Environmental Assessment

1.	**Date**	October 21st, 2016
2.	**Name of Applicant/Notifier**	Seeler Industries, Inc.
3.	**Address**	One Genstar Drive Joliet, IL 60435 Attn: Vincent Casalino, M.S., PMP

4. Description of the Proposed Action

A. **Requested Approval:**

Components of the FCS mixture will not exceed:

(1) 2000 parts per million (ppm) PAA, 773 ppm HP, and 118 ppm HEDP in spray, wash, rinse, dip, chiller water, low temperature (e.g., less than 40°F) immersion baths, or scald water for whole or cut poultry carcasses, parts, trim, and organs or in water for washing shell eggs.

(2) 460 ppm PAA, 177 ppm HP, and 27 ppm HEDP in spray, wash, rinse, dip, chiller water, or scald water for meat carcasses, parts, trim, and organs.

(3) 495 ppm PAA, 190 ppm HP, and 29 ppm HEDP in process water or ice for washing, rinsing, or cooling of processed and pre-formed meat products.

(4) 230 ppm PAA, 88 ppm HP, and 14 ppm HEDP in water or ice used for washing, rinsing, or cooling processed and pre-formed poultry products or in the commercial preparation of fish and seafood**.**

(5) 350 ppm PAA, 135 ppm HP, and 21 ppm HEDP in water or ice for washing or chilling fruits and vegetables in food processing facilities**.**

Mixtures containing peroxyacetic acid in an equilibrium solution with these ingredients have been previously researched and cleared by the FDA for the same uses as stated above.

The proposed FCS may be used in a heated preparation solution up to 40°C and does not require a potable water rinse. The applications of nearly identical PAA products have already been evaluated and approved for these uses at the same usage levels by the FDA.

B. **Need for action:** This product is to be applied to red meat carcasses, red meat carcass parts/trim, or red meat organs through spraying, submersion, or both. This product is applied to poultry as a rinse, dip, spray, in chiller water, or scald

water. Additionally, this product can be used in pre-formed poultry and/or meat, fish and/or seafood, fruits and/or vegetables, as well as an egg shell wash. Peroxyacetic acid exhibits an antimicrobial effect that reduces the presence and population of pathogenic and nonpathogenic microorganisms that may be present while subsequently retarding the spoilage of red meat and poultry.

C. **Locations of use and routes of disposal:** This mixture will be used in food processing facilities throughout the country. Meat and poultry facilities are required by the EPA to treat wastewater onsite where they may either discharge the effluent directly to surface waters if they are in possession of a National Pollutant Discharge Elimination System (NPDES) permit or the facilities may discharge into a publicly owned treatment works (POTW) for further treatment. Fruit, vegetable, and egg processing facilities (with the exception of canning facilities) are not at this time, required by the EPA to pre-treat their waste water. As a result, this submission will base the proposed FCS' environmental impact on a worst case scenario.

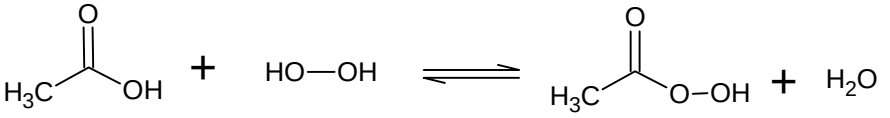
5. Identification of Substance that Is the Subject of the Proposed Action

This particular Food Contact Substance (FCS) is an equilibrium solution of peroxyacetic acid, hydrogen peroxide, and acetic acid. The three aforementioned constituents are blended together with a metal ion inhibitor (HEDP) to increase stability. Transition metals, particularly iron and copper degrade the mixture. The appropriate pre-reaction proportions are added in the blend to achieve the desired post-reaction composition. The chemistry behind the reaction of acetic acid, hydrogen peroxide, and its resulting equilibrium solution is complex and has been researched extensively at Seeler Industries Inc.'s laboratories with the help of previous scientific research.[1]

Ingredients are as follows:

Acetic acid	CAS# 64-19-7
Hydrogen peroxide	CAS# 7722-84-1
1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP)	CAS# 2809-21-4
Deionized water	CAS# 7732-18-5

The reaction to produce peroxyacetic acid CAS# 79-21-0 with a molecular weight of 76 grams per mole is as follows:



6. Introduction of Substances into the Environment

It has been determined per the burden of this environmental assessment (EA) that there are minimal to no known environmental effects as a result of the production and use of this

FCS.

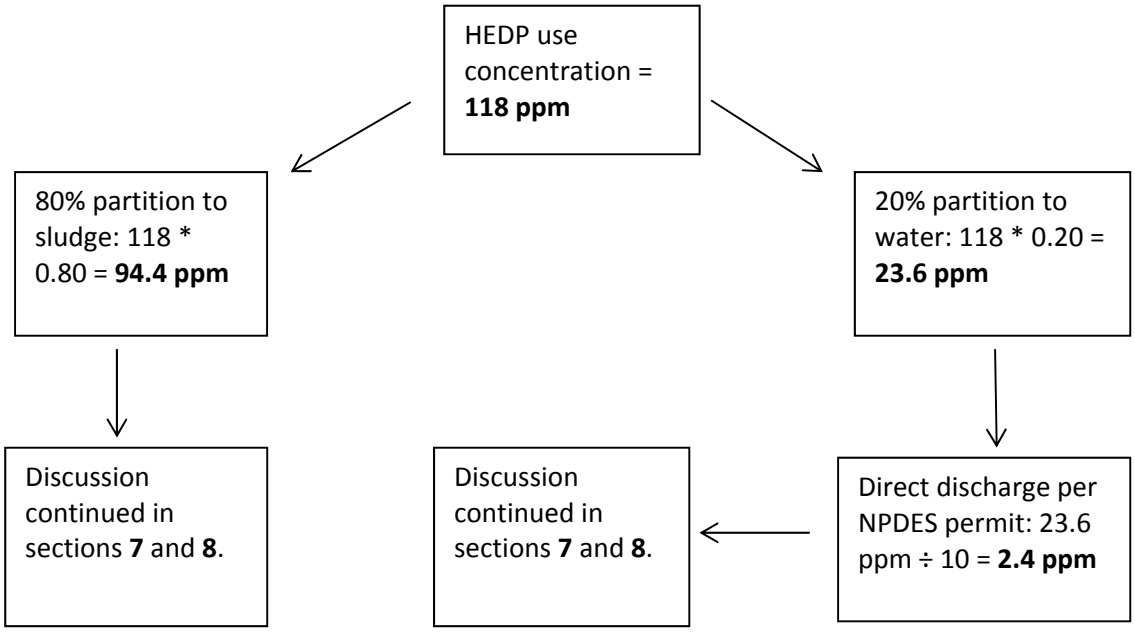
A. The FCS is manufactured at Seeler Industries, Inc. which is an EPA registered facility with the establishment number of 60156-IL-001. Any environmental threat as a result of the manufacture of this product does not exist.

B. As previously mentioned, the FCS proposed use in food processing facilities would find route to surface waters (should the facility have a NPDES) or to a POTW for further treatment.

C. The peroxygen components of this FCS would have an extraordinarily short half-life[2], with their fate being hydrogen, oxygen, and water. The only component not participating in the extreme high rate of degradation would be the 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP). However, the active ingredients and HEDP stabilizer would be diluted significantly.

Estimated Usage:

We will use the use level of 118 ppm for HEDP as the worst-case HEDP concentration for all processing facilities using the FCS in the intended applications. Further, even if a POTW receives and mixes water from two different facilities employing the FCS, the maximum effective environmental concentration (EEC) will never be greater than the highest single use concentration, i.e., 2.4 ppm HEDP. Therefore, the discussion of impacts from use of the FCS will focus on comparing the egg processing EECs to relevant ecotoxicity endpoints that are provided under Item 8.



7. Fate of Emitted Substances in the Environment

Treatment of the process water at an on-site wastewater treatment facility and/or at a Publicly Owned Treatment Works (POTW) is expected to result in complete degradation of peroxyacetic acid, hydrogen peroxide, and acetic acid.[2] Specifically, the peroxyacetic acid will break down into oxygen and acetic acid, while hydrogen peroxide will break down into oxygen and water. Acetic acid is rapidly metabolized by ambient aerobic microorganisms to carbon dioxide and water.[3] Therefore, these substances are not expected to be introduced into the environment to any significant extent as a result of the proposed use of the FCS. The remainder of the environmental assessment will therefore consider only the environmental introduction, fate and potential effects of HEDP.

Assuming, in the worst-case, that all of the water used in any processing plant is treated with the FCS, the total HEDP expected introduction concentrations (EICs) would be as shown in the table below. Specifically, 80 - 90% of HEDP will adsorb to wastewater treatment sludge.[4] We calculate the sludge partition EICs of HEDP by multiplying the stated HEDP use level concentration by 80% (use level × 0.8). The remaining 20% (use level × 0.2) is attributed to HEDP remaining in wastewater. To estimate the expected environmental concentrations (EECs), we have incorporated a conservative 10-fold dilution factor for discharge to surface waters of the effluent from an onsite treatment facility or POTW,[5] as indicated below.

Use	***HEDP Use Level***	***EIC_{water} = Use level x 0.2***	***EEC_{water} = EIC_{water} ÷ 10***	***EEC_{sludge} = Use Level x 0.8***
Meat	*27 ppm*	*5.4 ppm*	*0.54 ppm*	*21.6 ppm*
Preformed poultry	*14 ppm*	*2.8 ppm*	*0.28 ppm*	*11.2 ppm*
Preformed meat	*29 ppm*	*5.8 ppm*	*0.58 ppm*	*23.2 ppm*
Fish & seafood	*14 ppm*	*2.8 ppm*	*0.28 ppm*	*11.2 ppm*
Fruits & vegetables	*21 ppm*	*4.2 ppm*	*0.42 ppm*	*16.8 ppm*
Poultry	*118 ppm*	*23.6 ppm*	*2.4 ppm*	*94.4 ppm*
Eggs	*118 ppm*	*23.6 ppm*	*2.4 ppm*	*94.4 ppm*

8. Environmental Effects of Released Substances

Terrestrial toxicity:

HEDP present in the sludge is not expected to have any adverse environmental impact based on the terrestrial toxicity endpoints available for plants, earthworms, and birds. Specifically, the NOEC for soil dwelling organisms was >1,000 mg/kg soil dry weight for earthworms in soil, while the 14-day LC50 for birds was >248 mg/kg body weight.[4] Using extremely conservative methodology, we have estimated an upper-bound concentration in sludge, not accounting for dilution upon mixing with soil of 94.4 ppm, which is below these ecotoxicity endpoints. Therefore, no terrestrial environmental toxicity concerns exist at levels at which it is expected to be present in sludge. Moreover, the much smaller level of HEDP present in the surface water is not expected to have any adverse environmental impact with respect to sedimentation based on the terrestrial toxicity endpoints available for plants, earthworms, and birds.[4]

Aquatic toxicity:

A footnoted aquatic ecotoxicity table is provided below:

Environmental Aquatic Toxicity Data for HEDP		
Species	*Endpoint*	*mg/L*
Short Term		
Lepomis macrochirus[1]	*96 hr LC_{50}*	*868*
Oncorhynchus mykiss[1]	*96 hr LC_{50}*	*360*
Cyprindon variegates[1]	*96 hr LC_{50}*	*2180*
Ictalurus punctatus[1]	*96 hr LC_{50}*	*695*
Leciscus idus melanatus[1]	*96 hr LC_{50}*	*207 - 350*
Daphnia magna[1]	*24 – 48 hr LC_{50}*	*165 - 500*
Planemonetes pugio[1]	*96 hr EC_{50}*	*1770*
Crassostrea virginica[1]	*96 hr EC_{50}*	*89*
Selenastrum capricornutum[2]	*96 hr LC_{50}*	*3*
Selenastrum capricornutum[2]	*96 hr NOEC*	*1.3*
Algae[2]	*96 hr EC_{50}*	*0.74*
Chlorella vulgaris[1]	*48 hr NOEC*	*≥100*
Pseudomonas putida[1]	*30 minute NOEC*	*1000*
Long Term		
Oncorhychus mykiss[1]	*14 day NOEC*	*60 - 80*
Daphnia Magna[1]	*28 day NOEC*	*10 - <12.5*
Algae[2]	*14 day NOEC*	*13*

[1] Jaworska, J.; Van Genderen-Takken, H.; Hanstveit, A.; van de Plassche, E.; Feijtel, T. Environmental risk assessment of phosphonates, used in domestic industry and cleaning agents in the Netherlands. Chemosphere 2002, 47, 655-665.

[2] HERA – Human & Environment Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates. 06/09/2004. www.heraproject.com – Phosphonates.

According to Jaworska et. al. 2002[6], the primary adverse effects of HEDP result from chelation of nutrients rather than direct toxicity of HEDP. Chelation is not toxicologically relevant in the current evaluation because eutrophication, not nutrient depletion, has been demonstrated to be the controlling toxicological mode when evaluating wastewater discharges from food processing facilities. The lowest short-term EC50/LC50 values published for Selenastrum capricornutum (3 ppm), Daphnia magna (165 ppm), and Crassostrea virginica (89 ppm) are acute toxicity endpoints considered to result from this chelation effect. These values are not relevant when excess nutrients are present as expected in food processing wastewaters. According to Jaworska, et.al. 2002, the lowest relevant endpoint for food processing uses was determined to be the chronic NOEC of 10 ppm for Daphnia magna. The highly conservative upper-bound EEC of 2.4 ppm is 4-fold lower than the 10 ppm chronic NOEC for Daphnia magna.

9. Use of Resources and Energy

The notified use of the FCS mixture will not require additional energy resources for the treatment and disposal of waste solution. The raw materials that are used in the manufacture of the FCS are commercially manufactured chemicals that are produced for the use in various chemical reactions and used for production purposes. Thus, the energy

used for the production of the FCS is not significant.

10. Mitigation Measures

No potential adverse effects are identified herein which would necessitate alternative actions to that proposed in this Notification. If the proposed action is not approved, the result would be the continued use of the currently marketed antimicrobial agents that the subject FCS would replace. Such action would have no environmental impact.

11. Alternatives to the Proposed Action

No adverse environmental impacts have been identified via the burden of this environmental assessment. Should this Food Contact Notification not be approved, the use of peroxyacetic acid mixtures (which most, if not all, contain HEDP) would continue at the same rate. Additionally, the approval of this FCN would not increase market demand of this type of FCS but simply allow end users of the product with more options and feasible logistic solutions.

12. List of Preparers

Vincent M. Casalino, M.S., PMP
One Genstar Drive
Joliet, IL 60435
(815)740-2640
vcasalino@seeler.com

Vincent Casalino has obtained a Bachelor's degree from the University of Illinois at Chicago in Biological Sciences and a Master's degree from Lewis University in Project Management. Vincent Casalino has 6 years of experience working with Food Contact Substances with a concentration specifically related to the manufacture and applications of peroxyacetic acid.

13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge and the knowledge of Seeler Industries, Inc.

Date: 10/21/2016

[redacted]

Vincent M. Casalino, M.S., PMP

LITERATURE CITED

1. ZHANG, Xue-bing, Ting ZHANG, Yu-jie ZHOU, and De-hua LIU. "Preparation of Peracetic Acid from Acetic Acid and Hydrogen Peroxide: Experimentation and Modeling." *The Chinese Journal of Process Engineering* 8.1 (2008): 35-41.

2. EPA: *Reregistration Eligibility. Decision: Peroxy Compounds;* EPA Case 4072. Doc. #733-F-93-026; Dec. 1993

3. U.S. High Production Volume (HPV) Chemical Challenge Program: *"Assessment Plan for Acetic Acid and Salts Category."* Acetic Acid and Salts Panel, American Chemistry Council, June 28. 2001.

4. HERA, *Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates.* 06/09/2004. www.heraproject.com-Phosphonates.

5. Rapaport, Robert A., 1988. *Prediction of consumer product chemical concentrations as a function of publically owned treatment works treatment type and riverine dilution. Environmental Toxicology and Chemistry*, 7(2), 107-115. Found online at: http://onlinelibrary.wiley.com/doi/10.1002/etc.5620070204/abstract

6. Jaworska, et. al., *Environmental Risk Assessment of Phosphonates, Used in Domestic Laundry and Cleaning Agents in the Netherlands*, Chemisphere 2002, 47, 655-665