**FCN 1872**
**Environmental Assessment**

**1.** **Date**: February 28, 2018

**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), hydrogen peroxide (HP), acetic acid (AA), 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP) and, optionally, sulfuric 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) 1200 ppm PAA, 862 ppm HP, and 60 ppm HEDP 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 PAA, 1436 ppm HP, and 100 ppm HEDP 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) 466 ppm PAA, 335 ppm HP, and 23 ppm HEDP in water, brine, and ice for washing, rinsing, or cooling of processed and pre-formed meat products;
4) 230 ppm PAA, 165 ppm HP, and 12 ppm HEDP in water, brine, and ice for washing, rinsing, or cooling of processed and pre-formed poultry products;
5) 230 ppm PAA, 165 ppm HP, and 12 ppm HEDP in process water and ice used to commercially prepare fish and seafood;
6) 230 ppm PAA, 165 ppm HP, and 12 ppm HEDP in water and ice used for washing or chilling fruits and vegetables in a food processing facility;

7) 1200 ppm PAA, 862 ppm HP, and 60 ppm HEDP in water for washing shell eggs; and,

8) 46 ppm PAA, 33 ppm HP, and 2 ppm HEDP 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.

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 components of the FCS 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 cleared 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 antimicrobial agent is intended for use in meat, poultry, fish and seafood, egg wash, 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). Waste water 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 (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and optionally sulfuric acid (CAS Reg. No. 7664-93-9). 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, 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.

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 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. It is also affirmed as GRAS for use directly in or on food under 21 C.F.R. § 184.1095 ("Sulfuric acid"). 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 is not a toxicological or environmental concern at the proposed use levels. While the environmental effects of aerosols of sulfuric acid and sulfates on the atmosphere and rain are well known, small quantities of water or terrestrial discharges are not expected to have significant environmental effects.[3] Sulfate is a ubiquitous environmental anion and low concentrations are well tolerated in aquatic and terrestrial ecosystems. Sodium sulfate is a solid inorganic salt well soluble in water (161-190 g/1 at 20 °C), with a melting point of 884 °C and density of 2.7 g/cm$^3$. In water, sodium sulfate completely dissociates into sodium and sulfate ions. The ions cannot hydrolyze. In anaerobic environments, sulfate is biologically reduced to (hydrogen) sulfide by sulfate reducing bacteria, or incorporated into living organisms as a source of sulfur, and thereby included in the sulfur cycle. Sodium sulfate is not reactive in aqueous solution at room temperature. Sodium sulfate will completely dissolve, ionize and distribute across the entire planetary aquasphere. Some sulfates may eventually be deposited, but the majority of sulfates participate in the sulfur cycle in which natural and industrial sodium sulfate is not distinguishable.

Sodium sulfate is widely distributed in nature. It occurs as mineral salts (*e.g.*, thenardite, mirabilite); it is present in almost all fresh and salt waters, and sulfate as such is normally present in almost all natural foodstuffs. Both sodium and sulfate ions are among the most common ions found in all living organisms. In mammals, sulfate is a normal metabolite of sulfur-containing amino-acids; it is normally incorporated in a variety of body compounds; and it plays an important role in detoxification/excretion processes due to sulfo-conjugation. Sodium sulfate is a substance with a favorable ecological profile. Due to the low aquatic toxicity and the natural

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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* Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products, Sodium Sulfate, January 2006; *see also* 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.

recycling that occurs in the sulfur cycle, wide dispersive use of small amounts of sodium sulfate presents no significant hazard to the environment.[4]

The remainder of the environmental assessment will therefore consider only the environmental introduction, fate, and potential effects of the stabilizer, HEDP.

The FCS mixture is provided to users as a concentrate that is diluted on site. When diluted for use, the resulting concentration of HEDP for each use will be as follows:

| Application | Use | HEDP Concentration (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 |
| 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 |
| Processed and Pre-Formed Meat | Water, brine, and ice for washing, rinsing, or cooling of processed and pre-formed meat products | 23 |
| Processed and Pre-Formed Poultry | Water, brine, and ice for washing, rinsing, or cooling of processed and pre-formed poultry products | 12 |
| Fish and Seafood | Process water and ice used to commercially prepare fish and seafood | 12 |
| Fruits and Vegetables | Water and ice used for washing or chilling fruits and vegetables in a food processing facility | 12 |
| Shell Eggs | Water for washing shell eggs | 60 |
| 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 | 2 |

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

[4] HERA – *Cover Note of 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.

*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 a maximum level of 100 parts per million (ppm). 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 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.[6] 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,[7] as indicated below, to estimate the expected environmental concentrations (EECs).

The estimated environmental concentrations, calculated as described above, are provided in the table below.

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[5] 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.

[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.

| Use | HEDP Use Level | EIC | $EEC_{sludge}$ | $EEC_{water}$ |
|---|---|---|---|---|
| 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 ppm | 100 ppm | 80 ppm | 2.0 ppm |

**7. <u>Fate of Emitted Substances in the Environment</u>**:

*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 U.S.[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

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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 March 11, 2016, *available at* http://www.ers.usda.gov/data-products/fertilizer-use-and-price.aspx

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]

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]

**8. <u>Environmental Effects of Released Substances</u>**:

*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 $LC_{50}$ for birds was >248 mg/kg body weight.[17] 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 80 ppm. HEDP shows no toxicity to terrestrial organisms at levels of up to 1,000 mg/kg in soil.[18] Thus, the very conservatively estimated *maximum* concentration in sludge is only 8% 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.

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[12] *See* Footnote 6, HERA Report at p. 16.

[13] *See* Footnote 6, HERA Report at p. 19.

[14] *See* Footnote 6, HERA Report at p. 16.

[15] *See* Footnote 6, HERA Report at p. 18.

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

[17] *See* Footnote 6, HERA Report at Table 13.

[18] *See* Footnote 6, HERA Report at Table 13.

*Aquatic Toxicity*

Aquatic toxicity of HEDP has been summarized in the public literature, and is shown in the following table:[19]

| 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 $LC_{50}$ | 2180 |
| *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 $EC_{50}$ | 1770 |
| *Crassostrea virginica* | 96 hr $EC_{50}$ | 89 |
| *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 | ≥100 |
| *Pseudomonas putida* | 30 minute NOEC | 1000 |
| ***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.[20]

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 probable that

[19] *See* Footnote 10, Jaworska *et al*. (2002).

[20] *Id.*

there will be excess nutrients present in industrial wastewater because eutrophication occurs widely in industrial wastewater coming from food processing facilities.[21]

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.[22] 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.[23] 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 10 mg/L,[24] 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.

**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, the mixture is not reasonably expected to result in any new environmental issues that require mitigation measures of any kind.

**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

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[21] *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.

[22] *See* Footnote 10, Jaworska *et al*. (2002).

[23] *See* Footnote 6, HERA Report at p. 25.

[24] *See* Footnote 10, Jaworska *et al*. (2002).

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, NW, Suite 500W, 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, NW, Suite 500W, 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 28, 2018

[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.