Attachment 11
Environmental Assessment

1. **Date:** March 7, 2019

2. **Name of Applicant/Notifier:** Harcros Chemicals, Inc.

3. **Address:**

All communications on this matter are to be sent in care of Counsel for the Notifier:

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4. **Description of the Proposed Action:**

A. Requested Action

The action identified in this FCN is to provide for the use of the food-contact substance (FCS), an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid (AA), l-hydroxyethylidine-1,1-diphosphonic acid (HEDP) and, optionally, sulfuric acid and/or dipicolinic acid, as an antimicrobial agent for use in process water, ice, brines, sauces, and marinades used in the production and preparation of food as follows:

1) 2000 ppm peroxyacetic acid, 947 ppm hydrogen peroxide, 116 ppm 1-hydroxyethylidene-1,1-diphosphonic acid and 0.5 ppm dipicolinic acid in process water and ice used to spray, wash, rinse, or dip meat carcasses, parts, trim, and organs; and in chiller water or scald water for meat carcasses, parts, trim, and organs;

2) 2000 ppm peroxyacetic acid, 947 ppm hydrogen peroxide, 116 ppm 1-hydroxyethylidene-1,1-diphosphonic acid, and 0.5 ppm dipicolinic acid in process water and ice used to spray, wash, rinse or dip poultry carcasses, parts, trim, and organs; and in chiller water, immersion baths (e.g., less than 40 °F), or scald water for poultry carcasses, parts, trim, and organs;

3) 495 ppm peroxyacetic acid, 234 ppm hydrogen peroxide, 29 ppm 1-hydroxyethylidene-1,1-diphosphonic acid, and 0.1 ppm dipicolinic acid in water, brine, and ice for washing, rinsing, or cooling of processed and pre-formed meat products;

4) 230 ppm peroxyacetic acid, 109 ppm hydrogen peroxide, 13 ppm 1-hydroxyethylidene-1,1-diphosphonic acid, and 0.1 ppm dipicolinic acid in water, brine, and ice for washing, rinsing, or cooling of processed and pre-formed poultry products;

5) 230 ppm peroxyacetic acid, 109 ppm hydrogen peroxide, and 13 ppm 1-hydroxyethylidene-1,1-diphosphonic acid in process water and ice used to commercially prepare fish and seafood;

6) 350 ppm peroxyacetic acid, 166 ppm hydrogen peroxide, 20 ppm 1-hydroxyethylidene-1,1-diphosphonic acid, and 0.1 ppm dipicolinic acid in water and ice used for washing or chilling fruits and vegetables in a food processing facility;

7) 229 ppm PAA, 108 ppm HP, and 13 ppm HEDP in process water used as a spray on seeds for sprouting (alfalfa, clover, broccoli, flax, and chia) as a well as edible seeds (chia, flax, and hemp) and nuts (almond, cashew, and walnut). The FCS will be applied in the preparing, packing, or holding of the food for commercial purposes, consistent with the FD&C Act section 201(q)(1)(B)(i). The treated edible seeds can be consumed directly or further processed into flour, protein, or oil. The treated edible nuts are intended to be consumed as nuts. The treated seeds for sprouting are intended to be consumed as sprouts.;

8) 2000 ppm peroxyacetic acid, 94 7 ppm hydrogen peroxide, and 116 ppm l - hydroxyethylidene-1,1-diphosphonic acid in water for washing shell eggs; and,

9) 50 ppm peroxyacetic acid, 24 ppm hydrogen peroxide, and 3 ppm 1-hydroxyethylidene-1,1-diphosphonic acid in brines, sauces, and marinades applied either on the surface or injected into processed or unprocessed, cooked, or uncooked, whole or cut poultry parts and pieces; and surface sauces and marinades applied on processed and pre-formed meat and poultry products.

B. Need for Action

This FCS is intended for use as an antimicrobial agent to inhibit the growth of undesirable or pathogenic microorganisms in food processing water and ice and in the brines, sauces and marinades used in the production and preparation of the food products described in Item 4.A, above. Previous authorizations of these uses have allowed processing plants more flexibility in using and managing microbial interventions across the entire production process. The current FCN is needed only to allow market access for the Notifier identified herein.

C. Locations of Use/Disposal

The antimicrobial agent is intended for use in meat, poultry (as well as brines, sauces, and marinades used on poultry and pre-formed meat and poultry products), fish and seafood, egg wash, seeds and nuts, and fruit and vegetable processing plants throughout the United States. It may also be used aboard fishing vessels during initial evisceration and cleaning of fresh-caught seafood. The waste process water containing the FCS generated at facilities other than fishing vessels is expected to enter the wastewater treatment unit at the plants. It is assumed that very minor quantities of the mixture are lost to evaporation throughout the process. For the purposes of this Environmental Assessment, it is assumed that treated wastewater will be discharged directly to surface waters in accordance with the plants' National Pollutant Discharge Elimination System (NPDES) permit. This assumption can be considered a worst-case scenario since it does not account for any further treatment that may occur at a Publicly Owned Treatment Works (POTW). It is expected that wastewater will be discharged into the ocean where dilution is expected to be considerable, and therefore, the resultant concentration of the components in the ocean would be negligible. Direct discharge of wastewater is a common practice within the fishing industry. [1]

5. Identification of Chemical Substances that are the Subject of the Proposed Action:

Chemical Identity

The subject of this notification is an aqueous mixture of peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), l-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and optionally sulfuric acid (CAS Reg. No. 7664-93-9) and/or dipicolinic acid (CAS Reg. No. 499-83-2). PAA formation is the result of an equilibrium reaction between acetic acid and hydrogen peroxide.

$$CH_3CO_2H + H_2O_2 \leftrightarrows CH_3CO_3H + H_2O$$

6. Introduction of Substances into the Environment:

A. As a Result of Manufacture

Under 21 C.F.R. § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Information available to the Notifier suggests no extraordinary circumstances, in this case, indicating any adverse environmental impact as a result of the manufacture of the antimicrobial agent. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

B. As a Result of Use and Disposal

Process water containing the FCS will be treated at an on-site wastewater treatment facility and/or at a POTW. HEDP and dipicolinic acid, the only stable component of the FCS, will partition between the treated process water and the treated sludge, as described more fully below. Only extremely small amounts, if any, of the FCS constituents are expected to enter the environment due to the landfill disposal of sludge containing minute amounts of HEDP in light of the EPA regulations governing municipal solid waste landfills. EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have ground-water monitoring systems (40 C.F.R. Part 258). Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collections systems, they are required to monitor groundwater and to take corrective action as appropriate.

[1] U.S. EPA-800-R-11-005, November 2011, Fish Hold Effluent and Fish Hold Cleaning Wastewater Discharge. *Available at:* https://www3.epa.gov/npdes/pubs/vgp_fishfold.pdf

It is assumed, for the purposes of this Environmental Assessment, that treated wastewater will be discharged directly to surface waters in accordance with a National Pollutant Discharge Elimination System (NPDES) permit. This assumption may be considered a worst-case scenario since it takes no account of further treatment that may occur at a POTW.

Treatment of the process water at an on-site wastewater treatment facility and/or at a 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 when the FCS is used as intended.

Sulfuric acid is listed as an optional ingredient in the FCS formulation. Sulfuric acid is used to catalyze the reaction between acetic acid and hydrogen peroxide, more rapidly producing a stable PAA mixture, and to modify the pH of the FCS.

Sulfuric acid dissociates readily in water to sulfate ions (SO_4^{-2}) and hydrated protons; at environmentally-relevant concentrations, sulfuric acid is practically totally dissociated (OECD SIDS, 2001). As part of the natural sulfur cycle, sulfate is either incorporated into living organisms, reduced via anaerobic biodegradation to sulfides, deposited as sulfur, or re-oxidized to sulfur dioxide and sulfate (HERA, 2006). Therefore, any terrestrial or aquatic discharges of sulfate associated with the use described in this FCN are expected to have no significant environmental impact, as sulfate is a ubiquitous anion that is naturally present in the ecosystem and virtually indistinguishable from industrial sources (HERA, 2006). [4]

The remainder of the environmental assessment will therefore consider only the environmental introduction, fate, and potential effects of the stabilizers, HEDP and dipicolinic acid. The FCS mixture is provided to users as a concentrate that is diluted on site. When diluted for use, the resulting concentration of HEDP and dipicolinic acid for each use will be as follows:

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[2] EPA, Reregistration Eligibility Decision: Peroxy Compounds (December 1993), p. 18.

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

[4] HERA – *Cover Note* to Sodium Sulfate, Human and Environmental Risk Assessment on Ingredients of Household Cleaning Products Substance: Sodium sulfate (CAS# 7757-82-6), Page 5, Item 4. *Available at:*

http://www.heraproject.com/files/39-f-06_sodium_sulfate_human_and_environmental_risk_assessment_v2.pdf

Application	Use	HEDP Concentration (ppm)	Dipicolinic Acid (ppm)
Whole and Cut Meat	Process water and ice used to spray, wash, rinse, or dip meat carcasses, parts, trim, and organs; and in chiller water or scald water for meat carcasses, parts, trim, and organs	116	0.5
Whole and Cut Poultry	Process water and ice used to spray, wash, rinse or dip poultry carcasses, parts, trim, and organs; and in chiller water, immersion baths (e.g., less than 40 °F), or scald water for poultry carcasses, parts, trim, and organs	116	0.5
Processed and Pre-Formed Meat	Water, brine, and ice for washing, rinsing, or cooling of processed and pre-formed meat products	29	0.1
Processed and Pre-Formed Poultry	Water, brine, and ice for washing, rinsing, or cooling of processed and pre-formed poultry products	13	0.1
Fish and Seafood	Process water and ice used to commercially prepare fish and seafood	13	0.0
Fruits and Vegetables	Water and ice used for washing or chilling fruits and vegetables in a food processing facility	20	0.0
Seeds and Nuts	When applied to seeds and nuts	13	0.0
Shell Eggs	Water for washing shell eggs	116	0.0
Brines, Sauces and Marinades	Brines, sauces, and marinades applied either on the surface or injected into processed or unprocessed, cooked, or uncooked, whole or cut poultry parts and pieces; and surface sauces and marinades applied on processed and pre-formed meat and poultry products	3	0.0

As a worst case, we focus the remainder of the EA analysis on one of the uses with the highest concentrations of HEDP and dipicolinic acid, namely the use in whole and cut poultry.

Poultry Processing Facilities

Introduction of the components of the FCS into the environment will result from use of the FCS as an antimicrobial agent in processing water from spray and submersion applications for poultry carcasses, parts, organs, and trim, and the subsequent disposal of such water into the processing plant wastewater treatment facility. In poultry processing facilities, the defeathered, eviscerated carcasses are generally sprayed before being chilled via submersion in baths. The carcass is carried on a conveyor through a spray cabinet and then submerged in the chiller baths. Parts and organs may also be chilled by submersion in baths containing the antimicrobial agent. Chiller baths typically include a "main chiller" bath and a "finishing chiller" bath, both containing the FCS.

When the FCS is used at the maximum level under the proposed action, HEDP would be present in water at maximum levels of 116 parts per million (ppm) and 0.5 ppm, respectively. Water is used in poultry processing for scalding (feather removal), bird washing before and after evisceration, chilling, cleaning and sanitizing of equipment and facilities, and for cooling of mechanical equipment such as compressors and pumps. [5] Many of these water uses will not use the FCS, resulting in significant dilution of HEDP into the total water effluent. Assuming, in the very worst-case, that all the water used in a poultry processing plant is treated with the FCS, the level of HEDP and dipicolinic acid in water entering the plant's wastewater treatment facility, the environmental introduction concentration (EIC), would not exceed 116 ppm and 0.5 ppm, respectively.

As indicated by the Human & Environmental Risk Assessment Project (HERA), the treatment of wastewater at an onsite treatment facility or POTW will result in the absorption of approximately 80% of HEDP into sewage treatment sludge. [6] By applying this 80% factor, we differentiate the potential environmental introduction of HEDP to water and sewage sludge, respectively. Dipicolinic acid is water soluble and therefore is expected to remain predominantly with the water at the POTW. Also, we have incorporated a 10-fold dilution factor for discharge to surface waters, [7] of the effluent from an onsite treatment facility or POTW, as indicated below, to estimate the expected environmental concentrations (EECs).

The estimated environmental concentrations, calculated as described above, are provided in the table below for application to process water and ice used to spray, wash, rinse or dip poultry carcasses, parts, trim, and organs; and in chiller water, immersion baths (e.g., less than 40 °F), or scald water for poultry carcasses, parts, trim, and organs.

Use	**Use Level (ppm)**	**EIC (ppm)**	**EECsludge (ppm)**	**EECwater (ppm)**
HEDP	116	116	93	2.3
Dipicolinic acid	0.5	0.5	0	0.05

5 EPA, Technical Development Document for the Final Effluent Limitations ·Guidelines and Standards for the Meat and Poultry Products Point Source Category (40 C.F.R. 432), EPA-821R-04011, September 8, 2004, p. 6-7.

6 HERA- Human & Environment Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates (June 9, 2004). *Available at:* www.heraproject.com-Phosphonates.

7 Rapaport, Robert A., 1988 Prediction of consumer product chemical concentrations as a function of publicly owned treatment works, treatment type, and riverine dilution. Environmental Toxicology and Chemistry 7(2), 107-115.

7. Fate of Emitted Substances in the Environment:

HEDP Fate in Terrestrial Environment

HEDP is expected to partition between water and sludge during wastewater treatment. Sludge resulting from wastewater treatment may end up landfilled or land applied. If land applied, HEDP shows degradation in soil; as such, disposal on land should ensure mineralization and removal from the environment. [8] HEDP's half-life in soil is estimated to be 373 days, extrapolated from observed degradation of 20% after 120 days. [9] Phosphonates are also sensitive to radical-mediated degradation, which may operate in the soil environment and serve as a method for the removal of phosphonate pollution. [10]

Land applications related to the proposed use will result in phosphorus concentrations in soil that are an insignificant fraction of total phosphorus concentrations introduced into the environment as fertilizers. For example, USDA reported that, in 2011, over 8.5 million tons of phosphate fertilizers were consumed in the United States. [11] Annual production and use of the FCS itself is negligible when compared with this figure, and the annual land application of any HEDP containing sludge or treated effluent that could be expected from the proposed use represents an even more insignificant portion of land-applied phosphorus.

If HEDP-containing sludge is disposed of in a landfill, HEDP would be expected to be controlled by the relevant EPA regulations and state or local guidelines, as described in Item 6.B.

HEDP Fate in Aquatic Environment

Wastewater from food processing facilities that contains the diluted FCS mixture is expected to be disposed of through the processing plant wastewater treatment facility or through a local POTW. Once HEDP enters the aquatic environment, it is quite stable, though hydrolysis and degradation are enhanced in the presence of metal ions, aerobic conditions, and sunlight. [12] Photolysis can serve as an important route for the removal of phosphonates like HEDP from the environment, with photodegradation half-lives varying from hours to days depending on the presence of cofactors such as oxygen, peroxides, and complexing metals like iron, copper, or manganese. For example, in the presence of iron, 40-90% degradation occurs within 17 days. [13]

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8 *See* footnote 6, HERA Report at p. 18.

9 *Id.*

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

11 USDA (2013). Fertilizer Use and Price: Table 5 – U.S. consumption of selected phosphate and potash fertilizers, 1960-2011. Accessed December 2018. *Available at:* http://www.ers.usda.gov/data-products/fertilizer-use-and-price.aspx

12 *See* footnote 6, HERA Report at p. 16.

13 *Id.* at p. 19.

In sediment/river water systems, the ultimate biodegradation of HEDP is estimated as 10% in 60 days, with a corresponding half-life of 395 days. [14] In such systems, phosphonates like HEDP can become tightly adsorbed onto the sediment, indicating that the major part of biodegradation may occur in the sediment, where a half-life of 471 days was observed for HEDP. [15] While hydrolysis half-lives are comparatively long (50-200 days) when compared with photodegradation, hydrolysis may serve as a significant route of removal in soil and sediment environments. [16]

Dipicolinic Acid Fate in the Environment

Information in the scientific literature indicates that DPA, a disubstituted pyridine, readily biodegrades in fresh and marine water, and in soil under both aerobic and anaerobic conditions. [17, 18] In presenting a review on the microbial metabolism of pyridines, including dipicolinic acid, Kaiser, *et al.* describe aerobic metabolism of dipicolinic acid to carbon dioxide, ammonium, and water, and anaerobic metabolism to dihydroxypyridine which then rapidly photodegrades to organic acids (i.e., propionic acid, acetic acid), carbon dioxide, and ammonium. [19] Further information indicates that dipicolinic acid is soluble in water, with the estimated water solubility of 5,000 mg/L and an octanol-water partition coefficient estimated to be 0.57. [20] Based upon this information, it is reasonable to conclude that dipicolinic acid will remain substantially with water and not be absorbed to sludge, and that dipicolinic acid will be readily biodegraded during treatment at POTWs and on-site treatment facilities.

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[14] *Id.* at p. 16.

[15] *Id.* at p. 18.

[16] *See* footnote 10, Jaworska *et al.* (2002).

[17] Amador, J.A. and Tatlor, B.P., Coupled metabolic and photolytic pathway for degradation of pyridinecarboxylic acids, especially dipicolinic acid, Applied and Environmental Microbiology, 56(5): 1352-1356 (1990); Seyfried B. and Schnink, B. Fermentive degradation of dipicolinic acid (Pyridine-2, 6- dicarboxylic acid) by a defined coculture of strictly anaerobic bacteria, Biodegradation, 1(1): 1-7 (1990); Kaiser, J.P., Feng, Y., and Bollag, J.M., Microbial metabolism of pyridine, quinolone, acridine, and their derivatives under aerobic and anaerobic conditions, Microbiological Reviews, 60(3): 483-498 (1996).

[18] Naik, M.N. et al, Microbial Degradation and Phytotoxicity of Picloram and Other Substituted Pyridines, Soil Biology and Biochemistry, 4: 313-323 (1972), see p. 320; Sims, G.K. and Sommers, L.E., Biodegradation of Pyridine Derivatives in Soil Suspensions, 5:503-509 (1986).

[19] Kaiser, p. 488.

[20] *See* ChemID Plus Database entry for CAS Reg. No 499-83-2. *Available at.* https://chem.nlm.nih.gov/chemidplus/name/dipicolinic%20acid

8. Environmental Effects of Released Substances:

HEDP Terrestrial Toxicity

HEDP present in the surface water or on land applied sludge is not expected to have any adverse environmental impact based on the terrestrial toxicity endpoints available for plants, earthworms, and birds. Specifically, the no observed effect concentration (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 > 284 mg/kg body weight. [21] These values are all well above the EECs estimated in Item 6, above.

Additionally, as noted above, the maximum estimated concentration of HEDP in sludge is 93 ppm. HEDP shows no toxicity to terrestrial organisms at levels of up to 1,000 mg/kg in soil. [22] Thus, the very conservatively estimated maximum concentration in sludge is only 10% of the NOEC. The maximum concentration in soil will be lower due to dilution by the soil when the sludge is used as a soil amendment resulting in an even larger margin of safety with respect to this NOEC level. As such, the FCS is not expected to present any terrestrial environmental toxicity concerns.

HEDP Aquatic Toxicity Aquatic toxicity of HEDP has been summarized in the public literature and is shown in the following table. [23]

Environmental Toxicity Data for HEDP

Exposure	Species	Endpoint	mg/L
Short Term	*Lepomis macrochirus*	96 hr. LC50	868
	Oncorhynchus mykiss	96 hr. LC50	360
	Cyprinodon variegatus	96 hr. LC50	2180
	Ictalurus punctatus	96 hr. LC50	695
	Leuciscus idus melonatus	48 hr. LC50	207 – 350
	Daphnia magna	24 – 48 hr. EC50	165 – 500
	Palaemonetes pugio	96 hr. EC50	1770
	Crassostrea virginica	96 hr. EC50	89
	Selenastrum capricornutum [a]	96 hr. EC50	3
	Selenastrum capricornutum	96 hr. NOEC	1.3
	Algae [a]	96 hr. NOEC	0.74
	Chlorella vulgaris	48 hr. NOEC	≥ 100
	Pseudomonas putida	30-minute NOEC	1000

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21 *See* footnote 6, HERA Report at Table 13.

22 *Id.*

23 *See* footnote 10, Jaworska *et al.* (2002).

Exposure	Species	Endpoint	mg/L
Long Term	*Oncorhynchus mykiss*	14-day NOEC	60 - 180
	Daphnia magna	28-day NOEC	10 - < 12.5
	Algae [a]	14-day NOEC	13

[a] The source for this endpoint is the HERA Phosphonates, 2004, footnote 6, at Table 13.

Jaworska et al., and the 2004 HERA Phosphonates report, showed that acute toxicity endpoints for HEDP ranged from 0.74 – 2,180 mg/L, while chronic NOECs were 60 – 180 mg/L for the 14-day NOEC for *Oncorhynchus mykiss* and the 28-day NOEC for the *Daphnia magna* ranged from 10 mg/L to < 12.5 mg/L. Although a chronic NOEC of 0.1 mg/L for reproductive effects in *Daphnia magna* was reported, it is inconsistent with other toxicity data, and Jaworska et al. suggest that it is due to the depletion of micronutrients by HEDP instead of the intrinsic toxicity of HEDP. [24]

Because HEDP is a strong chelating agent, which can result in negative environmental effects, such as the complexing of essential nutrients, both an intrinsic NOEC (NOECi) and a NOEC that accounts for chelating effects (NOECc) are determined. The wastewater effluent from meat and poultry processing facilities are regulated because of excess nutrients (among other contaminants) in the wastewater, and therefore, HEDP toxicity resulting from complexing of essential nutrients is not anticipated to be relevant in the case of this FCN. [25]

The HERA report on phosphonates includes a discussion of aquatic toxicity resulting from chelation of nutrients, rather than direct toxicity to aquatic organisms. [26] 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. Jaworska et al. reports the lowest relevant endpoint for aquatic toxicity to be the 28-day NOEC for *Daphnia magna* of 10 mg/L, [27] which is well above the highest conservatively estimated EECwater of 2.3 ppm for the poultry application.

Dipicolinic Acid Environmental Toxicity

Scant publicly available data on the ecotoxicity dipicolinic acid were identified. A review of EPA's ECOTOX database provides one study indicating a freshwater fish 96-hour LC50 of 322 mg/L for the fathead minnow. Further evaluation of the dipicolinic acid structure using the Environmental Protection Agency's Ecological Structure Activity Relationships (ECOSAR) Class Program; a predictive program that provides estimates of a chemical's acute and chronic toxicity to aquatic organisms using Structure Activity Relationships (SARs) predicted low

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24 *Id.*

25 *See* EPA, Meat and Poultry Products Effluent Guidelines (last updated February 6, 2018). *Available at:* https://www.epa.gov/eg/meat-and-poultry-products-effluent-guidelines.

26 *See* footnote 6, HERA Report at p. 25.

27 *See* footnote 10, Jaworska et al. (2002).

toxicity. [28] The ECOSAR results for dipicolinic acid predict the following acute and chronic toxicity endpoints.

ECOSAR Class	Organism	Endpoint	Concentration (mg/L)
Pyridine-alpha-acid	Fish	96-hr. LC50	324
	Green Algae	96-hr. EC50	13.97
	Fish	Chronic Value	32.37
	Green Algae	Chronic Value	7.69

Based on these toxicity predictions, dipicolinic acid is not expected to result in any significant environmental effects at an estimated environmental concentration of 0.05 mg/L (0.05 ppm) resulting from the proposed use of the FCS.

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 wastes as the FCS is expected to compete with, and to some degree replace, similar HEDP stabilized peroxyacetic acid antimicrobial agents already on the market. The manufacture of the antimicrobial agent will consume comparable amounts of energy and resources as similar products, and the raw materials used in the production of the mixture are commercially manufactured materials that are produced for use in a variety of chemical reactions and processes.

10. Mitigation Measures:

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the dilute FCS mixture. Therefore, mitigation measures are not necessary for this FCN.

11. Alternatives to the Proposed Action:

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 significant environmental impact. The addition of the antimicrobial agent to the options available to food processors is not expected to increase the use of peroxyacetic acid antimicrobial products.

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28 This program is a sub-routine of the Estimation Program Interface (EPI) Suite -a structure-function predictive modeling suite developed and maintained by the U.S. EPA. Information on EPI Suite is available at: https://www.epa.gov/tsca-screening-tool/epi-suitetmestimation-program-interface (accessed 2/25/19).

12. List of Preparers:

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13. Certification:

The undersigned certifies that the information presented is true, accurate, and complete to the best of his knowledge.

Date: March 7, 2019

[redacted]

Devon Wm. Hill
Counsel for Notifier

14. List of References:

1. U.S. EPA-800-R-11-005, November 2011, Fish Hold Effluent and Fish Hold Cleaning Wastewater Discharge
2. EPA, Reregistration Eligibility Decision: Peroxy Compounds (December 1993), p. 18.
3. U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category; American Chemistry Council, June 28, 2001.
4. HERA -*Cover Note* to Sodium sulfate, Human and Environmental Risk Assessment on Ingredients of Household Cleaning Products: Substance: Sodium sulfate (CAS# 7757-82-6), Page 5, Item 4.
5. EPA, Technical Development Document for the Final Effluent Limitations Guidelines and Standards for the Meat and Poultry Products Point Source Category (40 C.F.R. 432), EPA-821R-04011, September 8, 2004, p. 6-7
6. HERA – Human & Environment Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates (June 9, 2004).
7. Rapaport, Robert A., 1988 Prediction of consumer product chemical concentrations as a function of publicly owned treatment works, treatment type, and riverine dilution. Environmental Toxicology and Chemistry 7(2), 107-115.
8. Jaworska, J.; Van Genderen-Takken, H.; Hanstveit, A.; van de Plassche, E.; Feijtel, T. Environmental risk assessment of phosphonates, used in domestic laundry and cleaning agents in the Netherlands. Chemosphere 2002, 47, 655-665.
9. USDA (2013). Fertilizer Use and Price: Table 5 -U.S. consumption of selected phosphate and potash fertilizers, 1960-2011.
10. Amador, J. A. and Tatlor, B. P., Coupled metabolic and photolytic pathway for degradation of pyridinecarboxylic acids, especially dipicolinic acid, Applied and Environmental Microbiology, 56(5): 1352-1356 (1990).
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