

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

**Date:** October 27, 2022

**Subject:** Peroxylactic Acid (PoLA)

**NOSB Chair:** Nate Powell-Palm

**The NOSB hereby recommends to the NOP the following:**

None

**Statement of the Recommendation:**

The NOSB recommends that peroxylic acid (POLA) not be added to the National List at § 205.605(b).

**Rationale Supporting Recommendation:**

The NOSB was hesitant to add another synthetic antimicrobial to the list and expand the organic industry's exposure to synthetic materials even though POLA is seemingly benign to human health and environmental impacts.

Stakeholder comments did not indicate a need for POLA and due to the age of the material, there is very little data and research to fully understand the impacts on human health and the environment.

The NOSB concurred with the Handling Subcommittee review and stakeholder comments that Peroxylactic Acid is not compatible with a system of sustainable agriculture due to the lack of essentiality and limited information on the impacts to human health and the environment.

**NOSB Vote:**

**Classification Motion:**

Motion to classify peroxylic acid (PoLA) as non-agricultural, synthetic

Motion by: Logan Petrey

Seconded by: Kyla Smith

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

Motion passed

**National List Motion:**

Motion to add peroxylic acid (PoLA) for use as an antimicrobial agent in process water, ice, or brine used in the production, processing, and preparation of meat and poultry products, at § 205.605(b) of the National List

Motion by: Logan Petrey

Seconded by: Kyla Smith

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

Motion Failed

**National Organic Standards Board**  
**Handling Subcommittee**  
**Petitioned Material Proposal**  
**Peroxlactic Acid (PoLA)**  
**August 2, 2022**

**Summary of [Petition](#)**

Peroxlactic Acid (“PoLA”) is being petitioned by Zee Company, Inc. for addition to the National List as an antimicrobial processing aid for application onto meat and poultry carcasses, parts, trim, and organs at 7 CFR 205.605 (b), “Nonagricultural (nonorganic) substances allowed in or on processed products labeled as “organic” or “made with organic (specified ingredients).” PoLA is a synthetic aqueous mixture for use in process water, ice, or brine for use in the production, processing, and preparation of meat and poultry. The petitioner identified PoLA to be more efficacious, safer, and less volatile than peroxyacetic acid (PAA) in the management of *Campylobacter jejuni*, a pathogen causing campylobacteriosis. A [Technical Report \(TR\)](#) was completed and found sufficient by the Handling Subcommittee on February 1, 2022. According to the TR, campylobacteriosis is one of the most common bacterial infections worldwide and contaminated poultry products are identified as the primary source of these infections. In the TR, other sources stated efficacy of PoLA for the reduction of *E. coli* and *Salmonella spp.* The TR recognized the scarcity of information available for PoLA at this time.

The Handling Subcommittee is bringing this petition forward for full NOSB review at its Fall 2022 meeting.

**Summary of Review:**

The Handling Subcommittee has reviewed the PoLA petition and TR and discussed the issues that are characteristic of most sanitizers and antimicrobials. The Handling Subcommittee is hesitant to add another synthetic antimicrobial to the list and expand the organic industry’s exposure to synthetic substances. However, unlike materials like cetylpyridinium chloride (CPC), which was petitioned in 2021 and subsequently rejected by the NOSB, and chlorine materials, which are on the National List, PoLA breaks down into lactic acid and eventually carbon dioxide and water within 60 minutes of application and therefore is a benign product when considering human health and environmental impacts.

The petition and TR state that PoLA is an effective antimicrobial and could provide better efficacy to producers in managing food borne pathogens in their facilities. The TR also stated that PoLA, if used in place of other antimicrobials, could significantly reduce water use which has dramatically increased over the last couple of decades due to food safety standards.

The Handling Subcommittee is supportive of new, innovative, efficacious synthetic materials that are less harmful or impactful to human health and the environment that could replace currently listed synthetics that require more recourses for use. It is helpful to the Handling Subcommittee to hear from stakeholders and more specifically, operators who need these materials.

**Reference Material:**

The petition and TR were used as reference to answer the following questions:

**Category 1: Classification**

1. Substance is for:  **Handling**  **Livestock**

2. For HANDLING and LIVESTOCK use:
- a. Is the substance \_\_\_\_\_ **Agricultural** or \_\_\_X\_\_\_ **Non-Agricultural**?  
Describe reasoning for this decision using [NOP 5033-2](#) as a guide:

PoLA is a non-agricultural synthetic substance.

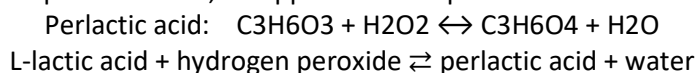
- b. If the substance is **Non-agricultural**, is the substance \_\_\_\_\_ **Non-synthetic**  
or \_\_\_X\_\_\_ **Synthetic**?

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:

PoLA is not derived from an agricultural source, is not a mineral or bacterial culture, is not a microorganism, and is not derived from a crop or livestock product.

According to the TR, "(PoLA) is a peroxycarboxylic acid is formed through an equilibrium reaction between DL-lactic acid (CAS No. 50-21-5) and hydrogen peroxide (CAS No. 7722-84-1) and both isomers of PoLA exist in equilibrium with unreacted lactic acid and hydrogen peroxide. As with other peroxycarboxylic acids, the formation of PoLA from lactic acid and hydrogen peroxide can be catalyzed by a strong mineral acid, such as sulfuric acid. The rate of formation without an added mineral acid was reported as being negligible. Once formed, peroxycarboxylic acids can be self-reactive and susceptible to exothermic degradation, releasing energy as heat as they spontaneously break down."

Perlactic acid, like peracetic acid, is supplied as an equilibrium mixture:



Chemical and physical properties of PoLA from the TR:

Color:	Colorless
Odor:	Odorless – low odor
Average Mass:	106.077 g/mol
Density at 20 °C:	1.140 g/cm
Vapor pressure at 20°C:	Not determined
Flash point:	>55 °C (>131 °F)
pH:	<2

The manufacturing process listed in the petition is the primary method of manufacturing for PoLA and is described as: from hydrogen peroxide (CASRN 7722-84-1) and lactic acid (CASRN 50-21-5), both of which are allowed substances on the National List in § 205.605(a) and § 205.605 (b), respectively. The finished mixture optionally contains a sequestering agent 1-hydroxy-ethylidene-1,1-diphosphonic acid (HEDP) and an optional catalyst (sulfuric acid).

## 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)]

PoLA is used as a processing aid for application onto meat and poultry carcasses, parts, trim, and organs in food processing facilities. It is applied as an antimicrobial agent in process water, ice,

or brine use in the production, processing, and preparation of raw meat and poultry products, it is unlikely that that PoLA will interact with other materials used in organic farming systems.

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)].

Toxicity information from the Safety Data Sheet (SDS) of NEOTOX (Zee Company) of the petitioned material:

Oral LD50: 3310 mg/kg (rat)  
Dermal LD50: 1060 mg/kg (rabbit)

The ecological toxicity information from the SDS of NEOTOX (Zee Company) reveals no further relevant information for aquatic toxicity, persistence, and degradability, bioaccumulative potential, and mobility in soil. The general notes indicate that it is a water hazard class 2, a danger to drinking water, and must not reach ground water, bodies of water, drainage ditches or sewage systems.

Globally Harmonized System (GHS) information of NEOTOX (Zee Company) - label from the petition.

**GHS INFORMATION**

Flam. Liq. 4 H227 Combustible liquid.  
Skin Corr. 1A H314 Causes severe skin burns and eye damage.  
Eye Dam. 1 H318 Causes serious eye damage.  
Acute Tox. 4 H302 Harmful if swallowed.  
Acute Tox. 4 H312 Harmful in contact with skin.  
Acute Tox. 4 H332 Harmful if inhaled.

Stabilizers are required for PoLA solutions due to the reactivity of peroxy-carboxylic acids. These stabilizers maintain shelf life by protecting from metal impurities. The decomposition of these acids would create heat production and be unsafe for transport. There are strict regulations under FDA and U.S. Department of Transportation for allowed stabilizers.

The mode of actions for other peroxy-carboxylic acids are listed in the TR:

- a. The O-OH bond is highly reactive releasing compounds that oxidize.
- b. Peroxy-carboxylic acids reacts with phospholipids in cell membranes

Like other oxidizing agents, PoLA's mode of action denaturates proteins, enzymes, and metabolites, and disrupts cell wall permeability and the oxidizing of sulfhydryl and sulfur bonds in proteins.

FDA also issued a Finding of No Significant Impact (FONSI) during its evaluation of Food Contact Substance Notification (FCN) No. 1946 that PoLA does not persist in the environment.

3. Describe the probability of environmental contamination during manufacture, use, misuse, or disposal of such substance? [§6518(m)(3)]

The TR confirms the petitioner's labeled use is approved under the FDA FCN 1946 as follows:

- 1000 parts per million (ppm) PLA, 2384 ppm Hydrogen Peroxide (HP), and 5.5 ppm HEDP in process water or ice that contacts meat or poultry carcasses, parts, trim, and organs; or
- 495 ppm PLA, 1180 ppm HP, and 2.7 ppm HEDP in process water, ice, or brine that contacts processed and pre-formed meat and poultry.

According to the petitioner “closed, automated injection systems are utilized to introduce concentrate into water lines that feed desired concentrations of this product to various application sites throughout the plant, including into spray cabinets and dip tanks.” These injection lines deliver at or below the surface of the water to minimize splashing.

Disposal of PoLA as described in the petition: “discharge occurs from dip tanks in two ways: 1) as drag-out on the carcasses and 2) deliberately when the tank is emptied for sanitation procedures. For drag-out, there is no difference between a sprayed or a dipped carcass dripping on the line before it enters the chiller. Some antimicrobial chemistry will be introduced into drip pans under the line and that chemistry will be dumped to the waste stream in the drain or back into the dip tank. For tank emptying for sanitation, the antimicrobial-treated water left in the tank at the end of processing will be dumped directly to drain just like the water from every other processing application, including large chiller tanks.”

The TR states, “the patent referenced in the petition claims that PoLA can pose a danger to drinking water if leaked into the ground. The SDS instructs users to not allow PoLA to reach ground water, watercourse or sewage systems, bodies of water, or drainage ditches if undiluted and not neutralized.”

Addition of the PoLA to the wastewater stream at 1000 ppm will have no negative environmental impact. This is further supported by the FDA’s FONSI evaluation of FCN No. 1946.

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

Human health concerns of PoLA are similar to that of PAA. When used in accordance with FCN No. 1946, PoLA is completely degraded on protein surfaces within 60 minutes and therefore there is no anticipated effect to the human health of consumers of the meat or poultry treated with PoLA. As confirmed in the TR, PoLA has little or no odor and has a lower odor profile than PAA. There is no data available to suggest a safety concern.

It states in the petition that “Considering the similarities of the chemistry and the considerably lower odor profile of PoLA, we propose that PoLA concentrations be maintained below the currently acceptable limit of PAA of 0.4 ppm PAA. At this level there might also be only 0.95 ppm hydrogen peroxide, 2.2 ppb HEDP, and 5.2 ppb sulfuric acid in the air – levels far below those that would be of concern for human health hazards. Testing of PAA vs. PoLA vapors above a drip tray apparatus has been performed to compare their volatility, and under identical conditions and amounts, the concentration of PoLA was 10 times less than that of PAA.”

Exposure to the concentrate can cause severe burns, eye damage, and respiratory distress. Effects of exposure to use dilutions should be easily controlled by washing eyes and skin with

water should contact occur. Risk can be minimized by using safety glasses and latex or nitrile gloves.

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)]

The substance will only be applied to meat and poultry products within the confines of a food processing facility and therefore, there will be no effect on soil organisms, crops, or livestock.

6. Are there any adverse impacts on biodiversity? (§205.200)

There is no literature addressing the impacts on biodiversity, however, there is likely to be little to no affect since the product breaks down into carbon dioxide and water. The TR did state that the use of PoLA may increase the use of recycled water and indirectly result in a reduction of water use in the poultry industry, which has significantly increased since 1998.

### 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)]

Nonsynthetic alternatives include bacteriophages, fatty acids, and essential oils.

The petitioner compares PoLA to PAA throughout the petition. They are compatible with each other but like PAA, PoLA is not compatible with reducing agents, alkali (caustic) chemicals, or heavy metals such as iron, copper, chromium, nickel, and aluminum. PAA is also a synthetic material.

The petition indicated the efficacy of PoLA over its alternative, PAA in control of two pathogens, *Campylobacter jejuni*, and *Salmonella infantis*. Neotox (PoLA product) resulted in a reduction of both pathogens under three concentrations (400 ppm; 500 ppm; and 800 ppm).

Antimicrobial materials are necessary to prevent food borne illnesses. There are multiple sanitizers listed for use including organic acids, and chlorine materials. Other allowed antimicrobial agents on the National List are sodium lactate and potassium lactate. PoLA is expected to be more efficacious than these materials.

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)]

Yes. PoLA is very similar to PAA (which is on the National List) with a potentially reduced environmental and human health effect and greater efficacy as an antimicrobial.

**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))

PoLA is synthetic and cannot be produced from natural sources. It is manufactured by a chemical process.

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))

It is unlikely that environmental contamination will occur from the petitioned use and from the patented manufacturing. Literature found in the patent claims that peroxy-carboxylic acids are environmentally benign sanitizers since they break down into naturally occurring elements and compounds (lactic acid, carbon dioxide, and water).

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))

The nutritional quality of the food is not affected by use of PoLA. Residues are undetectable after 60 minutes of use and have no effect on human health.

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))

PoLA is not used as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing. When used in accordance with FCN No. 1946, PoLA is completely degraded on protein surfaces within 60 minutes.

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))

PoLA is not designated as GRAS. As a food contact substance (FCS)(U.S. FDA, 2021a), its legal approval is 438 governed through the issuance of Food Contact Notifications [tr 437-438]

6. The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))

Presently, PoLA is not essential, however could provide a safer, more efficacious alternative to reduce pathogens in organic meat and poultry processing facilities.

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](#))

PoLA is manufactured, applied, and degrades in a manner that is in accordance with the principles of the USDA National Organic Program.

At this time, the Handling Subcommittee is seeking more information from stakeholders about the need for new antimicrobials. The Handling Subcommittee is also interested in the antimicrobial rotations and IPM strategies used in these facilities to help manage pathogens.

**Questions for Stakeholders:**

1. Are pathogen populations getting harder to control in meat and poultry processing facilities?
2. The petition compares PoLA to PAA; if PAA is not the dominant material used in your facility, what is?
3. Have chemical rotations aided in pathogen resistance management?
4. Are your current antimicrobial products preventing you from reducing water use in your facility?

**Classification Motion:**

Motion to classify peroxylic acid (PoLA) as non-agricultural, synthetic

Motion by: Logan Petrey

Seconded by: Kyla Smith

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

**National List Motion:**

Motion to add peroxylic acid (PoLA) for use as an antimicrobial agent in process water, ice, or brine used in the production, processing, and preparation of meat and poultry products, at § 205.605(b) of the National List.

Motion by: Logan Petrey

Seconded by: Kyla Smith

Yes: 3 No: 3 Abstain: 0 Recuse: 0 Absent: 2