

September 17, 2018

Ms. Michelle Arsenault National Organic Standards Board USDA-AMS-NOP 1400 Independence Ave., SW Room 2648-S, Mail Stop 0268 Washington, DC 20250-0268

Re. HS: Chlorine dioxide gas

These comments to the National Organic Standards Board (NOSB) on its Fall 2018 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

In reviewing this substance, the NOSB must apply the criteria in the Organic Foods Production Act (OFPA), that its use—

(i) would not be harmful to human health or the environment;

(ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products; and

(iii) is consistent with organic farming and handling.¹

The regulations also require:²

In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

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

(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;

(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;

² §205.600(b).

¹ OFPA §6517(c)(1)(A). Further details at OFPA §6518(m).

(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;

(5) The substance is listed as generally recognized as safe (GRAS) by 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; and
(6) The substance is essential for the handling of organically produced agricultural products.

The material petitioned should be chlorine dioxide gas, not sodium chlorite.

The HS proposal suggests some degree of confusion, partly resulting from the mistaken subject of the petition. We submitted early comments –apparently not early enough– regarding the petition process.

Sodium chlorite, which has been petitioned for use in handling, is an intermediate in the manufacturing process of chlorine dioxide gas. Chlorine dioxide gas is the material that is proposed to be used, and hence the material that should be petitioned.

The NOSB should not approve more sanitizers –particularly chlorine-based sanitizers until performing a comprehensive review of sanitizers and the need for sanitizers in organic production.

We have addressed this issue at length in our previous comments –most recently in comments on sanitizers, disinfectants, and cleansers in Spring 2018. We have discussed many alternatives that are available for use by organic producers and handlers. Rather than simply proposing another chlorine-based material, the NOSB subcommittees should commission a TR that (1) determines what disinfectant/sanitizer uses are required by law and by need to meet practical conditions of cleanliness, and (2) comprehensively examines more organically-compatible methods and materials to determine whether chlorine-based materials are actually needed for any uses. In doing so, the TR authors should consult with EPA's Safer Choice Program and investigate materials on the Safer Chemical Ingredients List. If there are uses for which chlorine is necessary, then the NOSB should include them in the National List and limit the use to those particular uses.

Resistance to antimicrobials is a growing concern, and as reported in the Technical Review for Silver Dihydrogen Citrate, "A number of gram-positive, vegetative bacteria have been isolated from equipment that used chlorine dioxide for high-level disinfection, and several strains, *Bacillus subtilis* and *Micrococcus luteus*, showed stable high-level resistance to the standard use concentration of chlorine dioxide."³ (Martin et al. 2008).

Chlorine dioxide is hazardous to humans and the environment.

Chlorine dioxide is hazardous to workers and consumers.

The toxic action of chlorite is primarily in the form of oxidative damage to red blood cells at doses as low as 10 mg/kg of body weight.⁴ Chlorine dioxide is a severe respiratory and eye irritant. According to the Occupational Safety and Health Administration (OSHA), inhalation can produce coughing, wheezing, respiratory distress, and congestion in the lungs. Irritating effects in humans were intense at concentration

³ Savan Group, 2018. Technical Review for Silver Dihydrogen Citrate, lines 427-430.

https://www.ams.usda.gov/sites/default/files/media/SilverDihydrogenCitrateTechnicalReport.pdf.

⁴ 2006 Chlorine TR. Lines 263-264.

levels of 5 ppm. OSHA has set a limit of 0.1 parts of chlorine dioxide or chlorite per million parts of air (0.1 ppm) in the workplace during an 8-hour shift, 40-hour workweek.⁵

OFPA §6518(I) requires the NOSB to "review available information from the Environmental Protection Agency, the National Institute of Environmental Health Studies, and such other sources as appropriate, concerning the potential for adverse human and environmental effects." Among the sources that should have been considered concerning the toxicity of chlorine dioxide are the *EPA Registration Eligibility Document (RED) for Chlorine Dioxide and Sodium Chlorite*⁶ and the *Toxicological Profile for Chlorine Dioxide and Chlorite* produced by the Agency for Toxic Substances and Disease Registry (ATSDR). We will use those sources, as well as Technical Reviews produced for the NOSB.

According to the 2006 Chlorine Technical Report, "[D]uring the 'activation' of chlorine dioxide (i.e., activating dilute aqueous solutions of sodium chlorite with an acid to produce chlorine dioxide), the release of gas to the air or 'off gassing' can be a safety hazard to users."⁷ The Agency for Toxic Substances and Disease Registry (ATSDR) identified respiratory effects of inhalation exposure including lymphocytic infiltration of the alveolar spaces, alveolar vascular congestion, hemorrhagic alveoli, epithelial erosions, and inflammatory infiltrations of the bronchi; in addition to slightly decreased body weight gain, decreased erythrocyte levels, and increased leukocyte levels, relative to controls.⁸

Other toxicological impacts mentioned by ATSDR include neurodevelopmental effects, which appear to be of greatest toxicological concern. These effects have been seen in both epidemiological and animal studies. They include delays in neurodevelopment, as evidenced by delayed brain growth, decreased locomotor and exploratory behavior, and altered auditory startle response in animals exposed during critical periods of neurodevelopment. ATSDR considers that adequate animal cancer bioassays for cancer have not been performed and that genotoxicity testing has produced mixed results.⁹

EPA says,

For most of the bystander/post application occupational scenarios, the inhalation risks for the bystander/post application occupational exposures are of concern using the EPA's selected inhalation toxicological endpoint (RfC). The occupational RfC, 0.003 ppm, is below the limit of detection for chlorine dioxide. Based on OSHA's Integrated Management Information System (IMIS) data available for chlorine dioxide, all air concentration measurements, even those that were undetectable, are above the RfC.¹⁰

This means that chlorine dioxide levels cannot be determined to be at a safe level by measurement because the safe level is lower than the lowest level that can be measured. In addition, EPA's Toxicological

 ⁵ 2006 Chlorine TR. Lines 284-289. See also <u>http://www.osha.gov/SLTC/healthguidelines/chlorinedioxide/recognition.html.</u>
 ⁶ EPA, 2006. *Registration Eligibility Document (RED) for Chlorine Dioxide and Sodium Chlorite* https://archive.epa.gov/pesticides/reregistration/web/pdf/chlorine_dioxide_red.pdf. p.61.

⁷ 2006 Chlorine TR. Lines 240-242.

⁸ ATSDR, 2004. Toxicological Profile for Chlorine Dioxide and Chlorite. p.11. Available at: <u>http://www.atsdr.cdc.gov/toxprofiles/tp160.pdf</u>.

⁹ ATSDR, 2004. Toxicological Profile for Chlorine Dioxide and Chlorite. p.15-55. Available at: <u>http://www.atsdr.cdc.gov/toxprofiles/tp160.pdf</u>.

¹⁰ EPA, 2006. Registration Eligibility Document for Chlorine Dioxide and Sodium Chlorite. P. 35.

Review of Chlorine Dioxide and Chlorite, which <u>was</u> reviewed by the TR writers, derives an RfC of $2.0X10^{-4}$ (0.0002) mg/m³ –even lower than the OSHA limit.¹¹

In view of the statement by the petitioner that no residue should be expected because of the high reactivity of chlorine dioxide and that produce surfaces are "naturally rich in reducing matter," it is surprising that the TR dismisses the possibility of effects on nutrients, even while citing the reactivity of chlorine dioxide with phenolic chemicals, which include well known phytonutrients such as quercetin, rutin, anthocyanins, curcumin, tannins, and capsaicin.

Chlorine dioxide must be removed from produce.

The petition addendum states, "Gas applications are different than water chemistry described above, and so, unlike traditional water interventions, precautionary potable rinses are not required. (see the directions page for EPA Reg. # 79814-5 and FCN 000949 - attached below)." A few points need to be made about these references. First, EPA Reg. #79814-5 is a <u>conditionally</u> registered product. Conditional registrations are temporarily granted while the registrant collects and supplies missing data. Environmentalists and consumer advocates unanimously oppose the issuance of conditional registrations because they allow use of –and promote dependence on– products that are not fully tested.

Second, the excerpt provided by the petitioner does not make it clear that the product is labeled only for use "in controlling microbiological growth such as late blight, brown rot, and others on <u>potatoes</u> during storage and shipment."¹² Although Section 2(ee) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) allows application "against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment," this provision does not apply in this case because the crop (potatoes) and site (potato storage facilities) are not the same as on the label. Even if allowed, the only supportive residue data come from two studies on tomatoes and cantaloupes, not reviewed by EPA, that were supported by the pesticide registrant (which is also the petitioner for this material.) In addition, the residues of chlorate and perchlorate found, while small, nonetheless would not be allowed because there are no tolerances or exemptions from tolerance for chlorine dioxide, chlorite, chlorate, or perchlorate on tomatoes or tomato products or cantaloupes.¹³

Third, FCN 000949 (as provided in the petitioner's addendum) states that it "is not applicable to usage of the FCS in the field, in facilities that only handle raw agricultural commodities, or in transportation from the field to such facilities." It is thus irrelevant to this petition.

In its Registration Eligibility Document (RED), EPA requires that for a chlorine dioxide fruit and vegetable treatment, the following appear on the label: "Fruits and vegetables treated with chlorine dioxide

¹¹ EPA (United States Environmental Protection Agency) 2000. Toxicological Review of Chlorine Dioxide and Chlorite. EPA/635/R-00-007. <u>https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0648tr.pdf</u>.

¹² <u>https://www3.epa.gov/pesticides/chem_search/ppls/079814-00005-20130827.pdf.</u>

¹³ EPA, Index to Pesticide Chemical Names, Part 180 Tolerance Information, and Food and Feed Commodities (By Commodity) <u>https://www.epa.gov/sites/production/files/2015-01/documents/tolerances-commodity.pdf</u>. 40 CFR Part 180. <u>https://www.gpo.gov/fdsys/pkg/CFR-2007-title40-vol23/pdf/CFR-2007-title40-vol23-part180.pdf</u>.

must be blanched, cooked, or canned before consumption or distribution in commerce." This is based on the need to reduce residues below 3 ppm.¹⁴

Chlorine dioxide is hazardous to the environment.

When chlorine dioxide gas is released into the environment, it readily dissociates into chlorine gas and oxygen.¹⁵ Toxic Release Inventory (TRI) data includes 5.7 million pounds of chlorine per year released by facilities making and using chlorine,¹⁶ and 1.7 million pounds of chlorine dioxide released by facilities making and using chlorine dioxide.¹⁷ Most of the reported chlorine dioxide released goes into the atmosphere, where degradation products are chlorine gas, oxygen, and chlorine trioxide.¹⁸

If released into water or soil, chlorine dioxide or sodium chlorite would have effects ranging from slightly to very highly toxic on a wide range of organisms. It is slightly acutely toxic to estuarine/marine fish and ranges from highly acutely toxic to slightly acutely toxic to estuarine/marine invertebrates. It is acutely toxic to freshwater and marine/estuarine fish and invertebrates and aquatic plants. It is moderately toxic to aquatic plants. For terrestrial plants, results of toxicity studies indicate that chlorine dioxide/sodium chlorite are moderately toxic to terrestrial plants. For aquatic plants, toxicity study results.¹⁹ EPA says, "Chronic risks to listed aquatic organisms cannot be assessed at this time; this risk will be assessed when required chronic toxicity data are submitted to and evaluated by the Agency."²⁰ (The lack of data is a consequence of conditional registration.)

Chlorine dioxide gas is not necessary.

The petitioner gives this reason for the need for chlorine dioxide gas: "The substance will improve the shelf life and safety of treated articles. It represents a significant new tool to advance current food safety directives and needs." This is not a reason that, as required by OFPA, chlorine dioxide gas "is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products."

In addition, Technical Reviews performed for the NOSB have repeatedly pointed out alternative practices and materials. Water, acetic acid, vinegar, citric acid, and other naturally occurring acids were mentioned in the 2006 Crops Chlorine TR, for example.²¹ Materials currently on the National List include hydrogen peroxide, acidified sodium chlorite, and peracetic acid. The NOSB recently voted to add hypochlorous acid. The TR for hydrogen peroxide also mentions alternative practices including UV light and temperature control.²² Other practices leading to better control of spoilage include care in handling produce

 ¹⁴ EPA, 2006. Registration Eligibility Document (RED) for Chlorine Dioxide and Sodium Chlorite <u>https://archive.epa.gov/pesticides/reregistration/web/pdf/chlorine_dioxide_red.pdf</u>. p.61.
 ¹⁵ ATSDR, 2004. Toxicological Profile for Chlorine Dioxide and Chlorite. p.9. Available at: <u>http://www.atsdr.cdc.gov/toxprofiles/tp160.pdf</u>.

¹⁶ ATSDR Tox Profile Chlorine, p.162.

¹⁷ ATSDR, 2004. Toxicological Profile for Chlorine Dioxide and Chlorite. P. 88. Available at: <u>http://www.atsdr.cdc.gov/toxprofiles/tp160.pdf</u>.

¹⁸ ATSDR, Tox Profile for Chlorine Dioxide and Chlorite. pp.88, 90.

¹⁹ EPA, 2006. Registration Eligibility Document for Chlorine Dioxide and Sodium Chlorite. pp.38-39.

²⁰ EPA, 2006. Registration Eligibility Document for Chlorine Dioxide and Sodium Chlorite. pp.39, 40.

²¹ 2006 Chlorine TR Crops lines 260-470.

²² 2015 TR for hydrogen peroxide in crops, lines 729-740.

to avoid injury to fruits and vegetables, avoiding contact with raw manure, and avoidance of sanitizers that kill beneficial microbes.²³

Chlorine dioxide gas is not compatible with organic and sustainable production.

The petitioned product has a conditional registration from EPA, meaning that not all essential data have been submitted. It is not labeled for this use. The necessary tolerances or exemptions from tolerances do not exist. It is a hazardous chemical used to take the place of care in handling and less hazardous materials. It does not enhance life and properties, is not made from renewable resources, and has a negative impact on biodiversity.²⁴

Conclusion

The petition should be rejected because it fails to meet all OFPA criteria.

Thank you for your consideration of these comments.

Sincerely,

Jeresahn Hit

Terry Shistar, Ph.D. Board of Directors

²³ See comments on hypochlorous acid.

²⁴ 2011 TR lines 270-271, 278-279, 349-352.