Attachment 4: Environmental Assessment (Revised)

1. Date: May 15, 2007 (Originally Filed March 28, 2007)

2. Name of Applicant/Petitioner: FMC Corporation

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4. Description of Proposed Action:

The action requested in this Notification is the establishment of a clearance to permit the use of a food contact substance (FCS) described as a mixture containing peroxyacetic acid (PAA), hydrogen peroxide, acetic acid, water, and 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP). The Food and Drug Administration (FDA) has designated this Notification as Food Contact Substance Notification FCN 000782 (FCN 728).

The mixture will be used to render the surfaces of polymeric food packaging commercially sterile. PAA has an antimicrobial effect and reduces populations of pathogenic and non-pathogenic microorganisms that may be present on the food packaging. Sterile food is introduced into the food packaging immediately after excess sterilant solution is removed from food packaging. Sterilization and filling of containers will occur within a controlled environment.

When the FCS is used to sterilize bottles, excess sanitizing solution will be rinsed from the bottles with sterile water.[1] Bottle rinsing generates a dilute, continuous wastewater stream containing the FCS components. When the FCS is used to sterilize food-packaging film, excess FCS solution will be mechanically stripped, not rinsed, from the film and returned to the sterilant bath. Although no continuous wastewater stream is generated in film-sterilization operations, as described in Attachment 1, FCN 728 ("100% Migration Calculations for 'No Rinse' Use"), a wastewater stream in the form of spent sterilant baths, which are drained at least once every 10 days, is generated from film-sterilization operations. Wastewater streams from bottle sterilization operations (consisting of rinse water), film sterilization operations (consisting of spent sterilant baths), and other operations unrelated to packaging sterilization merge in the main wastewater header of the food processing plant prior to being sent to wastewater treatment facilities.

[1] The environmental impact associated with the disposal of wastewater containing the FCS from bottle sterilization operations was addressed in the Environmental Assessment for FCN 561, however, based on our current knowledge of typical wastewater treatment operations at food processing plants, we have updated our environmental assessment for the use of the FCS in these "rinse applications."

Many food-processing plants operate on-site wastewater treatment plants (WWTPs) to treat their wastewater. Some of these on-site WWTPs discharge their effluent to publicly owned treatment works (POTWs) for additional treatment prior to discharge to receiving waters, while others are permitted to discharge their effluent directly into surface waters or over land.[2] Other food processing plants send their wastewater directly to POTWs without pretreatment at an on-site WWTP.[3]

The FCS is for use in food processing plants throughout the United States.

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

FCN 323 provides a full description of the FCS, which is incorporated by reference in Form 3480 of this Notification (filed March 28, 2007). The components of the FCS include peroxyacetic acid (PAA) (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), 1-hydroxyethylidene-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and water. The maximum concentrations of these components are provided in Attachment 5 ("Confidential Environmental Information"). Formation of PAA is the result of an equilibrium reaction between hydrogen peroxide and acetic acid.

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 the FCS mixture. 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:

For the reasons discussed in Section 7 below, only HEDP is expected to be present in environmentally significant concentrations upon discharge to the environment through aquatic or terrestrial routes. Therefore, the primary focus of this assessment is the potential introduction to the environment of HEDP resulting from the applications covered by FCN 728.

We estimated the concentration of FCS components that would be expected to persist in receiving waters based on a conservative model of downstream wastewater treatment as suggested by FDA in its May 2, 2007 letter. The following diagram provides an overview of the

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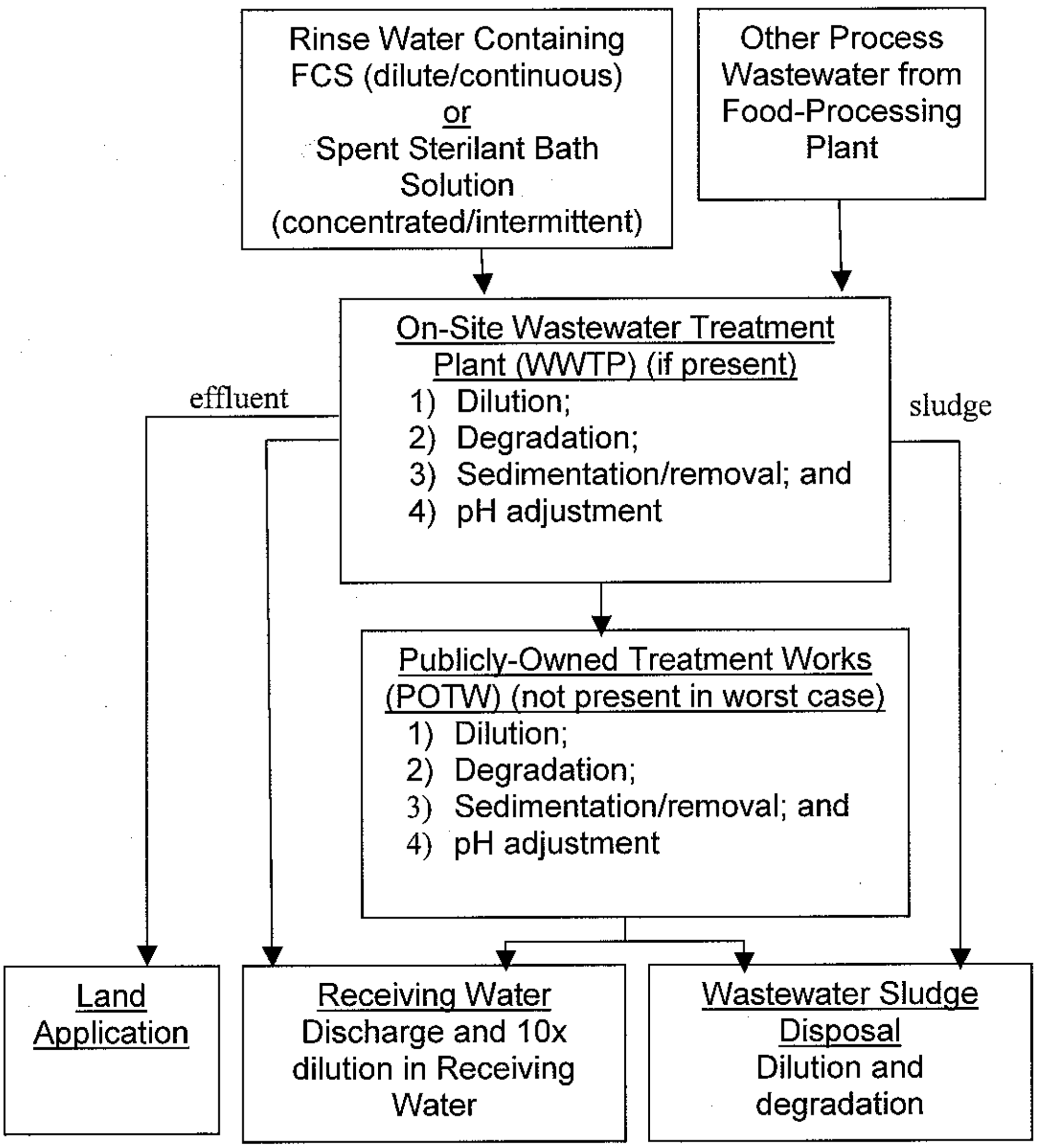
2 *Food Processing Business Sector Fact Sheet*, Wisconsin Department of Natural Resources: Jul 27, 2006 (available at http://dnr.wi.gov/org/caer/cea/assistance/foodprocessing/ info.htm#wastewater) (accessed May 3, 2007).

3 Specifically, FMC Corporation's current customers who would operate with this technology have indicated that they send their wastewater directly to a POTW, however at least one of these customers has indicated that it planned to install an on-site WWTP to pre-treat wastewater prior to sending it to a POTW in the near future.

route of wastewater containing the FCS from its point of generation in sanitizing operations to its discharge to the environment:



This diagram shows many of the common treatment steps that may be employed by food processing facilities using the FCS under the applications covered by FCN 728. Direct discharge from the WWTP would result in higher concentrations of FCS in the environment than the indirect discharge from the POTW. Thus, we have assumed in determining the worst-case environmental concentrations of the FCS components that food-processing facilities would treat their wastewater only in an on-site WWTP and discharge the effluent directly to receiving waters without secondary treatment in a POTW.

In considering the worst-case discharge scenario, we considered food-processing facilities that are permitted by state agencies to discharge their wastewater to direct land application systems for irrigation purposes.[4] We understand that the kinds of food processing facilities that are permitted to operate in this manner are primarily vegetable processors that operate only in the summer months when there is a demand for irrigation in close proximity with the wastewater source. We do not anticipate this would be common practice at food processing facilities using the sterilization technology covered by FCN 728, which are expected to operate year round independently of agricultural operations having a demand for irrigation. Nevertheless, we have calculated the expected terrestrial concentration based on direct discharge as an alternate worst-case discharge scenario. The more likely FCS discharge concentrations and flow rates are based on a food-processing facility conducting both bottle-sterilization operations and film-sterilization operations.[5]

The initial dilution of the FCS will occur at its point of use in sterilization operations. For bottle sterilization operations, the FCS will be applied at full strength and subsequently rinsed from the bottles using a combination of sterile water and steam. Thus, the concentration of the FCS in the wastewater from bottle sterilization operations reflects the dilution of the FCS solution by the rinse water and the steam used in rinsing. For film sterilization operations, food-packaging film will be immersed in a sterilant bath containing the FCS. The sterilant bath is a mixture of the FCS with water that is maintained at a concentration of approximately 4,000 parts per million (ppm) PAA, which corresponds to a 37.5-fold dilution of the full-strength FCS. Due to the processes described in Attachment 1 to FCN 728 (filed March 28, 2007), the HEDP concentration of the sterilant bath is expected to climb from its initial concentration over time. The spent sterilant bath will be emptied periodically (not less than once every 10 days) and the contents drained to the main wastewater header of the food processing plant. The total volume of a typical sterilant bath is 38 gallons, and the emptying process is assumed to take one hour. The detailed calculations included in the confidential section of this environmental assessment (Attachment 5) account for the rise in HEDP concentration during the time period in which a particular batch of sterilant bath is used (the maximum HEDP concentration after 10 days of operation are used in the calculations).

Treatment of the wastewater containing the FCS at on-site WWTPs would result in nearly 100% degradation of the PAA, acetic acid, and hydrogen peroxide. This expectation is based on the half-life of these substances as described in Section 7 below. The only component likely to be present in measurable quantities in wastewater discharged to the environment is HEDP.

We can draw a similar conclusion regarding the concentration of FCS components present in sludge removed from WWTPs and POTWs, *i.e.*, we would only expect HEDP to be

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4 *Food Processing Business Sector Fact Sheet*; Wisconsin Department of Natural Resources: July 27, 2006 (*available at* http://dnr.wi.gov/org/caer/cea/assistance/foodprocessing/info.htm#wastewater) (accessed May 3, 2007).

5 If a food-processing facility were to operate multiple packaging lines, our environmental exposure estimates would not be affected so long as the ratio of film-sterilization lines to bottle-sterilization lines is approximately 1-to-1. As the proportion of film-sterilization lines increased, however, exposure estimates would increase slightly because our model assumes that wastewater from "non-sterilization sources" is proportional to the flowrate of wastewater from bottle rinsing, but fixed with respect to wastewater flowrates from sterilant bath disposal.

present in measurable quantities in the sludge. Therefore, we have limited the remainder of our quantitative evaluation to estimation of the HEDP concentrations in the environment from discharge to receiving waters and in sludge mixed with surface soil (and, as an alternate worst-case discharge scenario, from direct application of wastewater to land).

The calculations in Attachment 5 include dilution of wastewater from packaging sterilization operations (*i.e.*, bottle sterilization and film sterilization) in the on-site WWTP upon mixing with wastewater from other operations in the food-processing plant, such as wash down of process vessels, tanks, floors, and pipes. In one case study of a bottling facility, bottle washing operations accounted for 62% of daily water used.[6] Thus, we have used a WWTP dilution factor of 38% in our calculations for estimated environmental concentrations of HEDP.

As the wastewater is treated in the WWTP, the HEDP decomposes or adsorbs to the solids in the sedimentation tank, thus further reducing its concentration in the WWTP effluent. We have accounted for reduction of HEDP concentration due to adsorption to the sludge based on an 80% sludge adsorption factor as determined in a risk assessment conducted in the Netherlands on phosphinate in wastewater treatment systems.[7]

We have not accounted for reduction of HEDP concentration in WWTP effluent attributable to decomposition because the WWTP effluent concentrations were well below acceptable limits without this additional reduction factor. We did, however, employ a decomposition reduction factor in estimating environmental concentrations of HEDP in sludge removed from WWTPs.

The pH of wastewater is adjusted to a level of 5 or greater as a final step prior to discharge from the WWTP to receiving waters.[8] We applied FDA's default 10-fold dilution factor to account for dilution expected to occur upon discharge to surface waters.

We estimated terrestrial environmental concentrations of the FCS components present in sludge removed from on-site WWTPs using the methodology described by *Harrass et al.*[9]

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6 Ait Hsine, E.; Benhammou, A.; Pons, M.-N. Industrial water demand management and cleaner production potential: a case of beverage industry in Marrakech – Morocco. *Afrique Science* **2005,** *1*, 95-108.

7 *Draft Human and Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates*; Human and Environmental Risk Assessment Initiative: Jun 9, 2004 (*available at* http://www.heraproject.com/RiskAssessment.cfm) (accessed May 3, 2007).

8 One purpose of on-site wastewater treatment facilities typically used by food-processing plants is to adjust the pH of wastewater, as required by 40 C.F.R. Part 403.5 and by various POTWs, prior to discharge, to ensure the pH of discharged water is not less than 5. Although the presence of acidic components in the FCS mixture may have a slight impact on the pH of the water discharged to POTWs from on-site wastewater treatment facilities, the pH of the water discharged would be 5 or greater, as required by law. We think that the general pH control measures employed at wastewater treatment facilities at food-processing plants would be sufficient to mitigate any impact on pH caused by the low levels of HEDP present in discharge water.

9 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, Philaderlphia, 1991, pp 12-28.

7. Fate of Emitted Components in the Environment:

As noted above, peroxyacetic acid, acetic acid, and hydrogen peroxide are not expected to survive treatment at the wastewater treatment facilities at food packaging 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 has been determined to be 63 hours at pH 7 for a 748 ppm solution, and 48 hours at pH 7 for a 95 ppm solution.[10] The half-life of hydrogen peroxide is concentration dependent, and is reported to range from 2.5 days in natural river water when initial concentrations of 10,000 ppm were introduced, and increased to 15.2 days when the concentration decreased to 250 ppm.[11] In biodegradation studies of acetic acid, 99% degraded in 7 days under anaerobic conditions,[12] and it is not expected to concentrate in the wastewater discharge.

The maximum concentration of HEDP released to the environment via WWTP effluent discharged to receiving water is calculated in Attachment 5 as 0.13 mg/L from the bottle washing application and 2.93 mg/L from the combined bath disposal and bottle washing, assuming that the entire contents of the bath was discharged over a one hour period. Because bath disposal is assumed to occur less than once a week, the maximum effluent concentration represents at maximum, a one-hour load in any seven-day period. Decomposition of HEDP occurs at a moderately slow pace of 33% in 28 days, based on information provided by the manufacturer (MSDS). FDA has determined that HEDP is adsorbed to sewage sludge resulting in 80% removal during treatment.[13]

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, 2.93 mg/L, we would not expect that phosphate released from HEDP would result in measurable increases in phosphate in water receiving treated effluent.

As previously explained, we do not think that food processors operating under FCN 728 would discharge their wastewater in land applications. Nevertheless, we have calculated the maximum concentration of HEDP released to the environment if the WWTP effluent were directly discharged to land to be 1.3 mg/L from the bottle washing application and 29.3 mg/L from the combined bath disposal and bottle washing, assuming that the entire contents of the bath were discharged over a one hour period (see Attachment 5). Since bath disposal is assumed to occur less than once a week, the maximum effluent concentration represents at maximum, a one-hour load in any seven-day period.

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

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

[12] See Footnote 10.

[13] Environmental Decision Memo for Food Contact Notification No. 000140. http://www.cfsan.fda.gov/~rdb/fnsi0140.html

8. Environmental Effects of Released Substances:

As noted above, wastewater from bottle sterilization operations as well as wastewater from other operations at the food processing plant will be directed to an on-site WWTP or a POTW, or both. It is expected that many of the components present in the FCS will completely decompose in the WWTP or POTW prior to water being discharged 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: 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 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.[14]

Acetic acid: Summary ecotoxicity data cited on the supplier MSDS and from the High Production Volume (HPV) Assessment Plan for Carboxylic Acids and Salts[15] 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 acetate anion readily biodegrades, with 99% consumed after 7 days (anaerobic conditions, in the presence of activated sludge). The LC_{50} values for fathead minnow are reported as 106-122 mg/L (24-hour), 92-106 mg/L (48-hour), and 79-88 mg/L (96-hour). The 48-hour LC_{50} for rainbow trout is 105 mg/L and the 48-hour EC_{50} for *Daphnia* is 65 mg/L. Toxicity thresholds for algae were reported on the MSDS for green algae (*Scenedesmus quadricauda*; 4000 mg/L), blue-green algae (*Anacystis aeruginosa*; 90 mg/L), and euglenoid (*Entosiphon sulcatum*; 78 mg/L).

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 treatment at the facility wastewater treatment plant. 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.[16]

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

[15] See Footnote 3.

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

1-Hydroxyethylidene-1,1-diphosphonic acid (HEDP): Jarworska et al. (2002)[17] have summarized the aquatic toxicity of HEDP. The available data are shown below:

Environmental Toxicity Data for HEDP

Species	Endpoint	mg/L
Short Term		
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 phophonates by the Human and Environmental Risk Assessment Project[18] 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[19]. 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.[20] FDA in its Finding of No

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17 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.

18 See Footnote 7

19 See Footnote 17

20 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) (on file with Keller and Heckman LLP).

Significant Impact (FONSI) for FCN No. 691 determined that the lowest relevant endpoint for this use pattern was 10 mg/L.

Biodegradation study results for HEDP are variable. Zahn-Wellens dissolved organic carbon testing indicated removal of 33% of HEDP 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 from effluent release from a WWTP to receiving waters is 0.13 mg/L from the bottle washing application and 2.93 mg/L from the combined bath disposal and bottle washing, assuming that the entire contents of the bath were discharged over a one-hour period. It was assumed that 80%[21] of the HEDP was removed by sedimentation to sludge in the WWTP prior to discharge and that the HEDP concentration was further diluted 10-fold upon discharge to the receiving waters. This level of exposure is well below the 10 mg/L level of concern determined by FDA. As indicated above, hydrogen peroxide and peroxyacetic acid are not expected to survive treatment processes at the wastewater treatment facility. FMC expects that all peroxy compounds and acetic acid, as well as the majority of the HEDP will decompose or be removed before release.

If effluent from the WWTP were discharged directly to land rather than to receiving waters, the maximum short-term effluent concentration of 29.3 mg/L HEDP present in the surface water 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 and this includes plants and earthworms. The 14-day median lethal dose (LD_{50}) for birds was greater than 284 mg/kg body weight.[22] 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.[23]

HEDP will be adsorbed to sludge during treatment in the WWTP. This sludge could be used as a soil amendment in land application resulting in an environmental release. As shown in Attachment 5, the estimated concentration of HEDP in sludge is 2194 mg/kg. Harrass et al (1991)[24] have given a 40-fold dilution factor for application to soil (after incorporation) (expressed by the authors as "2.5%"). The HEDP concentration would be 55 mg/kg of soil. The amount of sludge predicted to be generated from this use pattern would result in a land application to 1.26 hectares at a rate of 4.5 kg/m^2. Thus, this concentration is below any level of concern, either for toxicity to terrestrial organisms or as a significant source of phosphorus.

10. Use of Resources and Energy

The use of the FCS mixture will not require additional energy resources for treatment and disposal of waste solution, as the components readily degrade. The raw materials used in the

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21 See Footnote 13.

22 See Footnote 18

23 Phosphorus in soil, http://taipan.nmsu.edu/mvpfpp/phosphor.htm

24 See Footnote 9

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 FCS 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 FCS mixture. 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 alternative methods of ensuring the sterility of food packaging; such action would have no environmental impact.

12. List of Preparers

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13. Certification

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

Date: May 10, 2007

John B. Dubeck
Counsel for FMC Corporation