Environmental Assessment

1. **Date**: June 7th, 2023 *

2. **Submitter**: Enviro Tech Chemical Services, Inc.

3. **Address**: 500 Winmoore Way, Modesto, CA. 95358

4. **Description of Proposed Action**:

   a. Description of the Requested Action:
   The food contact substance (FCS) proposed in the Food Contact Notification is an aqueous solution composed of peroxyacetic acid (PAA, CAS Reg No 79-21-0), hydrogen peroxide (HP, CAS Reg No 7722-84-1), acetic acid (CAS Reg No 64-19-7), 1-hydroxy ethylidene-l,1-diphosphonic acid
   (HEDP, CAS Reg No 2809-21-4), and optionally sulfuric acid (CAS Reg No 7664-93-9). The FCS will be used in food processing facilities as an antimicrobial agent:
      1. 2000 ppm PAA, 800 ppm HP and 80 ppm HEDP in process water or ice used for washing, rinsing, or cooling whole or cut meat, including hides, carcasses, parts, trim, and organs
      2. 2000 ppm PAA, 770 ppm HP, and 100 ppm HEDP in process water or ice applied as a spray, wash, rinse, dip, chiller water, low temperature (e.g., less than 40°F) immersion baths, or scald water for washing, rinsing, or cooling whole or cut poultry, including carcasses, parts, trim, and organs;
      3. 500 ppm PAA, 115 ppm HP, and 14 ppm HEDP in process water or ice used for washing or chilling fruits and vegetables in food processing facilities.

   b. The Need for the Action:
   The FCS is intended to be used as an antimicrobial agent to reduce or eliminate pathogenic microorganisms on fruits, vegetables, whole or cut meat and poultry, including hides, carcasses, parts, trim, and organs. The proposed use concentrations of the FCS will allow relevant food processing plants greater flexibility to enhance processing techniques (i.e. more flexibility in terms of contact time, concentration, spray vs. immersion, etc.) in order to improve antimicrobial efficacy against spoilage and pathogenic microorganisms. The action requested by this FCN addresses current and future needs for processors and governmental agencies to respond to increased pressures to improve food safety.

* Subsequent to this date non-substantive edits using the Adobe text editor tool were made to clarify textual content and format this document for public posting.

c. Locations of Use/Disposal:
   Use: The FCS is intended for use in facilities processing meat, poultry, fruits, and vegetables.

   Disposal: After use, the diluted FCS solution will be disposed of with processing plant wastewater according to National Pollutant Discharge Elimination System (NPDES) regulations. For processing plants that hold a NPDES permit (i.e., direct dischargers), the FCS-containing wastewater will be treated on-site before direct discharge to surface waters. For processing plants without such NPDES permits (i.e., indirect dischargers), the FCS containing wastewater would travel through the sanitary sewer system into Publicly Owned Treatment Works (POTWs) for standard wastewater treatment processes before movement into aquatic environments.

The potential use and disposal of the FCS is discussed further below and describes worst case scenarios and associated potential risks along with the EIC and EEC calculations.

5. Identification of Substance:

The FCS is a liquid equilibrium mixture of peroxyacetic acid, hydrogen peroxide, and acetic acid. It is made by blending acetic acid, hydrogen peroxide, HEDP (as a chelating agent), optionally sulfuric acid (to speed the reaction process), and reverse osmosis purified water.

Ingredients:

Chemical Name	CAS#
Peroxyacetic acid	79-21-0
Hydrogen peroxide	7722-84-1
Acetic acid	64-19-7
Sulfuric acid (optional)	7664-93-9
HEDP (1-hydroxyethylidine-l,1-diphosphonic acid)	2809-21-4
Water	7732-18-5

The basic reaction by the above combination is as follows:

$CH_3CO_2H + H_2O_2$ $CH_3CO_3H + H_2O$ (molecular weight is 76.05 g/mole)

6. **Introduction of Substance into the Environment**:

a. **Introduction of substances into the environment as a result of manufacture**:
The FCS is currently manufactured in EPA approved facilities at the addresses listed below and no unusual or factual threat to the environment exist.

Establishment Number	**Establishment Name**	**Establishment Site Address**
63838-CA-01	Enviro Tech Chemical Services, Inc.	500 Winmoore Way, Modesto CA
63838-AR-01	Enviro Tech Chemical Services – Plant 6	724 Phillips County Road 411 , Helena, AR 72342

Below are the website links document the EPA Establishment Numbers at the addresses listed above:

http://iaspub.epa.gov/enviro/fii query detail.disp program facility?p registry id=110024498890 and https://iaspub.epa.gov/enviro/fii query detail.disp program facility?p registry i d=110063867383. No extraordinary environmental circumstances would apply to the continued on-going manufacture of the FCS.

b. **Introduction of substances into the environment as a result of use/disposal**:
The FCS is intended for use as an antimicrobial agent in meat, poultry, fruit, and vegetable processing facilities. The FCS is provided as a concentrate that is diluted on site. The maximum concentrations of the FCS by use are as follows:

Use	PAA	H_2O_2	HEDP
Process water or ice used for washing, rinsing, or cooling whole or cut meat, including hides, carcasses, parts, trim, and organs	2000	800	80
Process water or ice applied as a spray, wash, rinse, dip, chiller water, low temperature (e.g., less than 40°F) immersion baths, or scald water for washing, rinsing, or cooling whole or cut poultry, including carcasses, parts, trim, and organs;	2000	770	100
Process water or ice used for washing or chilling fruits and vegetables in food processing facilities	500	115	14

Based on the described use patterns above, the primary pathway for the FCS to reach the environment is by the use and disposal of the FCS. Following use or disposal of the FCS, the FCS enters the processor's on-site pretreatment facility before discharging to the local publicly owned treatment works (POTW) and surface waters, depending upon whether the facility has an individual NPDES permit.

Treatment of the process water 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[1]. 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[2]. 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[3].

Biodegradation is the most significant removal mechanism for acetic acid. In biodegradation studies with acetic acid, 99% degraded in 7 days under anaerobic conditions[4]. 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.

Sulfuric acid is an optional ingredient in the FCS formulation and is used to catalyze the reaction between acetic acid and hydrogen peroxide to more rapidly produce a stable PAA solution. Sulfuric acid is a strong mineral acid that dissociates readily in water to sulfate ions (SO_4^{-2}) and hydrated protons; at environmentally relevant concentrations, sulfuric acid is totally dissociated [10]. Sulfates, through the natural sulfate cycle will either incorporate into living organisms and be reduced via anaerobic biodegradations to sulfur, sulfides, or re-oxidized to sulfur dioxide and sulfate[11]. Therefore, aquatic or land discharges of sulfate associated with the FCS described in this FCN are not expected to have any significant impact on the environment as sulfate is an anion that is naturally present in the ecosystem and virtually indistinguishable from industrial resources[11].

The substances discussed above (PAA, hydrogen peroxide, acetic acid, and the optional ingredient 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. The remainder of this section will therefore consider only the environmental introduction of HEDP.

The Environmental Introduction Concentration (EIC) may be calculated by multiplying the concentration of HEDP in the FCS by the estimated percentage of degradation associated with use of the FCS in process water or ice used for washing, rinsing, or cooling whole or cut meat, including hides, carcasses, parts, trim, and organs HEDP has a much longer half-life than either PAA or H_2O_2, therefore, it is assumed all process effluents contain HEDP at the notified use level concentration. The maximum concentration of HEDP that may be expected is in the following:

Use	**HEDP EIC**
Process water or ice used for washing, rinsing, or cooling whole or cut meat, including hides, carcasses, parts, trim, and organs	100

The Human and Environmental Risk Assessment Project (HERA) report showed that HEDP adsorption to wastewater sludge is greater than 90%[7]. To be conservative, an estimate of 80% adsorption to wastewater sludge in sewage treatment plants will be used for the below Estimated Environmental Concentration (EEC) calculations.

The EIC of HEDP is based on use or disposal of the FCS into the meat processor's on-site pre-treatment facility. The subsequent EECs including EEC_{sludge} and EEC_{water} are calculated below using the 80:20 partition factor arrived at in the HERA report. With respect to the EEC_{water} calculation, a 10 fold dilution factor is recommended for use when estimating surface water concentrations[6]. Below are the worst-case EIC and EEC_{sludge} and EEC_{water} calculations for HEDP under each proposed application of the FCS:

<u>Process water or ice used for washing. rinsing or cooling whole or cut meat, including hides, carcasses, parts. trim and organs:</u>

HEDP EIC = 100 ppm HEDP × 100% remaining =100 ppm HEDP

HEDP EEC_{sludge} = 100 ppm HEDP × 80% partition to sludge = 80 ppm HEDP EEC_{sludge}

HEDP EEC_{water} = (100 ppm HEDP × 20% partition to water) / 10 fold dilution factor = 2.0 ppm HEDP EEC_{water}

7. **Fate of the Substance in the Environment:**

When wastewater from food processing operations described above is released to a POTW and surface waters, the concentration of HEDP will be further diluted by the additional waters processed by the POTW and surface waters. The maximum HEDP EEC_{water} for process water or ice used for washing, rinsing, storing, or cooling whole or cut meat, including hides, carcasses, parts, trim, and organs will be 2.0 ppm and the maximum HEDP EEC_{sludge} will be 80 ppm based on the above calculations using the 10 fold dilution factor for the EEC_{water} and the 80:20 partition ratio to wastewater sludge and wastewater, respectively. The chelating agent, HEDP, is added to the FCS to sequester transition metal ions in solution. HEDP increases shelf life of the product significantly by preventing metal ions from breaking down PAA and H_2O_2. HEDP is in a class of compounds known as phosphonates. HEDP slowly biodegrades into phosphates at a rate of about 1% per day when chelated with transition metal ions[5]. Because of the nature of the carbon-phosphorus bond in HEDP, it adsorbs very strongly to mineral surfaces and rarely exists free in solution[5]. The HERA report shows that HEDP adsorption to sludge is greater than 90%[7]. Our calculations used a conservative estimate of 80% adsorption to sludge in sewage treatment plants.

In wastewater, sulfuric acid will completely dissociate into sulfate ions and hydrated protons, neither of which are a toxicological or environmental concern[10,11].

8. **Environmental Effects of Released Substances**:

This FCS is intended for microbiological control in process water or ice used for washing, rinsing, storing, or cooling whole or cut meat, including hides, carcasses, parts, trim, and organs and the concentrations of the proposed FCS in each application are quite diluted and once the FCS contacts the balance of the site's wastewater, and subsequently further downstream with the main body of discharge/waste water at the POTW and surface waters, the pH would be such that the peroxygens, PAA and H_2O_2, would degrade rapidly[1–3].

a. Aquatic Environment

HEDP is a strong chelating agent and can result in adverse effects on environmental organisms by complexation of essential nutrients[7]. For strong chelating agents, it is suggested that two types of No Observed Effect Concentration's (NOEC's) be determined: an intrinsic NOEC (NOECi) measured with excess nutrients available and a NOEC measured to protect from the chelating effects in natural waters (NOECc)[9]. A realistic NOECc should be determined by testing in natural waters, by predicting metal speciation and algal trace element requirements, and/or using metal speciation modeling programs[9]. However, excess nutrients are expected to be present in industrial wastewater as eutrophication is a well-known phenomenon seen in industrial wastewaters from food processing facilities[8].

Aquatic toxicity of HEDP is summarized and shown in the Table 1.

Table 1: Environmental Toxicity Data for HEDP

Species	Exposure Duration	Endpoint	Conc. (mg/L)
Lepomis macrochirus [9]	Short Term	96 hr. LC_{50}	868
Oncorhynchus mykiss [9]	Short Term	96 hr. LC_{50}	360
Cyprinodon variegatus [9]	Short Term	96 hr. LC_{50}	2180
Ictalurus punctatus [9]	Short Term	96 hr. LC_{50}	695
Leuciscus idus melanatus [9]	Short Term	96 hr. LC_{50}	207 – 350
Daphnia magna [9]	Short Term	24 – 48 hr. LC_{50}	165 – 500
Palaemonetes pugio [9]	Short Term	96 hr. EC_{50}	1770
Crassostrea virginica [9]	Short Term	96 hr. EC_{50}	89
Selenastrum capricornutum [7]	Short Term	96 hr. LC_{50}	3
Selenastrum capricornutum [7]	Short Term	96 hr. NOEC	1.3
Algae [7]	Short Term	96 hr. EC_{50}	0.74
Chlorella vulgaris [9]	Short Term	48 hr. NOEC	≥ 100
Pseudomonas putida [9]	Short Term	30 min. NOEC	1000
Oncorhynchus mykiss [9]	Long Term	14-day NOEC	60 – 80
Daphnia magna [9]	Long Term	28-day NOEC	10 – <12.5
Algae [7]	Long Term	14-day NOEC	13

Jaworska *et. al*. showed that the acute toxicity endpoints for HEDP ranged from 0.74 – 2180 mg/L while the chronic NOECs ranged from 60-80 mg/L for the 14 day NOEC for *Oncorhynchus mykiss* and the 28 day NOEC for *Daphnia magna* was 10 mg/L. 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*. The relevant endpoint for a high orthophosphate environment is 10 mg/L (28 day) NOEC for *Daphnia magna* as published by Jaworska et al. The values calculated herein of HEDP EEC_{water} = 2.0 ppm for process water or ice used for washing, rinsing, storing, or cooling whole or cut meat, including hides, carcasses, parts, trim, and organs fall far below these limits, so no significant adverse impacts are expected.

b. Terrestrial Environment

HEDP accumulated in wastewater sludge is eventually discharged to land and is not expected to have any adverse environmental impact on the terrestrial toxicity endpoints for plants, earthworms, or birds. The NOEC for soil-dwelling organisms was 1000 mg/kg soil dry weight for red worms in soil[7]. The 14 day median lethal dose (LD_{50}) for birds was greater than 284 mg/kg body weight[7]. As a comparison, the HEDP EEC_{sludge} is 80 ppm for process water or ice used for washing, rinsing, storing, or cooling whole or cut meat, including hides, carcasses, parts, trim, and organs which is far less than the LD50 for birds at 248 ppm so no significant adverse impacts are expected.

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, use, or disposal of the FCS above and beyond those already existing, and the proposed use will not create any significant additional burden on resources or energy. The FCS is made in a PAA manufacturing facility with existing fixed costs that would not be increased in a significant way by the manufacture of this FCS. The ingredients used in the manufacture of the FCS are purchased in bulk quantities for several products and this FCS would not pose a significant additional burden on those requirements. The transportation of the FCS is similar to other PAA products at the facility and would only increase the cost of transportation by the weight and incremental fuel required for transport. The disposal of the FCS would not significantly increase any wastewater usage or processing costs any more than a similar volume of a product.

10. **Mitigation Measures:**

The proposed FCS is not reasonably expected to result in any adverse environmental impacts that would require mitigation measures of any kind.

11. **Alternatives to Proposed Action:**

There are no potential adverse environmental effects that would necessitate alternative actions to that proposed in this FCN. The alternative of not approving the action proposed herein would simply result in the continued use of the materials that the FCS would otherwise replace and such action would have no environmental impact.

12. **List of Preparers:**

Joseph Donabed, BS, Cal. State Stanislaus University, 12 years of experience preparing EPA and FDA regulatory submissions

Tina Rodriques, BS, Cal. State Stanislaus University, 13 years of experience preparing EPA and FDA regulatory submissions

13. **Certification:**

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Enviro Tech Chemical Services, Inc.

Signature______________________________________ Date:____6-7-2023_______

Name and Title: Joseph Donabed
Director, Research and Development

14. BIBLIOGRAPHY and LITERATURE CITATIONS

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