National Organic Standards Board Handling Subcommittee Petitioned Material Proposal Sodium chlorite, for the generation of chlorine dioxide gas August 16, 2016

Summary of Petition (initial petition; petition addendum):

On October 8, 2015, the NOP received a petition to add chlorine dioxide (ClO2) (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.

This material is petitioned for use as an anti-microbial pesticide, sanitizer and/or disinfectant for fruits and vegetables. It is used for the direct treatment of fruits and vegetables during storage, transportation and food preparation applications with no requirement for post treatment rinse.

ClO2 gas is produced by impregnating zeolite with sodium chlorite and then activating the zeolite with a solid or liquid acid such as citric acid. An unspecified buffer is used.

CIO2 gas is used in post-harvest handling as a disinfectant to kill microorganisms. It is used in the direct treatment of vegetables, fruits and nuts to reduce spoilage and pathogenic organisms. In these applications the mode of CIO2 is a killing agent of these pathogenic organisms.

It is applied as a dry pure gas in closed containment. Treatment is done over several hours until the substance is completely consumed. ClO2 is converted to a chloride ion on the food products. In processing facilities, use of this material is used as an oxidizer, cleaner, deodorizing agent. It is applied as a dry pure gas at the point of need. Application rates vary and will convert to chloride ion when reacting with a wide variety of organic matter.

Summary of Review:

The HS'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 ClO2 gas.

The HS returned the petition to the petitioner April 18, 2016, with a request to revise to "sodium chlorite, for the generation of chlorine dioxide gas." The HS believes a petition considering sodium chlorite for the particular use of gas generation is more consistent with how other sodium chlorite materials have been reviewed. It is very similar to the acidified sodium chlorite that is already on the list at 205.605(b), however that substance was petitioned as a solution, whereas this one is used as a fumigant gas.

Therefore, the HS asked that the petitioner revise the petition to "sodium chlorite, for generation of chlorine dioxide gas." If listed, certifiers and/or material review organizations will 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.

The petitioner responded to the two HS requests above, resubmitting the petition as "sodium chlorite, for generation of chlorine dioxide gas." In response to the question regarding need for a post-treatment potable water rinse, the petitioner noted that ClO2 gas rapidly reacts with produce surfaces and residues of concern, primarily ClO2 or chlorite ion, do not persist. Gas applications are different than water solution applications and precautionary potable rinses are not required.

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 ClO2 gas is for vegetables and fruit, the EPA label for the formulated product only allows for use on stored potatoes. It is likely the petitioner seeks EPA allowance for broader use on fruit and vegetables as evidenced by their formulated product name "FruitGard®."

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, ClO2 gas has the potential to offer handling operations a material that has strong antimicrobial properties and is compatible with the fundamental principles of organic production.

Category 1: Classification

Substance is for: X Handling
 For HANDLING and LIVESTOCK use:

 Is the substance _____ Agricultural or __X __ Non-Agricultural?
 Describe reasoning for this decision using NOP 5033-2 as a guide:

 The substance is a mineral.
 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

¹ Smith, D.J. et al. Chloroxyanion residues in cantaloupe and tomatoes after chlorine dioxide gas sanitation. Journal of Agricultural and Food Chemistry, 2015, 63, 9640-9649.

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)]
 - ClO2 gas is a known oxidizer. However, when used as prescribed in the petition, 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)]
 - CIO2 gas is not persistent and not a known bio-accumulative substance. When used in the intended use in an enclosed environment and allowed to degrade to CIO2 or the chlorite ion, there is no toxicity.
- 3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]
 - Manufacturing sodium chlorite produces some byproducts, such as chlorine dioxide, which cannot be immediately released into the environment. This petition is for the use of sodium chlorite as chlorine dioxide gas. As noted above, if used as intended, the substance degrades to CIO2 or chlorite ions.
- 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 the substance is acute toxicity related to inhalation where the substance is a known irritant to eyes and mucal membranes. Severe exposure (beyond amounts available by petitioned product) can result in chemically induced pneumonia and or death. However, if used as intended, the substance degrades to ClO2 or chlorite ions.
- 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)]
 - 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)]

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. However, presently there are no antimicrobial pesticides, sanitizers or disinfectants in gas form on the National List.

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 mineral not derived from a natural mined source.

- 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))
 - When used as intended, the substance degrades to ClO2 or chlorite ions that have no adverse effects on the environment.
- 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 ClO2 gas or its breakdown products of ClO2 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 petitioner describes the preservative qualities in the use of this substance. However, the preservative qualities are secondary to its primary action, which is a disinfectant used to kill microorganisms.
- 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 ClO2 gas does not appear in the FDA GRAS inventory.

However, ClO2 generated using sodium chlorite in calcined or sulfated kaolin clay², and ClO2 generated from particles composed of sodium polyphosphate, magnesium sulfate, sodium silicate and sodium chlorite that are incorporated into low density polyethylene (LDPE) foodpackaging films appear in the FDA GRAS inventory³.

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, none are currently present in gas form. As a gas form, ClO2 reacts rapidly and completely thereby reducing or negating the need for de-chlorination of waste water streams. Liquid forms of ClO2 mainly treat the rinse waters and are not as effective in treating microorganisms on produce. Dry gas applications appear to have greater effectiveness in penetrating coarse or porous produce. The use of ClO2 in gas 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)

Like acidified sodium chlorite and hypochlorous acid, ClO2 gas has the potential to offer handling operations a material that has strong antimicrobial properties and is compatible with the fundamental principles of organic production.

Category 5: Additional criteria for <u>agricultural</u> **substances used in Handling** (review of commercial unavailability of organic sources):

1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?

N/A

2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate <u>form</u> to fulfill an essential function in a system of organic handling?

N/A

3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?

N/A

4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill

² Tarantino, FDA Agency Response Letter GRAS Notice No. GRN 000161, 2005.

³ Rulis, FDA Agency Response Letter GRAS Notice No. GRN 000062, 2001.

an essential function in a system of organic handling?

N/A

- 5. Does the industry information about unavailability include (but is not limited to) the following?: Regions of production (including factors such as climate and number of regions);
 - a. Number of suppliers and amount produced;

N/A

b. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;

N/A

c. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or

N/A

d. Other issues which may present a challenge to a consistent supply?

N/A

6. In balancing the responses to the criteria in Categories 2, 3 and 5, 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)

N/A

Classification Motion:

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 as petitioned at 205.605(b)

Motion by: Scott Rice

Seconded by: Ashley Swaffar

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