1. Date: May 25, 2011

2. Name of submitter: Evonik Degussa Corporation

3. Address: 379 Interpace Parkway Parsippany NJ, 07054

4. DESCRIPTION OF THE PROPOSED ACTION:

a. Requested action:

The action requested is an establishment of a clearance to permit the use of peroxyacetic acid at a maximum of 230 ppm, hydrogen peroxide at a maximum of 50 ppm, acetic acid HEDP at a maximum of 1 ppm and DPA at a maximum of 0.5 ppm in aqueous antimicrobial solutions applied as a carcass wash to reduce the surface microbial populations on freshly killed beef and swine carcasses, parts, trim and organs. Mixtures containing these constituents have previously been cleared by FDA for the same uses. The proposed food contact substance is used at a slightly higher concentration than approved in the current CFR (See 21C.F.R. §173.370). However, the level of HEDP present in the proposed formulation is well below the previously approved levels. This FCN is looking to replace FCN 951 adding in dipicolinic acid for additional stability of the product. The approval for FCN 951 was a maximum of 13 ppm HEDP.

b. Need for action:

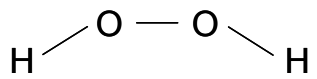
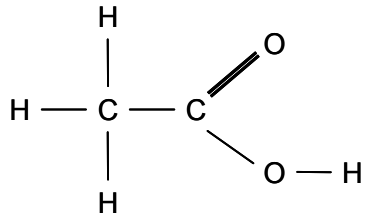
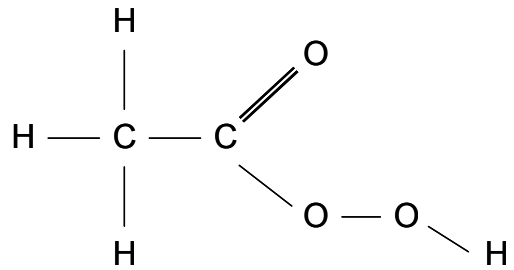
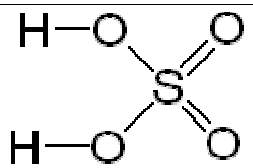
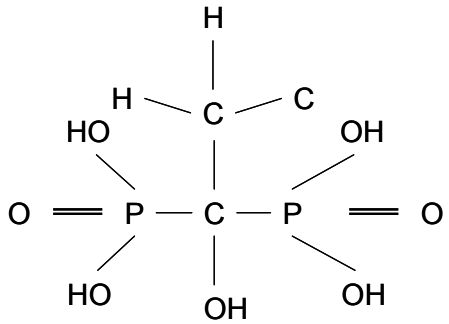
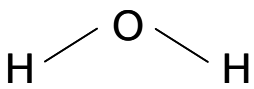
The antimicrobial effect of peroxyacetic acid reduces populations of pathogenic and nonpathogenic microorganisms that may be present and hampers the spoilage of the meat. This will aid in the provision of safer meat products for consumers. The use of the proposed product will also reduce the amount of HEDP that will be released into the environment compared to other formulations that are currently on the market.

c. Locations of use/disposal:

This product is for use in beef and swine processing plants. The food contact substance (FCS) will be used in the carcass washing process that takes place after evisceration in a meat packing facility in order to reduce the antimicrobial load present on the surface of the beef carcass and also at the end of the conveyor line prior to chilling.

5. IDENTIFICATION OF SUBSTANCES THAT ARE THE SUBJECT OF THE PROPOSED ACTION:

Complete nomenclature: An equilibrium mixture of Peracetic Acid, Hydrogen Peroxide, Acetic Acid.

Complete Name	CAS #	Molecular Weight	Molecular formula	Structural Formula
Hydrogen Peroxide	7722-84-1	34.01 g/mol	H_2O_2	
Acetic Acid	64-19-7	60.05 g/mol	$C_2H_4O_2$	
Peracetic Acid	79-21-0	76.05 g/mol	$C_2H_4O_3$	
Sulfuric Acid	7664-93-9	98.1 g/mol	H_2SO_4	
Hydroxy Ethylidene Diphosphonic Acid (HEDP)	2809-21-4	206.03 g/mol	$C_2H_8O_7P_2$	
Water	7732-18-5	18.01g/mol	H_2O	

Physical description; Clear liquid

6. Introduction of substances into the environment:

A. As a result of manufacture:

Under 21 C.F.R. § 25.40(a), an environmental assessment focuses on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated substances. The product is currently manufactured in at an EPA approved pesticide producing establishment. Moreover, information available to Evonik does not indicate any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the concentrated FCS mixture.

B. As a result of use:

Common to all meat first processing operations are the series of steps necessary to transform live animals into either whole or split carcasses. These steps include the assembly and holding of animals for slaughter; killing, which involves stunning before and bleeding after killing; hide or hair removal in the case of hogs; evisceration and variety meat (organ) harvest; carcass washing; trimming; and carcass cooling. Depending on the market served, cutting, deboning, and grinding and other further processing operations may occur at the same location (1).

In a typical meat processing facility the following conditions for use are assumed. A typical meat processing facility runs five days a week Monday-Friday running two 8 hour shifts everyday. At a large meat processing facility, which is what this assessment will try to represent, it is assumed that approximately 6000 heads of beef per day are slaughtered. Using the above assumptions it is estimated that 1,560,000 heads of beef are processed each year.

Animals are first received by meat processing facilities live. The typical first step in meat processing is to stun the animal prior to slaughter. Immediately after the animals are stunned shackles are attached to the animal's rear legs and are then suspended on an overhead rail conveyor system. This system is used to move the animals throughout the meat processing facility. Once the animals are hung on the conveyor line they proceed to be slaughtered by exsanguination. The animal then proceeds down the conveyor where the hide and/or hair of the animal is removed, the tails and hooves are also removed about this time. Once the hide or hair is removed from the animal the carcasses are washed with sprays of dilute FCS at a rate of 45 gallons dilute solution per hour[1]. The FCS is diluted by adding 1.14 oz of concentrated FCS for every 10 gallons of water. Assuming that 45 gallons of water are used per hour and there are 16 hours per day in a processing facility that would mean that 720 gallons of water are used in this step. Below is a calculation for the FCS used in this step:

720 gallons of water/day.

[1] Please refer to letter attached from survey of processing customers.

1.14 oz of concentrated FCS per 10 gallons of water
1.14 x 72 = 82.08 oz of concentrated FCS used in this step.
128 oz in 1 gallon
82.08 oz / 128 oz per gallon= .65 gallons of concentrated FCS used per day in this step

After this preliminary wash the animals move to the evisceration process. This step is used to remove all of the internal organs. A ventral incision that spans the carcass is made along with an incision through the diaphragm so the internal organs of the animal can be removed and collected.

Once the carcasses have been eviscerated the carcasses will move through a spray cabinet to be washed once again. At this point in the process the FCS is utilized again. The spray cabinet will have a rate of 45 gallons/hr of dilute FCS solution sprayed onto the carcasses as they move through the cabinet. The FCS will be diluted in the carcass washing step. The proposed dilution rate for the FCS is 1.14 oz into 10 gallons of water.

In the spray cabinet if water is flowing continuously for two 8 hour shifts at a rate of 45 gal./ hour there is a total of 720 gallons of water per day used in this step alone. If the FCS is used in this step at a rate of 1.14 oz of concentrated FCS per 10 gallons of water a total of 82.08 oz or .65 gallons of concentrated FCS would be used in this step[2] .

Once the carcasses leave the spray cabinet they are dressed and put on a conveyor where the carcasses will then be broken down further into parts. During the primal meat cut sprays the FCS may also be used at a rate of 20 gallons per minute that will contain the FCS. In this step although the flow rates are higher the dilution ration of FCS remains the same at 1.14 oz of concentrated FCS per 10 gallons of water. This would provide a total of 2200 oz or 18 gallons of concentrated FCS would be used in this step[3]

The flow rates used in the above scenario are real world rates obtained from surveying potential users of the FCS.

C. As a result of disposal:

In a meat processing facility the predominant type of discharge would be to an on-site pretreatment facility that would discharge to a local sewer treatment facility. For land-based operations the balance of the process water including the FCS would be discharged to the local

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[2] If 1.14 oz Concentrated FCS (Cfcs) is used for 10 gallons of water and the flow rate is 45 gallons per hour in the spray cabinet. Then 1.14 oz of Cfcs would be used per minute for 16 hours.
1.14 oz Cfcs x 72 gallons = 82.08 oz of Cfcs per day.
Conversion to gallons: 82.08oz / 128 oz per gallon /day is 0.65 gallons of Cfcs used per day during carcass washing in the spray cabinet.

[3] If 1.14 oz Concentrated FCS (Cfcs) is used for 10 gallons of water and the flow rate is 20 gallons per minute in the spray cabinet. Then 2.28 oz of Cfcs would be used per minute for 16 hours.
2.28 oz Cfcs x 60 minutes/hr x 16 hours = 2188.8 oz of Cfcs per day.
We rounded to 2200oz of Cfcs which when converted to gallons 2200oz / 128 oz per gallon will give you: 17.18 gallons of Cfcs used per day during carcass washing in the spray cabinet. We will round up to 18 gallons for this step.

municipal waster treatment or on-site pretreatment facility. When the FCS is treated in this manner it would result in a 98% degradation of the peroxyacetic acid, hydrogen peroxide and acetic acid into their degradation products carbon dioxide, water, oxygen, and acetic acid (2,3). The HEDP in the formulation will be diluted proportional to the combined wastewater discharge, which would not present an environmental concern. Currently, other products in the market place for similar or identical uses are using concentration of 13 ppm HEDP at use rate, the FCS discussed in this EA will use less than 10'x the amount of HEDP that is currently approved allowing for less phosphorus entering the environment. If Evonik were to come into the market and replace some or all of the peracetic acid based products market share with our current FCS we would reduce the amount of phosphorous introduced into the environment rather than add to it.

Since a dilution factor (DF) of 10 is commonly used by the FDA to estimate dilution from introduction to surface waters, then in a wastewater treatment application, assuming the FCS is used at it's maximum diluted concentration, a maximum of 1 ppm HEDP would be expected in the process waters. A DF of 10 would then yield a residual HEDP amount of 0.1 ppm. Assuming that this wastewater is then treated at a wastewater treatment facility and that 80% of the HEDP is removed from the water via adsorption then the expected introduction concentration (EIC) in surface waters is then 0.02 ppm HEDP in surface water. 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 (NOEC 1000 mg/kg soil dry weight), no environmental toxicity would be expected to occur (4). Currently the use rate at meat processing plants from the FCS's that are allowed have rates of HEDP use over 10 times higher than what Evonik is assuming.

For DPA we will use the same assumptions as we did above for HEDP. Using the DF of 10 and assuming a maximum concentration of 0.5ppm DPA we would yield a residual DPA of 0.05ppm. Assuming that this wastewater is then treated at a wastewater treatment facility and that 80% of the DPA is removed from the water via adsorption then the expected introduction concentration (EIC) in surface waters is then 0.01 ppm HEDP in surface water. If we look at the Environmental Assessment associated with FCN 323 they use a HEDP level of 14 ppm in process water at a poultry facility. This level of HEDP was associated to an environmental release to a POW of 36ppb.

So in order to estimate a "worst-case" scenario of the concentration of DPA released to a POW from it's use in a meat packing plant 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 the wastewater treatment the maximum discharge of DPA can be viewed as follows:

14 ppm HEDP/36 PPB HEDP

1ppm HEDP/ 2.6ppb HEDP= 0.5 ppm DPA **X** ppb DPA
= 0.19 ppb DPA

7. Fate of substances released into the environment:

In biodegradation studies of acetic acid 99% degraded in 7 days under anaerobic conditions[4], it is not expected to concentrate in the waste water discharged to the POTW. Peroxyactic acid and hydrogen peroxide compounds will rapidly degraded on contact with organic matter, transition metals, and upon exposure to sunlight. The half-life of PAA in buffered solutions was 64 hours at pH 7 for a 748 ppm solution, 48 hours at pH 7 for a 95 ppm solution (2). The half-life of hydrogen peroxide in different surface water types are varying. For a worst case, a half life of 5 days in natural surface water can be assumed(3).

Decomposition of HEDP occurs at a moderately slow pace; 33% in 28 days, based on the information provided by the manufacturer (MSDS)[5]. 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 by direct discharge is 0.02 ppm, we do not expect that phosphate released from HEDP will result in measurable increases in phosphate in soils amended with wastewater sludge, or in water receiving treated effluent.

DPA undergoes biodegradation under both aerobic and anaerobic conditions (16,17,18).

8. Environmental effects of released substances:

Terrestrial Toxicity:

HEDP in effluent discharged to land is not expected to have any adverse environmental impact. The effluent concentration of 1mg/L is expected to result in soil concentrations lower than terrestrial toxicity endpoints available for plants, earthworms and birds (4) . The NOEC for soil dwelling organisms was 1000 mg/kg soil dry weight and this includes plants and earthworms. The 14 day median oral lethal dose (LD50) for birds was greater than 248 mg/kg body weight (4). Application of the wastewater to land will result in phosphorus concentrations in soil that are a small fraction of total phosphorous concentrations currently found in the environment and used in fertilizers (5,6)[6]. Runoff of phosphorous into groundwater or surface water depends on the management practices and site specific factors. When best management practices developed by the EPA are followed, we believe that land application of wastewater will reduce use of water by recycling water for irrigation and the cost of treatment of wastewater[7]. The highest concentrations

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

[5] Attached after references

[6] Typical phosphorus concentrations in soil range from 12-1000 ppm total phosphorus (8,10). Environmental threshold soil test phosphorus values, developed to prevent soil phosphorus from becoming high enough to result in unacceptable phosphorus enrichment of agricultural runoff, ranged from 75-200ppm in eight states (8). The application rate of 30.ppm used for land application is minor compared to 75-200 ppm and thus will not result in adverse environmental effects.

[7] Information on EPA's best management practices is available at: http://www.epa.gov/ebtpages/envibestmanagementpractices.html.

of HEDP that will be seen if minimal degradation or dilution occurs will be 1 ppm which is significantly lower than the LD50.

Aquatic Toxicity

Comprehensive environmental risk assessments for HEDP were recently published by Jarworska et al. (2002) and by the Human & Environmental Risk Assessment (HERA) group on ingredients of household cleaning products (4,7). Acute toxicity endpoints ranged from 0.74 – 2180 mg/L which is shown in Table 1 *(7)*. Chronic no observable effects concentrations (NOECs) are also shown in Table 1. The 14 day NOEC for *Onchorhynchus mykiss* was between 60 – 180 mg/L and the 28 day NOEC for *Daphnia magna* was 10 mg/L (7). A chronic NOEC of 0.1 mg/L for reproductive effects in *Daphnia magna* was published but is inconsistent with other toxicity data for the phosphonates and Jaworska suggested that the value is due to the depletion of micronutrients by HEDP rather than its intrinsic toxicity (4). No systemic toxicity was found below 10 mg/L and Jaworska et al. used 10 mg/L to represent the chronic NOEC for *Daphnia magna (7)*.

HEDP is a strong chelating agent and can result in adverse effects on environmental organisms by complexation of essential nutrients (4). For strong chelating agents, it is suggested that two types of NOECs 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) (7). 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 (7). However, we believe 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 (8,9,10).

The lowest toxicity endpoints published for algae, *Selenastrum capricornutm*, *Daphnia magna*, and *Crassostrea virginica* are believed to be the result of the chelation effect and not the intrinsic toxicity of HEDP (7). These values are not relevant when excess nutrients are present as expected in food processing wastewaters (9,10)[8].

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 EPA which state, "As much as half of the Nation's waters surveyed by states and tribes do not support aquatic life because of excess nutrients" (9). 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 (9,10) . 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 (12). 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 phosphorous resulting from the use

[8] Food processing wastewaters are characterized by a high biological oxygen demand, total suspended solids, and excessive nutrient loading, namely nitrogen and phosphorus (11,12,13).

of HEDP was a small portion of total phosphorus levels found in wastewater of meat processing facilities (14).

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 (10,12). Since HEDP is only 30% phosphorus by weight (MSDS) we expect the proposed use of the FCS to contribute a small percentage of the total phosphorus load in the wastewater (13)[9]. However, food processing effluent released to POTWs and surface waters is typically treated to reduce total phosphorus prior to discharge (8).

1 -Hydroxyethylidene- 1,l -diphosphonic acid (HEDP): Ecotoxicity and environmental persistence of HEDP are available from the supplier, 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 368 mg/L for rainbow trout(Uncorhynchus mykiss) and 868 mg/L for Bluegill sunfish (Lepomis macrochzrus); 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%.

As calculated earlier with distribution from direct discharge the maximum amount of HEDP that would be released is 0.02 ppm which is lower than the lowest aquatic toxicity endpoint of 0.74 mg/L. As indicated above, hydrogen peroxide and peroxyacetic acid are not expected to survive wastewater treatment processes at the facility treatment plant.

There is little available ecotoxicology data for DPA. The MSDS from one supplier states that the freshwater fish 96 hour LC50 is 322 mg/L for fathead minnow. This is much higher than our "worst case" scenario of 1.3ppb. The use of DPA at such a minimal level is not expected to result in any adverse environmental effects.

Environmental Toxicity Data for HEDP[a]		
Species	**Endpoint**	**mg/L**
Lepomis macrochirus	96 hr. LC50	868
Oncorhynchus mykiss	96 hr. LC50	360
Cyprinodon Variegatus	96 hr. LC50	2180
Ictalurus punctatus	96 hr. LC50	695
Leuciscus idus melanatus	48 hr. LC50	207-350
Daphnia magna	24-48 hr. EC50	165-500
Palaemonetes pugio	96 hr. EC50	1770
Crassostrea virginica	96 hr. EC50	89
Selenastrum capricornutum	96 hr. EC50	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

[9] Typical total phosphorus in dairy effluent ranged from 9 – 210 mg/L and the primary sources of phosphorus were milk, detergents, and sanitizers (13).

Oncorhynchus mykiss	14 day NOEC	60-180
Daphnia magna	28 day NOEC	10-≤12.5
Algae	14 day NOEC	13

a: All data from: Jaworska, J.; Van Genderen-Takken, H.; Hanstveit, A.; can de Plassche, E.; Feijtel, T. Chemosphere. 2002, 47 655-665 and
Draft Human and Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates; Human and Environmental Risk Assessment Initiative: June 9, 2004

Use of resources and energy:

The use of the concentrated 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 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.

Mitigation measures:

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

Alternatives to the proposed action:

There are no potential adverse environmental effects identified that would necessitate alternative actions to that proposed in this FCN. The alternate of not approving this FCN would simply result in the continued use of nearly identical products by the beef, poultry and pork processing industry; such action would therefore have no environmental impact. The addition of the concentrated FCS mixture to the options that are currently available to meat processors is not expected to greatly increase the use of peroxyacetic acid products. However, the use of this formulation would reduce the phosphorous burden.

List of preparers:

Tiana M. Rosamilia, Registrations Manager, Evonik Degussa Corporation, 379 Interpace Parkway, Parsippany NJ 07054

Certification:

"The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Degussa Corporation."

May 25, 2011

(Date)

[redacted]

(Signature of responsible official)

Tiana M. Rosamilia Registrations Manager
(Name and title of responsible official, printed)

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