Formal Recommendation
From: National Organic Standards Board (NOSB)
To: National Organic Program (NOP)

Date: October 26, 2018

Subject: Sodium chlorite for the generation of chlorine dioxide gas - petitioned

NOSB Chair: Tom Chapman

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: None

Statement of the Recommendation:

The NOSB does not recommend sodium chlorite for the generation of chlorine dioxide gas be added to the National List at §205.605(b).

Rationale Supporting Recommendation:

The NOSB noted the availability of allowed natural and synthetic alternatives to this substance. The Board recognized the importance of having the ability to rotate among several materials in an antimicrobial regime to reduce the incidence of microbial resistance. However, in the absence of public comment advocating for the addition of sodium chlorite for the generation of chlorine dioxide gas to the National List and the availability of alternatives, the NOSB determined it is not essential to organic production.

NOSB Vote:

Classification Motion: Motion to classify sodium chlorite for the generation of chlorine dioxide gas as nonagricultural, synthetic (Classified in April 2016)
Motion by: Scott Rice
Seconded by: Jean Richardson
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Listing Motion: Motion to add sodium chlorite for the generation of chlorine dioxide gas at §205.605(b)
Motion by: Scott Rice
Seconded by: Lisa de Lima
Yes: 6 No: 9 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion Failed

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Sodium chlorite, for the generation of chlorine dioxide gas
June 5, 2018

Summary of Petition (initial petition; petition addendum; technical report)

On October 8, 2015, the NOP received a petition from ICA TriNova, LLC to add chlorine dioxide (CDO) (CAS #10049-04-4) dry gas to §205.605(b) of the National List, nonagricultural (nonorganic) synthetic substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." The petition was revised November 30, 2015, revised again on December 1, 2015, and forwarded to the Handling Subcommittee (HS) December 2, 2015. The petitioner presently manufactures and markets CDO as the formulated product Z-Series FruitGard (FCN 949, EPA Reg. #79814-5).

Use

This material is petitioned for use as an anti-microbial pesticide, sanitizer and/or disinfectant for fruits and vegetables. CDO gas is used in post-harvest handling for the direct treatment of fruits, vegetables and nuts during storage, transportation and food preparation applications to reduce spoilage and pathogenic organisms with no requirement for post treatment rinse. CDO acts as a killing agent of pathogenic organisms.

Chlorine dioxide gas is well known for its antimicrobial effects through oxidative inactivation (Stubblefield et al., 2014; Lee et al., 2015; Park and Kang, 2017). When used as a fumigation agent, there are no residual traces of the CDO disinfectant, or disinfection by-products (DBP) of chlorite and chlorate (JECFA, 2008). The efficacy of CDO gas against a wide range of microorganisms has been demonstrated in several studies across a variety of fruits and vegetables (2018 TR 97 – 99). These studies also relate the increased efficacy of CDO in gas form, compared to its use in aqueous solution, which is primarily due to the increased penetration of the gas treatments, as well as the ability to effectively treat irregular surfaces (Stubblefield et al., 2014; Lee et al. 2015; Park and Kang, 2017).

Chlorine dioxide is permitted by the FDA as an antimicrobial treatment for a range of food products, including fruits and vegetables and poultry processing (21 CFR §173.300). CDO is also used as a bleaching agent in both flour and whole wheat flour (21 CFR §137.105(a) and 137.200(a)). CDO is also widely used in the sanitation and treatment of water systems and is allowed by the FDA as a disinfectant in bottled water (21 CFR §165.110(b)).

In organic production, CDO is currently allowed for use in liquid solution in crop production as a pre-harvest algicide, disinfectant, and sanitizer, including in irrigation system cleaning systems (7 CFR §205.601(a)(2)(ii)); in organic livestock production for use in disinfecting and sanitizing facilities and equipment (7 CFR §205.603 (a)(7)(ii)); and in organic handling for disinfecting and sanitizing food contact surfaces (7 CFR §205.605(b)). For these uses, residual chorine levels in the water cannot exceed the maximum residual disinfectant limit under the Safe Water Drinking Act. The petition seeks to extend the use of CDO in gaseous form for the antimicrobial treatment of products labeled "organic" or "made with organic (specified ingredients or food group(s))."

Sodium chlorite, from which chlorine dioxide gas is produced, is not presently allowed in USDA organic regulations, however acidified sodium chlorite is permitted at 7 CFR §205.605(b) for "secondary direct antimicrobial food treatment and indirect food contact surface sanitizing."

Manufacture

Chlorine dioxide gas is produced by impregnating zeolite with sodium chlorite and then activating the zeolite, which is then treated with solid or liquid acids such as citric acid. If a liquid acid is used, as in the product manufactured by the petitioner, an unspecified buffer is used to control the formation and release of the CDO gas. The ability to produce the desired CDO gas from sodium chlorite with any acid allows for the selection of one of several GRAS acid sources (e.g., citric acid).

Several industrial synthetic procedures are used in the production of sodium chlorite, including the following: the treatment of chlorine dioxide with sodium hydroxide and a reducing agent (e.g., sodium sulfite), the treatment of chlorine dioxide with sodium peroxide (Na2O2), or an alkaline solution of hydrogen peroxide (H2O2) (TR 2018, 72-75).

Due to its reactivity and explosive nature when concentrated, CDO is generated on-site prior to required usage. There are several methods for the generation of CDO gas from sodium chlorite, all of which involve the oxidation of the chlorite ion to the neutral radical species. This oxidation process can be completed by treatment with H+ from an acid, or electrochemically by the electrolysis of a sodium chlorite solution, and by treatment with chlorine gas (Cl2) (TR 2018, 296-297).

Chlorine dioxide is applied as a dry pure gas in closed containment. Treatment is conducted over several hours until the substance is completely consumed by reactions with a wide variety of organic matter. CDO is converted to a chloride ion on the food products. In processing facilities, this material is used as an oxidizer, surface and equipment cleaner, and deodorizing agent. It is applied as a dry pure gas at the point of need. Application rates vary.

Summary of Review

The Handling Subcommittee's initial review of the petition determined a need for revision by the petitioner. The HS found the initial petition sought to list a process rather than a material. If reviewed as petitioned, the HS would have reviewed several materials: sodium chlorite, zeolite acting as a carrier which is impregnated with sodium chlorite, acidic chlorine dioxide activators and related buffers. When used together as directed, these materials produce CDO gas.

The HS returned the petition to the petitioner April 18, 2016, with a request to revise the title to "*Sodium chlorite, for the generation of chlorine dioxide gas*." The HS believed a petition considering sodium chlorite for the particular use of gas generation is more consistent with how other sodium chlorite materials have been reviewed. The proposed use is similar to the acidified sodium chlorite that is already listed at 205.605(b) for "secondary direct antimicrobial food treatment and indirect food contact surface sanitizing." That substance was petitioned and added as a solution, whereas this listing would be used as a fumigant gas for direct food contact with no requirement for post treatment rinse.

Under the current title, certifiers and/or material review organizations would review the sodium chlorite product and the attendant components noted above. In its revision request, the HS also asked the petitioner if, as with use of other sodium chlorite materials, produce treated with ClO2 dry gas requires a potable water rinse sufficient that residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

A petition addendum responding to these two requests was received by the HS May 5, 2016.

The petitioner responded to the two HS requests above, resubmitting the petition as "*Sodium chlorite, for generation of chlorine dioxide gas*" and, in response to the question regarding need for a post-treatment potable water rinse, the petitioner noted that CDO gas rapidly reacts with produce surfaces and potential residues of concern, primarily CDO or chlorite ion, do not persist. Water solution applications and precautionary potable rinses are not required for gas applications (Smith et al., 2015).

Because of this material's intended use as killing agent for pathogenic organisms, the petitioner's formulated product is EPA registered. While the petitioner notes the target use of CDO gas is for vegetables and fruit, the EPA label for the formulated product only allows for use on stored potatoes.

Summary of Public Comments

In advance of the Fall 2016 meeting during which this material was reviewed, the Board received a number of comments from the public; some supported the listing while others cited concerns.

- Several commenters noted the material should be petitioned or listed as "chlorine dioxide gas" with an annotation restricting the form to "generated from sodium chlorite." One commenter noted if "sodium chlorite for the generation of chlorine dioxide gas" appears on the National List, it is unclear how other precursors and activators other than sodium chlorite would be reviewed. It is important to note the initial petition was submitted in this way; however it was the HS's opinion that since the material would not be sold or distributed as the finished product of chlorine dioxide gas, it should be petitioned as stated in the proposal.

- A number of commenters noted that CDO gas does not have a place in organic production and see this as a substitute for good care and handling of produce. While care and handling certainly play a role in reducing microbial contamination, increased scrutiny of food safety measures and additional regulations are driving industry to identify other tools. The NOSB currently has a work agenda item to develop questions to assess the essentiality of sanitizer (antimicrobial) materials.

- Several commenters expressed concern for worker safety when using this material. Several commenters requested the HS review this material in relation to other sanitizers and/or chlorine materials. Some commenters noted the need for a technical report (TR) to provide more neutral input on this material and to address some of the concerns noted above.

- Several commenters noted the addition of CDO gas as a step forward for reducing microorganisms on fruit and vegetables and it would add another option for sanitation.

Given public comment citing the above questions and concerns, the Board referred the material back to the Handling Subcommittee for further review and subsequently requested a TR on June 6, 2017.On January 9, 2018, the NOP provided the TR to the Handling Subcommittee for review.

Allowance under other organic standards

- **Canadian General Standards Board Permitted Substances List**
  Sodium chlorite is not listed in CAN/CGSB-32.311-2015.

  Chlorine dioxide is listed in CAN/CGSB-32.311-2015, Table 7.3 "Food-grade cleaners, disinfectants and sanitizers permitted without a mandatory removal event," with the exception that CDO levels do not exceed maximum levels for safe drinking water, Table 7.4. "Cleaners, disinfectants, and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory," with permission for use "up to maximum label rates."

- **CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) -**
  Neither sodium chlorite nor chlorine dioxide are listed in the GL 32-1999 CODEX.

- **European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008**
  Neither sodium chlorite nor chlorine dioxide are listed in EC No. 834/2007 and 889/2008.

- **Japan Agricultural Standard (JAS) for Organic Production**
  Neither sodium chlorite nor chlorine dioxide are listed in the JAS for Organic Production.

- **International Federation of Organic Agriculture Movements (IFOAM)**
  Sodium chlorite is not listed in the IFOAM Norms. Chlorine dioxide is listed in the IFOAM Norms in Appendix 4, Table 2, "Indicative List of Equipment Cleansers and Equipment Disinfectants," with a limitation of "an intervening event or action must occur to eliminate risks of contamination."

Category 1: Classification

1. Substance is for: __X__ **Handling** _____ **Livestock**

2. For HANDLING and LIVESTOCK use:
   a. Is the substance _____ **Agricultural** or __X__ **Non-Agricultural?**
   Describe reasoning for this decision using NOP 5033-2 as a guide:

   The substance is a chemical compound.

   b. If the substance is **Non-agricultural**, is the substance _____ **Non-synthetic** or __X__ **Synthetic?**
   Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide:

   The substance is not manufactured, produced or extracted from a natural source.

3. For **LIVESTOCK**: Reference to appropriate OFPA category
   Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

   N/A

Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

   CDO gas is a known oxidizer. However, as described in the petition, when used in an enclosed environment such as a produce cold room, there are no known interactions with other substances used in organic production.

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

   CDO gas is not persistent and not a known bio-accumulative substance. However, it is a strong oxidizer and acutely toxic and would impact wildlife or other fauna if released in an uncontrolled fashion. Under the intended use in an enclosed environment there is minimal environmental hazard.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

   Manufacturing sodium chlorite produces several byproducts, such as chlorine dioxide, which cannot be immediately released into the environment. This petition is for the use of sodium chlorite to generate chlorine dioxide gas. When used as intended, the CDO rapidly decomposes to chlorite and chlorate, with the final endpoint being chloride (GRN 000161; JECFA, 2007a; Lee et al., 2015; Clordisys Systems, Inc., 2016; Park and Kang, 2017). Chloride is prevalent in nature and physiology, and therefore, will not provide an adverse impact at anticipated concentrations (WHO, 2000).

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

   As noted in the petition, the primary concern of exposure to chlorine dioxide is acute toxicity resulting from airborne gas. Chlorine dioxide is a strong oxidizer and known irritant to the respiratory system, eyes, and other mucous membranes. Thresholds for irritation are not well defined (WHO, 2000; IPCS, 2002). In prior studies of CDO, intense irritation in humans was seen at concentrations of 5 ppm, and this level is considered immediately dangerous to life or health by NIOSH (ATSDR 2004b). Permissible exposure limits (PEL) in air is a time weighted average of 0.1 parts per million (ppm) during an 8-hour shift, over a 40-hour workweek, and the recommended exposure limit (REL) is 0.3 ppm for short term (15 minute) exposures (NIOSH 2016b). Symptoms or chronic diseases resulting from exposure to bleach and/or chlorine dioxide identified by the U.S. National Institute of Occupational Health (NIOSH), the U.S. Centers for Disease Control (CDC), and the Association of Occupational and Environmental Clinics include skin irritation; irritation of eyes, nose, and throat; cough, wheezing, asthma, bronchitis, pulmonary edema, and/or chronic bronchitis (AOEC 2017; NIOSH 2016b; ATSDR 2010; ATSDR 2002; ATSDR 2004a).

   Chlorine dioxide is highly reactive and is expected to rapidly decompose to chloride and chlorate when used as intended. Due to the rapid decomposition of CDO the proposed use, and appropriate application procedures and industrial hygiene controls that prevent human exposures, the proposed use is unlikely to result in the adverse human health effects from CDO (TR 2018 428-429).

   Both chlorite and chlorate are readily absorbed in the body; however, due to the physiological prevalence of chloride in the body, there are no reliable analytical methods to track their metabolism (EPA, 2000; WHO, 2000). Current studies suggest that following ingestion of chlorate and chlorite, both oxychloro anions are reduced to chloride, which is excreted in urine (EPA, 2000).

The European Food Safety Authority (EFSA) has recently reviewed the possible effect of antimicrobial treatments for the emergence of antimicrobial resistance and has reported that there are no documented cases of antimicrobial resistance from CDO treatments (EFSA, 2008).

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

   The substance is used in an enclosed handling environment and not applied to soil or livestock. When used according to the petitioned use, applied at low levels and in secure conditions, the substance does not have adverse impacts in the agroecosystem.

6. Are there any adverse impacts on biodiversity? (§205.200)

   When used according to the petitioned use, applied at low levels and in secure conditions, the substance does not have adverse impacts on biodiversity.

Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

   Preventive practices are an essential aspect of organic production, and keeping fresh produce free of soil and reducing the potential for bacterial contamination of produce during pre- and postharvest is an FDA requirement. There are some fluid alternatives such as sodium hypochlorite or chlorine dioxide in liquid form, the latter of which is already listed on the National List. Presently the only non-fluid anti-microbial pesticide, sanitizer or disinfectant alternative on the National List is ozone (7 CFR §205.605(b)).

   Natural alternatives include weak organic acids such as alginic, citric and lactic acids, which are included on the National List (7 CFR §205.605(a)). However, the use of acids as disinfecting and sanitizing agents may result in changes to the organoleptic properties of the products, including flavor and other sensations (Meireles et al., 2016).

2. **For Livestock substances, and Nonsynthetic substances used in Handling**: In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]
   N/A

Category 4: Additional criteria for synthetic substances used in Handling (does not apply to nonsynthetic or agricultural substances used in organic handling):

Describe how the petitioned substance meets or fails to meet each numbered criterion.

1. The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1))

   The substance is a chemical compound.

2. The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2))

   As noted above, when used as intended, the substance rapidly degrades to chlorite and chlorate ions that have little adverse effects on the environment. Due to the lack of appreciable residues of chlorine dioxide, chlorate, or chlorite post CDO gas treatment, there is no need for the potable water rinse that is currently required for aqueous treatments, such as with acidified sodium chlorite. The ability to eliminate the requirement for the post-treatment rinse allows for a reduction in waste water effluent, further protecting environmental concerns (Clordisys Systems, Inc., 2016).

3. The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations; (§205.600(b)(3)

   Neither the nutritional quality of the food nor human health is impacted with use of CDO gas, or its breakdown products of CDO or chlorite ions.

4. The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law; (§205.600(b)(4))

   The petition and the 2018 TR describe the preservative qualities associated with the use of this substance. However, the preservative qualities are likely due to the inactivation of microorganisms that facilitate food spoilage and are secondary to its primary action (Gomez-Lopez et al., 2009; EFSA, 2016).

5. The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5))

   Sodium chlorite, for the generation of CDO gas does not appear in the FDA GRAS inventory. However, CDO generated using sodium chlorite in calcined or sulfated kaolin clay (GRN 000161), and CDO generated from particles composed of sodium polyphosphate, magnesium sulfate, sodium silicate and sodium chlorite that are incorporated into low density polyethylene (LDPE) food-packaging films appear in the FDA GRAS inventory (GRN 000062).

6. The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))

   While other sanitizers and disinfectant substances appear on the National List, only ozone is currently present in gas form. In gaseous form, CDO reacts rapidly and completely, thereby reducing or negating the need for de-chlorination of waste water streams. Liquid forms of CDO mainly treat the rinse waters and are not as effective in treating microorganisms on produce. As noted above, dry gas applications appear to have greater effectiveness in penetrating coarse or porous produce. The use of CDO in gaseous form stands to reduce water usage.

7. In balancing the responses to the criteria in Categories 2, 3 and 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, Compatibility with Organic Production and Handling, April 2004)

   As noted, acidified sodium chlorite is already listed at §205.605(b), and at the April 2016 NOSB meeting, the Board voted unanimously to add hypochlorous acid to §205.605(b). Like acidified sodium chlorite and hypochlorous acid, CDO gas has the added potential to offer handling operations a material that has strong antimicrobial properties on irregular surfaces, may reduce water use, and appears compatible with the fundamental principles of organic production.

Classification Motion: (The NOSB classified sodium chlorite as nonagricultural, synthetic in April 2016).

Motion to classify sodium chlorite, for the generation of chlorine dioxide gas as nonagricultural, synthetic.
Motion by: Scott Rice
Seconded by: Jean Richardson
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National List Motion:

Motion to add sodium chlorite, for the generation of chlorine dioxide gas at §205.605(b)
Motion by: Scott Rice
Seconded by: Lisa DeLima
Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Lisa de Lima, Subcommittee Chair, to transmit to NOSB, August 24, 2018

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