Revised Environmental Assessment For Peroxyacetic Acid/ Hydrogen Peroxide Formulation Food-Contact Notification (FCN)

1. **Date:** October 19, 2010

2. **Name of Applicant/Petitioner:** Solvay Chemicals, Inc.

3. **Address:** 3333 Richmond Avenue
Houston, Texas

4. **Description of Proposed Action:**

This FCN requests the use of a food-contact substance (FCS) that is a mixture containing peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid (AA), hydroxyethylidene 1,1-diphosphonic acid (HEDP) and dipicolinic acid (DPA) for use as an antimicrobial treatment for meat and poultry carcasses. The FCS will be added to: 1) process water used for washing, rinsing, cooling or otherwise for processing meat carcasses, parts, trim, and organs; and 2) process water applied to poultry parts, organs and carcasses as a spray, wash, rinse, dip, chiller water, or scald water. The maximum use-level for the components of the FCS in meat or poultry process water are shown below:

- Hydrogen Peroxide..350 ppm
- Peroxyacetic Acid..230 ppm
- Hydroxyethylidene-1,1-diphosphonic acid......... ..14.0 ppm
- Dipicolinic acid..0.50 ppm

Hydrogen peroxide and peroxyacetic acid function as the antimicrobial components of the formulation. Hydroxyethylidene 1,1-diphosphonic acid (HEDP) and dipicolinic acid (DPA) are present as stabilizers in the formulation. Acetic acid reacts with hydrogen peroxide to form peroxyacetic acid and some "free" acetic acid remains in the formulation.

Solvay will market the FCS under the PROXITANE® brand name. The FCS will be used in meat and poultry plants located throughout the United States.

The expected route of disposal for meat or poultry process water containing the FCS the processing plant wastewater treatment facility. The treated wastewater will be discharged to the local POTW. Only negligible quantities are expected to be released to air. Hydrogen peroxide, peroxyacetic acid and acetic acid are anticipated to be rapidly degraded upon contact with meat and poultry. Any residues that remain after contact with meat and poultry should be rapidly degraded during wastewater treatment. Consequently, environmental releases of hydrogen peroxide, peroxyacetic acid and acetic acid should be negligible. Due to their low use levels, environmental releases of HEDP and DPA will also be minimal.

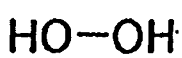
5. Identification of Substances that are the Subject of the Proposed Action:

The substances that are the subject of this notification are hydrogen peroxide, peroxyacetic acid, acetic acid, hydroxyethylidene 1,1-diphosphonic acid and dipicolinic acid.

Background chemical information on these substances is presented below:

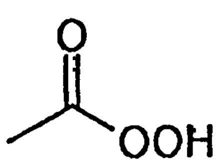
Hydrogen Peroxide

CASRN: 7722-84-1
Molecular Formula: H_2O_2
Molecular Weight: 34.02
Structure:



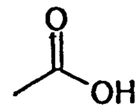
Peroxyacetic Acid

CASRN: 79-21-0
Molecular Formula: CH_3CO_3H
Molecular Weight: 76
Structure:



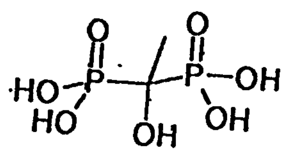
Acetic Acid

CASRN: 64-19-7
Molecular Formula: CH_3CO_2H
Molecular Weight: 60
Structure:



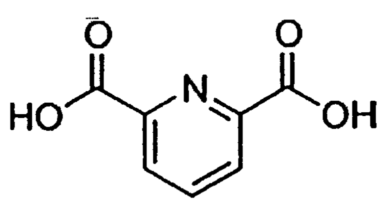
Hydroxyethylidene 1,1-diphosphonic acid

CASRN: 2809-21-4
Molecular Formula: $C_2H_8O_7P_2$
Molecular Weight: 206
Structure:



Dipicolinic acid.

CASRN: 499-83-2
Molecular Formula: $C_7H_5NO_4$
Molecular Weight: 167
Structure



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

a. Introduction of inert ingredient substances into the environment as a result of manufacture:

There are no extraordinary circumstances that apply to the manufacture of any of the components of the FCS (peroxyacetic acid, hydrogen peroxide, acetic acid, hydroxyethylidene 1,1-diphosphonic acid and dipicolinic acid) and, therefore, information about environmental introductions resulting from the production of these substances need not be included in the Environmental Assessment (EA).

b. Introduction of substances into the environment as a result of use/disposal:

The substances comprising the FCS will be discharged to the plant's wastewater treatment system. For both the meat and poultry uses, only trivial amounts, if any, of hydrogen peroxide, peroxyacetic acid and acetic acid are anticipated to be released to the POTW and the environment since: 1) all of these substances will readily decompose upon contact with meat and poultry; 2) any remaining residues will be rapidly degraded during the wastewater treatment process. Therefore, the only components that are expected to be released into the environment are HEDP and DPA. The environment releases of these substances is discussed below:

HEDP

The environmental assessment for HEDP in formulations that are applied to poultry and meat has been discussed in previous FDA Notifications. The maximum levels for HEDP in these notifications are 13 mg/kg in FCN No. 140, 14 mg/kg HEDP in FCN No 323, 11ppm in FCN No. 887 and 11 ppm in FCN No. 908.

This FCN is proposing a maximum HEDP level in meat and poultry process water of 14 ppm. According to the Environmental Assessment associated with FCN No. 323, this level (14 ppm) of HEDP in process water, at a poultry facility, resulted in an environmental release (to a POTW) of 36 ppb. At a meat or beef facility, this level of HEDP (14 ppm) in process water, resulted in an environmental release (to a POTW) of 22 ppb.

DPA

A reasonable "worst-case" estimate of the water concentration of DPA released to a POTW from its use in meat and poultry facilities can be based on the assumption that the concentration is proportional to the concentration of HEDP released since the HEDP released assumed no degradation upon contact with food or during wastewater treatment. Since this FCN is proposing a maximum use level in meat and poultry process water of 0.5 ppm DPA, the HEDP concentration in process water is approximately 28 times that of DPA. Therefore, for a poultry facility, the maximum discharge to a POTW of DPA is:

14 ppm HEDP/36 PPB HEDP = 0.5 ppm DPA/ X ppb DPA
= 1.3 ppb DPA

For a meat or beef facility, the maximum discharge to a POTW of DPA is:

14 ppm HEDP/22 PPB HEDP = 0.5 ppm DPA/ X ppb DPA
= 0.78 ppb DPA

7. Fate of Emitted Component in the Environment:

Data previously submitted to FDA shows that both hydrogen peroxide and peroxyacetic acid are hydrolytically and photolytically unstable and are readily biodegradable. Consequently, both hydrogen peroxide and peroxyacetic acid are expected to rapidly decompose if released into the environment. The decomposition products are water, oxygen and acetic acid. According to the published literature, acetic acid is expected to be rapidly biodegrade under both aerobic and anaerobic conditions. HEDP is expected to be relative stable since, as noted in the Environmental Assessment for FCN No. 323, decomposition of HEDP occurs at a moderately slow pace – 33% in 28 days. According to the published literature, DPA undergoes biodegradation under both aerobic and anaerobic conditions (refer to Attachment 1).

8. Environmental Effects of Released Substances:

Hydrogen peroxide: Hydrogen peroxide is moderately toxic to fish and aquatic invertebrates. As reported in FCN No. 323, the 96-hour LC_{50} is 16.4 ppm and 37.4 ppm for *Pimephales promelas* and *Ictalurus punctatus*, respectively. The 24-hour EC_{50} for *Daphnia magna* is 7.7 ppm. Several algae species are reported to have less than 5% of the original chlorophyll content when exposed to hydrogen peroxide concentrations ranging from 1.7 to 17 mg/ml for 24-48 hours.

Peroxyacetic acid: Peoxyacetic acid is relatively toxic to fish and aquatic invertebrates. As discussed in FCN No. 323, peroxyacetic acid decomposes rapidly to acetic acid and hydrogen peroxide (which decomposes to water and oxygen) when exposed to organic material. The 24-hour EC_{50} for *Daphnia magna* ranges from 0.50 to 1.1 ppm: the 96-hour EC_{50} for *Oncorhynchus mykiss* and *lepomis macrochirus* ranges from 0.91 to 2.0 ppm and 1.1 to 3.3 ppm respectively.

Acetic Acid: According to FCN No. 323, acetic acid is relatively non-toxic to fish, aquatic invertebrates and plants. The 96-hr. LC_{50} for fathead minnow ranges from 79-88 ppm; the 48-hr. LC_{50} for rainbow trout is 105 ppm and the 48-hr LC_{50} for *daphnia magna* is 65 ppm. Toxicity thresholds for green algae (*Scenedesmus quadricauda)* and blue-green algae (*Anacystis aeruginosa)* are 4000 ppm and 90 ppm, respectively.

1-Hydroxyethylidene-1,1-diphosphonic acid (HEDP): The ecotoxicity of HEDP is discussed in FCN No. 323. HEDP is relatively non-toxic to fish and aquatic invertebrates. The aquatic invertebrate acute toxicity (*Daphnia magna)* is 878 ppm (48 hour; EC_{50}); and the freshwater fish acute toxicity ($LC_{50,}$ 96 hr) is 300 ppm (for rainbow trout (*Oncorhynchus mykiss*) Consequently, the environmental release levels of HEDP (22-36 ppb) are orders of magnitude lower than the fish and aquatic invertebrate toxicity values.

Dipicolinic acid (DPA): Limited ecotoxicity data are available for DPA from the manufacturers MSDS sheets. The freshwater fish 96 hour LC_{50} is 322 mg/L (for fathead minnow, *Pimephales promelas*). This value is much higher than the "worst-case" environmental release values (0.78-1.3 ppb) for this substance. Given the low levels released into the environment, the proposed uses of DPA are not expected to result in any adverse environmental effects.

9. Use of Resources and Energy:

The components of the FCS are commercially-manufactured substances that are produced for a wide variety of uses. Resources and energy used specifically in the production of these components, for this FCN, is insignificant. Moreover, except for dipicolinic acid, all the components of the FCS are currently used for the same uses as proposed by this FCN.

10. Mitigation Methods:

Since no adverse environmental impacts have been identified for any of the components that are covered by this FCN, mitigation measures are not necessary.

11. Alternatives to the Proposed Action:

Alternatives to the proposed action do not need to be considered since no potential adverse environmental effects are anticipated to occur if this FCN becomes effective.

12. List of Preparers:

This Environmental Assessment was prepared for Solvay Chemicals Inc., by Robert Quick and Eliot Harrison of Lewis & Harrison, LLC. Mr. Quick's training and background is in chemistry and Mr. Harrison's background is in biology and chemistry.

13. Certification:

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

Name: Eliot I. Harrison

Title: Agent for Solvay Chemicals

Signature: ______________________________

Date: October 19, 2010

ATTACHMENT 1

Biodegradation of Dipicolinic Acid

Attachment 1 contains three copyrighted publications that are not displayed:

JA Amador and BP Tatlor, *Applied and Environmental Microbiology*, **56**(5), 1352-1356 (1990), "Coupled metabolic and photolytic pathway for degradation of pyridinecarboxylic acids, especially dipicolinic acid."

B Seyfried and B Schink, *Biodegradation*, **1**, 1-7 (1990), "Fermentative degradation of dipicolinic acid (pyridine-2,6-dicarboxylic acid) by a defined coculture of strictly anaerobic bacteria."

JP Kaiser, Y Feng, and JM Bollag, *Microbiological Reviews*, **60**(3), 483-498 (1996), "Microbial metabolism of pyridine, quinoline, acridine, and their derivatives under aerobic and anaerobic conditions."