Environmental Assessment

1. **Date**: July 29, 2021

2. **Name of Applicant/Notifier**: Cargill, Incorporated

3. **Address**:

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4. Description of the Proposed Action

A. Requested Action

The action identified in this FCN is to permit the use of the food-contact substance (FCS), a hydrogen peroxide solution (CAS Reg. No. 7722-84-1) complying with the identity and specifications of the Food Chemicals Codex, as a processing aid in the manufacture of corn protein. The FCS will not exceed 2% hydrogen peroxide when applied to insoluble corn protein.

Hydrogen peroxide is thermodynamically unstable and decomposes readily into oxygen and water upon exposure to heat and/or sunlight or in the presence of transition metal ions. Commercial solutions of food-grade hydrogen peroxide may contain stabilizer systems comprised of alkali phosphate salts such as sodium or potassium phosphate,[1] and/or alkali stannate salts, such as sodium or potassium stannate.[2] The Food Chemicals Codex provides specifications for maximum phosphate and tin in the hydrogen peroxide monograph that limit the amounts of these stabilizers that may become components of food. Specifically, the Food Chemicals Codex describes hydrogen peroxide solutions containing not more than 0.005% phosphate (≤ 50 ppm) and not more than 10 mg stannate/kg (≤ 10 ppm).

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[1] *See*, for example, P.C. Wenger, United States Patent Application Publication No.: US 2003/0151024 A1, August 4, 2003, *available at*: http://appft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PG01&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.html&r=1&f=G&l=50&s1=%2220030151024%22.PGNR.&OS=DN/20030151024&RS=DN/20030151024.

[2] Schumb *et al.*, in Hydrogen Peroxide, American Chemical Society Monograph Series. New York: Reinhold Publishing Corporation (1955) pages 534 to 539; and W. Schumb, Ind. Eng. Chem. 1957, 49, 10, 1759–1762.

The FCS will have no ongoing effect in or on the food products due to its rapid decomposition into molecular oxygen and water. Further, the proposed use of the FCS will result in no introductions of the FCS into the environment. The only environmental introductions anticipated are relatively minor amounts of phosphate and stannate stabilizers present in the FCS solution.

B. Need for Action

This FCS is intended for use as a processing aid in the production of corn protein. An antimicrobial intervention is completed during the wet milling stage of corn by sulfur dioxide (SO_2) liberated from addition of sodium- or ammonium bisulfite (§ 182.3739, food grade). Once isolated, the insoluble protein is recovered on a filter and rinsed with fresh water and a 2% hydrogen peroxide solution to yield the wet de-starched corn protein. The purpose of the hydrogen peroxide wash is to oxidize residual sulfur dioxide remaining from the wet milling stage.

C. Locations of Use/Disposal

Hydrogen peroxide is intended for use in corn protein processing facilities throughout the United States. The waste process water containing the FCS is expected to enter the wastewater treatment unit at the plants. It is assumed that very minor quantities of the mixture are lost to evaporation throughout the process. It is further assumed for the purposes of this Environmental Assessment that treated wastewater will be discharged directly to surface waters in accordance with the plants' National Pollutant Discharge Elimination System (NPDES) permit. This assumption can be considered a worst-case scenario since it does not account for any further dilution or treatment that may occur at a Publicly Owned Treatment Works (POTW).

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

Chemical Identity

The FCS that is the subject of this FCN is hydrogen peroxide (CASRN 7722-84-1), which will usually have a concentration between 30% and 50% prior to being diluted to the at-use concentration. The FCS concentrate is stabilized with not more than 0.005% phosphate (≤ 50 ppm) and not more than 10 mg tin/kg (≤ 10 ppm). The solution is diluted to 2% hydrogen peroxide when applied to the corn protein. The corresponding stabilizer concentrations in the at-use solution are 3.3 ppm phosphate and 0.67 ppm stannate.[3]

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[3] Phosphate in At-Use Solution = (50 ppm in concentrate) ÷ (15-fold dilution) = 3.3 ppm phosphate. Stannate in At-Use Solution = (10 ppm in concentrate) ÷ (15-fold dilution) = 0.67 ppm stannate.

6. Introduction of Substances into the Environment

A. Introductions as a Result of Manufacture

Under 21 C.F.R. § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Information available to the Notifier suggests no extraordinary circumstances, in this case, indicating any adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

B. Introductions as a Result of Use and Disposal

Excess process water containing the FCS components will leave the processing plant as a dilute, continuous wastewater stream when the FCS is present in water used to wash corn protein. Wastewater streams from these and other operations unrelated to use of the FCS will merge in the main wastewater header of the corn protein processing plant prior to being sent to wastewater treatment facilities.

Process water containing the FCS will be treated at an on-site wastewater treatment facility and/or at a POTW. Hydrogen peroxide decomposes rapidly to water and oxygen when exposed to transition metals (such as Fe or Mn) and/or organic material. It is not expected to enter the environment after treatment at the facility wastewater treatment plant.

Additives necessary for a functional shelf life of hydrogen peroxide, however, could potentially be present at very low concentrations upon discharge of wastewater from processing facilities to the environment through aquatic or terrestrial routes. This assessment therefore addresses the potential introduction of phosphate and stannate into the environment as a result of the proposed use of this FCS, *i.e.*, use as a processing aid in the production of corn protein.

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. The additives, the only stable components of the FCS, will partition between the treated process water and the treated sludge, as described more fully below. Only extremely small amounts, if any, of these additives are expected to enter the environment due to the landfill disposal of sludge containing minute amounts of the additives in light of the EPA regulations governing municipal solid waste landfills. EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have ground-water monitoring systems (40 C.F.R. Part 258).

It is assumed, for the purposes of this Environmental Assessment, that treated wastewater will be discharged directly to surface waters in accordance with a NPDES permit. This assumption may be considered a worst-case scenario since it takes no account of further dilution and treatment that may occur at a POTW.

The FCS mixture is provided as a 30% – 50% solution that will experience a 15- to 25-fold dilution prior to use. When diluted for use, the resulting concentration of the FCS additives will also be diluted at least 15-fold. The corresponding highest stabilizer concentrations in the at-use solutions are 3.3 ppm phosphate and 0.67 ppm stannate.

Hydrogen peroxide solutions containing the stabilizers are intended for use as a rinse for insoluble corn protein. This application generates only one waste stream. Thus, the worst-case instantaneous and long-term average environmental release concentrations can be evaluated by considering this waste stream.

All wastewater streams from corn protein processing operations (including those containing the FCS) will enter the main wastewater header of the food processing facility and undergo treatment with other wastewater generated at the food processing facility. Many food-processing plants operate on-site wastewater treatment plants (WWTPs) to treat their wastewater. Some WWTPs discharge their effluent to 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. Other food processing plants send their wastewater directly to POTWs without pretreatment at an on-site WWTP. Sludge removed from WWTPs or POTWs may be disposed of in one of two ways (land spreading or incineration).

For the purposes of this Environmental Assessment, we have considered a food processing plant using only one water treatment operation (*i.e.*, either a WWTP or a POTW, but not both) followed by final wastewater discharge to receiving waters or discharge over land. We have considered land spreading as the worst-case sludge disposal scenario.

Only the additives used in the FCS are expected to be present upon discharge to the environment through aquatic or terrestrial routes. Thus, the primary focus of this assessment is the potential introduction into the environment of the stabilizers resulting from the use of this FCS.

Corn protein is treated with the 2% hydrogen peroxide solutions on a drum filter. Some of the hydrogen peroxide solution therefore passes through the filter and joins other wastewater from the plant. Direct discharge from the WWTP would result in higher concentrations of stabilizers 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 then discharge the WWTP effluent directly to receiving waters or to land application. We have also addressed disposal of sludge removed from the WWTP by assuming it is mixed with surface soil. These assumptions ensure that we are considering the worst-case potential environmental exposure to the additives.

The estimates below also include a 10-fold receiving water dilution factor to account for dilution expected to occur upon discharge of the treated wastewater to surface waters. The food processing facilities that would use the FCS for applications covered by the current FCN may operate throughout the year, including winter months when absorption of pollutants by growing plants would not be a suitable means of environmental remediation. Although land application systems are not an expected disposal route for the FCS, we have nevertheless, addressed this possibility.

The additives are the only components likely to be present in measurable quantities in wastewater or sludge discharged to the environment. In the remainder of this Environmental Assessment, we will focus on the potential environmental discharge of the additives to receiving waters and in sludge mixed with surface soil.

Aquatic Introductions

Significant dilution of wastewater from corn protein treatment operations occurs in the on-site WWTP upon mixing with wastewater from other operations in the same food-processing plant, such as wash down of process vessels, tanks, floors. Nevertheless, we consider the simple case where all the water entering the WWTP contains the full 3.3 ppm phosphates and 0.67 ppm stannate. We anticipate an additional 10-fold dilution upon discharge of WWTP/POTW to receiving water (which is the expected scenario for the kinds of facilities that would operate under the FCN). The expected environmental concentrations (EEC) of phosphate and stannate in aquatic environmental compartments therefore would not exceed 0.33 ppm and 0.067 ppm, respectively, due to the proposed use of the FCS.

Terrestrial Introductions

It is assumed here that the additives treated in the WWTP partition into the solids in the sedimentation tank with no specific affinity for the solid phase (sludge). Sludge is typically dewatered prior to land application. The solids content of mechanically dewatered sludge typically ranges from 20 to 45 percent solids by weight; most processes produce concentrations of solids at the lower end of that range.[4] Thus, assuming sludge is an average of 67% water and the concentration of phosphate and stannate in that water is 3.3 ppm and 0.67 ppm, respectively, the concentration of phosphate and stannate in the sludge that may be land applied is 2.2 ppm and 0.45 ppm, respectively.[5] It is reasonable to assume that components of sludge will be diluted to a concentration of 2.5% of their concentration in sludge upon incorporation of sludge into soil,[6] which is equivalent to a concentration of phosphate and stannate in the soil of 0.06 ppm and 0.01 ppm, respectively.[7]

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[4] Use of Reclaimed Water and Sludge in Food Crop Production, Committee on the Use of Treated Municipal Wastewater Effluents and Sludge in the Production of Crops for Human Consumption, Water Science and Technology Board, Commission on Geosciences, Environment, and Resources, National Research Council, National Academy Press, Washington, D.C., 1996, Chapter 3, page 52.

[5] Phosphate = 3.3 ppm × 67% = 2.2 ppm; Stannate = 0.67 ppm × 67% = 0.45 ppm.

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

[7] Phosphate = 2.2 ppm × 2.5% = 0.06 ppm; Stannate = 0.45 ppm × 2.5% = 0.01 ppm.

Atmospheric Introductions

Examination of the structure of the additives indicates that volatilization from an aqueous solution is not an important fate process for these additives. We may therefore conclude that introduction of these additives into the atmosphere would be virtually nil.

The environmental introduction concentrations (EIC) and the expected environmental concentrations (EEC) of phosphates and stannate resulting from the use of the FCS proposed herein are summarized in the following table.

Additive	Use Level	EIC	EEC_{sludge}	EEC_{water}
Phosphate	3.3 ppm	3.3 ppm	0.06 ppm	0.33 ppm
Stannate	0.67 ppm	0.67 ppm	0.01 ppm	0.067 ppm

The estimated concentrations of the additives in WWTP effluent and sludge are below levels of concern for *toxicity* of these materials in the environment (*see* Item 8, below). Nevertheless, even low concentrations of phosphate may raise concerns for excessive nutrification of the receiving waters. The actual environmental concentrations of phosphate, however, will be controlled by the Clean Water Act (CWA) through the establishment of receiving water quality standards, and, when indicated, through establishment of permit limits for phosphate during the NPDES permitting process.

7. Fate of Emitted Substances in the Environment

As noted above, hydrogen peroxide is not expected to survive treatment at the wastewater treatment facilities at food packaging plants. The substance is rapidly degraded on contact with organic matter, transition metals, and upon exposure to sunlight. 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.[8] The additives, however, are emitted to the environment.

Phosphorus is indispensable to life on Earth, as it is involved in the passage of genetic information, energy transfer, and the construction of plant cells. Despite this, the amount of phosphorus available for biological uptake is relatively small, so productivity in many terrestrial and aquatic ecosystems is often limited by phosphorus availability.[9] In the natural environment, phosphorus usually exists as fully oxidized phosphate. The phosphorous cycling comprises a geological (long-term) cycle and a biological (short-term) cycle, the latter with both terrestrial and aquatic components. Phosphate introduced into the environment will participate in both cycles. On a geologic scale, phosphate cycles from phosphate rock to soil by weathering then to

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

[9] Turner BL, Raboy V. 2019. Phosphorus cycle. In: AccessScience. McGraw-Hill Education. doi:10.1036/1097-8542.508930 (last accessed 2021 Jun 1), *available at:* https://www.accessscience.com/content/phosphorus-cycle/508930.

water and is ultimately deposited in ocean sediment wherein it can be re-transformed into phosphate rock. In the biological cycle, phosphate is absorbed by plants from water or soil and incorporated into plant tissues which are consumed by animals and ultimately returned to the soil.[10] Because P is almost always limiting and ecosystems have evolved to deal with low levels of P, the addition of P even in relatively low concentrations into water-bodies can cause adverse effects such as eutrophication. The potential of the treated wastewater from the food-processing plants using the FCS contributing to nutrient pollution and eutrophication of the water-bodies receiving treated wastewater (TWW) will be addressed during the NPDES permitting for facilities treating wastewater containing the additives.

Land applications related to the proposed use will result in phosphorus concentrations in soil that are an insignificant fraction of total phosphorus concentrations introduced into the environment as fertilizers. USDA reported, in 2019, that over 7.79 million tons of phosphate fertilizers were consumed in the U.S in 2015, the most recent year for which data are available.[11] Annual production and use of the FCS itself is negligible when compared with this figure, and the annual land application of any phosphate-containing sludge or treated effluent that could be expected from the proposed use represents an even more insignificant portion of land-applied phosphorus.

Tin compounds are generally only sparingly soluble in water and are likely to partition to soils and sediments. In water, inorganic tin exists as either divalent (Sn^{2+}) or tetravalent (Sn^{4+}) cations under environmental conditions.[12] Cations such as Sn^{2+} and Sn^{4+} generally will be adsorbed by soils, which reduces their mobility. Tin(II) dominates in reduced (oxygen-poor) water and will readily precipitate as tin(II) sulfide or as tin(II) hydroxide in alkaline water. Tin(IV) readily hydrolyses and can precipitate as tin(IV) hydroxide. The solubility product of tin(IV) hydroxide has been measured at approximately 10–56 g/litre at 25°C. In general, tin(IV) would be expected to be the only stable ionic species in the weathering cycle.[13] On release into estuaries, inorganic tin is principally converted to the insoluble hydroxide and rapidly scavenged

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[10] V. Smil, *Phosphorus in the Environment: Natural Flows and Human Interferences*, Annual Review of Energy and the Environment, Vol. 25:53-88 (November 2000).

[11] USDA. (2019). Fertilizer Use and Price: Table 5 – U.S. consumption of selected phosphate and potash fertilizers, 1960-2015. Accessed July 26, 2021, *available at:* http://www.ers.usda.gov/data-products/fertilizer-use-and-price.aspx.

[12] International Programme on Chemical Safety, (2005), Concise International Chemical Assessment Document 65, Tin and Inorganic Tin Compounds, Geneva, World Health Organization, *available at:* https://www.who.int/ipcs/publications/cicad/cicad_65_web_version.pdf?ua=1.

[13] IPCS (1980) Tin and organotin compounds: a preliminary review. Geneva, World Health Organization, International Programme on Chemical Safety (Environmental Health Criteria 15).

by particles, which are the largest sink. Thus, tin is generally regarded as being relatively immobile in the environment.[14]

8. Environmental Effects of Released Substances

The results of the ecotoxicity tests of tricalcium phosphate and calcium hydrogen orthophosphate are summarized as follows:[15] in an acute toxicity test with *Oryzias latipes*, 96 hr 50% lethal concentration (LC_{50}) was > 100 (measured:> 2.14) mg/L and > 100 (measured: > 13.5) mg/L, respectively. In the *Daphnia* test, 48 hr 50% effective concentration (EC_{50}) was > 100 (measured: > 5.35) mg/L and > 100 (measured: > 2.9) mg/L, respectively. In a growth inhibition test with *Pseudokirchneriella subcapitata*, 72 hr EC_{50} was > 100 (measured: > 1.56) mg/L and > 100 (measured: > 4.4) mg/L, respectively.

Based on these results, it is concluded that phosphate, with nominal concentrations above 100 mg/L, possessed no toxicity in aquatic organisms. Thus, the expected environmental concentration of 0.33 ppm resulting from the proposed use of the FCS presents no environmental toxicity concerns.

Extensive data on toxicity of inorganic tin to aquatic organisms has been summarized in a chemical assessment of tin and organic tin compounds conducted by the World Health Organization.[16] This summary is as follows:

> "The most sensitive microalgae are the marine diatoms *Skeletonema costatum* and *Thalassiosira guillardii*, with 72-h EC_{50}s of tin(II), based on growth inhibition, of around 0.2 mg/litre. Acute LC/EC_{50}s of tin(II) for aquatic invertebrates range from 3.6 to 140 mg/litre, with a 21-day EC_{50}, based on reproductive success in daphnids, of 1.5 mg/litre. The fish toxicity tests clearly show that tin(IV) chloride is less toxic than the more soluble tin(II) chloride. Ninety-six-hour LC_{50}s for fish range from 35 mg/litre for tin(II) to > 1000 mg/litre for tin(IV). Embryo-larval test results (7- to 28-day LC_{50}s) for fish and amphibians range from 0.1 to 2.1 mg/litre for tin(II)."

Adverse effects on the yield of spring wheat (expressed as dry weight) at soil inorganic tin(II) concentrations of 125 mg/kg were completely eliminated after the addition of sludge due

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[14] Gerritse R.G., Vriesema R., Daleberg J.W. (1982) Effect of sewage sludge on trace element mobility in soils. Journal of Environmental Quality, 11:359–364.

[15] E. Kim, S. Yoo, H-Y. Ro, H-J. Han, Y-W. Baek, I-C. Eom, H-M. Kim, P. Kim, and K. Choi, Aquatic Toxicity Assessment of Phosphate Compounds, Environ Health Toxicol. 2013; 28, *available at:* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3577115/.

[16] *See supra* Footnote 12, at 34.

to an increase in soil nutrient content and a decrease in soil acidity.[17] *Sinapis alba* seeds showed low sensitivity to inorganic tin, with 72-h EC_{50}s, based on root growth inhibition, of 281 mg/litre for tin(II) (as tin(II) chloride) and 417 mg/litre for tin(IV) (as sodium stannate).[18] Thus, the expected environmental concentration of 0.067 ppm resulting from the proposed use of the FCS 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 wastes as the FCS is expected to be treated in existing wastewater treatment plants. The manufacture of the FCS will consume comparable amounts of energy and resources as the same products used in different applications, and the raw materials used in the production of the mixture are commercially manufactured materials that are produced for use in a variety of chemical reactions and processes.

10. Mitigation Measures

No significant adverse environmental impacts are expected to result from the use and disposal of the dilute FCS solution. Therefore, the solution is not reasonably expected to result in any new environmental issues that require mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse effects are identified herein that would necessitate alternative actions to that proposed in this Notification.

12. List of Preparers

Devon Wm. Hill, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Mr. Hill has a J.D., with many years of experience drafting food additive petitions and FCN submissions and environmental assessments.

Mark Hepp, Ph.D., Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, DC 20001. Dr. Hepp has a Ph.D. in Chemistry with many years of experience with FCN submissions and environmental assessments.

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[17] Kick H., Nosbers R., Warnusz J. (1971) The availability of Cr, Ni, Zn, Cd, Sn and Pb for plants. In: Proceedings of the international symposium on soil fertility evaluation, New Delhi. New Delhi, Indian Society of Soil Science, pp. 1039–1045.

[18] Fargasova A. (1994) *A comparative study of the toxicity and inhibitory effects of inorganic tin compounds on various biological subjects*, Biologia, 49(3):307–311.

13. Certification

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

Date: July 29, 2021

[redacted]

Devon Wm. Hill
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