National Organic Standards Board
Crop 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 and later that summer the Crops Subcommittee was asked to review this material as well, since there are multiple listings being requested by the petitioner. The Livestock Subcommittee is also reviewing hypochlorous acid.

The petition was submitted by Botanical Food Company Pty Ltd. Hypochlorous acid (electrolyzed water) is being petitioned for use in organic crop production for a couple of different uses, including: a) as a post-harvest sanitizer for raw herb and spice materials <60ppm and b) as an equipment and cold room sanitizer <200ppm.

This petition has been submitted in response to a policy memo issued by the NOP on June 9, 2014: PM 14-3 Electrolyzed Water. The memo was 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 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 then submit a petition to get it added to the National List. Thus, the rationale for the petition currently before the Crops 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 ions to pass through. In the process, hypochlorous acid, hypochlorite ion, and hydrochlorite 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).

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 against foodborne pathogens on raw agricultural products. Similar studies and actual in field use (and facility use) has demonstrated similar activity when used to sanitize equipment and storage facilities. This material was (prior to the USDA/NOP memo PM 14-3 Electrolyzed Water) previously approved by at least one material review organization and multiple certifiers for use on crops and allowed for uses other than what is currently being petitioned. Prior

to the NOP memo it was also beginning to be used for control of powdery mildew in apples and to aid in prevention of other pathogens or microbial contamination on fresh fruits and vegetables (leafy lettuce) that might pose a risk to human health.

According to the Hypochlorous Acid TR (August 13, 2015) it states that some of the advantages of using EW 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, etc.,3) the apparatus used to produce EW is relatively inexpensive and easy to operate, 4) because only water and sodium chloride (salt) are used in EW production, it is environmentally more friendly of a compound compared to some of the alternative materials, and 5) the properties of EW are controlled on site during the electrolysis process. It should also be mentioned that since the materials from both of the cathodes are actually used during this process and final product use, there are no bi-products created during the formulation of Electrolyzed Water and therefore nothing to dispose of or that could be considered to be of a negative environmental concern.

Discussion:
From an environmental impact perspective, EW would appear to pose less of a risk for the environment than some of the alternatives since 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 EW 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 hypochlorous acid at a pH 6.0 to 7.5 is safer to use that other disinfectants containing chlorine. The level of chlorine in EW 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 optimum range for the material that previously was being used in organic farming or currently is being used (in conventional farming) is at a pH of 6.0 to 7.5 according to the petitioner. This pH range gives a more effective and a more stable product that is safer for the environment and human safety as well than those using the lower pH levels. According to the TR it mentions that in forms of hypochlorous acid that are at a pH<4.0, dissolved chorine 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.

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

The petition seeks to add electrolyzed water/hypochlorous acid to the National List for use in organic crop production as an alternative to the other substances currently allowed. The petitioner states that EW will be used post-harvest on farm as a sanitizer for use on raw herbs and spices including, but not limited to; basil, cilantro, parsley, chili peppers, garlic, and ginger. EW would also be used on farm to sanitize equipment and as a cold room sanitizer.

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. The reason hypochlorous acid can be ten thousand times less concentrated than sodium and calcium hypochlorous 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.

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. These articles also helped to provide support that this material might better support the basic fundamental principles of organic crop production compared to many of the alternatives currently being used. These also helped to support the petitioners claim as to why this material is needed – because it is safer to use on such crops as lettuce, spinach, and other sensitive vegetables and herb crops.

This material does appear like it could help the organic crop producers meet the requirements of compliance with the FDA's Food Safety Modernization Act, while at the same time providing the producer with a material more compatible with the fundamental principles of organic crop production. It could possibly be looked at to provide a material that is less concerning for its impact on human and environmental health, while helping to meet a necessary need of the organic producer for materials that they can use in the sanitizer/anti-microbial listing for use in organic crop production.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	☒ Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	☒ Yes	☐ No	☐ N/A
3. Compatibility & Consistency	☒ Yes	☐ No	☐ N/A

Subcommittee Action & Vote

Classification Motion: Move to classify hypochlorous acid as synthetic.
Motion by: Harold V. Austin IV
Seconded by: Francis Thicke
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion: Move to list hypochlorous acid at §205.601 of the National List: Synthetic substances allowed for use in organic crop production. §205.601(a) As algicide, disinfectants, and sanitizer. (2)chlorine materials (iv) Hypochlorous acid.
Motion by: Harold V. Austin IV
Seconded by: Emily Oakley
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB February 16, 2016

NOSB Evaluation Criteria for Substances Added To the National List – Crops

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		x		

	changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]				
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); copper and sulfur compounds		x		
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