Environmental Assessment

1. Date February 25, 2011

2. Name of Applicant/Petitioner FMC Corporation

3. Address All communications on this matter are to be sent in care of Counsel for Notifier:
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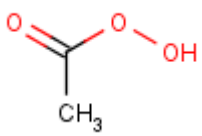
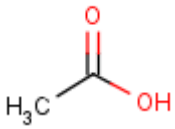
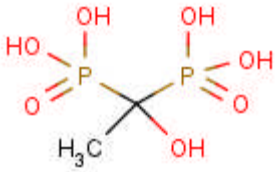
4. Description of Proposed Action:

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), an aqueous peroxyacetic acid (PAA) solution stabilized with 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (hereinafter referred to as "antimicrobial agent") as an antimicrobial agent to treat the process water used in process water or ice for washing, rinsing, storing or cooling of processed and pre-formed meat and poultry products. The components of the antimicrobial agent are limited to use in process water at levels not exceeding 220 parts per million (ppm) PAA, 85 ppm hydrogen peroxide, and 11 ppm HEDP. The intended effect of the FCS is to inhibit the growth of undesirable or pathogenic microorganisms from the process water and ice used to wash, rinse, store or cool processed and pre-formed meat and poultry products, to retard the spoilage of the contacted food, ultimately providing for safer products for consumers.

The antimicrobial agent is intended for use in processed and pre-formed meat and poultry processing plants throughout the United States. The waste process water containing the FCS is expected to be disposed of through the processing plant wastewater treatment facilities or through a local publicly owned treatment works (POTW).

5. Identification of the Subject of the Proposed Action

The subject of this notification is a mixture containing peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and water (chemical structures provided below). PAA formation is the result of an equilibrium reaction between acetic acid and hydrogen peroxide. The mixture is provided as a concentrate that is diluted on site.

Peroxyacetic Acid CAS Reg. No. 79-21-0  MW: 76.0506	Hydrogen Peroxide CAS Reg. No. 7722-84-1) MW: 34.0138
Acetic Acid CAS Reg. No. 64-19-7  MW: 60.0516	HEDP (CAS Reg. No. 2809-21-4)  MW: 206.026
Water CAS Reg. No. 7732-18-5 MW: 18.0148	

6. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment as a Result of Manufacture:

Under 21 C.F.R § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. 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 here.

b. Introduction of Substances into the Environment as a Result of Use/Disposal:

Introduction of dilute solutions of the antimicrobial agent into the environment will take place primarily via release in wastewater treatment systems.

It is difficult to determine the amount of the antimicrobial agent that could be released into the environment as a result of the intended uses, as amounts used in processing will depend on the equipment used and the amount of pre-formed meat and poultry processed.

Introduction of dilute solutions of the antimicrobial agent into the environment will take place primarily via release in wastewater treatment systems. Wastewater containing the FCS would be discharged to an on-site pretreatment facility or POTW. As discussed below, the PAA, hydrogen peroxide, and acetic acid are expected to degrade rapidly into their degradation products carbon dioxide, water, oxygen, and acetic acid. The HEDP is, thus, expected to be the only component that remains for any period in the wastewater.

Assuming the FCS is used at its maximum diluted concentration, a maximum anticipated amount of HEDP would be 11 ppm in the process water. The antimicrobial agent is primarily intended for use as a treatment for water that is used to cool ready-to-eat (RTE) meat and poultry products after they have been processed and formed into various shapes. The cooking process generally kills microbial contamination in and on the RTE product, but the cooling water may become contaminated over time and repeated contact with contaminated foods, and may re-contaminate otherwise safe foods. This cooling system is not large by most processing standards, and may only use up to 1,000 gallons of water. The system is typically discharged at a rate of 10% of its overall volume per hour, depending on the amount of organic matter present, and fresh water is used to make up the difference. Wastewater discharges from this system may equal twice the total volume of the system over a processing day of 18 hours.

If we assume that a pre-formed meat and poultry plant uses a similar amount of water as for poultry processing, due to the amount of organic matter generated in this type of process facility, it is appropriate to utilize a dilution factor (DF) of 50. However, as a conservatism, calculations also include values using a DF of 10.[1] A DF of 50 would yield a concentration of 0.22 ppm[2] in the water, while a DF of 10 would result in a concentration of 1.1 ppm[3] in the water. This wastewater is expected to be released to either on-site or publicly owned treatment facilities, at which point 80% of the HEDP is expected to be adsorbed to sludge during sedimentation or filtration treatment.[4] As a result, the expected environmental concentration in surface waters is 0.2 – 0.04 ppm,[5] depending on the DF.

7. Fate of Emitted Subjects in the Environment

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[1] See FCN No. 908 Environmental Assessment, citing J. Cleland, M. Rodriquez, M. Huang, and B. Wrenn, Background Research Related to Aquatic Expected Exposure Concentrations from Poultry First Processing, Draft Memorandum, FDA Contract No. 233-00-2450, WA No. 314, Task 2 (2003).

[2] 11 ppm ÷ 50 = 0.22 ppm

[3] 11 ppm ÷ 10 = 1.1 ppm

[4] Environmental Decision Memo for Food Contact Notification No. 000140. Available at http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=opaListing&id=140.

[5] (0.22 ppm OR 1.1 ppm) × 20% = 0.2 ppm OR 0.04 ppm

PAA and hydrogen peroxide are not expected to survive treatment at a wastewater treatment facility. PAA rapidly degrades on contact with organic matter, transition metals, and upon exposure to sunlight. The half-life of PAA in buffered solutions is 63 hours at pH 7 for a 748 ppm solution, and 48 hours at pH 7 for a 95 ppm solution.[6] 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.[7] In biodegradation studies of acetic acid, 99% degraded in 7 days under anaerobic conditions; it is not expected to concentrate in the wastewater discharged to a POTW.[8]

Decomposition of HEDP occurs at a moderately slow pace; 33% in 28 days.[9] The calculations above of HEDP concentrations in discharged processing water assume that 100% of the HEDP remains in the water following treatment at the first wastewater plant. This is a very conservative assumption, as several treatment steps, including sedimentation, aerobic or anaerobic treatment, filtration and chemical disinfection of the effluent, will remove or decompose at least a portion of the HEDP that is present in the wastewater.

HEDP that is removed via sedimentation or filtration will slowly degrade into carbon dioxide, water and phosphates. Phosphate anions are strongly bound to organic matter and soil particles, and phosphate is a required macronutrient of plants. However, given the maximum level estimated to be released of 1.1 ppm, we would not expect that phosphate released from HEDP would result in measurable increases in phosphate in soils amended with wastewater sludge, or in water receiving treated effluent.

Sludge removed from WWTPs (or POTWs) can be used as a soil amendment in land application resulting in an environmental release. Harrass, *et. al.* (1991)[10] provided a soil amendment dilution factor of 2.5% after incorporation. However, given the maximum level estimated to be released, 0.2 – 0.04 ppm, it is not expected that phosphate released from HEDP would result in measurable increases in phosphate in water receiving treated effluent or in soils amended with wastewater sludge.

8. Environmental Effects of Released Substances

Wastewater containing the FCS residue from preformed and processed meat and poultry operations will be directed to an on-site WWTP or a POTW, or both. It is expected that all

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[6] Peracetic Acid and its Equilibrium Solutions. JACC No. 40. European Centre for Ecotoxicology and Toxicology of Chemicals, January 2001.

[7] Hydrogen Peroxide. JACC No. 22. European Centre for Ecotoxicology and Toxicology of Chemicals, January, 1993.

[8] U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Panel, American Chemistry Council.

[9] *See* environmental assessment for FCN No. 323.

[10] Harrass, M.C., Erickson, C.E. III, Nowell, L. H., "Role of Plant Bioassays in FDA Review: Scenarios for Terrestrial Exposure," *Plants for Toxicity Assessment: Second Volume, ASTM STP 11115,* J. W. Gorsuch, W.R. Lower, W. Wang, and M. A. Lewis, Eds., American Society for Testing and Materials, Philadelphia, 1991, pp 12-28.

components of the FCS, excluding HEDP, will completely decompose in the WWTP or POTW prior to discharge to the environment. Below is a summary of the decomposition reactions and, if applicable, environmental persistence and ecotoxicity of each component of both mixtures.

Peroxyacetic Acid: PAA rapidly decomposes to acetic acid and hydrogen peroxide (which decomposes to water and oxygen) when exposed to organic material. The environmental release is anticipated to be well below concentrations found to have a negative impact on aquatic organisms. The 48-hour EC_{50} for *Daphnia magna* ranges from 0.50 to 1.1 mg/L; the 96-hour EC_{50} for *Oncorhynchus mykiss* and *Lepomis macrochirus* ranges from 0.91 to 2.0 mg/L and 1.1 to 3.3 mg/L, respectively.[11]

Hydrogen Peroxide: Hydrogen peroxide rapidly decomposes to water and oxygen when exposed to organic material. It is not expected to enter the environment after wastewater treatment. The 96-hour LC_{50} is 16.4 µg/L and 37.4 µg/L for *Pimephales promelas* and *Ictalurus punctatus*, respectively. The 24-hour EC_{50} for *Daphnia magna* is 7.7 mg/L. 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/L for 24-48 hours.[12]

Acetic acid: Summary ecotoxicity data from the High Production Volume (HPV) Assessment Plan for Acetic Acid and Salts[13] indicate that acetic acid is not highly toxic to aquatic plant and animal species. In water, acetic acid dissociates into the acetate anion and hydrogen proton. The anion is readily biodegradable, with 99% degraded after 7 days (anaerobic conditions, in the presence of activated sludge). The LC_{50} for fathead minnow is 106-122 ppm (24-hour), 92-106 ppm (48-hour), and 79-88 ppm (96-hour). The 48-hour LC_{50} or rainbow trout is 105 ppm and the 48-hour EC_{50} for *Daphnia* is 65 ppm. Toxicity thresholds for algae were reported on the MSDS for green algae (*Scenedesmus quadricauda*; 4000 ppm), blue-green algae (*Anacystis aeruginosa*; 90 pprn), and euglenoid (*Entosiphon sulcatum*; 78 ppm).

1-Hydroxyethylidene-1,1-diphosphonic acid (HEDP): Jarworska et al (2002)[14] have summarized the aquatic toxicity of HEDP, as indicated in the following table:

Environmental Toxicity Data for HEDP		
Species	**Endpoint**	**mg/L**
Short Term		

[11] Peracetic Acid and its Equilibrium Solutions. JACC No. 40. European Centre for Ecotoxicology and Toxicology of Chemicals, January, 2001.

[12] Hydrogen Peroxide. JACC No. 22. European Centre for Ecotoxicology and Toxicology of Chemicals, January, 1993.

[13] U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category. Acetic Acid and Salts Panel, American Chemistry Council, June 28, 2001.

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

Lepomis macrochirus	96 hr LC_{50}	868
Oncorhynchus mykiss	96 hr LC_{50}	360
Cyprinodon variegates	96 hr LC_{50}	2180
Ictalurus punctatus	96 hr LC_{50}	695
Leciscus idus melanatus	48 hr LC_{50}	207 – 350
Daphnia magna	24 – 48 hr LC_{50}	165 – 500
Planemonetes pugio	96 hr LC_{50}	1770
Crassostrea virginica	96 hr LC_{50}	89
Selenastrum capricornutum	96 hr LC_{50}	3
Selenastrum capricornutum	96 hr NOEC	1.3
Algae	96 hr NOEC	0.74
Chlorella vulgaris	48 hr NOEC	≥100
Pseudomonas putida	30 minute NOEC	1000
Long Term		
Oncorhychus mykiss	14 day NOEC	60 -80
Daphnia Magna	28 day NOEC	10 - <12.5
Algae	14 day NOEC	13

A recent risk assessment of phosphonates by the Human and Environmental Risk Assessment Project[15] included a discussion of aquatic toxicity resulting from chelation of nutrients, rather than direct toxicity to aquatic organisms. The lowest toxicity endpoints, those shown above for algae, *Selenastrum capricornutm*, *Daphnia magna*, and *Crassostrea virginica* are considered to result from chelation of nutrients, not from direct toxicity of HEDP. Chelation is not toxicologically relevant in the current evaluation because eutrophication, not nutrient depletion, has been demonstrated to be the controlling toxicological mode when evaluating wastewater discharges from food processing facilities.[16] FDA in its Finding of No Significant Impact (FONSI) for FCN No. 691 determined that the lowest relevant endpoint for this use pattern was 10 mg/L.

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[15] Human and Environmental Risk Assessment (HERA) on ingredients of European Household Cleaning Products: Phosphonates (2004). Available at http://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf (hereinafter "HERA Assessment").

[16] The Environmental Review Group concluded during its review of FCN No. 691 that "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." Memorandum re FCN No. 691 from Katrina E. White, Ph.D., Environmental Review Group, Division of Chemistry Research and Environmental Review (HFS-246), to Division of Food Contact Notifications (HFS-275) (Jan. 18, 2007).

Biodegradation study results were variable. Zahn-Wellens dissolved organic carbon removed 33% after 28 days; modified OECD screening theoretical carbon dioxide evolution was 2% after 70 days; modified SCAS dissolved organic carbon removed 90%; and closed container BOD_{30}/COD was 5%.

The calculated environmental exposure to HEDP is a maximum of 0.2 – 0.04 ppm, and included an assumption that no decomposition of the stabilizer occurs during wastewater treatment. This level of exposure is orders of magnitude below the LC_{50} of Daphnia, rainbow trout and Bluegill sunfish, and is substantially below the endpoint of 10 mg/L calculated in FCN No. 691. As indicated above, hydrogen peroxide and peroxyacetic acid are not expected to survive wastewater treatment processes at the facility treatment plant. Since this wastewater will be discharged to a local POTW for further treatment before release into the environment, all peroxy compounds and acetic acid, as well as the majority of the HEDP likely will decompose before release.

HEDP in effluent discharged to land is not expected to have any adverse environmental impact based on the terrestrial toxicity endpoints available for plants, earthworms, and birds. The NOEC for soil dwelling organisms was > 1000 mg/kg soil dry weight for red worms and > 980 mg/kg for oats.[17] The 14-day median lethal dose (LD_{50}) for birds was greater than 284 mg/kg body weight.[18] 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.[19]

9. Use of Resources and Energy

No net increase in the use of energy and resources is expected for the use of the antimicrobial agent as the components readily degrade. The Notifier's FCS is expected to compete with, and to some degree replace, similar antimicrobial agents already on the market, including, e.g., the FCS identified in FCN No. 908.

The partial replacement of other substances by the Notifier's antimicrobial agent is not expected to have any adverse impact on the use of energy and resources. The manufacture of the antimicrobial agent will consume comparable amounts of energy and resources as similar products, and the raw materials used in the production of the mixture 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 mixture components is not significant.

10. Mitigation Measures

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17 Finding of No Significant Impact (FONSI) and supplement to the environmental record for FCN 728, July 17, 2007.

18 *See* HERA Assessment.

19 D.W. Litke, Review of Phosphorus Control Measures in the United States and Their Effects on Water Quality: Water-Resources Investigations Report 99-4007; U.S. Geological Survey: Denver, Colorado (1999), available at http://pubs.usgs.gov/wri/wri994007/.

The intended use of the FCS is not reasonably expected to create any new environmental problem that would require mitigation measures of any kind. As discussed above, the use and disposal of the antimicrobial agent is not expected to result in significant adverse environmental impacts. Furthermore, the National Pollution Discharge Elimination System (NPDES) Program under the Clean Water Act (33 U.S.C. 125 1 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. 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.

11. Alternatives to the Proposed Action

No potential adverse effects are identified herein which would necessitate alternative actions to that proposed in this Notification. If the proposed action is not approved, the result would be the continued use of the materials that the subject FCS would replace. Such action would have no environmental impact. The addition of the antimicrobial agent to the options available to fish and seafood processors is not expected to increase the use of PAA antimicrobial products.

12. List of Preparers

Devon Wm. Hill, Partner, Keller and Heckman LLP

Bethany M. Walls, Scientist, Keller and Heckman LLP

13. Certification

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

Date: February 25, 2011

Devon Wm. Hill

[redacted]

Keller and Heckman LLP