ENVIRONMENTAL ASSESSMENT

1. Date: April 26, 2024

2. Name of Submitter: Safe Foods Chemical Innovations /LPR Technologies

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4. Description of the Proposed Action

A. Requested Action

The action requested in this notification is to provide for the use of the Food Contact Substance (FCS), which is an aqueous solution of hydrogen peroxide (CAS Reg. No. 7722-84-1), as an antimicrobial agent in poultry scald tanks. The FCS will not exceed 2000 ppm hydrogen peroxide when applied to scald water for whole carcass processing. During commercial synthesis of hydrogen peroxide, phosphate stabilizers may be present as phosphate salts in the FCS. The Food Chemicals Codex provides the specification for the maximum phosphate content as no more than 0.005% (50 ppm) in hydrogen peroxide (HP) suitable for food use.[1]

The FCS has been approved for other food uses such as for use in frozen desserts, ready to drink beverages and in corn protein manufacturing, under effective FCNs 2245 and 2165, respectively. The FCS is also commonly used in the manufacture of peroxyacetic acid (PAA) substances and has been previously approved for use as an ingredient in PAA and peroxylactic acids (PLA) with several Food Contact Notifications (FCNs) (No. 1946, 1995, 2168 and 2210) permitting the use of hydrogen peroxide at concentrations at or above the level proposed above.

In addition, the FCS is affirmed as a Generally Recognized As Safe (GRAS) food substance when used at concentrations ranging from 400 ppm to 1.25% (12,500 ppm) in certain foods.[2]

B. Need for Action

The intended use of the FCS is as an antimicrobial agent in the scald immersion tank used to treat poultry carcasses with hot water or steam to loosen feathers from the follicle to aid in their removal. The introduction of the FCS at this early step of processing, in conjunction with mechanical separation of fecal and other organic matter and dirt from the scald water is expected to aid in reduction of pathogenic and non-pathogenic microorganisms further downstream in the process. In addition, hydrogen peroxide presents a non-odor forming antimicrobial alternative at the end-use concentration compared to the currently approved antimicrobials for scalder use, such as PAA.

The requested action to expand the currently approved uses of the FCS is needed to address current and future needs of food processors and governmental agencies to improve food safety. Use of the FCS provides more options for antimicrobial interventions.

C. Locations of Use/Disposal

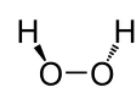
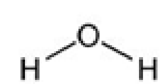
The antimicrobial agent is intended for use in poultry processing plants throughout the United States. After use, the FCS will be disposed of with processing plant wastewater according to National Pollutant Discharge Elimination System (NPDES) regulations. For processing plants that hold a NPDES permit (i.e., direct dischargers), the FCS-containing wastewater will be treated on-site before direct discharge to surface waters. For processing plants without such NPDES permits (i.e., indirect dischargers), the FCS-containing wastewater would travel through the sanitary sewer system into Publicly Owned Treatment Works (POTWs) for standard wastewater treatment processes before movement into aquatic environments. It is expected that process water not containing the FCS will be used in processing facilities for activities such as cleaning and sanitation, resulting in significant dilution of the FCS into the total water effluent.

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

The Food Contact Substance is an aqueous solution of hydrogen peroxide (HP). The FCS is supplied in concentrated form and is diluted at the processing plant to achieve the desired level of HP needed to address the microbial load.

The descriptions, chemical formulae, structures and molecular weight of the FCS is described in Table 1 below:

Table 1: Chemical Identity of Food Contact Substance Components

Component	CAS Number	Molecular Weight	Molecular Formula	Molecular Structure
Hydrogen peroxide	7722-84-1	34.0147 g/mol	H_2O_2	
Water	7732-18-5	18.015 g/mol	H_2O	

6. Introduction of Substances into the Environment

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

As provided in 21 CFR 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.

The FCS is manufactured in plants which meet all applicable federal, state and local environmental regulations. Notifier asserts that no extraordinary circumstances apply to the manufacture of the FCS including situations where: 1). unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; 2). a proposed action threatens a violation of Federal, State or local environmental laws or requirements; and 3). production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

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

The FCS is supplied in concentrated form and is diluted at the processing plant. When diluted for use, the target levels of HP in the process water for use will vary according to microbial load and type of application. The maximum at-use concentration of hydrogen peroxide (H_2O_2) for the intended application will be 2000ppm. The maximum phosphate stabilizer that would be present in the FCS at the maximum at-use concentration would be 0.286 ppm. [i]

Treatment of the process water at the on-site wastewater treatment plant or at the POTW is expected to result in complete degradation of hydrogen peroxide based on the half-life of HP (described in detail in section 7 of this EA). Specifically, hydrogen peroxide will break down into oxygen and water. Therefore, hydrogen peroxide is not expected to be introduced into the environment in any significant extent as a result of the proposed use of the FCS. Consequently, the remainder of this section will consider only the environmental introduction of the phosphate stabilizer in the FCS.

[i] FCC specification for the maximum phosphate content is no more than 0.005% (50 ppm) in 30-50% hydrogen peroxide formulations. Therefore, phosphate content in 2000 ppm HP from a 35% HP formulation = (2000 ppm HP 350,000 ppm HP) x 50 ppm phosphate = 0.286 ppm phosphate.

Poultry Processing Facilities

After the live birds arrive at the processing plant, they are automatically unloaded from the catching crates onto an automated conveyor belt. The live birds are then placed on shackles by their feet on stainless steel shackles. The birds are then processed through stunning and bleed-out before they are totally submerged in a large tank of circulating hot water (136° to 140°F) for about 2 minutes to loosen the feathers. This process is referred to as "scalding." The feathers and skin of the bird come out of the scalding process totally drenched with water. This added water aids in the picking process that is accomplished just moments after the birds exit the scalding water.

The picking process of defeathering the carcass is followed by evisceration where the organs, neck and viscera are removed. Evisceration is followed by a thorough carcass wash using inside/outside bird washers (IOBWs) to wash both the external surface as well as the cavity (inside surface) of the carcass. This process consumes a large amount of water to remove visible fecal material and other residual pieces of organs on the bird.

The eviscerated and washed carcasses in a poultry processing plant will typically be sprayed with an antimicrobial agent before being chilled in immersion chiller baths. The carcass is carried on a shackle or conveyer through a spray cabinet prior to submersion in a chiller bath. Poultry parts and organs may also be chilled by submersion in the chiller baths. Chiller baths typically include a "main chiller" bath as well as a "finishing chiller" bath, both containing an antimicrobial agent.

The intended application of the FCS is as a diluted solution to be added to the scalder tank where the feathered carcasses are introduced. The introduction of the FCS at this early step of processing, in conjunction with mechanical separation of fecal and other organic matter and dirt from the scald water is expected to aid in reduction of pathogenic and non-pathogenic microorganisms further downstream in the process.

Since the volume of water used in typical poultry processing facility due to the multiple washes and chilling process is quite large (approximately 1,000,000 gallons per day)[ii], any remaining FCS from the treatment process is significantly diluted by the end of the chilling process, hence significantly diluting the concentration of phosphate introduced into the environment. With respect to environmental impact, the contents of the main chiller will enter the wastewater treatment system and ultimately be released into the environment. Therefore, even though the maximum at-use concentration of phosphate in the FCS is limited to 0.286 ppm, the actual environmental introduction concentration (EIC) will be diluted below this level.

A 10-fold dilution factor accounts for the expected dilution in surface waters of effluent from an on-site wastewater treatment facility or POTW. This information is reported by Rapaport

[ii] In a typical processing facility processing 200,000 birds per day a total of 5 to 11 gallons of water is used to process each bird therefore water usage per day = 200,000 birds/day x 5 gallons/bird = 1,000,000 gallons water/day.

(1988).[3] The environmental introduction concentrations (EIC) and expected environmental concentration (EEC) of each use is presented in Item 7 of the EA.

7. Fate of Substances Released into the Environment

As previously mentioned, treatment of the process water at the on-site wastewater treatment plant or at the POTW is expected to result in complete degradation of hydrogen peroxide. Hydrogen peroxide rapidly degrades upon contact with organic matter, transition metals, and upon exposure to sunlight. According to the European Center for Ecotoxicology and Toxicology of Chemicals (ECETOC), the half-life of hydrogen peroxide in natural rivers ranged from 2.5 days when initial concentration was 10,000 ppm, to 20.1 days when initial concentration decreased to 100 ppm.[4] Given the degradation of hydrogen peroxide into oxygen and water, hydrogen peroxide is not expected to be introduced into the environment to any significant extent as a result of the proposed use of the FCS. The remainder of this EA will therefore consider only the environmental introduction of phosphate.

<u>Phosphates:</u>
Phosphorus exists in the natural environment in the form of oxidized phosphates. The primary source of phosphates, specifically orthophosphate, is rocks and minerals. The phosphorus cycle moves slowly from weathering of rocks and erosion that makes phosphorus available to soil, to absorption of phosphorus by plants, microorganisms, and animals (by drinking water and eating plants) and eventually return to the environment via decomposition.

Phosphates play an essential role in biological systems, such as in linkage of RNA and DNA units, and in the energy-releasing bonds for ATP generation in metabolism. In addition, phosphates are used in industrial applications as food additives, providing nutrients for growth and development in plants (as fertilizers), and in detergents.[5] Although phosphates play a vital role in various biological systems, the solubility of phosphorous from rocks is poor. Soluble phosphates released during weathering of rocks are usually rapidly immobilized into insoluble forms.[6] Consequently, only a small fraction of the phosphorus present in soil is readily available to plants as dissolved oxy-anion, making phosphorus the growth-limiting nutrient in terrestrial and aquatic environments. The ecosystem has evolved to use the low levels of Phosphorus with high efficiency, making the addition of phosphorus in aquatic environments, even in relatively low levels, result in overgrowth of microorganisms that deplete oxygen. This process, referred to as eutrophication, is marked by algae blooms that take over the aquatic environment.[7]

It is estimated that 90% of phosphorus in sewage wastewater accumulates in sewage sludge and recovery rates of phosphorus from sewage sludge and sewage sludge ash can reach up to 90%.[8,9] Therefore, the sludge partition expected introduction concentration (EIC) of phosphates are calculated by multiplying the stated phosphate use level concentration by

90% (use level x 0.9). Multiplying the use level by 10% (use level x 0.1) provides the phosphate concentration remaining in wastewater.

The expected environmental concentration (EEC) of phosphates introduced into the environment due to the proposed use of the FCS would be miniscule. However, to assess a worst-case, but not likely scenario, the ECC was calculated using a conservative 10-fold dilution factor for discharge to surface waters of the effluent from an onsite treatment facility or POTW, as determined by Rapaport (Rapaport 1988). Using a 10-fold dilution, the EEC was determined to be 0.00286 ppm (or 2.86 ppb) in water.[iii] A summary of these calculations is shown below.

Table 2: Phosphate EICs / EECs

Application	**Phosphate** (ppm)	**EIC$_{sludge}$ and EEC$_{sludge}$** (ppm) [a]	**EIC $_{water}$** (ppm)	**EEC $_{water}$** (ppm) [b]
Whole poultry carcasses	0.286	0.2574	0.0286	0.00286

a. EIC $_{sludge}$ = phosphate x 90%
b. EEC $_{water}$ = (phosphate x 10%) / 10 dilution factor)

8. Environmental Effects of Released Substances

Terrestrial Toxicity
According to the 2004 HERA report, phosphonates (which are also phosphorous-containing compounds) in sludge are not expected to have any adverse environmental impact based on toxicity endpoints for terrestrial organisms. Phosphonates show no toxicity to terrestrial organisms (plants, earthworms, worms in soil, etc.) at levels up to 1000 mg/kg soil dry weight (No Observed Effect Concentration; NOEC).[10] Therefore, there is no toxicity expected from land application of sludge containing 0.2574 ppm phosphate.

As noted in Section 7 above, hydrogen peroxide is not expected to be introduced into the environment to any significant extent as a result of the proposed use of the FCS. Therefore no toxicological effects to aquatic or terrestrial organisms are expected from the released substances, namely oxygen and water.

Aquatic Toxicity

As mentioned previously, phosphorus is the growth-limiting nutrient in terrestrial and aquatic environments. Therefore, the toxicological effects of wastewater discharge containing phosphates in aquatic environments are due to eutrophication, rather than direct toxicity to aquatic organisms.

[iii] EEC= (phosphate concentration x 10%)   10 dilution factor = 0.0286 ppm   10 = 0.00286 ppm.

A study by Kim et al.[11] on phosphates summarizes the aquatic toxicity data for two phosphate compounds, tricalcium phosphate and calcium hydrogenorthophosphate, as shown in the table below:

Table 3: Environmental Toxicity Data for Phosphates

Species	Endpoint	Tricalcium phosphate (mg/L)	Calcium hydrogenorthophosphate (mg/L)
Oryzias latipes	96 hr LC50	>100 (N); >2.14 (M)	>100 (N); >1.56 (M)*
Daphnia magna	48 hr EC50	>100 (N); >5.35 (M)	>100 (N); >2.9 (M)
Pseudokirchneriella subcapitata	72 hr EC50	>100 (N); >1.56 (M)*	>100 (N); >4.4 (M)**

N = nominal concentration;
M = measured concentration;
LC50 = 50% lethal concentration;
EC50 = 50% effective concentration.
* N = growth area, area under growth curve method; M = growth area, area under growth curve method.
** N = growth rate, yield; M = growth rate, yield.

Kim et al. found acute toxicity endpoints for both tricalcium phosphate and calcium hydrogenorthophosphate were at nominal concentrations of greater than 100 mg/L for all three organisms tested (fish, daphnia and alga). Based on these results, Kim et. al. concluded that phosphates with the above concentration possessed no toxicity in aquatic organisms. Therefore, the EEC value of 0.00286 ppm of phosphates in water resulting from the proposed use of the FCS in poultry presents no environmental toxicity concerns.

9. Use of Resources and Energy

The notified use of the FCS will not require additional energy resources for the treatment and disposal of waste solution because the components readily degrade. The FCS is expected to compete with, and to some degree replace peroxyacetic antimicrobial agents already on the market and approved for use in the poultry scalders. Thus, the FCS will consume comparable amounts of energy and resources as similar products. The raw materials that are used to manufacture the FCS are commercially manufactured chemicals that are produced for use in a variety of chemical reactions and production processes. Therefore, the energy used to produce the FCS 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 dilute FCS mixture. Thus, the use of the FCS as proposed does not require mitigating measures.

11. Alternatives to the Proposed Action

No adverse environmental impacts are identified herein that would necessitate alternative actions to that proposed in this Notification. The alternative of not approving the action proposed herein would result in continued use of currently marketed antimicrobial agents that the subject FCS would replace. Such action would have no significant environmental impact. The addition of the FCS to the options available to food processors is not expected to increase the use of similar antimicrobial products.

12. List of Preparers

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13. Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Safe Foods Chemical Innovations/ LPR Technologies.

Date: April 26, 2024

Beatrice Maingi
Senior Manager, QA, Compliance & Regulatory
Safe Foods Chemical Innovations / LPR Technologies

14. References

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