Environmental Assessment

1. **Date**: February 24, 2023

2. **Name of Applicant/Notifier**: Hydrite Chemical Co.

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) (CAS Reg. No. 79-21-0), hydrogen peroxide (HP) (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), optionally, sulfuric acid (CAS Reg. No. 7664-93-9), and optionally, 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4) and/or dipicolinic acid (DPA) (CAS Reg. No. 499-83-2) as an antimicrobial agent in process water, ice, brines, sauces, and marinades used in the production and preparation of food as follows:

1) 1800 ppm PAA, 1203 ppm HP, 60 ppm HEDP, and 1.64 ppm DPA in process water and ice used to spray, wash, rinse, or dip meat carcasses, parts, trim, and organs, and in chiller water for meat carcasses, parts, trim, and organs;

2) 2000 ppm PAA, 1474 ppm HP, 100 ppm HEDP, and 2.01 ppm DPA in process water and ice used to spray, wash, rinse, or dip poultry carcasses, parts, trim, and organs, and in chiller water, low-temperature (e.g., less than 40 °F) immersion baths, or scald water for poultry carcasses, parts, trim and organs;

3) 495 ppm PAA, 367 ppm HP, 23 ppm HEDP, and 0.50 ppm DPA in water, brine, or ice for washing, rinsing, or cooling processed and pre-formed meat products;

4) 230 ppm PAA, 323 ppm HP, 12 ppm HEDP, and 0.44 ppm DPA in water, brine, or ice for washing, rinsing, or cooling processed and pre-formed poultry products;

5) 600 ppm PAA, 880 ppm HP, 32 ppm HEDP, and 1.20 ppm DPA in water or ice used for washing or chilling fruits and vegetables in a food processing facility;

6) 230 ppm PAA, 280 ppm HP, 12 ppm HEDP, and 0.38 ppm DPA in process water or ice used to commercially prepare fish and seafood;

7) 50 ppm PAA, 33 ppm HP, 2 ppm HEDP, and 0.05 ppm DPA in brines, sauces and marinades applied 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;

8) 2000 ppm PAA, 947 ppm HP, 60 ppm HEDP, and 1.29 ppm DPA in water for washing shell eggs;

9) 987 ppm PAA, 1447 ppm HP, 53 ppm HEDP, and 1.97 ppm DPA in spray, wash, dip, rinse, mist, or chiller water for hard boiled, peeled eggs; and,

10) 234 ppm PAA, 344 ppm HP, 13 ppm HEDP, and 0.47 ppm DPA during the tempering and before the milling of grains of wheat, corn, and rice.

Although sulfuric acid is identified as an optional component of the FCS formulation, it does not react with or become a part of the FCS. Sulfuric acid is affirmed as GRAS for use directly in or on food in accordance with 21 C.F.R. § 184.1095. Sulfuric acid is explicitly identified in this FCN only to provide clarity regarding the FDA status during registration of the product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and inspection of meat and poultry facilities by the United States Department of Agriculture's (USDA) Food Safety Inspection Service (FSIS).

Due to its rapid decomposition into substances that are GRAS for use in food, the active component of the FCS, peroxyacetic acid, will have no ongoing antimicrobial effect in or on the food products.

Mixtures containing these substances at the same concentrations, or even higher, have been authorized by previous Notifiers for the same uses. The FCS identified herein therefore will compete for a share of the market already occupied by these other products rather than introduce a new product or create a new market when this notification becomes effective. Consequently, all potential environmental introductions will be substitutional for previously authorized products. No new environmental introductions are anticipated.

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 4A, 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 food-contact substance (FCS) is intended for use in facilities that process meat and poultry, fruits and vegetables, fish and seafood, shell eggs and hardboiled peeled eggs, and in facilities that temper grains prior to milling. Such processing plants are distributed throughout the United States in patterns corresponding to population density. The FCS 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 food plants. It is assumed that very minor quantities of the mixture are lost to evaporation throughout the process. It is assumed, for the purposes of this Environmental Assessment, 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). Wastewater from fishing vessels is expected to be disposed in the ocean.

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 (PAA) (CAS Reg. No. 79-21-0), hydrogen peroxide (HP) (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), optionally, sulfuric acid (CAS Reg. No. 7664-93-9), and optionally, 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4) and/or dipicolinic acid (DPA) (CAS Reg. No. 499-83-2). A detailed confidential manufacturing process is included in the Form 3480 of this Notification. PAA formation is the result of an equilibrium reaction between acetic acid and hydrogen peroxide.

$$CH_3CO_2H + H_2O_2 \rightleftarrows CH_3CO_3H + H_2O$$

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 DPA, the only stable components 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 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).

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 dilution and treatment that may occur at a Publicly Owned Treatment Works (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.[1] 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.[2] 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 concentrate.

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.[3] 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.[4] Therefore, the minute terrestrial or aquatic discharges of sulfate associated with the use described in this FCN are not expected to have any significant environmental impact, as sulfate is a ubiquitous anion that is naturally present in the ecosystem and virtually indistinguishable from industrial sources.[5] The remainder of the environmental assessment will therefore discuss

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[1] Environmental Protection Agency, Reregistration Eligibility Decision: Peroxy Compounds (December 1993), p. 18.

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

[3] *See* The Organization for Economic Cooperation and Development (OECD) SIDS Voluntary Testing Programme for International High Production Volume Chemicals (OECD SIDS), Sulfuric Acid, 2001, at https://hpvchemicals.oecd.org/UI/handler.axd?id=248f397d-64b3-4e14-8be9-473974e8dfdb.

[4] *See* Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products, Sodium Sulfate, January 2006.

[5] *Id.*

only the environmental introduction, fate, and potential effects of the stabilizers, HEDP and DPA.

The FCS mixture is provided to users as a concentrate that is diluted on site in accordance with the FIFRA required label instructions. When diluted for use, the resulting concentrations of HEDP and DPA for each use will be as follows:

Application	Use	HEDP Conc. (ppm)	DPA Conc. (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	60	1.64
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	100	2.01
Processed and Pre-Formed Meat	Water, brine, and ice for washing, rinsing, or cooling of processed and pre-formed meat products	23	0.5
Processed and Pre-Formed Poultry	Water, brine, and ice for washing, rinsing, or cooling of processed and pre-formed poultry products	12	0.44
Fruits and Vegetables	Water and ice used for washing or chilling fruits and vegetables in a food processing facility	32	1.2
Fish and Seafood	Process water and ice used to commercially prepare fish and seafood	12	0.38
Brines, Sauces & Marinades	Applied to the surface or injected into processed or unprocessed, cooked or uncooked, whole or cut poultry parts and pieces and surface sauces and marinades applied to processed and pre-formed meat and poultry products	2	0.05
Shell Eggs	Water for washing shell eggs	60	1.29
Hardboiled, Peeled Eggs	In spray, wash, dip, rinse, mist, or chiller water for hard boiled, peeled eggs	53	1.97
Tempering of Grains prior to Milling	In process water during the tempering and before the milling of grains of wheat, corn, and rice.	13	0.47

We focus the remainder of the EA analysis on the use with the highest concentration of HEDP, namely the use on whole and cut poultry. This use also corresponds to the highest concentration of DPA in the at-use dilution.

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.

HEDP will be present in water at a maximum level of 100 parts per million (ppm) when the FCS is used at the maximum level under the proposed action. 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.[6] These additional water uses will not contain 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 in water entering the plant's wastewater treatment facility, the environmental introduction concentration (EIC), would not exceed 100 ppm.

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.[7] By applying this 80% factor, we differentiate the potential environmental introduction of HEDP to water and sewage sludge, respectively. Also, we have incorporated a conservative 10-fold dilution factor for discharge to surface waters of the effluent from an onsite treatment facility or POTW,[8] as indicated below, to estimate the expected environmental concentrations (EECs). We assume, as a worst case, no adsorption of DPA to wastewater sludge in sewage treatment plants. The estimated environmental concentrations, calculated as described above, are provided in the following table.

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[6] U.S. Environmental Protection Agency, 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.

[7] HERA – Human & Environment Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates (June 9, 2004), *available at* www.heraproject.com – Phosphonates.

[8] 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.

Use	Component	Use Level (ppm)	EIC (ppm)	$\text{EEC}_{\text{sludge}}$ (ppm)	$\text{EEC}_{\text{water}}$ (ppm)
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.	HEDP	100	100	80	2
	DPA	2.0	2.0	0	0.2

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.[9] HEDP's half-life in soil is estimated to be 373 days, extrapolated from observed degradation of 20% after 120 days.[10] 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.[11]

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

Wastewaters from food processing facilities that contain the diluted FCS mixture are 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

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[9] *See* Footnote 7, HERA Report at p. 18.

[10] *Id.*

[11] 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.

[12] *See* Footnote 7, HERA Report at p. 16.

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]

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] Phosphonates like HEDP can become tightly adsorbed onto the sediment in such systems, 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] Kaiser, *et al.* describe aerobic microbial metabolism of 2,6-pyridinedicarboxylic 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] This information indicates that dipicolinic acid will remain substantially

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[13] *See* Footnote 7, HERA Report at p. 19.

[14] *See* Footnote 7, HERA Report at p. 16.

[15] *See* Footnote 7, HERA Report at p. 18.

[16] *See* Footnote 11, 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] *See* Footnote 17, 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.

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.

8. Environmental Effects of Released Substances

Terrestrial Toxicity

HEDP present in the surface water or on land applied sludge is expected to have no 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 greater than 1,000 mg/kg soil dry weight for earthworms in soil, while the 14-day LC_{50} for birds was greater than 248 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 (from chicken processing as a worst case) is necessarily less than 43 ppm because the solution is diluted when combined with other process water used in the plant prior to entering the treatment plant. 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 4% 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. The FCS is not expected to present any terrestrial environmental toxicity concerns.

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		
Species	**Endpoint**	**mg/L**
Short Term		
Lepomis macrochirus	96 hr LC_{50}	868
Oncorhynchus mykiss	96 hr LC_{50}	360
Cyprinodon variegatus	96 hr LC_{50}	2,180
Ictalurus punctatus	96 hr LC_{50}	695
Leuciscus idus melonatus	48 hr LC_{50}	207 – 350
Daphnia magna	24 – 48 hr EC_{50}	165 – 500
Palaemonetes pugio	96 hr EC_{50}	1,770
Crassostrea virginica	96 hr EC_{50}	89

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[21] *See* Footnote 7, HERA Report at Table 13.

[22] *See* Footnote 7, HERA Report at Table 13.

[23] *See* Footnote 11, Jaworska *et al*. (2002).

Environmental Toxicity Data for HEDP		
Species	**Endpoint**	**mg/L**
Selenastrum capricornutum[a]	96 hr EC_{50}	3
Selenastrum capricornutum	96 hr NOEC	1.3
Algae[a]	96 hr NOEC	0.74
Chlorella vulgaris	48 hr NOEC	$\geq$ 100
Pseudomonas putida	30 minute NOEC	1,000
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.* 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. As noted, it is expected that there will be excess nutrients present in industrial wastewater because eutrophication occurs widely in industrial wastewater coming from food processing facilities.[25]

We note that the 96 hour NOEC, 24-48 hour EC_{50}, and 96 hour EC_{50} values reported by Jarworska *et al*. for *Selenastrum capricornutum*, *Daphnia magna*, and *Crassostrea virginica,* respectively, were all likely due to chelation effects rather than intrinsic toxicity.[26] As such, these levels are not relevant in situations such as food processing plants, where excess nutrients are present. The HERA report on phosphonates includes a discussion of aquatic toxicity resulting from chelation of nutrients, rather than direct toxicity to aquatic organisms.[27] 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

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[24] *Id.*

[25] *See* US EPA Office of Water, Fact Sheet EPA-822-F-01-010; Ecoregional Nutrient Criteria, Dec 2001, *available at* http://www.epa.gov/sites/production/files/documents/ecoregions_9docfs.pdf.

[26] *See* Footnote 11, Jaworska *et al.* (2002).

[27] *See* Footnote 7, HERA Report at p. 25.

relevant endpoint for aquatic toxicity to be 10 mg/L,[28] which is well above the highest conservatively estimated EEC_{water} of 2.0 ppm for the poultry application. It is important to again emphasize, however, that these estimated EEC values are entirely substitutional for the EEC values resulting from previously effective FCNs for the same use. Consequently, there will be no new environmental introductions when this FCN becomes effective.

Dipicolinic Acid Environmental Toxicity

Very little experimental ecotoxicity data on dipicolinic acid were identified in the public literature. EPA's ECOTOX database identifies one study indicating a freshwater fish 96-hour LC_{50} of 322 mg/L for the fathead minnow. Nevertheless, the Environmental Protection Agency's Ecological Structure Activity Relationships (ECOSAR) Class Program predicts that dipicolinic acid has low ecotoxicity based on its chemical structure.[29] The ECOSAR results for dipicolinic acid predict the following acute and chronic toxicity endpoints. The complete ECOSAR report for this analysis is attached to this EA.

ECOSAR Class	Organism	Endpoint	Concentration (mg/L)
Pyridine-alpha-acid	Fish	96 hr LC_{50}	324
	Green Algae	96 h EC_{50}	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 0.2 mg/L (0.2 ppm from the chicken processing application, as a worst case) resulting from the proposed use of the FCS.

9. Use of Resources and Energy

The notified use of the FCS mixture will require no 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 and DPA 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

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[28] *See* Footnote 11, Jaworska *et al*. (2002).

[29] 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-tools/epi-suitetm-estimation-program-interface.

mixture are commercially manufactured materials that are produced for use in a variety of chemical reactions and processes.

10. Mitigation Measures

No significant adverse environmental impacts are expected to result from the use and disposal of the dilute FCS mixture. Therefore, no significant adverse impacts were identified that require mitigation measures.

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.

12. List of Preparers

Catherine R. Nielsen, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Ms. Nielsen has a J.D., with many years of experience drafting food additive petitions and FCN submissions and environmental assessments.

Mark Hepp, Ph.D., Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Dr. Hepp has a Ph.D. in Chemistry with many years of experience with FCN submissions and environmental assessments.

13. Certification

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

Date: February 24, 2023

[redacted]

Catherine R. Nielsen
Counsel for Notifier

14. List of References

1. Environmental Protection Agency, Reregistration Eligibility Decision: Peroxy Compounds (December 1993).

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

3. Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products: Sodium Sulfate (January 2006).

4. The Organization for Economic Cooperation and Development (OECD) SIDS Voluntary Testing Programme for International High Production Volume Chemicals (OECD SIDS), Sulfuric Acid, 2001; *available at* https://hpvchemicals.oecd.org/UI/handler.axd?id=248f397d-64b3-4e14-8be9-473974e8dfdb.

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

6. U.S. Environmental Protection Agency (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.

7. 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.

8. Department of Agriculture (USDA), Fertilizer Use and Price: Table 5 – U.S. consumption of selected phosphate and potash fertilizers, 1960-2011 (2003), accessed March 11, 2016, *available at* http://www.ers.usda.gov/data-products/fertilizer-use-and-price.aspx.

9. EPA Office of Water, Fact Sheet EPA-822-F-01-010; Ecoregional Nutrient Criteria, (December 2001), *available at* http://www.epa.gov/sites/production/files/documents/ecoregions_9docfs.pdf.