Mr. Julius Smith
March 17, 2003
FCN 323

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Appendix E

Antimicrobial Agent

Environmental Assessment (revised)

000233

Environmental Assessment

1. Date: March 17, 2003

2. Name of Applicant/Petitioner: FMC Corporation, Chemical Products Division

3. Address: All communications on this matter are to be sent in care of Counsel for Notifier, Melvin S, Drozen, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: 202-434-4222.

4. Description of Proposed Action:

The action requested in this Notification is the establishment of a clearance to permit the use of peroxyacetic acid at a maximum of 230 ppm, hydrogen peroxide, acetic acid and 1-hydroxyethylidene-1,1-diphosphonic acid in aqueous antimicrobial solutions applied as a carcass wash to reduce the surface microbial populations on freshly killed meat carcasses, parts, trim and organs, and defeathered poultry carcasses, parts and organs. Mixtures containing these constituents have previously been cleared by FDA for the same uses, although the maximum concentration cleared for each component is slightly lower than those proposed above (*See* 21 C.F.R. § 173.370).

This product is applied directly to the exposed surface of the meat carcass (beef or swine) via a sprayer after the hide is removed and the head and the hooves are cut off. It is applied to poultry carcasses, poultry carcass parts, or poultry organs through spraying, submersion, or both. The antimicrobial effect of peroxyacetic acid reduces populations of pathogenic and non-pathogenic microorganisms that may be present and retards the spoilage of the meat and poultry. This should provide for safer meat and poultry products for consumers.

This product is for use in meat and poultry processing plants throughout the United States. The expected route of disposal for waste solution is the processing plant wastewater treatment facilities.

Meat processing facilities: This product will be applied to the surface of freshly killed beef or swine carcasses following removal of the hide, head and hooves. This is accomplished by spraying the carcasses on a moving conveyor line. The carcasses are suspended from a hook attached to the conveyor, which carries the carcass into an enclosed cabinet. Spray nozzles are distributed within the cabinet in such a manner that ensures even application of the dilute solution on the surface of the beef carcass. The carcass exits the other side of the spray cabinet and continues on the processing line.

After the diluted product is sprayed onto the carcass, the majority of the product drains off of the meat and ultimately runs into drains and enters the meat processing plant water treatment facility. Very minor quantities are lost to evaporation.

Poultry processing facilities: Spray application of the diluted product will usually take place prior to chilling by submersion. A de-feathered, eviscerated carcass hung on a shackle is carried into a spray cabinet by a conveyor system. Spray nozzles inside the cabinet apply the diluted product to the carcass surface. The carcass then exits the spray cabinet for further processing.

Application of the diluted product by submersion of multiple carcasses into a chiller bath will occur immediately following the spray application step. Carcasses are moved through the chiller bath by a paddle or auger-type conveyor, then exit the chiller bath for further processing. Carcass parts or organs may also be chilled by submersion in water containing *Antimicrobial Agent.*

After the diluted *Antimicrobial Agent* is sprayed onto the poultry carcasses, the bulk of the solution drains off of the poultry carcass. The waste solution ultimately run into drains and enter the poultry processing plant water treatment facility. The diluted product in chiller water will also be disposed of by pouring it down drains that lead to the poultry processing plant water treatment facility. All of this water is collected and treated by the facility prior to it being sent to a POTW. Very minor quantities are lost to evaporation into the air.

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

A confidential description of the product composition appears in Attachment I of this Notification. The raw materials used in this product are hydrogen peroxide, acetic acid, HEDP, and water. Peroxyacetic acid formation is the result of an equilibrium reaction between hydrogen peroxide and acetic acid. When the mixture is diluted for use on beef carcasses, poultry carcasses, poultry parts and organs (up to 7.5 ounces per 50 gallons of water), the solution contains no more than 230 ppm peroxyacetic acid. The concentration in solution will vary slightly with the age of the product.

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 ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated substances. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of *Antimicrobial Agent.*

[redacted]

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 *Antimicrobial Agent* into the environment will take place primarily via release in wastewater treatment systems. Introduction of the components of *Antimicrobial Agent* into the environment will result from use of the product as an antimicrobial agent in processing water and spray application onto carcasses, and the subsequent disposal of such water and spray drainage into the processing plant wastewater treatment facility. The total amount of *Antimicrobial Agent* used at a typical facility can be estimated, although the actual amounts used will vary, depending on equipment used and the number of meat or poultry carcasses processed. Examples of each use scenario are presented below. The calculations presented below and in the Confidential Attachment to this EA are based on information presented in FAPs 0A4720, 1A4728 and 1A4731.

Beef:

Antimicrobial Agent is diluted to a maximum of 230 ppm peroxyacetic acid, and the diluted solution applied as a continuous pressurized spray onto fresh beef carcasses following slaughter and removal of the head, hide and hooves. The carcasses are attached to an overhead conveyor, which carries each carcass inside an enclosed cabinet, where the spray is applied. Following application of the antimicrobial spray, the carcass exits the cabinet, the excess solution is allowed to drain from the carcass, and is flushed down drains to the wastewater treatment facility.

To estimate the potential volume of product released into the environment, we estimated the daily volume required. At the maximum use rate of 230 ppm peroxyacetic acid, and an estimated 1300 gallons of diluted antimicrobial solution applied per hour, the maximum amount of concentrated *Antimicrobial Agent* used is 195 ounces per hour.[1] Assuming two operating shifts at the beef processing plant, and two spray cabinets in operation on both shifts, the total volume of *Antimicrobial Agent* used per day is calculated below:

[195 oz./hour] x [16 hours] x [2 spray cabinets] = 6240 oz. or 48.75 gallons/day

Treatment of the process water at the on-site wastewater treatment plant is expected to result in nearly 100% degradation of the peroxyacetic acid, hydrogen peroxide, and acetic acid. This expectation is based on the half-life of peroxyacetic acid and hydrogen peroxide and acetic acid (summary provided in Section 7 of this Assessment). The only component that is likely to be present in measurable quantities in wastewater discharged to publicly-owned treatment works (POTWs) is HEDP. We have calculated a maximum daily load of HEDP is approximately 0.022 ppm or 22 ppb.

Poultry:

Antimicrobial Agent is diluted to a maximum of 230 ppm peroxyacetic acid before application to the surface of the poultry carcass as a spray. This carcass wash is sprayed continuously as the carcasses pass through the spray cabinet. After spray application, the excess carcass wash drains off and is flushed to the wastewater treatment plant. The amount of *Antimicrobial Agent* solution applied by spray to an individual carcass is

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1 $\frac{7.5\ oz.\ product}{50\ gallons\ water} \times \frac{1300\ gallons\ water}{hour} = 195\ oz./\ hour$

approximately 0.25 gallons for each poultry carcasses (in this example, chickens are considered, as they constitute the majority of poultry processed in the U.S.).

After spraying, the carcass is placed in the chiller bath, which will contain a maximum of 30 ppm peroxyacetic acid. The chiller bath is normally filled once per day with approximately 25,000 gallons of water. Fresh make-up water will be added to the bath at the rate of approximately 0.5 gallons/bird. About 200,000 birds are sprayed and submersed per day at a typical processing facility.

Based on the above information, an estimate of the daily use of *VigorOx® SP-15 Antimicrobial Agent* in a poultry processing plant can be calculated as follows:

Spray Application:
200,000 carcasses x 0.25 gallons of spray/carcass = 50,000 gallons (200 ppm solution)
50,000 gallons x 7.5 ounces product/50 gallons = 58.6 gallons of *VigorOx® SP-15 Antimicrobial Agent*

Chiller Bath:
25,000 gallons (initially) x 1 ounce product/50 gallons = approximately 4 gallons of *VigorOx® SP-15 Antimicrobial Agent*

Make up water is required at the rate of 0.5 gallons/carcass, and we assume 200,000 carcasses are processed/day. Thus, 100,000 gallons of water are added to the bath during the course of the day, which is treated at the rate of 1 ounce per 50 gallons. 100,000 gallons x 1 ounce product/50 gallons water = 15.6 additional gallons of *VigorOx® SP-15 Antimicrobial Agent*

The total amount of *Antimicrobial Agent* used for both spray and chiller bath applications per day is approximately 78.2 gallons in a typical poultry processing plant. For purposes of this example, it is assumed that all of the product used on carcasses will ultimately reach the drain and be discharged to the on-site wastewater treatment facility.

As noted in the previous discussion of the release of *Antimicrobial Agent* components, it is not expected that any of the constituents of the antimicrobial solution except

[redacted]

HEDP will survive initial treatment at the on-site wastewater treatment facility. Therefore, we have only estimated the potential release of this component for poultry processing facilities as well. Assuming that all of the HEDP remains in the wastewater following initial treatment, the maximum daily load of HEDP is 0.036 ppm or 36 ppb.

7. Fate of Emitted Components in the Environment:

Peroxyacetic acid and hydrogen peroxide are not expected to survive treatment at the primary wastewater treatment facilities at either poultry or beef processing plants. Both compounds are rapidly degraded 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] In biodegradation studies of acetic acid, 99% degraded in 7 days under anaerobic conditions;[4] it is not expected to concentrate in the wastewater discharged to the POTW.

Decomposition of HEDP occurs at a moderately slow pace; 33% in 28 days, based on information provided by the manufacturer (MSDS). 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

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

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

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, 36 ppb, 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.

8. Environmental Effects of Released Substances:

In each of the use scenarios described above, waste antimicrobial solution (from application and drainage) will be directed to an on-site wastewater treatment facility. There, it is expected that decomposition of all of the components excluding HEDP will occur prior to water being discharged. Below is a summary of the decomposition reactions and, if applicable, environmental persistence and ecotoxicity of each component in the formulation.

Peroxyacetic acid: Decomposes rapidly to acetic acid and hydrogen peroxide (which decomposes into water and oxygen) when exposed to transition metals (such as Fe, or Mn) and organic material. The fate of acetic acid is discussed below. However, 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

[4] 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. Copy in Appendix 1 of this Attachment.

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.[5]

Hydrogen peroxide: Decomposes rapidly to water and oxygen when exposed to transition metals (such as Fe, or Mn) and organic material. It is not expected to enter the environment after wastewater treatment. The 96-hour LC_{50} is 16.4 Φg/L and 37.4 Φg/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.[6]

Acetic acid: Summary ecotoxicity data cited on the supplier MSDS and from the High Production Volume (HPV) Assessment Plan for Acetic Acid and Salts[7] 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} for 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 ppm), and euglenoid (*Entosiphon sulcatum*; 78 ppm).

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

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

7 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. Copy in Appendix 1 of this Attachment.

1-Hydroxyethylidene-1,1-diphosphonic acid (HEDP): Ecotoxicity and environmental persistence of HEDP are available from the supplier (see MSDS for Dequest 2010 in Attachment II), and are summarized here. Aquatic invertebrate acute toxicity (*Daphnia magna*) is 527 mg/L (48-hour; EC_{50}); freshwater fish acute toxicity (LC_{50}) is 348 mg/L for rainbow trout (*Oncorhynchus mykiss*) and 868 mg/L for Bluegill sunfish (*Lepomis macrochirus*); and aquatic plant toxicity (EC_{50}) is 3 mg/L for the algae, *Selenastrum capricornutum.* 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 bottle BOD_{30}/COD was 5%.

The calculated environmental exposure to HEDP is a maximum of 0.18 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 an order of magnitude below the EC_{50} of algae. 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, FMC expects that all peroxy compounds and acetic acid, as well as the majority of the HEDP will decompose before release.

9. Use of Resources and Energy

The use of the antimicrobial mixture, *Antimicrobial Agent*, will not require additional energy resources for treatment and disposal of waste solution, as the components readily degrade. 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 production processes. Energy used specifically for the production of the mixture components 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 antimicrobial mixture, *Antimicrobial Agent.* Thus, the use of the subject mixture is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact Notification. The alternative of not approving the action proposed herein would simply result in the continued use of nearly identical products by the beef, poultry and pork processing industry; such action would have no environmental impact. The addition of *Antimicrobial Agent* to the options available to meat processors is not expected to increase the use of peroxyacetic acid antimicrobial products; rather, FMC expects to provide a replacement product for those peroxyacetic acid products already in use.

12. List of Preparers

Elizabeth Heger, Pesticide Registration Manager, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

13. Certification

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

Date: March 17, 2003

Melvin S. Drozen

Counsel for FMC Corporation