

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 §205.603 (a)(7)(iv) 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 Recommendations:

That hypochlorous acid be classified as synthetic, and that hypochlorous acid be listed as petitioned at §205.603 of the National List, (a) As disinfectants, sanitizer, and medical treatments as applicable, (7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, (iv) 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: Francis Thicke

Seconded by: Jean Richardson

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

Listing Motion: Move to list hypochlorous acid generated from electrolyzed water, as petitioned, at §205.603(a)(7)Chlorine materials ... (iv) hypochlorous acid generated from electrolyzed water.

Motion by: Francis Thicke

Seconded by: Jesse Buie

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

Motion Passed

National Organic Standards Board
Livestock 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 of synthetic substances allowed for use in organic production and handling (7 CFR §205.600-606) at §205.605. This material is being petitioned for use as an antimicrobial/sanitizer for use on equipment and raw agricultural products.

This petition has been submitted in response to a policy memo issued by the NOP on June 9, 2014: PM 14-3 Electrolyzed Water. That was a memo issued as a response to requests asking for the National Organic Program to clarify whether electrolyzed water (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 7 CFR 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 then 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:

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 specific ions to pass through. In the process, hypochlorous acid, hypochlorite ion, and hydrochloric 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)

The effectiveness of hypochlorous acid as an active sanitizing agent is determined in large part by the solution pH. Hypochlorous acid exists interchangeably with other chlorine species, including chlorine, hydrogen chloride (aqueous and gaseous) and hypochlorite. In a controlled pH environment, hypochlorous acid will exist as the dominant chlorine species under pH conditions ranging from 2 to 7. (TR lines 84-89)

At a pH of 6.0-7.5 (neutral), EW contains primarily hypochlorous acid, hypochlorite ion and trace amounts of chlorine (TR 118-119). At pH <4.0, dissolved chlorine gas can be rapidly lost due to volatilization, decreasing the biocidal effectiveness of the solution over time, and also creating human health and safety issue (TR 150-152). Therefore it is important that neutral EW be used for sanitizing, not acidic EW.

EW has received recent attention as an alternative to other chlorine disinfectants and sanitizers. A number of studies have demonstrated the strong antibacterial activity of EW water against foodborne pathogens on raw agricultural products and food contact surfaces. Applications of EW 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. Some advantages of using EW water are: 1) EW 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 EW is relative inexpensive and easy to operate, 4) because only water and sodium chloride are used EW production is environmentally friendly and 5) the properties of the EW can be controlled at the preparation site. (TR lines 99-108)

Discussion:

In general, neutral hypochlorous acid (EW) at pH 6.5-7.5 is safer to use than other chlorine-containing disinfectants. The concentration of chlorine present in electrolyzed water is usually over ten thousand times less than household bleach. There is also the advantage of its production on site, alleviating the need to transport dangerous material. (TR lines 616-619)

Hypochlorous acid is the same active sanitizing ingredient that is present in sodium hypochlorite and calcium hypochlorite. The reason hypochlorous acid can be ten thousand times less concentrated than sodium and calcium hypochlorite solutions and still be an effective sanitizer is that sodium and calcium hypochlorite solutions (bleach) have a high pH. When the pH is high, the hypochlorous acid/hypochlorite chemical equilibrium strongly shifts towards the presence of hypochlorite, whereas at neutral pH the chemical equilibrium shifts towards the presence of hypochlorous acid, the effective sanitizing compound. Therefore, hypochlorous acid (EW) is a safer product, for the environment and for human health, than chlorine sanitizer materials currently on the National List.

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

Classification Motion: Move to classify hypochlorous acid as synthetic.

Motion by: Francis Thicke

Seconded by: Jean Richardson

Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Listing Motion: Move to list hypochlorous acid as petitioned at §205.603 of the National List (a) As disinfectants, sanitizer, and medical treatments as applicable. (7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act. (iv) hypochlorous acid.

Motion by: Francis Thicke

Seconded by: Jesse Buie

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

Approved by Ashley Swaffar, Livestock Subcommittee Chair, to transmit to NOSB February 16, 2016

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

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