 Technical Advisory Panel (TAP) review of ozone noted that ozone was not specifically listed.

Environmental Issues
When ozone is used for water treatment it oxidizes or disinfects many components that impact water quality. It will oxidize iron and manganese, which precipitate as ferric and manganese hydroxides. This could result in crop iron deficiencies. It partially oxidizes organic matter to forms that are more easily biodegradable. Ozone is also germicidal against many types of pathogenic organisms including viruses, bacteria, and protozoa. It is rated as a strong irritant via inhalation and to skin, eyes and mucous membranes. Ozone systems that inject directly into irrigation lines use relatively low concentrations of ozone and there is little potential for off-gassing. In water ozone decomposes rapidly and the only decomposition product is oxygen as opposed to chlorine which can generate trihalomethanes. Cleaning of irrigation lines should not lead to problems with soil structure because most of the ozone is contained in the irrigation tubing.

Discussion
Ozone is still in active use by the organic community. One certifier indicated they have ozone listed for use in 50 Organic system plans (OSPs). Users include wineries, mushroom operations, and grain handlers.

Questions to our Stakeholders
None.

Peracetic acid

Reference: §205.601(a)(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material. Also permitted in hydrogen peroxide formulations as allowed in §205.601(a) at concentration of no more than 6% as indicated on the pesticide product label; and, §205.601(i)(8) Peracetic acid - for use to control fire blight bacteria. Also permitted in hydrogen peroxide formulations as allowed in §205.601(i) at concentration of no more than 6% as indicated on the pesticide product label.
Technical Report: 2000 TAP, 2016 TR
Petition(s): 2008
Past NOSB Actions: 11/2007 recommendation; 11/2009 annotation change; 12/2011 sunset recommendation; 10/2016 sunset recommendation
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987); Sunset Review 10/09/2008 (73 FR 59479) ; Annotation change 05/28/2013 (78 FR 31815); Sunset renewal notice effective 5/29/2018 (83 FR 14347)
Sunset Date: 5/29/2023

Subcommittee Review

Use
In organic crop production, peracetic acid, or PAA, is used to disinfect equipment. It can also be used as a disinfectant to treat seeds or asexually propagated planting material. It can be used to disinfect pruning equipment to help prevent the spread of the fire blight bacterium and is also used in one of the hydrogen peroxide formulations for control on the tree canopy of this same disease. PAA is also used in formulations of hydrogen peroxide, allowed at a concentration of no more that 6%, for use in organic crop production. Peracetic acid was relisted during the 2016 sunset review for Handling and the 2017 sunset listing for Livestock.

Peracetic acid is an unstable oxidizing agent, which is what makes it such an effective sanitizer. According to the 2016 TR, solutions of peracetic acid, hydrogen peroxide, acetic acid and water are produced by reacting glacial acetic acid with hydrogen peroxide, frequently in the presence of a catalyst such as a mineral acid (e.g., sulfuric acid). Most commercially available PAA solutions contain a synthetic stabilizer and chelating agent such as HEDP (1-hydroxyethylidene-1, 1-diphosphonic acid) or dipicolinic acid (2, 6-dicarboxypyridine) to slow the rate of oxidation or decomposition.

Manufacture
Peracetic acid appears to be a straightforward material in that it is made from, and decomposes back to, acetic acid, oxygen, and water. PAA is a very strong oxidizing agent and can be produced by the interaction between methyl (or acetaldehyde) and air, or by mixing acetic acid and hydrogen peroxide (methyl itself derives from plants, commonly coffee, bread grains, and ripe fruit). It can also be produced within laundry detergents and is considered a more effective bleach than hydrogen peroxide.

First industrially developed in 1950, it has historically been used to treat fruits and vegetables to reduce spoilage from bacteria and various fungi. It is used to treat bulbs, to disinfect potting soil, clean irrigation equipment, and in seed treatment to inactivate fungi or other plants diseases. Additionally, in organic crop production it is also used as a bactericide/fungicide in wash waters to help decrease *Escherichia coli O157:H7* on some fruit and vegetable crops. With the removal of two antibiotics previously allowed for use in organic crop production to assist in fire blight reduction, use of this substance as part of a rotational control and fire blight prevention program has increased in recent years, according to information provided by some organic stakeholders during public comment periods.

International Acceptance

Canadian General Standards Board Permitted Substances List

Permits the use of peracetic (peroxyacetic) acid at paragraph 4.3 (Crop Production Aids and Materials) with the following annotation: "Permitted for: a) controlling fire blight bacteria; and b) disinfecting seed and asexually propagated planting material". This allowance is consistent with NOP regulations.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

Peracetic acid is not listed in Annex II – Pesticides – plant protection products. Nonetheless, as of June 1, 2012, the European Union and the United States have an equivalency agreement whereby organic products certified to the USDA or European Union (EU) organic standards may be sold and labeled as organic in both the U.S.A. and the EU.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

Not listed.

International Federation of Organic Agriculture Movements (IFOAM) Norms

IFOAM norms permit the use of peracetic acid for cleaning equipment and/or disinfecting equipment with no final rinse (IFOAM Appendix 4, Table 2), for pest and disease control, and for disinfection of livestock housing and equipment (IFOAM Appendix 5).

Japan Agricultural Standard (JAS) for Organic Production

Not listed in the Japanese Agricultural Standard for Organic Production. However, the United States entered into an equivalency agreement with Japan, effective on January 1, 2104. The scope of the arrangement is limited to plants and plant-based products which undergo final processing, packaging, or labeling within the boundaries of those two countries.

Environmental Issues

If misused, peracetic acid can irritate eyes, skin, and breathing.

Discussion

Peracetic acid was registered by the EPA for indoor antimicrobial use in 1985. In the December 2, 2011, NOSB recommendation for the 2013 sunset review of peracetic acid for the two Crops listings at § 205.601(a)(6) and § 205.601(i)(8), the Board clarified the annotation change from the 2009 recommendation and supported it.

The original recommended annotation change was:

> §205.601(a)(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material. Permitted in hydrogen peroxide formulations at concentration of no more than 5%.
>
> §205.601(i)(8) Peracetic acid—for use to control fire blight bacteria. Permitted in hydrogen peroxide formulations at concentrations of no more than 5%.

This annotation was later implemented by the NOP with a slight change. The recommended 5% limit was changed to a 6% limit, based on information provided during public comment stating the recommended 5% limit was too low compared to percentages in use at the time. This point of concern was discussed at the

Spring NOSB meeting and it was decided that this slight increase in the percentages was necessary to adequately accommodate use rates.

While there do appear to be other materials that could be used as possible alternatives, peracetic acid is selected for use by many organic crop producers for many reasons: It is a strong oxidizing compound, works well in colder conditions, does not give off chlorine into the environment, used as part of a rotation process in fire blight disease control, and is the more benign of the sanitizers and disinfectants, since it reverts back to acetic acid, oxygen, and water in the environment. It has also been described as a no-rinse material. This is according to information provided during public comment, and also found in the 2016 TR.

Concerns were raised during public comment submitted for the Spring 2016 NOSB meeting regarding the various forms of peracetic acid mentioned in the TR. This was discussed during the meeting and the NOSB determined the majority of those other sources (that were raising a concern) would not be allowed for use in organic crop production or other currently allowed uses, as currently shown on the National List. Several commenters also mentioned that they felt that all sanitizers and disinfectants should be looked at for a determination of need and prioritization of allowed uses. It was determined that request was outside of the scope of this specific sunset review and would need to be addressed as a separate issue/topic.

Other public comment mentioned that the implementation of the Food Safety Modernization Act (FSMA), to oversee an enhanced approach to food safety both at the farm and at the handling levels, places an even higher degree of necessity in having this material and/or other sanitizers available for use in organic crop production.

There was overwhelming support for the continued (relisting) of peracetic acid for use in organic crop production. While a few commenters took a neutral position, there were no commenters, either during the written or oral public comment periods, that were specifically opposed to the relisting of peracetic acid. Based on the information provided (comments, new TR, etc.), discussion during public comment periods (in-person, webinar, and written), and Subcommittee review and Discussion it was determined this material satisfies the OFPA Evaluation criteria and the Crops Subcommittee supported the relisting of peracetic acid. Additionally, peracetic acid was relisted during the 2016 Sunset review for Handling and the 2017 Sunset listing for Livestock.

14 NOSB members (with one absent) voted for peracetic acid to remain on the National List for use at §205.601.

Questions to our Stakeholders
The NOSB, through its various Subcommittees is engaging in a critical assessment of how it reviews the full suite of sanitizers either available in organic or petitioned for use in organic. As part of that assessment, the following draft framework has been suggested as a means of polling stakeholders to determine the appropriateness of certain materials in organic production:

1. Base Process: How does the material fit into an adequate system of cleaning (contact time, scrubbing effort and force, water source, etc.), rinsing, and sometimes testing, as the essential first step in sanitation?

2. Use: Is it a direct food contact material or a surface contact material?

3. Need: Has the material met the need addressed by its original petition?

4. Efficacy: How well does the material work for the specific need identified?

5. Alternatives: Are existing alternatives adequate? Are there materials already on the list that can be employed in a new use, rather than adding or a new material or continuing to allow use of a less appropriate older material?

6. Rotation: How does this material fit into rotations and/or the need for back up materials?

7. Other Regulatory Reviews: How can we look to FDA and EPA to help us assess risk while, also evaluating against the OFPA criteria (particularly environmental fate and human contact impacts)?

EPA List 3 – Inerts of unknown toxicity

Reference: §205.601(m)(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.
Technical Report: N/A
Petition(s): N/A
Past NOSB Actions: 10/2002 meeting minutes and vote (see pheromones); 11/2007 recommendation; 05/2012 recommendation; 08/2015 recommendation to change annotation at 7 CFR §205.601(m); 10/2016 sunset recommendation; NOSB resolution (2020)
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987); Sunset Review 10/09/2008 (73 FR 59479) Sunset Review 10/03/13 (78 FR 61154); Sunset renewal notice effective 5/29/2018 (83 FR 14347)
Sunset Date: 5/29/2023

Subcommittee Review

Use
The annotation for the List 3 Inerts limits their use in organic crop production to passive pheromone dispensers. The dispensers are normally manufactured as either tubes that contain pheromones or as an impregnated substance containing the pheromone. They may be used to trap and monitor insect populations or they may be used for control of a pest through pheromone mating disruption. For trapping, the pheromone-impregnated dispenser is placed in a trap and the insect catch is monitored to determine when an economic threshold is reached, and the particular insect needs to be controlled. For pheromone mating disruption, the dispensers are tied to branches of trees or placed in such a manner that they are distributed throughout an area being covered by the pheromones. Throughout the season the construction of the pheromone dispensers regulates the volatilization of pheromones into the air. Once in the air of the production area, the pheromones act to disrupt mating of the by interfering with the insect communication systems. A wide variety of insects, mostly Lepidoptera, can be managed with pheromones including codling moth, peach twig borer, peach crown borer, leafrollers, pink bollworm, boll weevil, gypsy moth, and others. When they are placed in the production area, the pheromone dispensers are not in contact with the organic product being grown but are instead suspended from the trees or plants. Since the pheromone dispensers do not contact the product grown, there is no movement of the pheromones into the product. Passive pheromone dispensers are different from other forms of dispensers such as microencapsulated products, which are sprayed throughout the production area and could be in direct contact with the fruit or other product being grown.

Manufacture
Manufacture varies based on which List 3 inert is being used, so will not be addressed. International Acceptance

Canadian General Standards Board Permitted Substances List
Synthetic and non-synthetic pheromones and semiochemicals are permitted. For pest control. Use in pheromone traps or passive dispensers.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Pheromones, Attractant; sexual behaviour disrupter; only in traps and dispensers.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Pheromone preparations for traps.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Pheromones – in traps and dispensers only.

Japan Agricultural Standard (JAS) for Organic Production
Limited to the agent containing sex pheromone activity for pest as active ingredient.

Environmental Issues
Passive pheromone dispensers used for monitoring insects are crucial to integrated pest management programs in that they help to determine the size and impact of insect populations. The use of passive pheromone dispensers for mating disruption often precludes the need for other chemical controls. When used with adequate sanitation practices, monitoring, biocontrol methods, and environmental controls, pheromones can be effective in controlling certain Lepidoptera insects. Without pheromone use, and despite the other natural controls listed, other insecticides may be needed for control of the specific pest insect. These insecticides may be either natural or synthetic but would most often be applied directly to the product being grown and might require preharvest intervals. While pheromones are very specific to individual insect species, these other insecticides may be broader spectrum and affect more species than those requiring control and may have more detrimental environmental impacts.

Other potential environmental issues relate to the number of List 3 Inerts pheromone dispensers used per acre. Often maximum dispenser applications are in the range of 400 per acre. Information from the package of one manufacturer shows ingredients other than pheromones as 8% and that the total amount of pheromone applied per acres is 50 grams. Given the small amount of pheromone applied, there is a very small volume of List 3 Inerts applied to any given acre. This application rate might be compared to the amounts of allowed List 4 Inerts applied in spray materials or the amount of synthetics applied in allowed newspaper mulch. While any application of any material to organic acreage should be considered, it is also important to consider the scale of the application. In addition, the ingredients other than pheromones are heavier than the pheromone itself and remain inside the dispenser. Thus, the List 3 Inerts are not dispersed into the atmosphere and do not have direct fruit contact.

The manufacture of pheromones may have possible environmental impacts, but because these materials are grouped together as List 3 Inerts, these impacts cannot be independently categorized.

Discussion

For reference, the old EPA lists can be found at: https://www.epa.gov/pesticide-registration/categorized-lists-inert-ingredients-old-lists

As with the discussion of the listing for List 4 Inerts reviewed during 2020, this listing is outdated in that the EPA no longer maintains its listing of List 4 or List 3 inerts. Thus, the system to review materials for addition or removal is broken. The listing for List 3 Inerts is more specific than that for List 4 Inerts in that it is limited to only those materials needed for and used in passive pheromone dispensers. These dispensers do not come into direct contact with the agricultural product being produced, whether they be used for trapping or mating disruption.

During the previous review by the NOSB, the NOSB supported the recommendation that these inerts move into a separate listing that would cover all inert ingredients. The inert ingredients used in passive pheromone dispensers were to be a subheading of inerts. However, the process recommended by the NOSB in that review was not initiated and the review of these materials is similar to the previous review. As with List 4 Inerts, the NOSB strongly recommends and asks the National Organic Program to develop an alternative to these List 4/List 3 references that would allow for review (and addition or removal) of inerts and that would not rely on an antiquated list. Public comments from prior reviews supported moving quickly with an annotation change so that the List 3 Inerts could be systematically and thoroughly reviewed.

However, NOSB, in prior reviews, found that these materials are an essential component of passive dispensers and have a history of use in organic farming. They have reduced the use of many other pest control products. The specificity of the annotation leads to limited use in very controlled situations. There was no new information that caused the NOSB to question their safety to human health or the environment. In prior reviews, public commenters supported moving quickly with the annotation change so that the List 3 Inerts, as well as the other inerts, could be systematically and thoroughly reviewed. The continued need for the pheromones was a common theme in the public comments as well.

Questions to our Stakeholders

1. Are there any new health or environmental concerns with the use of the List 3 inerts in passive pheromone dispensers?

2. Are there any natural alternatives to the use of List 3 inerts in passive pheromone dispensers?

3. What percent of ingredients in passive pheromones do List 3 inerts represent?

4. Do the List 3 ingredients in the passive dispensers diffuse into the environment or do they remain in the dispensers?

Chlorine materials – Calcium hypochlorite

Reference: §205.601(a) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials -For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.
(i) Calcium hypochlorite
Technical Report(s): 1995 TAP; 2006 TR; 2011 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation
Recent Regulatory Background: Sunset renewal notice 3/21/2017 (82 FR 14420); Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use
Calcium hypochlorite is an EPA-registered pesticide (OPP Nos. 014701). Calcium hypochlorite is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. Allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl2).

Calcium hypochlorite is an "indirect" food additive approved by FDA. Calcium hypochlorite may be used as a final sanitizing rinse on food processing equipment (21 CFR 178.1010). Hypochlorites also can be used in postharvest, seed, or soil treatment on various fruit and vegetable crops (EPA, 1991).

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration or the Environmental Protection Agency for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

In water, sodium and calcium hypochlorite separate into sodium, calcium, and hypochlorite ions, and hydrochlorous acid molecules. Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with the hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triosephosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function.

Manufacture
Calcium hypochlorite is produced by passing chlorine gas over slaked lime. It is then separated from the coproduct, calcium chloride, and air dried or vacuumed.

International Acceptance
Canadian General Standards Board Permitted Substances [List](http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf)
http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf

International Federation of Organic Agriculture Movements (IFOAM) Norms
Equipment cleaner/disinfectant: https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-standard. An intervening event or action must occur to eliminate risks of contamination

Environmental Issues
Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposures occur or from chronic lower-level exposures – especially in occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) and can cause asthma, as classified by the Association of Occupational and Environmental Clinics (http://www.aoecdata.org/ExpCodeLookup.aspx Code 332.10). Given the similar chemistries and mechanisms of action, other chlorine-based oxidant sanitizers, already known to be respiratory irritants, also likely cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in a 2006 and 2011 Technical Reports (TR) (referenced above.).

Discussion
Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food-safety regulations under the Food Safety Modernization Act (FSMA). The Crops Subcommittee (CS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The CS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.

Questions to our Stakeholders
The NOSB, through its various Subcommittees, is engaging in a critical assessment of how it reviews the full suite of sanitizers either available in organic or petitioned for use in organic. As part of that assessment, the following draft framework has been suggested as a means of polling stakeholders to determine the appropriateness of certain materials in organic production:

1. Base Process: How does the material fit into an adequate system of cleaning (contact time, scrubbing effort and force, water source, etc.), rinsing, and sometimes testing, as the essential first step in sanitation?

2. Use: Is it a direct food contact material or a surface contact material? *Do stakeholders see any distinction in the use of this material in this crop production context versus a food handling/processing context?*

3. Efficacy: How well does the material work for the specific need identified?

4. Alternatives: Are existing alternatives adequate? Are there materials already on the list that can be employed in a new use, rather than adding or a new material or continuing to allow use of a less appropriate older material?

5. Rotation: How does this material fit into rotations and/or the need for back up materials?

6. Other Regulatory Reviews: How can we look to FDA and EPA to help us assess risk while also evaluating against the OFPA criteria (particularly environmental fate and human contact impacts)?

Chlorine materials – Chlorine dioxide

Reference: §205.601(a) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials - For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.
(ii) Chlorine dioxide
Technical Report(s): 1995 TAP; 2006 TR; 2011 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation
Recent Regulatory Background: Sunset renewal notice 3/21/2017 (82 FR 14420); Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use
Chlorine dioxide is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. It is allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl2).

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration or the Environmental Protection Agency for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

Chlorine dioxide is a strong oxidant. It is likely a better bactericide than hypochlorous acid. In general, the disinfection efficiency of chlorine dioxide decreases as temperature decreases.

Manufacture
To form chlorine dioxide, sodium chlorate ($NaClO_3$) and sulfuric acid (H_2SO_4) are reacted with sulfur dioxide (SO_2), or chloric acid is reacted with methanol (CH_3OH) (HSDB, 2005). Alternatively, chlorine dioxide can be formed with chlorine (Cl_2) and sodium chlorite; sodium hypochlorite with hydrochloric acid; potassium chlorate with sulfuric acid; or by passing nitrogen dioxide through a column of sodium chlorate.

International Acceptance
Canadian General Standards Board Permitted Substances List
http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf

International Federation of Organic Agriculture Movements (IFOAM) Norms
Equipment cleaner/disinfectant: https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-standard. An intervening event or action must occur to eliminate risks of contamination

Environmental Issues
Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposures occur or from chronic lower level exposures – especially in occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) can cause asthma, as classified by the Association of Occupational and Environmental Clinics (http://www.aoecdata.org/ExpCodeLookup.aspx Code 332.10). Given the similar chemistries and mechanisms of action, other chlorine-based oxidant sanitizers, already known to be respiratory irritants, also likely cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in 2006 and 2011 Technical Reports (TR) (referenced above).

Discussion
Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food-safety regulations under the Food Safety Modernization Act (FSMA). The Crops Subcommittee (CS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The CS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.

Questions to our Stakeholders
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3. Efficacy: How well does the material work for the specific need identified?

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5. Rotation: How does this material fit into rotations and/or the need for back up materials?

6. Other Regulatory Reviews: How can we look to FDA and EPA to help us assess risk while also evaluating against the OFPA criteria (particularly environmental fate and human contact impacts)?

Chlorine materials – Hypochlorous acid – generated from electrolyzed water

Reference: §205.601(a) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials -For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.
(iii) Hypochlorous acid - generated from electrolyzed water.
Technical Report(s): 1995 TAP (Chlorine materials); 2006 TR (Chlorine materials); 2011 TR (Chlorine materials); 2015 TR (Hypochlorous acid)
Petition(s): 2015
Past NOSB Actions: 04/2016 recommendation to add
Recent Regulatory Background: Added to NL 12/27/2018 (83 FR 66559)
Sunset Date: 1/28/2024

Subcommittee Review

Use
Hypochlorous acid is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces primarily in indoor environments. Allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl_2).

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration or the Environmental Protection

Agency for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triosephosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function.

Manufacture
Electrolyzed water (EW) is the product of the electrolysis of a dilute sodium chloride solution in an electrolysis cell containing a semi-permeable membrane that physically separates the anode and cathode but permits ions to pass through. In the process, hypochlorous acid, hypochlorite ion, and hydrochlorite acid are formed at the anode, and sodium hydroxide is formed at the cathode. The solution formed on the anode side is acidic EW (pH 2 to 6), and the solution formed on the cathode side is basic EW (pH 7.5 to 13). Neutral EW, with a pH of 6 to 7.5 is produced by mixing the anodic solution with hydroxide, or by using a single-cell chamber for electrolysis. (TR lines 48-68).

International Acceptance
Canadian General Standards Board Permitted Substances *List*
http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf

Japan Agricultural Standard (JAS) for Organic *Production*
https://www.maff.go.jp/e/policies/standard/jas/specific/attach/pdf/criteria_o-12.pdf

Environmental Issues
Hypochlorous acid, generated from electrolyzed water, is present in solutions of two chlorine sanitizers (sodium hypochlorite and calcium hypochlorite) currently allowed at §205.601(a)(2)(i, ii). Like other chlorine compounds, hypochlorous acid is also an oxidant and can pose risks to human health. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in 2006 and 2011 Technical Reports (TR) (referenced above).

As formulated via electrolyzed water, hypochlorous acid is effective as a sanitizer at a lower chlorine concentration and is likely safer for health and the environment than other currently listed chlorine sanitizers.

Discussion
Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food-safety regulations under the Food Safety Modernization Act (FSMA). The Crops Subcommittee (CS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The CS supports research priorities that investigate alternatives to

chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.

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3. Efficacy: How well does the material work for the specific need identified?

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5. Rotation: How does this material fit into rotations and/or the need for back up materials?

6. Other Regulatory Reviews: How can we look to FDA and EPA to help us assess risk while also evaluating against the OFPA criteria (particularly environmental fate and human contact impacts)?

Chlorine materials – Sodium hypochlorite

Reference: §205.601(a) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials -For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.
(iv) Sodium hypochlorite
Technical Report(s): 1995 TAP; 2006 TR; 2011 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 04/2006 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation
Recent Regulatory Background: Sunset renewal notice 3/21/2017 (82 FR 14420); Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use
Sodium hypochlorite is an EPA-registered pesticide (OPP No 014703). Sodium hypochlorite is an antimicrobial disinfectant and pesticide used to control harmful microorganisms including bacteria, viruses,

and fungi on inanimate objects and surfaces primarily in indoor environments. Allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (SDWA) (currently 4mg/L expressed as Cl_2).

Sodium hypochlorite is an "indirect" food additive approved by FDA. Sodium hypochlorite may be used as a final sanitizing rinse on food processing equipment (21 CFR 178.1010); sodium hypochlorite may be used in washing and lye peeling of fruits and vegetables (21 CFR 173.315). These hypochlorites also can be used in postharvest, seed, or soil treatment on various fruit and vegetable crops (EPA, 1991).

For organic food handling facilities and equipment, chlorine materials may be used up to maximum- labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration or the Environmental Protection Agency for such purposes. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

In water and soil, sodium and calcium hypochlorite separate into sodium, calcium, and hypochlorite ions and hydrochlorous acid molecules. Hypochlorous acid molecules are neutral and small in size. As a result, when hypochlorous acid molecules exist in equilibrium with the hypochlorite ions, they easily diffuse through the cell walls of bacteria. This changes the oxidation-reduction potential of the cell and inactivates triosephosphate dehydrogenase, an enzyme which is essential for the digestion of glucose. Inactivation of this enzyme effectively destroys the microorganism's ability to function.

Manufacture
Generally, sodium hypochlorite is produced by reacting chlorine with a solution of sodium hydroxide (NaOH, also called lye or caustic soda). This method is used for most commercial productions of sodium hypochlorite. A more active, but less stable formulation of sodium hypochlorite can be produced by chlorinating a solution of soda ash (Na_2CO_3).

International Acceptance
Canadian General Standards Board Permitted Substances List
http://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-311-2020-eng.pdf

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:250:0001:0084:EN:PDF. Products for cleaning and disinfection referred to in Article 23 (4).

International Federation of Organic Agriculture Movements (IFOAM) Norms
Equipment cleaner/disinfectant: https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-standard. An intervening event or action must occur to eliminate risks of contamination.

Japan Agricultural Standard (JAS) for Organic Production https://www.maff.go.jp/e/policies/standard/jas/specific/attach/pdf/criteria_o-12.pdf

Environmental Issues
Chlorine sanitizing compounds currently on the National List are strong oxidants and can pose serious risks to human health if acute high exposure occurs or from chronic lower-level exposures – especially in occupational environments when these materials are used on a daily basis. These compounds are dermal, respiratory, ocular, and mucous membrane irritants. Sodium hypochlorite (bleach) can cause asthma, as classified by the Association of Occupational and Environmental Clinics. Given the similar chemistries and mechanisms of action, other chlorine-based oxidant sanitizers, already known to be respiratory irritants, also likely cause asthma. Chlorine compounds are toxic to fish and other aquatic organisms. Strict adherence to the label is required when used, including the use of personal protective equipment when appropriate. Use of chlorine compounds in organic processing and crop production have been reviewed in 2006 and 2011 Technical Reports (TR) (referenced above.).

Discussion
Protecting food from contamination by human pathogens is essential to safeguard organic integrity. Despite the potential for significant risks to human health and the environment, chlorine compounds have been judged essential to ensure food safety and to comply with food-safety regulations under the Food Safety Modernization Act (FSMA). The Crops Subcommittee (CS) generally supports continued listing of these materials but encourages ongoing discussion about the listing of sanitizers and disinfectants for post-harvest handling and processing. The CS supports research priorities that investigate alternatives to chlorine compounds and encourages the use of alternative, less toxic materials, when their use can meet strict food safety standards.

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5. Rotation: How does this material fit into rotations and/or the need for back up materials?

6. Other Regulatory Reviews: How can we look to FDA and EPA to help us assess risk while also evaluating against the OFPA criteria (particularly environmental fate and human contact impacts)?

Magnesium oxide

Reference: §205.601(j)(5) Magnesium oxide (CAS # 1309-48-4)—for use only to control the viscosity of a clay suspension agent for humates.
Technical Report(s): 2021 TR Pending
Petition(s): 2013
Past NOSB Actions: 5/2014 NOSB recommendation to add
Recent Regulatory Background: Added to NL 12/27/2018 (83 FR 66559)
Sunset Date: 1/28/2024

Subcommittee Review

Use
Magnesium oxide (MgO) is a synthetic substance approved for use in organic crop production to control the viscosity of a clay suspension agent for humates. MgO occurs as the mineral magnesia, and in its hydrated form – magnesium hydroxide - as the naturally occurring mineral periclase. Magnesium oxide appears to be a fairly benign compound that has a wide range of uses, including as an antacid and laxative (milk of magnesia), and in lots of industrial processes such as in producing cement, abrasive materials, and furnace linings.

MgO is neither a strong acid nor a strong base. Instead it acts as a buffering agent when in aqueous solution. Buffering agents are materials that create an effective resistance to change in pH of aqueous solution when a strong acid or base is added.

Manufacture
There are several manufacturing processes used to produce MgO. It is commonly made from sea water or salt brines but can also be made by heating magnesium carbonate (MgCO3) limestone to drive off carbon dioxide (CO2) and produce MgO. The production of MgO from sea water or salt brine uses the following procedure: The raw materials are lime and salt water -- either sea water or brine from salty wells. The lime is heated to produce calcium oxide. Fresh water is then added to the calcium oxide to produce calcium hydroxide. Sea water or salt brine from a well is treated with a small amount of sulfuric or hydrochloric acid which is then added to the calcium hydroxide, causing the magnesium chloride in the salt water to react with calcium hydroxide to produce magnesium hydroxide and calcium chloride. The magnesium hydroxide is then heated to produce magnesium oxide.

International Acceptance
Canadian General Standards Board Permitted Substances List
There are no current references to synthetic magnesium oxide for use in crop production.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
There are no current references to synthetic magnesium oxide for use in crop production.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
There are no current references to synthetic magnesium oxide for use in crop production.

International Federation of Organic Agriculture Movements (IFOAM) Norms
There are no current references to synthetic magnesium oxide for use in crop production.

Japan Agricultural Standard (JAS) for Organic Production

There are no current references to synthetic magnesium oxide for use in crop production.

Environmental Issues
When magnesium oxide is produced using sea water or salt brine, a small amount of acid is used to lower the pH of the salt solution to prevent the formation of carbonates. When MgO is produced using magnesium carbonate limestone, carbon dioxide is released into the atmosphere. Additional carbon dioxide is produced through the burning of fossil fuels used to achieve the high heat required to decompose the limestone.

The code of federal regulations (CFR), title 21, Part 184-Direct food substances affirmed as generally recognized as safe lists magnesium oxide at § 184.1431 as an ingredient used in food with no limitation other than current good manufacturing practice and affirms the ingredient as generally recognized as safe (GRAS) as a direct human food ingredient.

The original petitioner noted that magnesium oxide is safely used in numerous applications in preference to other materials because it is considered to be nonhazardous, environmentally safe, and nontoxic. Some of the applications include:

- wastewater treatment
- toxic metal removal
- adsorption of dyes and excess phosphorus from industrial wastewater
- odor control
- treatment of acid mine drainage
- non-toxic flame retardant for clothing
- flue gas desulfurization
- hazardous spill clean up

Magnesium oxide and the hydrated form magnesium hydroxide have been used safely for over a century as a laxative and antacid (milk of magnesia).

Discussion
This is the first sunset review for magnesium oxide since it was added to the National List. There was a previous technical report which covered the uses of magnesium oxide in livestock production and the petitioner noted that aspects from that report were relevant to the listing for crops use. The NOSB has requested, but not yet received, a technical report specifically for the use of this material in crops. The technical report should be received in enough time to include the information in the review for the fall NOSB meeting.

According to the original petition, natural humic substances stimulate biological activity, foster cycling of resources by making fertilization more efficient, conserve water, promote ecological balance, conserve biodiversity, and improve soil and water quality. Non-synthetic humic substances are used in organic agriculture to improve soil structure and fertility, increase plant nutrient uptake, and improve root architecture.

The petitioner further stated that magnesium oxide is used to:

> modify clays in such a manner to effectively suspend humic substances while simultaneously preventing recrystallization of any fertilizer or micronutrient salts that may be in solution. Reducing the growth of crystals is necessary to prevent the plugging of spray nozzles during spray applications. The use of the magnesium oxide-modified clay also increases the viscosity of aqueous

suspensions of humates, which in turn delays settling and keeps the solids from forming a hard cake when settling eventually occurs.

Alternatives to magnesium oxide include periclase and brucite, dolomitic limestone, phlogopite, wood ash, and pelletized non-synthetic humates. The petitioner states that these are either not commercially available or do not meet chemical or physical specifications for suspending humates in solution.

In the review to add magnesium oxide to the National List, the NOSB determined that magnesium oxide, as petitioned, satisfied all three evaluation criteria - minimal impact on humans and environment, essentiality for use in organic agriculture, no commercial availability of non-synthetic material, and compatibility & consistency with organic agriculture. They found that magnesium oxide appeared to be a fairly benign compound that has a wide range of uses. The petitioned use is for a very low level and specific use. The NOSB chose to add the restrictive annotation to clarify the language in the petition, which they felt was too broad.

Questions to our Stakeholders

1. Has magnesium oxide been used for the purposes of suspending humates in a clay solution as described in the original petition?

2. Are there any commercially available, non-synthetic alternatives that achieve the same purpose as magnesium oxide?

3. Is there still a need for liquid humates in organic agriculture?

4. Can non-synthetic acids be used in place of sulfuric acid in the manufacture of magnesium oxide?

5. Are there environmental or human health issues that should be noted in the decision to retain magnesium oxide on the National List?

Calcium chloride

Reference: §205.602(c) Calcium chloride, brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.
Technical Report: 2001 TAP; 2021 TR Pending
Petition(s): 2005; 2015
Past NOSB Actions: 09/1996 minutes and vote; 11/2006 annotation change (failed); 11/2007 sunset recommendation; 12/2011 sunset recommendation; 10/2016 sunset recommendation
Recent Regulatory Background: National List amended 10/31/2003 (68 FR 61987); Sunset renewal notice effective 11/03/13 (78 FR 61154); Sunset renewal notice effective 5/29/2018 (83 FR 14347)
Sunset Date: 5/29/2023

Subcommittee Review

Use
Calcium chloride is used to manage almost three dozen physiological disorders on crops. These include a reduction of cork spot on pears, bitter pit in apples, fruit cracking on developing figs, rain cracking in cherries, blossom end rot on tomatoes, and tipburn on Chinese cabbage (TAP lines 156-175). “Application of foliar calcium sprays relieves calcium physiological disorders because these are local deficiencies due to

calcium transport problems. Local availability of calcium in new shoots and fruits can help solve the problem" (lines 197-98). Application of nonsynthetic calcium chloride in organic crop production is limited to foliar sprays to treat a physiological disorder associated with calcium uptake.

Manufacture
According to the 2007 TAP, "calcium chloride can be produced from a number of sources by various methods. Some of these are naturally occurring, some require extraction and beneficiation that is not considered by most reviewers to be a chemical reaction, and some are entirely synthetic. Those extracted from brine are generally considered nonsynthetic, although certain steps to purify the brine may be considered synthetic (lines 8-11)." The TAP goes on to explain that "calcium chloride can be obtained by extraction of nonsynthetic brines. When calcium chloride is extracted from a nonsynthetic source, its molecular structure is not changed during extraction and thus should be classified nonsynthetic. However, Dow (the major supplier) and other producers use synthetic chemicals during the purification of the brine (lines 62-4)." Industrial production of calcium chloride occurs mainly through 1) the hydrochloric acid method, 2) the Solvay process, and 3) the Dow process. "Productions by the Solvay process and by reaction of a calcium source with hydrochloric acid are both clearly synthetic" (lines 11-12). The 2001 TAP explains that:

> Calcium chloride can be obtained by extraction of nonsynthetic brines. When calcium chloride is extracted from a nonsynthetic source, its molecular structure is not changed during extraction and thus should be classified nonsynthetic (lines 62-3).

Calcium chloride from naturally occurring brine is nonsynthetic as long as there are no manufacturing steps (see NOP 5033 4.6 Extraction of Nonorganic Materials) that change the classification to synthetic.

International Acceptance
Canadian General Standards Board Permitted Substances List
States "non-synthetic calcium chloride may be used to address nutrient deficiencies and physiological disorders".

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Allows for calcium chloride as a "foliar treatment of apple trees, after identification of deficit of calcium" with the limitation that the need be "recognized by the inspection body or inspection authority".

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Lists calcium chloride for "leaf treatment in case of proven calcium deficiency".

International Federation of Organic Agriculture Movements (IFOAM) Norms
Permits calcium chloride under Appendix 2, Fertilizers and Soil Conditioners of mineral origin with no restrictions on use.

Japan Agricultural Standard (JAS) for Organic Production
Lists calcium chloride under Fertilizers and Soil Improvement Substances.

Environmental Issues
The 2007 TAP describes that, when used as a foliar spray, calcium chloride "probably has low potential for interaction or interference with other materials used in organic farming" (lines 295-96). It has a low toxicity to mammals, though it can be a skin, eye, and breathing irritant. When used in foliar applications, "it should not affect beneficial insects. It should not persist on foliage. Any not absorbed by the plant should

be washed off with rain. Calcium chloride is extremely soluble in water, and low concentrations from foliar use should not build up in soil, unless it is used in low rainfall areas with minimal irrigation. Any water-soluble calcium or chloride not absorbed by plant roots would drain into surface waters or be leached into groundwater (lines 304-08)." Additionally, during manufacture from brines, the liquid brines are pumped out from underground, and do not present the kind of problem usually seen with strip mining. The only toxic chemicals involved are chlorine and bromine, and they are handled so that environmental contamination is low. The chlorine is recycled, and bromine is isolated as bromide or bromine and is sold as a chemical product. Excess lime added in processing is isolated as part of the final calcium chloride. The magnesium hydroxide produced is used to prepare other magnesium salts and magnesium metal by electrolysis. It is not dumped into the environment. The sodium chloride isolated in the process is sold as table salt or for chemical production. Spent solutions are recycled and pumped back underground to isolate a new concentrated brine (lines 311-319). Finally, "calcium chloride obtained from natural salt brines has a significant amount of sodium chloride, usually about 3-4%. Sodium chloride has a high salt index and should not be applied to soil (Rader, et al., 1943)… Application to soil could lead to chloride phytotoxicity (Greenway and Munns, 1980) (TAP lines 355-58).

Discussion

This is a unique §205.602 material in that while not completely prohibited for use, the listing serves to annotate or the restrict use of this nonsynthetic. Since it is only allowed for a very specific use (foliar application to treat a calcium uptake disorder), Material Review Organizations list it with the restriction to reflect the very narrow permitted use. Certifiers are responsible for verifying that growers use it in a manner consistent with the restriction.

In 1996, the NOSB originally voted to allow calcium chloride for use to control bitter pit in apples and as an emergency defoliant for cotton; the material was categorized as nonsynthetic and was not included on sections 205.601 or 205.602. In 2003, calcium chloride was subsequently added to National List at § 205.602 as a non-synthetic substance prohibited for use in organic crop production with the current annotation. The annotation states: "brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake." In 2005, the NOSB rejected a petition to remove the prohibition for use as a soil-applied nonsynthetic substance due to high chloride and solubility concerns. The board received another petition in 2015 to remove the prohibition on direct soil applications but determined it to be ineligible as no new substantive information was presented to warrant reconsideration of the petition.

The NOSB has consistently concluded that brine process calcium chloride is a mined substance of high solubility, and as such, its use is subject to the conditions established on the National List of non-synthetic materials prohibited for crop production. The foundational principle for placing high solubility materials such as calcium chloride on the prohibited non-synthetic materials list is elaborated in §205.203(d) – Soil fertility and crop nutrient management practice standard: "A producer may manage crop nutrients...in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients..." The NOSB has established that the potential for overuse of this natural substance resulting in subsoil, surface water, and ground water contamination, warrant continued limitation through the annotation restrictions.

Questions to our Stakeholders

1. On which crops and for what physiological disorders associated with calcium uptake is calcium chloride used by producers?

2. The 2007 TAP states: "Since bitter pit of apples is a calcium deficit disorder, an alternate form of calcium, such as limestone, gypsum, or rock phosphate, could be used". Please comment.

Rotenone

Reference: §205.602(f) Rotenone (CAS # 83-79-4).
Technical Report(s): N/A
Petition(s): N/A
Past NOSB Actions: 10/2012 NOSB recommendation to add
Recent Regulatory Background: Added to NL 12/27/2018 (83 FR 66559)
Sunset Date: 1/28/2024

Subcommittee Review

Use
Rotenone is a potent non-synthetic botanical pesticide that is also used as a piscicide. In the U.S. rotenone is registered only for piscicidal (fish killing) purposes. Since it is no longer registered by the EPA as a pesticide, it is not available for purchase as an insecticide in the U.S. although it might be available for purchase in other countries. Rotenone was added to §205.602 in December 2018 as a non-synthetic substance that is prohibited for use in organic crop production.

Manufacture
Rotenone is commonly derived from the roots of various tropical plants native to Southeast Asia, South America, and East Africa. Historically farmers have used this extract as a foliar spray to control pests on vegetables, berries, tree fruit, nuts, and forage crops.

International Acceptance
The UK and European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Rotenone is banned in the EU.

United Kingdom (UK)
The UK banned the sale of rotenone in 2009.

Environmental Issues
Adverse health effects from rotenone have been well documented since the NOSB reviewed botanicals in 1994. In 2004 the EPA required an inhalation neurotoxicity study to investigate the possibility of rotenone leading to Parkinson's Disease-like symptoms at high dose exposure in animals. Instead the companies distributing and selling rotenone products voluntarily cancelled all food use registration for it, except for piscicide uses.

Questions to our Stakeholders
None.