

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

Date: April 27, 2016

Subject: Addition of hypochlorous acid generated from electrolyzed water, as petitioned, at §205.605(b) of the National List

NOSB Chair: Tracy Favre

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

Guidance Statement:

Other:

Statement of the Recommendation:

That hypochlorous acid be classified as synthetic, and that hypochlorous acid be listed as petitioned at §205.605 of the National List, (b) Chlorine materials—disinfecting and sanitizing facilities and equipment, Except that, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act. (Calcium hypochlorite, chlorine dioxide, sodium hypochlorite, and hypochlorous acid generated from electrolyzed water).

There were some concerns raised during public comment regarding the source, so the Board voted to add the annotation: “generated from electrolyzed water”. The petition, subcommittee review, and technical review were all for hypochlorous acid generated via electrolyzed water. The annotation clarifies the source is limited to generation from electrolyzed water, as petitioned.

Rationale Supporting Recommendation:

The substance was found to be consistent with OFPA criteria. Hypochlorous acid is present in solutions of two chlorine sanitizers (sodium hypochlorite and calcium hypochlorite) already listed on §205.603(a)(7). As formulated via electrolyzed water, hypochlorous acid is effective as a sanitizer at a much lower chlorine concentration and is safer for health and the environment than the currently listed chlorine sanitizers. This material better aligns with the fundamental principles of organic production than many of the alternative materials currently allowed.

NOSB Vote:

Classification Motion: Move to classify hypochlorous acid as synthetic

Motion by: Ashley Swaffar

Seconded by: Jean Richardson

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Listing Motion: Move to list hypochlorous acid generated via electrolyzed water, as petitioned, at §205.605(b) Chlorine materials -...(Calcium hypochlorite, Chlorine dioxide, Sodium hypochlorite, and Hypochlorous acid generated from electrolyzed water).

Motion by: Ashley Swaffar

Seconded by: Jean Richardson

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Motion Passed

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal - Hypochlorous Acid
February 16, 2016**

Summary of Proposed Action:

On May 29, 2015 the NOP received a petition to add hypochlorous acid (CAS #7790-92-3) to the National List at §205.601 - Synthetic substances allowed for use in organic crop production. This material is being petitioned for use as an antimicrobial/sanitizer for use on equipment and raw agricultural products. The petition was forwarded to the Handling Subcommittee on June 3, 2015.

The petition was submitted by Botanical Food Company Pty Ltd. hypochlorous acid is being petitioned for use in the following areas:

1. On Farm
 - a. As a post-harvest sanitizer for raw herb and spice material <60 ppm
 - b. As an equipment and cold room sanitizer <200 ppm
2. In Processing plants
 - a. As a post-harvest, pre-process sanitizer for herbs and spices <200 ppm
 - b. As a microbial rinse for herbs and spices <60ppm
 - c. As an equipment and room sanitizer <200 ppm

This petition has been submitted in response to a policy memo issued by the NOP on June 9, 2014: PM 14-3 Electrolyzed Water (EW). The memo was issued as a response to requests asking for the National Organic Program to clarify whether EW was allowed as a sanitizer and antimicrobial agent for use in organic production and handling.

The NOP felt that the allowance of EW by a certifier or a material evaluation program were based on an incorrect interpretation of the allowance for chlorine materials on the National List of Allowed and Prohibited Substances at 7CFR §205.600-606. The NOP requested that certifiers ensure that the use of EW was not allowed in organic handling or production and that any party wishing for further consideration of EW for use in organic handling or production should submit a petition to get it added to the National List. Thus, the rationale for the petition currently before the Handling Subcommittee and the full NOSB is in response to the NOP policy memo.

Manufacture and Uses of the Substance:

Hypochlorous acid is produced by electrolysis of a dilute water-sodium chloride solution flowing through specialized equipment designed to separate alkaline and acidic products. This electrolytic process facilitates the conversion of chloride ions and water molecules into chlorine oxidants (chlorine gas, hypochlorous acid, and hypochlorite ion) within the anode chamber and sodium hydroxide in the cathode chamber of the production equipment. At an acidic to neutral pH, the predominant chemical species is hypochlorous acid (HOCl) with a high oxidation reduction potential (ORP) of $\geq 1,000$ mV.

Hypochlorous acid has received recent attention as an alternative to other chlorine disinfectants and sanitizers. A number of studies have demonstrated the strong antibacterial activity of hypochlorous acid against foodborne pathogens on raw agricultural products and food contact surfaces. Applications of hypochlorous acid as a disinfectant for reducing microbial contamination have been reported for fresh fruits and vegetables, poultry carcasses, shell eggs, cutting boards, and food processing surfaces.

According to the TR, some advantages of using hypochlorous acid water are: 1) It is as effective as any chlorine treatment; 2) it is not necessary to handle potentially dangerous chemicals, e.g. chlorine gas, chlorine dioxide, bleach; 3) the apparatus to produce hypochlorous acid is relatively inexpensive and easy to operate; 4) because only water and sodium chloride are used, hypochlorous acid production is environmentally friendly; and 5) the properties of the hypochlorous acid can be controlled at the preparation site.

Hypochlorous acid can be used as an ingredient in an antimicrobial pesticide formulation and may be applied to dairy processing equipment, and food processing equipment and utensils. The Food and Drug Administration (FDA) regulations (21 CFR Part 178) permit the use of sanitizing solutions containing sodium hypochlorite on food processing equipment and food contact surfaces. In addition to sanitizing food contact surfaces, cleaning solutions containing the active ingredient hypochlorous acid may be used for sanitizing raw fruits and vegetables during the washing or peeling process. The USDA's Food Safety and Inspection Service Directive 7120.1 "Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products", has approved the use of electrolytically generated hypochlorous acid as a food additive for use on meat and poultry products. It is allowed for use on red meat carcasses down to a quarter of a carcass, whole or eviscerated poultry carcasses, in water used in meat and poultry processing, in poultry chiller water, for reprocessing contaminated poultry carcasses, on giblets and salvaged parts, and on beef primal cuts of beef. Depending on the product sanitized from 5 to 50 ppm free available chlorine can be used.

Discussion:

From an environmental impact perspective, hypochlorous acid would appear to pose less of a risk for the environment than some of the alternatives as it is made from water and salt. There are no by-products to be disposed of since all of the materials are formulated and used in the final application process. Also, it would appear that hypochlorous acid would pose less of a risk to human health and/or worker health compared to some of the possible alternative products as well. According to the August 13, 2015 TR it states that hypochlorous acid at a pH 6.5-7.5 is safer to use than other disinfectants containing chlorine. The level of chlorine in hypochlorous acid is usually over ten thousand times less than that of common household bleach. The on-site production helps to alleviate the need to transport other materials that may be more hazardous to handle, thus reducing the risk of exposure to the worker and for possible environmental contamination if improperly handled.

The primary functions of hypochlorous acid are as an anti-microbial, sporicidal, and bactericidal agent. Some currently allowed alternatives to hypochlorous acid are: Sodium and/or calcium hypochlorite (bleach), isopropanol, chlorine dioxide, peracetic/peroxyacetic acid, citric acid, acetic acid, ascorbic acid, vinegar are some of the materials currently allowed for use.

Electrolyzed water, although produced via a different mechanism, has the same mode of action as sodium and calcium hypochlorite (both of these materials are currently on the National List). In fact, the main active ingredient in their dilute aqueous solution form is hypochlorous acid, the same material produced as the anolyte component of electrolyzed water.

During the public comment period prior to the fall 2014 NOSB meeting there were several public comments submitted in response to the NOP's decision to halt the allowed use of hypochlorous acid per their memo PM 14-3 sent out on June 9, 2014. One of those organic stakeholders provided written public comment on September 28, 2014 that included multiple peer-reviewed scientific journal articles. These articles provided support to the claim that electrolyzed water was a safe sanitizer, providing the

same degree of anti-microbial control without the toxic risk to employees, the crops, or the harvested products it is applied to.

This material does look like it could provide organic handling operations a material that has strong antimicrobial properties and is more compatible with the fundamental principles of organic production.

Evaluation Criteria

	Criteria Satisfied?		
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

Subcommittee Action & Vote

Classification Motion: Move to classify hypochlorous acid as synthetic.

Motion by: Ashley Swaffar

Seconded by: Jean Richardson

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

Listing Motion: Move to list hypochlorous acid at §205.605(b), chlorine materials.

Motion by: Ashley Swaffar

Seconded by: Jean Richardson

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

Approved by Harold V. Austin IV, Handling Subcommittee Chair, to transmit to NOSB February 16, 2016

NOSB Evaluation Criteria for Substances Added To the National List - Handling

Category 1. Adverse impacts on humans or the environment? Hypochlorous acid

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]		x		According to the petition electrolyzed water can be made on-site. In this process there would not be any residual product to dispose of. If produced off-site and sold as a finished product then there could be a possibility of environmental contamination as the result of an accident or a spill. The TR does state that in forms of hypochlorous acid that are at a pH<4.0, dissolved chlorine gas can be rapidly lost due to volatilization, decreasing the biocidal effectiveness of the solution over time, but also creating possible human health and safety issues (Fisher, 2009). The more neutral, the pH of the material, the safer and more stable the substance appears to become.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		x		This substance is formed by the electrolysis of a sodium chloride solution. Any environmental concerns would be from a spill during manufacturing or transport of a formulated end product.
3. Are there any adverse impacts on biodiversity? (§205.200)	x			The TR, (lines 596-612) does state that hypochlorous acid in aqueous solutions at pH< 7 was of minimal toxicity to birds, but could be very toxic to fish and freshwater invertebrates.
4. Does the substance contain inerts classified by EPA as ‘inerts of toxicological concern’? [§6517 (c)(1)(B)(ii)]		x		Contaminants listed in the US Food and Drug Administration’s Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed, are unlikely to be found in hypochlorous acid since it is the electrolysis product of two generally recognized as safe materials, salt and water (TR lines 568-571).
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]	x			The TR (lines 140-153) mentions that there can be a reaction with organic material (humic acid) which can lead to some potential concerns. It does go onto state though: It is generally accepted that carcinogenic and teratogenic trihalomethanes and haloacetic acids are not formed by the action of hypochlorous acid in neutral or near-neutral solutions (Satyawli et al., 2007).

6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		x		
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		x		According to the TR (lines 602-612) hypochlorous acid solution decomposes very slowly in the dark but more rapidly in the presence of light, rapidly in full sun light by producing hydrogen chloride and oxygen. Released into the environment it is distributed into water and air, with an estimated half-life of 1-4 hours. A potential for bioaccumulation or bioconcentration of active chlorine species can be disregarded, because of their water solubility and their high reactivity.
8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		x		Information provided in the petition states that compared to other types of chlorine, electrolyzed water is usually used at an active rate that is ten thousand times less than that of common household bleach. The TR (lines 624-626) mentions that the human innate immune system uses hypochlorous acid to fight infection but also directs it against host tissue in inflammatory diseases (Kettle et al.,2013). Chlorine disinfectants have been shown to cause occupational dermatitis or skin irritation (TR line 662).
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		x		See the answer to question #5 above.
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		x		

Category 2. Is the Substance Essential for Organic Production? Hypochlorous acid

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		x		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	x			Electrolyzed water is the product of the electrolysis of a dilute sodium chloride solution in an electrolysis cell containing a semi-permeable membrane. This process creates hypochlorous acid, hypochlorite ion, and hydrochlorite at the anode and sodium hydroxide at the cathode. (TR lines 48-68) August 13, 2015 TR.

3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]		x		
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		x		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		x		
6. Is there an organic substitute? [§205.600(b)(1)]	x			Organic acids such as citric acid, lactic acid, malic acid, and vinegar are some alternative materials.
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	x			Hot water can be used in some instances.
8. Are there any alternative substances? [§6518(m)(6)]	x			Some alternative substances are: Sodium and/or calcium hypochlorite (bleach), isopropanol, chlorine dioxide, peroxyacetic acid, citric acid, acetic acid, ascorbic acid, and vinegar. Copper sulfate is another possible alternative depending on the use.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		x		

Category 3. Is the substance compatible with organic production practices? Hypochlorous acid

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	x			Compared to many of the alternative materials currently being used electrolyzed water could provide a safer and effective alternative. (especially when produced using the on-site electrolysis process)
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	x			See answer to question #1 of this category.
3. If used in livestock feed or pet food, is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	x			
4. If used in livestock feed or pet food, is the primary use as a preservative? [§205.600(b)(4)]		x		
5. If used in livestock feed or pet food, is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]		x		

<p>6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i);</p> <p>copper and sulfur compounds</p>		x		
<p>toxins derived from bacteria</p>		x		
<p>pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals</p>		x		
<p>livestock parasiticides and medicines</p>		x		
<p>production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers</p>	x			May be used to sanitize equipment