

ENVIRONMENTAL ASSESSMENT

1. Date: **September 2, 2020**

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All communication regarding this food contact notification (FCN) environmental assessment (EA) should be sent to the attention of:

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4. Description of Proposed Action:

a) Requested Action

This submission details a request to permit the use of the food contact substance (FCS) described herein as an antimicrobial agent in process water or ice used for washing or chilling fruits and vegetables. The FCS proposed in the Food Contact Notification (FCN) is an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (H₂O₂), acetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) and, optionally, sulfuric acid. The trade name for this FCS is PERASAFE FC-100.

The FCS will be used in food processing facilities as an antimicrobial agent in process water or ice used for washing or chilling or otherwise processing fruits and vegetables in food processing facilities. When used in fruit or vegetable process water, PERASAFE FC-100 will be mixed with water to achieve no more than 500 ppm PAA in solution. This may be accomplished by adding 19.2 fluid ounces of PERASAFE FC-100 per 50 gallons of water.

In process water or ice applied to fruits and vegetables, the components of the FCS mixture will not exceed 500 ppm PAA, 208 ppm H₂O₂, and 24 ppm HEDP.

b) Need for Action

The FCS is intended to be used as an antimicrobial agent to reduce or eliminate pathogenic and non-pathogenic microorganisms that may be present on fruits and vegetables, which will help to retard the spoilage and ultimately provide for safer foods for customers. AFCO is seeking a new FCN that would increase the FCS concentration limit in process water or ice

applied to fruit and vegetables as previously described in the Notifier's effective FCN 1389 to improve food safety.

c) Locations of Use/Disposal

The FCS is intended for use as an antimicrobial agent in process water or ice used for washing or chilling fruits and vegetables in food processing facilities throughout the United States.

Following appropriate use, waste process water containing the diluted FCS solution will be disposed of at industrial wastewater treatment facilities established at processing plant use sites, in combination with publicly owned treatment works (POTWs), or privately owned treatment plants. For processing plants with active National Pollutant Discharge Elimination System (NPDES) permits (i.e., direct dischargers), FCS-containing wastewater will be treated on-site before discharge to surface waters or reuse. For processing plants without NPDES permits (i.e., indirect dischargers), wastewater that contains diluted FCS material is collected and treated by the facility. Wastewater treated at processing facilities is then directed through sanitary sewer systems into POTWs for standard wastewater treatment before movement into aquatic environments (i.e., surface water).

5. Identification of the Food Contact Substance:

The FCS (trade name PERASAFE FC-100) is an aqueous, clear liquid mixture containing PAA, H₂O₂, acetic acid, HEDP, and water. PAA formation is the result of an equilibrium reaction between acetic acid and H₂O₂ (see Figure 1).



Figure 1. PAA Formation

Chemical information for all components in the FCS and diluted FCS solution is outlined in the table below.

Chemical Name	CAS Reg. No.	Formula	Molecular Weight (g/mol)
Peroxyacetic acid (PAA)	79-21-0	C ₂ H ₄ O ₃	76.0506
Hydrogen peroxide (H ₂ O ₂)	7722-84-1	H ₂ O ₂	34.0138
Acetic acid	64-19-7	C ₂ H ₄ O ₂	60.0516
Sulfuric acid (optional)	7664-93-9	H ₂ SO ₄	98.0778
1-hydroxyethylidine-1,1-diphosphonic acid (HEDP)	2809-21-4	C ₂ H ₈ O ₇ P ₂	206.0262

6. Introduction of Substances into the Environment:

a) As a Result of Manufacture

Under 21 Code of Federal Regulations (CFR) § 25.40(a), an Environmental Assessment (EA) should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Manufacture of the FCS occurs only in plants that comply with all applicable federal, state, and local environmental regulations. Information available to the Notifier does not suggest that there are any 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.

b) As a Result of Use/Disposal

Noting the specific use patterns for the FCS described above (i.e., FCS solution used in process water or ice for washing or chilling fruits and vegetables in food processing facilities), the primary pathway by which the FCS is anticipated to be introduced into the environment is through the treatment and disposal of plant processing wastewater. Thus, following use of the FCS at an industrial food processing facility, waste processing water generated at the facility and containing the diluted FCS material may be introduced into the environment via treatment and disposal of plant processing wastewater on-site, at local POTWs, or some combination thereof.

The total amount of FCS used at a given food processing facility will depend on the volume of fruit and vegetable products processed with the FCS at that site, and the microbial stress level specific to that site. To adjust for variation in microbial stress and volume of fruit and vegetable products that may be processed at a given site, the expected introduction concentration (EIC) in surface water was calculated according to an intentionally conservative, worst-case assumption that all the diluted FCS solution used at a given site is discharged to surface waters.

As stated in Item 4(a) above, the FCS is an aqueous mixture of PAA, H₂O₂, acetic acid, HEDP, and, optionally, sulfuric acid. PAA, H₂O₂, and acetic acid all degrade rapidly in contact with organic matter. Sulfuric acid dissociates readily to sulfate in the presence of water. Therefore, none of these components are anticipated to be introduced to the environment to any significant extent as a result of use (i.e., as a solution used in process water or ice for washing or chilling fruits and vegetables in food processing facilities) or disposal of the FCS. A qualitative assessment describing the environmental fate of these components is provided in Item 7 of this EA. Due to the chemical properties of PAA, H₂O₂, acetic acid, sulfuric acid and their rapid degradation, quantitative evaluations of the expected introduction or environmental concentrations and ecotoxicity for these compounds are not necessary.

HEDP is the only chemical component of the FCS anticipated to reach the environment to any extent following on-site or off-site wastewater treatment.

The maximum concentration of HEDP in process water or ice for washing or chilling fruits and vegetables is 24 ppm. As outlined above, assumptions representing a worst-case scenario, in which 100% of the diluted FCS solution would be discharged into surface water, were used to calculate the Expected Introduction Concentration (EIC). Based on the above worst case-assumption, the upper-bound EIC for HEDP in pre-treated wastewater is 24 ppm.

Diluted FCS solution introduced to processing plant wastewater is expected to be disposed of through the treatment facility or through a local POTW. During on-site wastewater treatment or treatment at a POTW, HEDP is removed from water primarily through adsorption onto sludge. HEDP is anticipated to partition unequally, with 80% expected to adsorb to sludge (HERA, 2004). Therefore, based on the unique partitioning behavior of HEDP (80:20) and assuming a maximum of 80% of the introduced HEDP is adsorbed onto sludge, 19.2 ppm HEDP ($24 \text{ ppm} \times 80\% = 19.2 \text{ ppm}$) is anticipated to be removed by adsorption onto wastewater treatment sludge. Only 20% of HEDP entering wastewater (i.e., $24 \text{ ppm} \times 20\% = 4.8 \text{ ppm}$) is anticipated to remain in aqueous wastewater treatment effluent for eventual release to surface water (HERA, 2004).

Within the U.S., residual sludge from the wastewater treatment process is most commonly disposed of by land application, by relocation to a surface disposal site, or by incineration. Such disposal is regulated under the Clean Water Act (CWA) as promulgated in 40 CFR Part 503 (Standards for the Use of Disposal of Sewage Sludge). Thus, HEDP entering sludge material following proper use of the FCS may be incinerated, landfilled or land applied. However, releases of HEDP to the environment from such subsequent pathways are expected to be significantly controlled through relevant EPA regulations and state and local guidelines (see 40 CFR Part 503, Standards

for the Use or Disposal of Sewage Sludge).

Should HEDP-containing sludge be disposed of in a municipal solid waste (MSW) landfill, U.S. EPA regulations would enforce restricted movement of waste into the environment, including location restrictions, composite liner requirements, leachate collection and removal systems, operating practices, and groundwater monitoring requirements (40 CFR Part 258). HEDP introduced to the environment via MSW landfills is anticipated to be present at extremely low concentrations, if at all.

While sludge may be disposed of by land application, relocation to a surface disposal site, or by incineration, landfills and surface impoundments are the most common destinations for wastewater treatment sludge. Less commonly, generated sludge may be land applied. Land applications are regulated under U.S. EPA 40 CFR 503 Standards, which establish pollutant limits, general requirements, operational standards for pathogen and vector attraction reduction, management practices, monitoring frequency, and recordkeeping and reporting requirements for land applicators and facilities generating sludge for use in land application (U.S. EPA, 1994). Our knowledge of disposal methods for food treatment facilities indicates that incineration is not a common disposal method for sludge generated at food treatment facilities. General MSW sludge is more commonly disposed of via incineration.

We do not expect waste or sludge generated from wastewater at food processing facilities to be incinerated. However, should sewage sludge generated as a byproduct of processing plant wastewater treatment indeed be incinerated, incinerators and incineration practices are sufficiently regulated under 40 CFR Part 60. If or when HEDP is combusted, there is nothing to suggest that HEDP incineration would threaten a violation of 40 CFR Part 60, the regulations governing sewage sludge incinerators, as carbon, hydrogen, phosphorus, and oxygen are typical elements in MSW and in sludge.

7. Fate of Substances Released into the Environment:

As introduced in Item 6(b), the unique chemical properties of PAA, H₂O₂, and acetic acid impart rapid degradation in contact with organic matter. Likewise, sulfuric acid degrades readily in water. Thus, of the chemical components in the FCS, only HEDP is expected to survive wastewater treatment and to be introduced into the environment in any measurable quantity. The environmental fate of other component chemicals (PAA, H₂O₂, acetic acid, sulfuric acid) is discussed qualitatively below.

Treatment of the process water at an on-site wastewater treatment facility or at a POTW is expected to result in nearly 100% degradation of PAA, H₂O₂, sulfuric acid, and acetic acid. Upon contact with organic materials, contact with transition metals, or exposure to sunlight, PAA and H₂O₂ rapidly degrade. PAA and H₂O₂ are short-lived due to the inherent instability of

their peroxide (O-O) bonds, for which breaking such bonds to form water and O₂ is highly thermodynamically favored (U.S. EPA, 1993). The half-life for PAA in buffered solutions (pH = 7) is 64 hours for a 748 ppm solution and 48 hours for a 95 ppm solution, while the half-life for H₂O₂ varies with the surface water (ECETOC, 2001). Degradation data demonstrates a half-life of only 2 minutes in sewage treatment plants (HERA, 2005).

Acetic acid readily degrades to CO₂ and water via a two-step process in which acetic acid first dissociates in water to form a hydrogen proton and acetate anion. These constituents then biodegrade to carbon dioxide and water (The Weinberg Group, 2003; U.S. EPA, 1993).

Sulfuric acid dissociates readily in water to sulfate ions (SO₄²⁻) 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 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 (HERA, 2006).

Due to their rapid degradation, none of the above-outlined components (PAA, H₂O₂, acetic acid, or sulfuric acid) are expected to accumulate in living tissues.

The only FCS component anticipated to survive wastewater treatment in any measurable quantity is HEDP. Fate properties of HEDP are outlined in Table 2. A detailed discussion of the fate of HEDP in the environment is provided below.

Table 2. Environmental Fate Properties of HEDP

Property	Value	Source
Vapor Pressure	1×10^{-10} mmHg	HERA (2004)
Water Solubility @ 25°C	6.9×10^5 mg/L	
Henry's Law Constant	5×10^{-17}	
log K _{ow}	-3.49	
pK _s (Ca ²⁺)	6.8	Jaworska et al. (2002)
pK _s (Cu ²⁺)	18.7	
K _{water-soil}	20-190	
K _{water-active sludge}	2600-12700	
K _{water-river sediment}	920-1300	

As outlined above, HEDP is anticipated to be removed from processing plant wastewater primarily through adsorption onto sludge (80%). Some studies have demonstrated >90% HEDP adsorption to sludge (HERA, 2004). Therefore, it is estimated that a maximum of only 20% of the HEDP concentration introduced to processing plant wastewater (i.e., 24 ppm × 20% = 4.8 ppm) is anticipated to remain in the aqueous phase for eventual release to surface water. Exposure of organisms in the environment is reflected in calculated Expected Environmental

Concentration (EEC) values. To calculate EECs for organisms exposed to HEDP via wastewater treatment and discharge from POTWs, a 10-fold dilution factor is applied to the aquatic EIC (Rapaport, 1988).

Expected Environmental Concentration (EEC) in Surface Water: Applying a 10-fold dilution factor to the aquatic EIC for HEDP (EIC = 4.8 ppm), the EEC for HEDP from the proposed use in food processing facilities as an antimicrobial agent in process water or ice used for washing or chilling fruits and vegetable is estimated to be **0.48 ppm in surface waters** directly receiving the treated effluent.

Expected Environmental Concentration (EEC) in Wastewater Sludge: Assuming 80% of HEDP introduced into processing plant wastewater is adsorbed onto sludge as a result of the wastewater treatment process, 19.2 ppm HEDP ($24 \text{ ppm} \times 80\% = 19.2 \text{ ppm}$) is anticipated to be removed by adsorption onto wastewater treatment sludge. Assuming disposal of sludge in accordance with EPA regulations, sludge may be considered the “terminal” fate for HEDP introduced to sludge material. Therefore, the EEC for HEDP in wastewater sludge does not incorporate degradation. No additional dilution factor or removal mechanism is applied. Thus, the EIC is assumed to be equal to the EEC in this scenario (**EEC = EIC = 19.2 ppm**).

A summary of the EIC and EEC for HEDP is provided in Table 3 below.

Table 3. Maximum Expected Introduction Concentrations and Expected Environmental Concentrations for HEDP

Use	Maximum EIC _{pre-treatment wastewater} (ppm)	EIC _{effluent} (ppm)	EIC _{sludge} (ppm)	EEC _{water} (ppm)	EEC _{sludge} (ppm)
Antimicrobial agent used in process water or ice for washing or chilling fruits and vegetables in food processing facilities in food processing facilities	24	4.8	19.2	0.48	19.2

HEDP Fate in Aquatic Environment: Processing-plant wastewater that contains diluted FCS material is expected to be disposed of through on-site industrial wastewater treatment or downstream sewage treatment at a local POTW. HEDP is stable in the environment. However, hydrolysis and degradation of HEDP are enhanced in the presence of metal ions, aerobic conditions, and light (HERA, 2004). A significant removal route for phosphonates like HEDP from the environment is via photolysis, with photodegradation half-lives for phosphonates varying from hours to days. Photolysis rate may vary depending on the presence of cofactors

such as oxygen, peroxides, and complexing metals like iron, copper, and manganese (Jaworska et al., 2002). For example, HEDP in the presence of iron ions degrades by 40-90% within 17 days (HERA, 2004).

HEDP introduced into sediment/river water systems is estimated to biodegrade by 10% in 60 days, with a corresponding half-life of 395 days (HERA, 2004). Further, phosphonates like HEDP tightly adsorb to sediment in river ecosystems. As a result, primary biodegradation pathways for HEDP may occur in sediment. A half-life of 471 days has been calculated for HEDP in sediment (HERA, 2004). 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 (Jaworska et al., 2002).

HEDP Fate in Terrestrial Environment: As noted above, 80% of HEDP introduced into processing plant wastewater is anticipated to be adsorbed onto sludge as a result of the wastewater treatment process. An estimated 19.2 ppm HEDP ($24 \text{ ppm} \times 80\% = 19.2 \text{ ppm}$) is anticipated to be removed by adsorption onto wastewater treatment sludge. Sludge resulting from wastewater treatment may end up landfilled or land applied. Incineration of sludge generated from food processing facilities is not likely. Should sludge containing HEDP be land-applied, HEDP is expected to biodegrade. Therefore, disposal on land should ensure mineralization and removal from the environment (HERA, 2004). Thus, final concentrations in soil are expected to fall below 19.2 ppm over time. HEDP's half-life in soil is estimated at 373 days. This half-life value was extrapolated from an observed degradation rate of 20% after 120 days (HERA, 2004). 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 (Jaworska et al., 2002).

Based upon confidential FCS market volume information, land applications of HEDP-containing sludge material related to the proposed use of the FCS will result in phosphorus concentrations in soil that are an insignificant fraction of total phosphorus concentrations introduced into the environment as fertilizers (**Confidential Attachment A**). In 2015 alone, over 7.8 million tons of phosphate fertilizers were consumed in the U.S. (USDA, 2019). Accounting for anticipated annual sales, phosphorous concentrations resulting from use of the FCS are negligible when compared with this figure (**Confidential Attachment A**). Further, phosphorous that may be introduced to the environment via HEDP-containing sludge or treated wastewater effluent resulting from disposal of diluted FCS material would represent an even smaller, insignificant fraction of total annual 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) above.

8. Environmental Effect of Released Substances:

Because of the chemical properties of the FCS component chemicals, HEDP is the only FCS component chemical anticipated to reach the environment to any significant extent following disposal and wastewater treatment, as discussed in Item 7. Therefore, environmental effects are evaluated by comparing the most relevant sensitive aquatic and terrestrial toxicity endpoints against the EECs for HEDP alone. See Table 4 for a summary of HEDP's ecotoxicity endpoints, with the most-sensitive relevant endpoint bolded.

Table 4. Summary of Environmental Toxicity Endpoints for HEDP

Duration	Test Species	Endpoint	Source
Aquatic Ecotoxicity Data			
Short-Term	<i>Lepomis macrochirus</i> (Bluegill Sunfish)	96-hr LC ₅₀ = 868 ppm	Jaworska et al. (2002)
	<i>Onchorhynchus mykiss</i> (Rainbow Trout)	96-hr LC ₅₀ = 360 ppm	
	<i>Cyprinodon variegatus</i> (Sheepshead Minnow)	96-hr LC ₅₀ = 2180 ppm	
	<i>Ictalurus punctatus</i> (Channel Catfish)	96-hr LC ₅₀ = 695 ppm	
	<i>Leuciscus idus melonatus</i> (Ide)	48-hr LC ₅₀ = 207-350 ppm	
	<i>Daphnia magna</i> (Water Flea)	24-48-hr EC ₅₀ = 165-500 ppm	HERA (2004)
	<i>Chironomus</i> (Midge)	48-hr EC ₅₀ = 8910 ppm	
	<i>Palaemonetes pugio</i> (Grass Shrimp)	96-hr EC ₅₀ = 1770 ppm	Jaworska et al. (2002)
	<i>Crassostrea virginica</i> (Eastern Oyster)	96-hr EC ₅₀ = 89 ppm	
	<i>Selenastrum capricornutum</i> (Green Algae)	96-hr EC ₅₀ = 3.0 ppm	HERA (2004)
Long-Term	Algae	96-hr NOEC = 0.74 ppm	
	<i>Chlorella vulgaris</i> (Green Algae)	48-hr NOEC \geq 100 ppm	
	<i>Pseudomonas putida</i> (Bacterium)	30-min NOEC = 1000 ppm	
	<i>Oncorhynchus mykiss</i> (Rainbow Trout)	14-day NOEC = 60-80 ppm	Jaworska et al. (2002)
	<i>Daphnia magna</i> (Water Flea)	28-day NOEC = 10-<12.5 ppm	
	<i>Selenastrum capricornutum</i> (Green Algae) ¹	14-day NOEC = 13.2 ppm	HERA (2004)
Terrestrial Ecotoxicity Data			
Short-Term	Terrestrial plants	14-day EC ₅₀ > 960 ppm	HERA (2004)
	<i>Eisenia foetida</i> (Earthworm)	14-day NOEC = 1000 ppm	
	Avian	Oral LD ₅₀ = >2500 ppm (diet) >284 ppm (bw)	

¹ For chelating agents, including HEDP, it is important to consider chelation of trace nutrients when assessing outcomes of algal growth inhibition. While algal growth inhibition is often interpreted as a toxic effect, the actual cause of inhibition is nutrient limitation. For such tests, results are likely to be of questionable value for classifying substances or for use in risk estimations (HERA, 2004).

a) Aquatic Environment

Jaworska et al. showed that the acute toxicity endpoints for HEDP ranged from 0.74 to 2,180 mg/L, while the chronic NOECs ranged from 6080 mg/L for the 14-day NOEC for *Oncorhynchus mykiss* to 10 mg/L for the 28-day NOEC for *Daphnia magna*. Although a chronic NOEC of 0.1 mg/L was reported for reproductive effects in *Daphnia magna*, 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.

The highest short-term LC₅₀ values reported by Jaworska et al. were for *Selenastrum capricornum*, *Daphnia magna*, and *Crassostrea virginica*; these are likely due to chelation effects rather than intrinsic toxicity. The most sensitive relevant endpoint for HEDP is associated with long-term exposure to the freshwater invertebrate *Daphnia magna* (NOEC = 10 to <12.5 ppm). However, the surface water EEC for HEDP (0.48 ppm) is below the NOEC range of the most relevant sensitive aquatic toxicity endpoint. EECs for HEDP were derived using a conservative assumption that 100% of the FCS used at a food processing facility enters an on-site or off-site wastewater treatment system and results in eventual environmental introduction. Comparison of derived EECs against known aquatic toxicity endpoints, when considering the conservative assumptions used in this assessment, shows that environmental effects to aquatic organisms are not expected.

b) Terrestrial Environment

From the available terrestrial toxicity endpoints for plants, invertebrates, and avian species, HEDP in treated wastewater effluent or land-applied sludge is not expected to have any adverse environmental impacts in terrestrial environments. Available terrestrial toxicity endpoints for HDPE range from no-observed-effect levels (NOELs) of 100 ppm in plants to a 14-day NOEL of 1000 ppm in earthworms. The worst-case theoretical EEC of HEDP in sludge is 19.2 ppm, which is below even the most sensitive terrestrial endpoints for HEDP. Notably, the estimated 19.2 ppm introduced to sludge and potentially applied to land was calculated assuming no degradation of HEDP following introduction to sludge. While this assumption was made to support the conservative nature of the assessment, this assumption is not likely to be accurate, and HEDP would likely further degrade over time. Additionally, this worst-case calculation assumes no dilution of HEDP as it mixes with other soil, another conservative assumption.

9. Use of Resources and Energy:

The proposed FCS would not pose any significant additional burden on existing resources or energy in the manufacture, transport, proposed use, or disposal of the FCS above and beyond those already existing. The raw materials that are used in the manufacture of the FCS are commercially manufactured chemicals that are produced for the use in various chemical reactions and used for production purposes.

FCS material will be transported from manufacturing site(s) to food processing use sites. Transportation of FCS material is anticipated to occur via typical means (e.g., railway, highway) with no extraordinary fuel demands. Use of the FCS will entail water for use in preparing the diluted FCS solution. This is an insignificant demand on water resources (as demonstrated in **Confidential Attachment A** via estimating water usage per this FCN compared with other water usage). Disposal of the FCS will occur via wastewater treatment on-site at the food processing

facility or downstream at a local POTW. Treatment of wastewater containing the FCS on-site at a food processing facility would require the use of water resources and energy to operate, while disposal and wastewater treatment at a local POTW would impact an insignificant increase, if any, on resource and energy use at the POTW. Impacts on terrestrial environments resulting from POTW wastewater sludge disposal will be the same with or without use of the FCS. No impacts on soil mineral content are associated with production, transportation, use, or disposal of the FCS. In summary, the impacts of the FCS on natural resources and energy are insignificant.

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 that would necessitate alternative actions to those proposed in this Notification. If the proposed action is not approved, the result would be the continued use of the currently marketed antimicrobial agents that the subject FCS would replace. Such action would have no environmental impact. 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:

Brian P. Sylvester, Counsel for Notifier, Foley & Lardner LLP, 3000 K Street NW, Washington DC 20007. Telephone : 202-295-4118. Email: bsylvester@foley.com

Mr. Sylvester has 6 years of experience with FCN submissions and environmental assessments.

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Dr. Scrafford has a background in environmental health and has more than 20 years of experience in chemical safety and health risks assessment as well as the research and review of chemical residue and toxicity data.

Rebecca Wilken, M.S., Senior Scientist, Exponent, Inc., 1150 Connecticut Ave NW, Suite 1100, Washington, DC 20036. Telephone: 202-772-4936. Email: rwilken@exponent.com

Ms. Wilken has a background in biology and ecotoxicology and has over 3 years in the research and review of chemical residue and environmental fate data.

13. Certification

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

Signature

Brian P. Sylvester
Counsel for Notifier

Date: September 2, 2020

14. References:

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15. Attachments

**CONFIDENTIAL ATTACHMENT A: SALES PROJECTION OF FCS AND
ASSOCIATED LAND APPLICATIONS OF HEDP AND WATER USE (SEPARATE
ENCLOSURE)**