PART IV – ENVIRONMENTAL INFORMATION

SECTION B. ENVIRONMENTAL ASSESSMENT

1. Date June 20, 2017

2. Name of Applicant/Petitioner Biosan LLC

3. Address 3 Duplainville Road
Saratoga Springs, New York 12866

Lewis & Harrison LLC (Agent)
122 C Street NW Suite 505
Washington DC 20001

4. Description of Proposed Action

A. Description of the Requested Action

1. This Food Contact Notification (FCN) requests the clearance of a food-contact substance (FCS) that is an aqueous solution containing peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid (AA), hydroxyethylidene 1,1-diphosphonic acid (HEDP), and optionally, sulfuric acid. The FCS will be used in food processing facilities as an antimicrobial agent used in:

   i. Process water or ice used during commercial preparation of fish and seafood;

   ii. Brines, sauces, and marinades to be applied on the surface or injected into processed or unprocessed, cooked or uncooked whole or cut poultry; and,

   iii. Surface sauces and marinades applied on processed and preformed meat and poultry products as described in 21 CFR 170.3(n)(29) and (34)

2. The FCS is a concentrate that must be diluted by the end-users prior to use. The end-users will dilute the FCS in the process waters for fish and seafood and in the water added to their marinade, brine and sauce recipes for processing meat and poultry products. The FCS

use-dilution is either poured or pumped into the marinade, brine or sauce after the batch is initially made. The amount added to the process waters and marinade, brine and sauce batches will depend on the volume, but it will be calculated and adjusted by the end-users so that the amount of FCS will not exceed the maximum levels indicated in this notice.

After dilution, the maximum concentrations of the FCS components in process water will be:

i. In process water used to commercially prepare fish and seafood, the maximum concentrations requested are 230 ppm PAA, 110 ppm HP, and 15 ppm HEDP. The FCS also contains acetic acid as required to stabilize the solution and optionally sulfuric acid.

ii. For brines, sauces, and marinades to be applied on the surface or injected into processed or unprocessed, cooked or uncooked whole or cut poultry, the maximum concentrations requested are 50 ppm PAA, 18 ppm HP, and 6 ppm HEDP. The FCS also contains acetic acid as required to stabilize the solution and optionally sulfuric acid.

iii. For surface sauces and marinades applied on processed and preformed meat and poultry products as described in 21 CFR 170.3(n)(29) and (34), the maximum concentrations requested are 50 ppm PAA, 18 ppm HP, and 6 ppm HEDP. The FCS also contains acetic acid as required to stabilize the solution and optionally sulfuric acid.

B. Need for Action

The FCS is a well-known antimicrobial agent that effectively reduces or eliminates pathogenic and non-pathogenic microorganisms that may be present on food. As a result, the FCS will contribute to increasing the safety and shelf-life of poultry, meat, fish and seafood.

This antimicrobial agent is intended for use to inhibit the growth of undesirable or pathogenic microorganisms in fish and seafood processing plants, and may also be used aboard fishing vessels during the initial evisceration and cleaning of fresh caught seafood.This will ultimately provide for safer fish and seafood products for consumers throughout the United States,

The need for an antimicrobial to treat brines, sauces or marinades in meat and poultry plants

arises from the re-use or re-application on meat and poultry that can cross-contaminate fresh otherwise uncontaminated meat and poultry. The FCS is requested as an antimicrobial intervention to eliminate such cross-contamination.

The action requested by this FCN addresses current and future needs for processors and governmental agencies by responding to increased pressure to improve food safety.

C. Locations of Use and/or Disposal

The FCS is intended for use in meat, poultry, and fish and seafood processing plants throughout the United States. All waste process water containing the FCS at these plants is expected to enter the wastewater treatment unit at the plants or through a local publicly owned treatment works (POTW). When used aboard fishing vessels, the water containing the FCS is expected to be disposed back into the open waters in compliance with local fishing discharge regulations 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 take into account any further treatment that may occur at a POTW. It is further assumed that very minor or negligible quantities of the FCS are lost via evaporation.

Land Based Seafood Processing Facilities: Seafood products are caught in open waters or grown in seafood farms. Caught seafood products are sorted and separated into parts. Parts of seafood products are then flash frozen and packaged. The diluted FCS is sprayed directly onto the raw or processed seafood products before flash-freezing. The bulk of the solution drains off of the seafood products. The waste solution ultimately runs into drains and enters the seafood processing plant water treatment facility. All of this water is collected and treated by the facility prior to it being sent to a POTW or discharged directly to surface water in accordance with the plants' NPDES permit. Direct discharge to surface water is considered the worst-case scenario as it does not take into account any further treatment that may occur at a POTW. Very minor quantities are lost to evaporation into the air.

The diluted FCS may also be frozen into ice and then packaged with the frozen seafood product. The dilute frozen product will eventually thaw and drain off the seafood products at downstream facilities in the supply chain (e.g. grocery stores). This waste solution ultimately runs into drains and is sent to a POTW.

On-Board Seafood Processing: Our proposed use in seafood and fish processing also includes use aboard fishing vessels during the initial evisceration and cleaning of freshly caught seafood. It is expected that wastewater will be discharged into the ocean where the peroxygen components in the FCS would have a very short half-life. In this discharge case, the component dilution residuals into the ocean would be impossible to calculate, and the resultant concentration of the components in the ocean would be negligible. Direct discharge of wastewater is an accepted practice within the fishing industry.[1]

Brines, Sauces, Marinades for Meat and Poultry: In a typical marinade operation, a fresh marinade batch containing the FCS may be made prior to each 4 hour interval of an 8 hour shift, and then disposed after 4 hours of use. The marinade batches are commonly blended in 50-200 gallon tanks. Following each 4 hour interval, the remainder of the marinade batch, typically up to 30-40 percent, is treated at the meat or poultry processor's on-site pretreatment facilities before discharge to a POTW or surface waters, depending upon whether the facility has an individual NPDES permit. Therefore, meat and poultry processors discharge their waste water first to onsite treatment facilities and subsequently to POTWs or discharged directly to surface waters if the facility has an individual NPDES permit. Direct discharge to surface water is considered the worst-case scenario as it does not take into account any further treatment that may occur at a POTW.

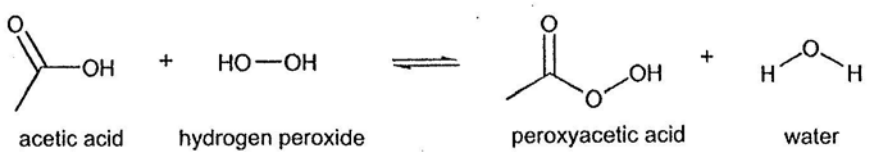
The marinade may be treated with the FCS after the batch is initially made and again treated with the FCS after each hour of use in the marinade operation to maintain the target PAA concentration. For each 4 hour interval, the total amount of marinade that may be typically disposed of in an on-site pretreatment facility or wastewater discharge system is 80 gallons based on a 200 gallon marinade batch. For an 8 hour shift, the total amount of marinade containing the FCS that may be disposed of into an on-site pretreatment facility or wastewater discharge system is 160 gallons. For two 8 hour shifts, the total amount of marinade containing the FCS that may be disposed of into an on-site pretreatment facility or wastewater discharge system is 320 gallons. Within a meat or poultry processor's on-site wastewater discharge system, the FCS components would be diluted in a similar manner to other liquid products, then subsequently diluted further upon entry into the POTW and surface waters. The potential use and disposal of the FCS is discussed below and describes worst case scenarios and associated potential risks along with the Environmental

[1] U.S. EPA-800-R-11-005, November 2011, Fish Hold Effluent and Fish Hold Cleaning Wastewater Discharge,

Introduction Concentration (EIC) and Expected Environmental Concentration (EEC) calculations.

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

As discussed in Item 4, the FCS is an aqueous mixture of HP, PAA, AA HEDP, and sulfuric acid (optionally). It is produced by blending AA, HP, HEDP and water. During the blending process, PAA is formed, *in situ*, as a result of an equilibrium reaction between HP and AA. Sulfuric acid is optionally added as a catalyst in the reaction process.



The aqueous mixture is provided to users as a concentrate which is then diluted, prior to use, on-site. The chemical structures for the components of the FCS and associated chemical identification information is provided below:

Hydrogen Peroxide

CASRN: 7722-84-1

Molecular Formula: H_2O_2

Molecular Weight: 34.01

Structure:

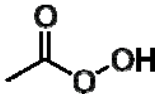
Peroxyacetic Acid

CASRN: 79-21-0

Molecular Formula: CH_3CO_3H

Molecular Weight: 76.05

Structure:



available at http://www3.epa.gov/npdes/pubs/vgp_fishfold.pdf

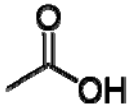
Acetic Acid

CASRN: 64-19-7

Molecular Formula: CH_3CO_2H

Molecular Weight: 60.05

Structure:



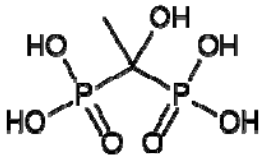
Hydroxyethylidene 1,1-diphosphonic acid

CASRN: 2809-21-4

Molecular Formula: $C_2H_8O_7P_2$

Molecular Weight: 206.02

Structure:



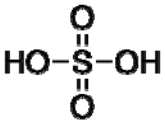
Sulfuric Acid

CASRN: 7664-93-9

Molecular Formula: H_2SO_4

Molecular Weight: 98.079

Structure:



6. Introduction of the Substances into the Environment

A. Introduction of Ingredient Substances into the Environment as a Result of Manufacture

The FCS is currently manufactured at facilities which meet all applicable federal, state and local environmental regulations. The notifier is responsible for all effluent, solid, and airborne discharges from these facilities.

The notifier asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS such as: 1) unique emission circumstances that have not already been addressed by general or specific emission requirements (including occupational) imposed by Federal, State and local environmental agencies and the emissions may harm the environment; 2) a proposed action that threatens a violation of Federal, State or local environmental laws or requirements (40 CFR §1508.27(b)(10)); 3) production associated with a proposed action that may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention of International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

B. Introduction Of Substances Into The Environment As A Result Of Use/Disposal

i. Process water or ice used during commercial preparation of fish and seafood:

The FCS mixture is provided as a concentrate that is diluted on site. When diluted for use, the target levels of PAA in the process water will vary depending on the application. The resulting maximum concentrations for process water used to commercially prepare fish and seafood will be 230 ppm PAA, 110 ppm HP, and 15 ppm HEDP.

Treatment of the process water at an on-site waste water treatment facility is expected to result in complete degradation of PAA, HP, and acetic acid. Specifically, the PAA will breakdown into oxygen and acetic acid, while HP will breakdown into oxygen and water.[2] All three compounds are rapidly degraded on contact with organic matter, transition metals, and upon exposure to sunlight. As cited in the Joint Assessment of Commodity Chemicals report on PAA[3] Mucke suggested that hydrolysis of PAA occurs almost exclusively by hydrolytic cleavage.[4] He showed hydrolysis half-lives at 20°C for a 2% PAA solution of about 1 week at pH 4.4 and less than 1 day at pH 7. As cited in the Joint Assessment of Commodity Chemicals report on hydrogen peroxide[5], the half-life of HP in natural river water ranged from 2.5 days when initial concentrations were 10,000 ppm,

[2] Environmental Protection Agency, Reregistration Eligibility Decision: Peroxy Compounds (December 1993) EPA Case 4072. Doc #738-F-93-026, p.18. http://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_G-67_1-Dec-93.pdf
[3] European Centre for Ecotoxicology and Toxicology of Chemicals, January 2001. Peracetic Acid (CAS No. 79-21-0) and its Equilibrium Solutions. JACC No. 40. http://members.ecetoc.org/Documents/Document/JACC%20040.pdf
[4] Ibid.
[5] European Centre for Toxicology and Toxicology of Chemicals, January, 1993 Joint Assessment of Commodity Chemicals No. 22. Hydrogen Peroxide. CAS No. 7722-84-1 http://members.ecetoc.org/Documents/Document/JACC%20022.pdf.

and increased to 15.2 days when the concentration decreased to 250 ppm.[6] In biodegradation studies of acetic acid, 99% was degraded in 7 days under anaerobic conditions.[7] Acetic acid it is not expected to concentrate in the wastewater discharged to the POTW. In wastewater, sulfuric acid will completely dissociate into sulfate ions and hydrated protons,[8] neither of which are a toxicological or environmental concern at the proposed use levels. Therefore, peroxyacetic acid, hydrogen peroxide, acetic acid and sulfuric acid are not expected to be introduced into the environment to any significant extent as a result of the proposed use of the FCS.

HEDP is the substance of environmental concern in this EA. HEDP is anticipated to persist in the environment, as discussed under Item 7.

Assuming in the very worst-case, that all the water used in a processing plant is treated with the FCS, the HEDP EIC would be 15 ppm.

As large-scale facilities do not typically process more than one type of food, we will use the use levels of 15 ppm for HEDP as the worst-case EIC for all land-based fish and seafood processing facilities using the FCS. Therefore, the discussion of impacts from use in land-based processing facilities will focus on comparing the land-based fish and seafood EEC to appropriate ecotoxicity endpoints that are provided under Item 8. Onboard fish and seafood processing will also be discussed in Items 7 and 8.

As indicated above, the use concentration of HEDP and DPA is the expected introduction concentration (EIC). Based on the unique partitioning behavior of HEDP (80:20)[9] the expected environmental concentration (EEC) for sludge may be estimated by applying 80% to the EIC. To estimate the EEC_{water}, a 20% factor is applied to the EIC_{water}, and the product divided by ten (10) to account for water dilution in receiving aquatic bodies.[10]

The EECs for sludge and water from fish and seafood processing are provided in the

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[6] Ibid.

[7] U.S. High Production (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category. Acetic Acid and Salts Panel, American Chemistry Council, June 28, 2001 as referenced in Environmental Assessment for FCN 323. http://iaspub.epa.gov/oppthpv/document_api.download?FILE=c13102tp.pdf#_ga=1.33870884.425726753.1445002626

[8] Sulfuric Acid. The organization for Economic Co-operation and Development (OECD) SIDS Voluntary Testing Program for International High Production Volume Chemicals. 2001, available at http://www.inchem.org/documents/sids/sids/7664939.pdf

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

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

following table:

HEDP EIC (max use)	HEDP EIC_{water}*	HEDP EEC_{sludge}*	HEDP EEC_{water}*
15 ppm	3 ppm	12 ppm	0.3 ppm

*EIC_{water} = use concentration x 20%

EIC_{sludge} = use concentration x 80%

Our proposed use in seafood and fish processing also includes use aboard fishing vessels during the initial evisceration and cleaning of freshly caught seafood. It is expected that wastewater will be discharged into the ocean where the peroxygen components in the FCS would have a very short half-life. In this discharge case, the component dilution residuals into the ocean would be impossible to calculate, and the resultant concentration of the components in the ocean would be negligible. Direct discharge of wastewater is an accepted practice within the fishing industry.[11]

ii. Brines, sauces, and marinades for poultry and surface sauces and marinades for meat and poultry products

The FCS is proposed for use as an antimicrobial agent in: 1) brines, sauces, and marinades to be applied on the surface or injected into processed or unprocessed, cooked or uncooked whole or cut poultry and 2) in surface sauces and marinades applied on processed and preformed meat and poultry products. As discussed in Item 4.B, the marinade containing the FCS is commonly blended in 50-200 gallon tanks and used in 4 hour intervals. The FCS is re-applied on an hourly basis to maintain the desired PAA concentration. Following each 4 hour interval of an 8 hour shift, the remainder of the marinade batch is disposed of into the processor's on-site pretreatment facility before discharging to the local POTW and surface waters, depending upon whether the facility has an individual NPDES permit. Typically, the amount of marinade that may be discharged into the processing plant pre-treatment facility would be no more than 30-40 percent of the marinade batch or 60-80 gallons of marinade during each 4 hour interval based on a maximum batch size of 200 gallons. Assuming that an operation may operate for two 8 hour shifts, the maximum total potential amount of marinade containing the FCS that may be disposed into the on-site pre- treatment facility is 320 gallons per day.

For the purpose of the environmental assessment, we will assume that all of the marinade

containing the FCS would be washed down the drains as a worst-case scenario.

Treatment of the marinade containing the FCS at an on-site waste water treatment facility and then at a POTW and surface waters is expected to result in a complete degradation of PAA, hydrogen peroxide and acetic acid. The PAA will breakdown into oxygen and acetic acid while hydrogen peroxide will breakdown into oxygen and water.[12] PAA, hydrogen peroxide and acetic acid all rapidly degrade on contact with organic matter, transition metals and upon exposure to sunlight. The half-life of PAA in buffered solutions was 63 hours at pH 7 for a 748 ppm solution, and 48 hours at pH 7 for a 95 ppm solution.[13] The half-life of hydrogen peroxide in natural river water ranged from 2.5 days when initial concentrations were 10,000 ppm and increased to 15.2 days when the concentration decreased to 250 ppm.[14]

Biodegradation is the most significant removal mechanism for acetic acid. In biodegradation studies with acetic acid, 99% degraded in 7 days under anaerobic conditions.[15] Acetic acid is not expected to concentrate in the wastewater discharged to the POTW and surface waters. Therefore, these substances are not expected to be introduced into the environment to any significant extent as a result of the proposed use of the FCS. As a result, the remainder of this section will consider only the environmental introduction of HEDP.

The worst-case EIC may be calculated by assuming there is no degradation of HEDP associated with use of the FCS in brines, sauces and marinades that is surface applied or injected in preformed meat or poultry products. The maximum concentration of HEDP that may be expected in a worst case scenario in the FCS from its use in brines, sauces and marinades is 6 ppm.

As noted above, it is expected that the sludge:water partition ratio for HEDP is 80:20. In addition, a 10-fold dilution factor (DF) is assumed to account for dilution in aquatic bodies receiving HEDP.[21]

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

[12] Environmental Protection Agency, Reregistration Eligibility Decision: Peroxy Compounds (December 1993) EPA Case 4072. Doc #738-F-93-026, p.18. http://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_G-67_1-Dec-93.pdf

[13] European Centre for Ecotoxicology and Toxicology of Chemicals, January 2001. Peracetic Acid (CAS No. 79-21-0) and its Equilibrium Solutions. JACC No. 40. http://members.ecetoc.org/Documents/Document/JACC%20040.pdf

[14] European Centre for Toxicology and Toxicology of Chemicals, January, 1993 Joint Assessment of Commodity Chemicals No. 22. Hydrogen Peroxide. CAS No. 7722-84-1 http://members.ecetoc.org/Documents/Document/JACC%20022.pdf.

[15] U.S. High Production (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category. Acetic Acid and Salts Panel, American Chemistry Council, June 28, 2001 as referenced in Environmental Assessment for FCN 323. http://iaspub.epa.gov/oppthpv/document_api.download?FILE=c13102tp.pdf#_ga=1.33870884.425726753.1445002626

Below are the worst-case EIC, EEC_{sludge} and EEC_{water} calculations for HEDP:

HEDP EIC = 6 ppm HEDP x 100% remaining = 6 ppm HEDP

HEDP EIC_{sludge} = 6 ppm HEDP x 80% partition to sludge = 4.8 ppm HEDP

HEDP EEC_{water} = (6 ppm HEDP x 20% partition to water)/10-fold DF = 0.12 ppm HEDP

7. Fate of Emitted Substances in the Environment:

As previously mentioned, PAA, HP, and AA are not expected to survive treatment at the primary wastewater treatment facilities; therefore, Expected Environmental Concentrations (EECs) have not been calculated for these substances. The EEC for sulfuric acid has also not been calculated since, as noted above, no environmental impact is expected for this substance.

The EEC for HEDP in surface water has been calculated by applying a 10-fold dilution factor to the estimated EIC[16]. This dilution factor accounts for the expected dilution in surface waters of effluent from an onsite treatment facility as supported by data reported by Rapaport.[17] Finally, we note that the EEC for sludge is a maximum for terrestrial impacts as any sludge used as a soil amendment will likely be significantly diluted by soil or sludge from other sources.

No terrestrial or aquatic biodegradation is assumed for HEDP. According to the published literature, decomposition of HEDP occurs at a moderately slow pace in water; 33% in 28 days.[18] Regarding soil biodegradation, the HERA report estimates a half-life in soil of 373 days. Therefore, any aquatic or soil biodegradation of HEDP is not expected to significantly lower the estimated EECs for HEDP provided in the table above.

Based on the above, the EICs and EECs for HEDP, for all uses, are summarized in the table below.

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

[17] Ibid

[18] HERA, Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products, Phosphonates (CAS 6419-19-8; 2809-21-4; 15827-60-8), Draft 06/09/2004, Table 7, p. 16, available at: http://www.heraproject.com/files/30-f-04-%20hera%20phosphonates%20full%20web%20wd.pdf

EICs and EECs for HEDP

Use	HEDP EIC (max use)	HEDP EIC_{water} *	HEDP EIC_{sludge} *	HEDP EEC_{sludge} *	HEDP EEC_{water} *
Fish & Seafood	15 ppm	3 ppm	12 ppm	12 ppm	3 ppm
Brine, Marinade & Sauce for Poultry	6 ppm	1.2 ppm	4.8 ppm	4.8 ppm	0.12 ppm
Surface Sauce & Marinade for Meat & Poultry	6 ppm	1.2 ppm	4.8 ppm	4.8 ppm	0.12 ppm

* Calculations:
HEDP-EIC_{water} = max. use x water partition (20%)
HEDP-EIC_{sludge} = max. use x sludge partition (80%)
HEDP-EEC_{sludge} = assume that the EIC_{sludge} = EEC_{sludge} since there is no dilution
HEDP-EEC_{water}= EIC_{water} ÷ dilution in aqueous receiving body

8. Environmental Effects of Released Substances:

The terrestrial and aquatic toxicity of HEDP are summarized below.

A. Terrestrial Toxicity:

The No-Observable Effect Concentration (NOEC) for HEDP toxicity to terrestrial organisms is greater than 1000 mg/kg soil dry weight for *Eisenia foetida*).[19] The maximum estimated concentration in sludge (12 ppm) is approximately 100- fold lower than the NOEC level and the maximum concentration in soil when used as a soil amendment should have an even larger margin of safety with respect to the NOEC level. Therefore, HEDP is not expected to have any terrestrial environmental toxicity concerns at levels at which it is expected to be present in sludge. Moreover, the much smaller level of HEDP present in the surface water is not expected to have any adverse environmental impact with respect to sedimentation based on the terrestrial toxicity endpoints available for plants, earthworms, and birds.[20]

B. Aquatic Toxicity

HEDP

An extensive database has been compiled on the toxicity of HEDP to aquatic organisms. Studies have been conducted on the toxicity of HEDP to freshwater and marine organisms and algae. The test results from the studies is shown in the following table:

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

Aquatic Toxicity Data for HEDP

Species	Endpoint	(mg/l)=ppm
Short Term		
Lepomis macrochirus[A]	96h LC50	868
Oncorhynchus mykiss[A]	96h LC50	360
Cyprinodon variegatus[A]	96h LC50	2180
lctalurus punctatus[A]	96h LC50	695
Leuciscus idus melonatus[A]	48h LC50	207-350
Daphnia magna[A]	24 - 48h EC50	165-500
Palaemonetes pugio[A]	96 h EC50	1770
Crassostrea virginica[A]	96h EC50	89
Selenastrum capricornutum[B]	96h LC50	3
Selenastrum capricornutum[B]	96h NOEC	1.3
Algae[B]	96h NOEC	0.74
Chiarella vulgaris[A]	48h NOEC	>100
Pseudomonas putida[A]	30 minute NOEC	1000
Long Term		
Oncorhynchus mykiss[A]	14 d NOEC	60-180
Daphnia magna[A]	28 d NOEC	10 - <12.5
Algae[B]	14 day NOEC	13

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

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

The aquatic toxicity data on HEDP needs to be assessed in the context of the known chelation effects of HEDP. Work by Jaworska *et. al.* showed that the primary adverse effects of HEDP result from chelation of nutrients rather than direct toxicity of HEDP.[21] Chelation is not toxicologically relevant to wastewater discharges containing HEDP from food processing plants since eutrophication, not nutrient depletion, has been demonstrated to be the controlling toxicological mode for this type of wastewater discharge. The lowest short-term or acute LC50 values published for algae (*Selenastrum capricornutum* - 3 ppm), freshwater invertebrate (*Daphnia magna* -165 ppm), and mollusks *Crassostrea virginica* (89 ppm) are acute toxicity endpoints considered to result from this chelation effect. These values are not relevant when excess nutrients are present as expected in food processing wastewaters.

[20] Ibid

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

The lowest relevant endpoint for food processing uses was determined to be the chronic NOEC of 10 ppm for *Daphnia magna*.[22, 24] Although uncertainties intrinsic to its derivation make the usefulness of the NOEC debatable, based on the available environmental toxicology data, reliance upon the NOEC for *Daphnia magna* is appropriate for HEDP in this use.[23, 24] The EEC of 6 ppm is lower than the 10 ppm chronic NOEC for *Daphnia magna*.

9. Use of Resources and Energy:

No net increase in the use of energy and resources is expected from the use of this FCS since it is expected to compete with, and to some degree replace, similar products (e.g. the FCS identified in FCN Nos. 1389, 1638, and 1654) that are currently on the market and being utilized for the same uses as proposed in this FCN.

In addition, the manufacture of the FCS will consume comparable amounts of energy and resources as similar products, and the raw materials used in the product of the FCS are commercially manufactured materials that are produced for use in a variety of chemical reactions and processes. Energy used specifically for the production of the FCS is not significant.

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. Thus, the use of the solution is not reasonably expected to result in any new environmental problems requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action:

There are no potential significant adverse environmental effects identified that would necessitate alternative actions to that proposed in this FCN. The alternate of not approving this FCN would simply result in the continued use of nearly identical products by the food processing industry; such action would therefore have no significant environmental impact. The addition of the concentrated FCS mixture to the options that are currently available to processors is not

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

[23] J Blok and F Balk, "Environmental regulation in the European Community," in *Fundamentals of Aquatic Toxicology: Effects, Environmental Fate, and Risk Assessment*, (GM Rand, Ed.), Taylor & Francis, New York, 1995, chapter 27.

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

expected to greatly increase the use of peroxyacetic acid products; rather provide a replacement product for those peroxyacetic acid products already in use.

12. List of Preparers:

This Environmental Assessment was prepared on behalf of Biosan, LLC, by Wendy A. McCombie of Lewis & Harrison, LLC. Ms. McCombie has a B.S. in Biology with 25 years of experience providing consulting services for chemical regulations.

13. Certification:

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

Name: Wendy A. McCombie, Lewis & Harrison LLC

Title: Agent for Biosan, LLC

Signature: 

Date: June 20, 2017

14. List of References:

J Blok and F Balk, "Environmental regulation in the European Community," in *Fundamentals of Aquatic Toxicology: Effects, Environmental Fate, and Risk Assessment*, (GM Rand, Ed.), Taylor & Francis, New York, 1995, chapter 27 *"NOEC determinations are likely more statistically variant (uncertain) than EC50 determinations."*

Environmental Protection Agency, Reregistration Eligibility Decision: Peroxy Compounds (December 1993) Doc #738-F-93-026
http://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_G-67_1-Dec-93.pdf

European Centre for Ecotoxicology and Toxicology of Chemicals, January 2001 Peracetic Acid (CAS No. 79-21-0) and its Equilibrium Solutions. JACC No. 40.
http://members.ecetoc.org/Documents/Document/JACC%20040.pdf

European Centre for Toxicology and Toxicology of Chemicals, January, 1993 Joint Assessment of Commodity Chemicals No. 22. Hydrogen Peroxide. CAS No. 7722-84-1
http://members.ecetoc.org/Documents/Document/JACC%20022.pdf.

Food and Drug Administration, 2014, Environmental Decision Memo for Food Contact Notification 1379, available at
http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/EnvironmentalDecisions/ucm394968.pdf

Food and Drug Administration, 2014, Environmental Decision Memo for Food Contact Notification 1419, available at http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/EnvironmentalDecisions/ucm399873.pdf.

HERA - Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates. 06/09/2004. www.heraproject.com- Phosphonates http://www.heraproject.com/files/30-f-04-%20hera%20phosphonates%20full%20web%20wd.pdf

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

OECD, Current Approaches in the Statistical Analysis of Ecotoxicity Data: A guideline to Application, OECD Environmental health and Safety Publications, Series on Testing and Assessment, No. 54 Environmental Directorate, Paris, 2006.

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

USDA FSIS Federal Register Notice, "New Performance Standards for Salmonella and Campylobacter in Young Chicken and Turkey Slaughter Establishments: Response to Comments and Announcement of Implementation Schedule," 76 Fed. Reg. 15282; *see also* FSIS Notice 54-12, "New Performance Standards for Salmonella and Campylobacter in Chilled Carcasses at Young Chicken and Turkey Slaughter Establishments," dated 9/11/12, available at http://www.fsis.usda.gov/wps/wcm/connect/ebf83112-4c3b-4650-8396-24cc8d38bf6c/10250.1.pdf?MOD=AJPERES

U.S. High Production (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category. Acetic Acid and Salts Panel, American Chemistry Council, June 28, 2001 as referenced in Environmental Assessment for FCN 323. http://iaspub.epa.gov/oppthpv/document_api.download?FILE=c13102tp.pdf#_ga=1.33870884.425726753.1445002626