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ENVIRONMENTAL ASSESSMENT

RE: FCN # 699

1. **Date:** February 4, 2007 (revision v1)

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

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

4. **Description of Proposed Action:**
   a. The FCS proposed in the Food Contact Notification is composed of peroxyacetic acid, hydrogen peroxide, acetic acid, HEDP, and (optionally) sulfuric acid for microbiological control in process water during the production and preparation of fish and seafood. Maximum concentrations of the FCS is 190 ppm as peroxyacetic acid, 75 ppm as H2O2, and 10 ppm as HEDP, as noted on page 16 of FDA Form 3480.
   b. As noted, the FCS is intended to be diluted on-site to approximately 190 ppm as peroxyacetic acid with associated proportional ingredients. The FCS is used by injecting the equilibrium peroxyacetic acid product (PAA) using flow-proportional dispensing equipment in the process water.

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, RO water, and HEDP as a transition metal stabilizer. Sulfuric acid is optionally added in winter time to aid in the speed of the reaction process.

Ingredients: (note pg. 4 of FDA Form 3480):

Acetic acid	CAS # 64-19-7
Hydrogen Peroxide	CAS # 7722-84-1
HEDP	CAS # 2809-21-4
Sulfuric acid	CAS # 7664-93-9
Purified water	CAS # 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 gms/mole)

6. Introduction of Substance into the Environment:

a. The FCS is currently manufactured in an EPA approved facility (EPA Establishment Number 63838-CA-01) at the address listed above, and no unusual or factual threat to the environment exists. No extraordinary environmental circumstances would apply to the continued on-going manufacture of the FCS.

b. The FCS is proposed for use in water as an antimicrobial during the commercial processing and storage of fish and seafood. The FCS may be used on-board during the initial evisceration and cleaning of fresh-caught seafood. In this case we would anticipate the water used to process the fish or seafood would be discharged back into the ocean whereas the peroxygen actives in the FCS would have a very short half-life [1] @ less than 20 minutes [10]. In this discharge case, the HEDP dilution residuals into the ocean would be impossible for this applicant to calculate. An obvious example would be 20 gallons of the diluted FCS containing 10 ppm active HEDP discharged into the Pacific Ocean. The resultant concentration would be a subjective guess, and this applicant cannot perform this calculation.

c. For land-based operations the balance of the process water including the FCS would be discharged to the local municipal waste treatment or on-site pretreatment facility, whereas the peroxygen components of the FCS would have a very short half-life (less than hours [1, 10]). The FCS substance, if accidentally discharged or released as over-flow from the process area, would be directed to the food plant wastewater discharge system. Treatment of the FCS in this method would represent a 99.4% degradation of the peroxyacetic acid, hydrogen peroxide and acetic acid into their degradation products carbon dioxide, water, oxygen, and acetic acid [2, 3]. The active components and HEDP stabilizer in the formulation would subsequently be diluted proportional to the combined wastewater discharge, which would not present an environmental concern.

The FDA has examined dilution factors (DF) at poultry processing plants and found that 71% of facilities had DF's >100, and 96% had a DF of 20 or greater [11]. A DF of 10 for all food processing facilities is assumed by this applicant to be a conservative DF for the majority of food processing facilities. However, in this instant case this applicant believes the equivalent majority of the water used to process fish would be nearer the amount used for poultry processing, due to the amount of evisceration and preparation in this type of process facility. Thus, for calculation purposes, this applicant would prefer to use a DF of 50 in subsequent calculations.

In wastewater treatment land-based applications, assuming the FCS is used at it's maximum diluted concentration, a maximum anticipated HEDP would thus be 10 ppm in the process water. Assuming continuous spray-bar application to the fish processing line is the method used, a spray bar would typically consist of 3 nozzles at 1 gpm. Assuming there will be 3 spray bars, the total water utilized would be 9 gpm. This would equate to 12,960 gal over a continuous 24 hr. period. A DF of 10 would yield a HEDP residual of 1 ppm, and a DF factor of 50 would yield a residual of 0.2 ppm. Assuming this HEDP was released to the wastewater treatment facilities, and also assuming that all wastewater is treated, and that 80% of the HEDP is removed from the water via adsorption (9, 12), the expected environmental concentration (EEC) in surface waters is then 0.2-0.04 ppm, depending on one's DF. Additionally, resultant wastewater sludge may be land applied. However, due to the FCS's projected low end-use level compared to concentrations where terrestrial toxicity is expected (1000 mg/kg soil dry weight), no environmental toxicity would be expected to occur (9).

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

It is well documented and accepted in the scientific community that PAA and HP are short lived in the environment, do not bioaccumulate, have innocuous degradation byproducts, and are of no toxicological or ecotoxicity concern (1, 2, 3). The HEDP biodegrades into carbon dioxide, water, and simple orthophosphate (9).

Peroxyacetic acid and hydrogen peroxide are not expected to survive treatment at the primary wastewater treatment facility due to their reactivity and pH sensitivity (1). Both compounds are rapidly degraded on contact with organic matter, transition metals, and upon exposure to sunlight (2, 3). The half-life of PAA in buffered solution solutions was 63 hrs at pH 7 for a 748 ppm solution, and 48 hrs for a 95 ppm solution, also at pH 7 (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). In filtered lake water the half-life of H_2O_2 (initial concentration 3.4 ug/l) was 8.6 hrs-31 hrs. (page 21 reference #3).

Since PAA and HP rapidly degrade, they will not be introduced into the natural environment in wastewater at toxic levels. Therefore toxicity and fate data should not be required for these compounds.

In biodegradation studies of acetic acid, 99% degraded in 7 days under anaerobic conditions [5].

Degradation of HEDP phosphonate occurs slowly in sunlight-illuminated river water as shown by loss of chelant titer and the production of orthophosphate. Some species of algae can slowly utilize the phosphorous present in HEDP as a nutrient, and thus degrading the active molecule [6].

In addition, literature reports indicate that HEDP is removed from water and wastewater by classical precipitation treatment with aluminum sulfate or lime [7, 8].

According to HERA, HEDP has a very high adsorption rate coefficient in wastewater activated sludge operations, and this rate of removal has been estimated at >90% for secondary-treated wastewater (page 20, HERA), and further proportionate reductions for tertiary treatment [9].

For sea-based wastewater discharges of this FCS, the peroxygen ingredients would decay rapidly [1, 2, 3, 10]. Since a significant amount of species in ocean-based sea life is dependent upon the food-chain, beginning with plankton-like subspecies, bioaccumulation of the HEDP may be a consideration. However, page 27 of HERA states: "the low K_{ow} values (octanol/water partition coefficient) are extremely low and range from –3.4 to –4.4 depending on the type of (phosphonate) product. Tests on …HEDP (EG&G bionomics, 1976c; Sterber and Wierich, 1986) gave BCF values of …<2-18 (Chemstar PAC, 2003). This confirms that there is no risk of bioaccumulation in the organism and subsequently in the food chain.[9]"

This applicant cannot find any references citing the half-life of HEDP in seawater, so we will assume it is no less than reported for fresh water. The half-life for HEDP in water was estimated in another risk assessment to be 395 days based on reported average data of 10% degradation over 60 days [9].

8. Environmental Effects of Released Substances:

In the current FCN, the FCS is proposed for use in water used to commercially process fish and seafood. The concentrations proposed 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, the pH would be such that the peroxygens PAA and HP would degrade rapidly [1, 2, 3]. HEDP would be the most probable candidate for any potential for environmental toxicity.

a. Aquatic Environment

HEDP is a strong chelating agent and can result in adverse effects on environmental organisms by complexation of essential nutrients [9]. For strong chelating agents, it is suggested that two types of NOEC's be determined: an intrinsic NOEC (NOECi) measured with excess nutrients available and an NOEC measured to protect from the chelating effects in natural waters (NOECc)[12]. 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 [12]. 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 [13, 14, 15].

Table 1. Environmental toxicity data for HEDP.[a]

Species	Endpoint[b]	mg/L
Lepomis macrochirus	96 hour LC50	868
Oncorhynchus mykiss	96 hour LC50	360
Cyprinodon variegatus	96 hour LC50	2180
Ictalurus punctatus	96 hour LC50	695
Leuciscus idus melanatus	48 hour LC50	207-350
Daphnia magna	24-48 hour EC50	165-500
Palaemonetes pugio	96 hour EC50	1770
Crassostrea virginica	96 hour EC50	89
Selenastrum capricornutum	96 hour EC50	3
Selenastrum capricornutum	96 hour NOEC	1.3
Algae	96 hour NOEC	0.74
Chlorella vulgaris	48 hour NOEC	≥100
Pseudomonas putida	30 minute NOEC	1000
Oncorhychus mykiss	14 day NOEC	60-180
Daphnia magna	28 day NOEC	10-<12.5
Algae	14 day NOEC	13

[a] All data from Jaworska et al. (2002) and the HERA risk assessment, references 12 and 9.

[b] The median lethal concentration (LC50) is a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals.
The median effects concentration (EC50) is a statistically derived concentration of a substance that can be expected to cause a specified effect in 50% of test animals.

The lowest toxicity endpoints published for algae, *Selenastrum capricornutm*, *Daphnia magna*, and *Crassostrea virginica* are the result of the chelation effect and not the intrinsic toxicity of HEDP [(12)]. These values are not relevant when excess nutrients are present as expected in food processing wastewaters [(14)]. This leaves the lowest aquatic toxicity endpoint published by Jaworska et al. at 10 mg/L, which is higher than the more conservative EEC of 0.2 mg/L calculated by this applicant. This is the basis of the FONSI for HEDP in relation to intrinsic aquatic toxicity.

Eutrophication is a process whereby water bodies, such as lakes, rivers, and streams, receive excess nutrients that stimulate excessive growth of algae and other plant material. This enhanced plant growth can result in low dissolved oxygen, fish kills, and a depletion of desirable flora and fauna. The relevance of this environmental issue is reflected in reports from the Environmental Protection Agency (EPA) stating that, "As much as half of the nation's waters surveyed by states and tribes do not support aquatic life because of excess nutrients"[(14)]. The main cause of eutrophication in lakes and streams are high levels of nitrogen and phosphorus and phosphates usually originate from municipal or industrial effluents [(13, 14)]. Primary industrial point source contributions of phosphorus include dairy, meat, and vegetable processing facilities, indicating that excess phosphates in food processing effluent is a relevant environmental issue [(16)]. HEDP contains phosphorus and has the potential to contribute to eutrophication. The FONSI and "Supplement to the Environmental Information Available for Food Contact Notification 140" reviewed the use of HEDP in meat processing facilities and discussed the possible contribution of HEDP to total phosphorus and thus eutrophication. It was found that the total phosphorus resulting from the use of HEDP was a small portion of total phosphorus levels found in wastewater of meat processing facilities [(20)].

In 1998, permissible discharge levels for industries ranged from 0.1 – 0.5 mg/L total phosphorus and a goal of 1 mg/L total phosphorus was set in a phosphorus management plan for POTWs in the Upper Mississippi River Basin [(13, 16, 17)]. Since HEDP is only 30% phosphorus by weight [(6)], this applicant expects the proposed use of the FCS to contribute only a small percentage of total phosphorus load in wastewater [(18)]. On the other hand however, food processing effluent released to POTWs and surface waters are typically treated to reduce total phosphorus prior to discharge [(15)].

b. Terrestrial Environment

HEDP in effluent discharged to land is not expected to have any adverse environmental impact. The process effluent concentration DF of 1.0 mg/L (an EEC of 0.2 ppm) is expected to result in soil concentrations lower than terrestrial toxicity endpoints available for plants, earthworms, and birds [(9)]. The NOEC for soil-dwelling organisms was 1000 mg/kg soil dry weight, and this includes plants and earthworms [(9)]. The 14 day median lethal dose (LD50) for birds was greater than 284 mg/kg body weight [(9)]. Application of the wastewater to land will result in phosphorus concentrations in soil that are a small fraction of total phosphorus concentrations currently found in the environment and used in fertilizers [(17, 19)]. Runoff of phosphorus into groundwater or surface waters depends on the management practices and site-specific factors. When best management practices (BMP's) developed by the EPA are followed, this applicant believes that land application of wastewater will reduce use of water by recycling water for irrigation and the overall cost of treatment of wastewater.

9. Use of Resources and Energy:

The proposed FCS would not pose any 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 additional burden on resources or energy.

10. Mitigation Measures:

The National Pollution Discharge Elimination System (NPDES) Program under the Clean Water Act (33 U.S.C. 1251 et seq.) require the users of an antimicrobial agent such as hydrogen peroxide and peroxyacetic acid to have a current NPDES permit and to notify the permitting authority in writing prior to the discharge of an effluent to waters of the United States. Any discharge to ocean waters must also comply with the Ocean Discharge Criteria under Section 403 of the Clean Water Act. The supplement to the EA for FAP 8A4568, dated June 28, 1999, provides further discussions on these subjects. This document (Docket No. 1998F-014) is available at the Division of Dockets Management of the Food and Drug Administration (http://www.fda.gov/OHRMS/DOCKETS/98fr/980014fn.pdf). Review of discharge of the FCS by the appropriate NPDES permitting program will help to mitigate any adverse effects resulting from use of the FCS.

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the FCS mixture. Thus, the use of the FCS mixture is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to Proposed Action:
There are no known alternatives to this proposed FCN.

12. List of Preparers:

a. Michael Harvey, BS. Cal. State University, Chico (Chemistry)
b. Jonathan N. Howarth, Ph.D., Physical Chemistry, Univ. of Southampton, England
BS (Honors), Applied Chemistry, Leicester Polytechnic, England

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.

Date: Feb 4, 2007

Signature: Michael S Harvey

Name and Title: Michael S. Harvey, President

NOTE:
Items #1-9 in the Bibliography on the following page were submitted to the Agency in July, 2006 in support of another FCN by this applicant, which has become effective and has been assigned FCN #641.

BIBLIOGRAPHY and LITERATURE CITED

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(16) Minnesota Technical Assistance Program. Final Report. *Pollution Prevention for Industrial Wastewater Discharges in the Upper Mississippi River Basin Using City-wide Inventories*. Grant No. 03-025. Funding Period June 2003 to May 2005., University of Minnesota. http://mntap.umn.edu/POTW/McKnight05.pdf

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(18) PCA Consultants Ltd. Technical Pollution Prevention Guide for the Dairy Processing Operations in the Lower Fraser Basin. DOE FRAP 1996-11, Environment Canada. http://www.p2pays.org/ref/04/03995.pdf

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(20) FDA, "Supplement to the Environmental Record for Food Contact Notification No. 641", http://www.cfsan.fda.gov/~rdb/opa-envt.html