

**ENVIRONMENTAL ASSESSMENT
PEROXYCHEM, LLC
FOOD-CONTACT NOTIFICATION**

1. **Date:** December 20, 2017
2. **Name of Applicant:** PeroxyChem, LLC
3. **Address:** All communications on this matter are to be sent in care of Counsel for the Notifier:
Devon Wm. Hill
Keller and Heckman LLP
1001 G Street, N.W., Suite 500 West
Washington, D.C. 20001
Telephone: (202) 434-4279
Facsimile: (202) 434-4646
E-mail: Hill@khlaw.com

4. Description of Proposed Action

a) Requested Approval

The action identified in this notification is to provide for the use of an aqueous solution of hydrogen peroxide (CAS Reg. No. 7722-84-1) stabilized with aluminum nitrate, nonahydrate (CAS Reg. No. 7784-27-2) and phosphoric acid (CAS Reg. No. 7664-38-2). Hydrogen peroxide solution identified in this FCN is intended for use as an antimicrobial additive that may be used alone or in combination with other processes for the commercial sterilization of food packaging materials prior to filling and to aseptic filling systems to the extent that FCS residues may transfer from the aseptic filling system to food packaging materials. The FCS may be used on food packaging materials intended to contact infant formula products.

More specifically, the FCS is intended to be applied to food packaging materials and aseptic food packaging equipment in the manner and at levels necessary for the aseptic processing system to comply with 21 C.F.R. §§ 108 (“Emergency permit control”), 113 (“Thermally processed low-acid foods packaged in hermetically sealed containers”), and/or 114 (“Acidified foods”). In accordance with FDA’s regulations governing low acid canned food (LACF) and acidified food, specific details regarding the intended use of the FCS must be established independently by a qualified process authority for each aseptically processed food and each aseptic processing system.

Title 21 C.F.R. § 178.1005 (“Hydrogen peroxide”) permits the use of aqueous solutions of hydrogen peroxide (up to 35%) to sterilize certain polymeric food-contact surfaces provided the concentration of hydrogen peroxide in distilled water packaged under production conditions does not exceed 0.5 parts per million (ppm). We propose the same limitation for this FCN.

In addition, the interior of the cabinet may be sterilized prior to a production run by spraying the machine surfaces with the FCS solution prior to introducing the packaging films or bottles into the aseptic filling machine. During a filling operation, food is introduced directly into the sterilized package through a valved pipe or tube. Neither the packaging nor the FCS can access the interior of the pipe carrying the food thus, none of the machine surfaces accessible to the FCS are food-contact surfaces.

The FCS is intended as an alternative to other aqueous hydrogen peroxide-based sterilizing solutions used in aseptic processing applications involving polymeric food packaging materials. The FCS is expected to be applied in a manner similar to currently approved alternative products, which generally would involve spraying the FCS on food-contact materials, or immersing packaging material in the FCS. Furthermore, this FCS is not expected to expand the types of food products packaged in aseptic packaging, nor is it expected to expand the types of packaging material on which sterilizing treatments may be used.

b) Need for Action

The antimicrobial agent reduces or eliminates pathogenic and non-pathogenic microorganisms that may be present on the food-contact surfaces of containers and closures used to package food. The requested action is needed to address current and future needs of food processors to improve food safety. Use of the FCS provides another option for antimicrobial interventions. The FCS is intended for use as an antimicrobial solution for sanitizing food-contact surfaces of aseptically filled packaging materials and the non-food-contact surfaces of the filling equipment.

c) Location of Use/Disposal

The antimicrobial agent is intended for use in food processing facilities engaged in aseptic packaging of food throughout the United States. Disposal of the FCS is expected to occur nationwide within the United States. “Unused” quantities of the FCS (*i.e.*, solution remaining in reservoirs at the end of production runs, as well as solution that is drained or otherwise removed from packaging material and aseptic processing equipment) are expected to be deposited to the food processing facilities’ wastewater discharge streams.

Waste process water containing the FCS is expected to be disposed of through the plant’s onsite wastewater treatment facility before discharge either to surface waters under National Pollution Discharge Elimination System (NPDES) permitting or to a publicly owned treatment works (POTW). In addition, when sewage sludge from POTW is treated and processed, the resulting biosolids can be safely recycled and applied as fertilizer to sustainably improve and maintain productive soils and stimulate growth.¹ In consideration of the potential land

¹ <https://www.epa.gov/biosolids/basic-information-about-biosolids>

application of such biosolids, we have also estimated maximum potential concentrations in soil from this route of disposal.

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

The food contact substance (FCS) that is the subject of this FCN is an aqueous solution of hydrogen peroxide (CASRN 7722-81-1) that is stabilized with aluminum nitrate, nonahydrate (CAS Reg. No. 7784-27-2) and phosphoric acid (CAS Reg. No. 7664-38-2). The FCS is therefore characterized as follows:

FCS Mixture Component	Weight Percent	
	Nominal	Maximum
Hydrogen peroxide	35	36.1
Water	64.9969	66.95
Aluminum nitrate, nonahydrate	0.0018	0.002
Phosphoric acid	0.0013	0.0014

6. Introduction of Substances into the Environment

a. Introduction of substances into the environment resulting from 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 resulting from the manufacture of solutions containing the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. Introduction of substances into the environment resulting from use/disposal

As noted above, sterilizing solution remaining in reservoirs at the end of production runs, as well as solution that is drained or otherwise removed from packaging material and aseptic processing equipment during production is expected to enter the wastewater discharge streams of the commercial food processors using the FCS. In this regard, the FCS is intended as an alternative to other aqueous sterilizing solutions used in aseptic processing applications involving polymeric food packaging materials, such as 35% aqueous hydrogen peroxide solutions currently used in aseptic food packaging systems in accordance with 21 C.F.R. § 178.1005 (“Hydrogen peroxide”). The FCS is expected to be applied in a similar manner as currently approved alternative products, which generally would involve spraying the FCS on food-contact materials and/or equipment, or immersing packaging material in the FCS. Furthermore, this FCS is not expected to expand the types of food products packaged in aseptic packaging, nor is it expected to expand the types of packaging material on which sterilizing treatments may be used.

When the FCS is used to sterilize bottles, excess sanitizing solution may be drained from the bottle back into the sterilant reservoir, or rinsed from the bottles with sterile water. Draining results in no environmental introductions because the excess solution is simply returned to the sterilant reservoir. Bottle rinsing generates a dilute, continuous wastewater stream containing the FCS components and therefore represents the worst-case for environmental introductions due to bottle operations. Disposal of sterilant baths is not addressed for bottle sterilization operations, because the sterilant solution is consumed continuously and any residual sterilant bath volumes are expected to be negligible.

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, a wastewater stream in the form of spent sterilant baths 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.

An additional intermittent waste stream of intermediate concentration results from the application of the FCS to the interior of the equipment cabinet prior to introducing the packaging films or bottles into the aseptic filling machine. As discussed more fully below, the potential environmental introductions of the stabilizers due to the application of the sterilant to the filling equipment at the commencement of a filling operation is fully encompassed by the calculations provided for the container rinsing and reservoir draining operations. Thus, the worst-case instantaneous and long term average environmental release calculations can be determined by considering only the first and second waste streams (*i.e.*, the method used to estimate environmental concentrations attributable to application to bottles and films fully encompasses the release attributable to the other waste streams).

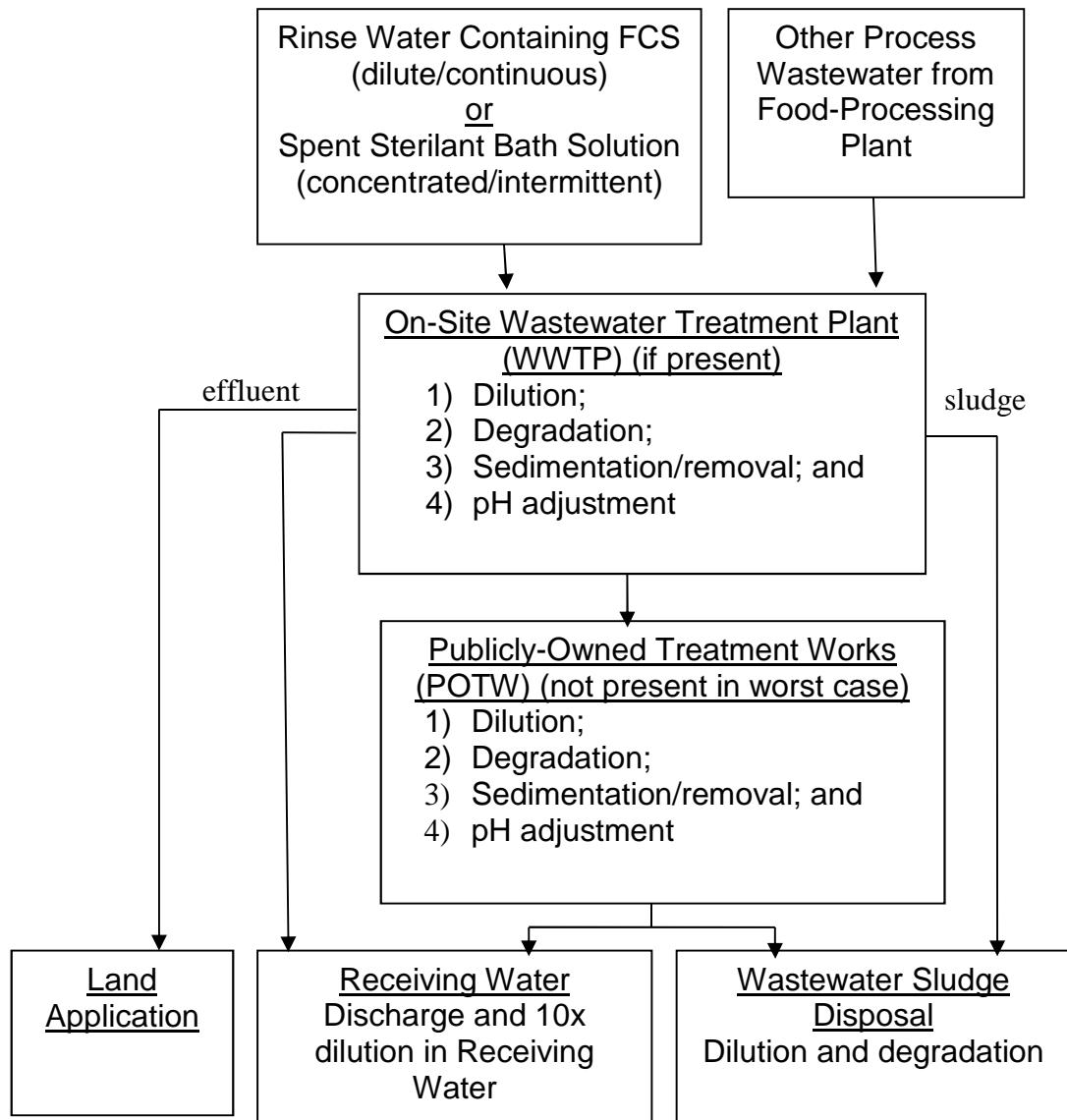
Many food-processing plants operate on-site wastewater treatment plants (WWTPs) to treat their wastewater. Some of these on-site WWTPs discharge their effluent to publicly owned treatment works (POTWs) for additional treatment prior to discharge to receiving waters, while others are permitted to discharge 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.

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.

² EPA's Multimedia Environmental Compliance Guide for Food Processors, EPA 305-B-99-005, pg. 16 (*available at* <https://nepis.epa.gov/Exe/ZyPDF.cgi/100043WJ.PDF?Dockey=100043WJ.PDF>) (accessed March 21, 2017).

Thus, the stabilizers are the only components of the FCS that may be present at environmentally significant concentrations upon discharge of wastewater streams from processing facilities to the environment through aquatic or terrestrial routes. Thus, the primary focus of this assessment is the potential introduction to the environment of the stabilizers resulting from the use of this FCS in aqueous mixtures.

The following diagram provides an overview of the route of wastewater containing the FCS from its point of generation in sterilization 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 this FCN. 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. 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 near the wastewater source. We do not anticipate this would be common practice at food processing facilities using the sterilization technology covered by this FCN, 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.³

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 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. Furthermore, we have considered that the levels of stabilizer in sterilization baths may be up to 3 times higher at the end of an operational cycle (the time between filling and draining of the bath) than at the beginning of the cycle, due to the evaporation of water and hydrogen peroxide at typical operating temperatures of 85°C. The baths are automatically supplemented with fresh hydrogen peroxide solution to compensate for this loss. While the water and hydrogen peroxide concentrations in the bath effectively do not change from the concentrations charged after the previous draining, the levels of non-volatile components, *i.e.*, stabilizer, necessarily will increase. The calculations provided below relating to the stabilizer for sterilant bath use account for a 3-fold concentration factor at the end of the operational cycle (*i.e.*, when the baths are drained).

Treatment of the wastewater containing the FCS at on-site WWTPs would result in nearly 100% degradation of the hydrogen peroxide. This expectation is based on the half-life of

³ 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.

these substances as described in Section 7 below. The only components likely to be present in measurable a quantity in wastewater discharged to the environment are the stabilizers.

We can draw a similar conclusion regarding the concentration of FCS components present in sludge removed from WWTPs and POTWs, *i.e.*, even using the most conservative assumptions we would expect only the stabilizers to be present in measurable quantities in the sludge.⁴ We provide quantitative estimates of the stabilizer 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).

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.*⁵

Detailed calculations of estimated environmental introduction concentrations and concentrations in the environment are presented below.

Estimate of Environmental Concentration of FCS Components Released in Wastewater

As indicated in the EA, two general types of sterilization operations for food packaging are covered by this FCN. The information referenced below was taken from the environmental assessment employed in FCN 728, also submitted by the same Notifier, but for a different sterilant;⁶ the same information is applicable to this Notification. In bottle sterilization operations, the FCS solution is applied at full strength and then rinsed from the packaging using sterile water after sterilization is complete. The wastewater stream from bottle sterilization operations is continuous (during packaging operations) yet relatively dilute in terms of FCS concentration. The wastewater stream is sent to the main wastewater header of the food

⁴ Due to the appreciable solubility of hydrogen peroxide and the stabilizer in water, it is expected that they would not be adsorbed to the sludge during treatment, and therefore it is unlikely that the sludge from treatment in the WWTP would contain stabilizer, and therefore, an environmental release of either of these compounds is unlikely when the sludge is used as a soil amendment in land application (For H₂O₂ See page 7, JACC No. 22 ECETOC; for stabilizer, see Footnote 12).

⁵ 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.

⁶ This information was used in the Environmental Assessment for FCNs 1430 and 1471, for hydrogen peroxide sterilants that are similar to those described in this notification, but with different stabilizers.

processing plant where it merges with wastewater from other operations in the plant prior to treatment in wastewater treatment facilities.⁷

In film sterilization operations, FCS solution is applied to food packaging via immersion of the packaging in a bath containing the sterilant solution. Excess sterilant solution is mechanically stripped rather than rinsed from the food packaging, and returned to the sterilant bath; thus, there is no continuous wastewater stream generated from film sterilization operations. Spent sterilant solution baths are drained periodically to the main wastewater header of the food processing plant. The concentrations of aluminum nitrate in the sterilant bath may be expected to rise over time due to its relative stability compared to other components of the FCS. Specifically, we have considered that the level of aluminum nitrate in sterilization baths may be up to 3 times higher at the end of an operational cycle (the time between filling and draining of the bath) than at the beginning of the cycle, due to the evaporation of water and hydrogen peroxide at typical operating temperatures of 85°C. To compensate for this loss, the baths are automatically supplemented with fresh hydrogen peroxide solution. While the water and hydrogen peroxide concentrations in the bath effectively do not change from the concentrations charged after the previous draining, the levels of non-volatile components, *i.e.*, aluminum nitrate, necessarily will increase. The calculations relating to aluminum nitrate for sterilant bath use take the 3-fold concentration factor at the end of the operational cycle (*i.e.*, when the baths are drained) into account. Because the concentration increase of aluminum nitrate is linear, emptying the bath at more frequent intervals would result in the lower quantities of aluminum nitrate released to the waste water treatment plants (WWTP) and subsequently into the environment. Therefore, as a worst-case assumption for purposes of this calculation, we assumed that the 38-gallon bath is emptied every 10 days, which is the maximum expected life of a given batch of sterilant, and that the concentrations of non-volatiles (aluminum nitrate) increase 3-fold.

Application of the FCS to sanitize the filling equipment prior to the introduction of packaging to the machine will not affect the maximum instantaneous estimated concentration in the wastewater at the treatment plant in any significant way for several reasons. First, because the application occurs only once at the beginning of the production run, the concentration of the stabilizer in the sterilant solution is not concentrated by recharging the sterilant reservoir. This accounts for a 3-fold lower stabilizer concentration in the solution applied to the equipment. Second, the application of the sterilant to the equipment is followed by a sterile water rinse that provides an additional 2-fold reduction of stabilizer concentration at the wastewater header. Third, the volume of sterilant applied to the equipment, and the time required to apply the sterilant to the equipment are far less than the volume of the reservoir tank and the time required to drain the reservoir tank. Thus, the environmental introductions due to the application of the FCS to aseptic packaging equipment is fully encompassed by the maximum instantaneous value estimated in the calculations below.

⁷ Disposal of sterilant baths, as discussed below, is not addressed for bottle sterilization operations, as the sterilant solution is consumed continuously and any residual sterilant bath volumes are expected to be negligible.

Because bottle sterilization operations represent steady state operation that could potentially result in higher total quantities of FCS components entering the environment, whereas film sterilization operation (and associated sterilant bath draining) may result in higher instantaneous concentrations entering the environment, we have evaluated both scenarios here. Direct discharge to receiving water and land application of sludge from the WWTP will result in the highest concentrations, so those concentrations are shown below.

Bottle Sterilization Operations

The amount of FCS mixture used, steam use, and the sterile water rinse will vary depending on the size of bottles undergoing treatment. Furthermore, wastewater from other plant operations, such as wash downs of tanks, floors and pipes, and other water uses in the facility, will be mixed with the wastewater from sanitizing operations in the WWTP. Based on expected dilutions at various treatment stages, as well as demonstrated sedimentation rates for aluminum nitrate, we estimated the concentration of aluminum nitrate upon discharge to receiving waters. The following table summarizes the flows and dilutions that occur in the on-site WWTP:

Table 2

<u>Flows and Concentrations From Point of Application to Discharge to Receiving Waters</u>					
Stream	Bottle Volume				
	8-oz	16-oz	24-oz	32-oz	Avg
FCS Flow to WWTP (from bottle rinse) (L/hr) ^I	6.0	6.5	7.2	7.6	6.8
Steam Flow to WWTP (from bottle rinse) (kg/hr or L/hr)	108	133	162	180	146
Rinse water Flow to WWTP (from bottle rinse) (L/hr) ^{II}	6,840	7,700	12,740	14,000	10,320
Total Wastewater from Bottle Rinsing to WWTP (L/hr)	6,954	7,840	12,909	14,188	10,473
Other Process Wastewater Flow to WWTP (L/hr) ^{III}	2,643	2,979	4,905	5,391	3,980
Total Flow to WWTP (L/hr)	9,597	10,819	17,814	19,579	14,453
Initial FCS Concentration in WWTP (mg/L) ^{IV}	625	601	404	388	470
Aluminum Nitrate Concentration in WWTP (mg/L) ^V	0.0125	0.0120	0.0081	0.0078	0.0094
Aluminum Nitrate Concentration in Receiving Water after 10 Fold dilution (mg/L)^{VI}	0.00125	0.00120	0.00081	0.00078	0.00094

^I Includes 0.4 L/hr for sterilization of bottle caps

^{II} Includes 500 L/hr for rinsing of bottle caps

^{III} Calculated as 38% of “Total Wastewater from Bottle Rinsing” per Ait Hsine, *et. al.*, 2005⁸

^{IV} Calculated as FCS Flow to WWTP (Row 1) ÷ Total Flow to WWTP (Row 6)

^V Based on maximum concentration of 0.002% aluminum nitrate in FCS

^{VI} Ten-fold surface water dilution factor per R.A. Rapaport (1988)⁹

⁸ 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.

⁹ Rapaport, R.A., 1988. Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution. Environmental Toxicology and Chemistry 7:107-115.

The highest aluminum nitrate concentration in receiving water from the above representative calculations is 0.00125 mg/L.¹⁰

Film Sterilization Operations

As described in the EA, use of the FCS to sanitize polymeric food-packaging film generally involves immersion of the film in the sterilant solution followed by mechanical stripping of excess sanitizing solution using nip rollers and doctor blades. Sanitizing solution is not rinsed from packaging with water; therefore, no continuous waste stream results from this “no rinse” use. Rather, the waste stream that results stems from periodic sterilant bath disposal, which represents an instantaneous volume of FCS components in which the aluminum nitrate content is approximately $0.0020\% \times 3 = 0.0060\%$. The 38-gallon (144 L) bath is assumed to drain in one hour and is mixed as it enters the WWTP with the wastewater from bottle sterilization operations and other wastewater from the plant as described above. As a worst case, we have assumed that the concentration of FCS components present in the sterilant bath would only be diluted with other wastewater being generated at the time the bath is drained, not with the entire volume of wastewater present in the wastewater treatment plant. In fact, there will be a significant residence time in the WWTP and further dilution of the bath contents from the large hold-up volumes present in the WWTP. The total contributions of aluminum nitrate from sterilant bath disposal was combined with the contributions of aluminum nitrate from bottle sterilization operations (using 8-oz bottles determined above to be a worst case) to determine a total instantaneous environmental release (as opposed to a steady state environmental release calculated above):

Table 3
Combined Bottle Rinsing and Disposal of Spent Sterilant Baths

FCS Concentrations from Point of Waste Generation, through WWTP to Receiving Water	
Flow from Disposal of FCS Sterilant Bath to WWTP (L)	144
Aluminum nitrate Concentration in Sterilant Bath Flow (mg/L)	60
Aluminum nitrate from the Sterilant Bath (kg)	0.0086
Total Flow to WWTP (L/hr)¹	9,597
Aluminum nitrate Concentration in WWTP ^{II} from Sterilant Bath (mg/L)	0.90
Aluminum nitrate Concentration in WWTP from bottle washing – 8 oz example (mg/L)	0.0125
Aluminum nitrate Concentration, total (mg/L)	0.91
Aluminum nitrate Concentration in Receiving Water after 10 X dilution (mg/L)	0.091

¹ Based on the total flow to the WWTP as calculated in bottle rinsing operations

^{II} Assumes that the sterilant bath is drained in 1 hour and ignores additional dilution in the WWTP

Thus, the total concentration of aluminum nitrate upon release to the receiving water is 0.091 mg/L. This level of aluminum nitrate is only released when the sterilant bath is emptied on a 10-day schedule. While the bath is in use, the environmental releases arise only from bottle

¹⁰ As explained above, we do not think that food processing facilities operating under this Notification would be permitted for direct land application of wastewater (e.g., for irrigation purposes). Nevertheless, we note that the highest concentrations for land application would be 0.00125 mg/L.

washing, a maximum level of 0.00125 mg/L, as calculated above. Thus, the time averaged release to surface waters will be no more than 0.00162 mg/L.¹¹ Also, in many cases, the effluent will be discharged to a publicly owned treatment works (POTW) for further treatment. The highest one-hour application rate for land application would be 0.91 mg/L for aluminum nitrate.¹²

Estimate of Environmental Concentration of FCS Components Present in Sludge

Because of the good solubility of nitrate salts, as indicated in an OECD SIDS document regarding the aquatic and terrestrial toxicity of nitrates¹³, it is expected that aluminum nitrate would not be adsorbed to sludge during treatment in the WWTP. Thus, it is unlikely that the sludge from treatment in the WWTP would contain aluminum nitrate and, hence, an environmental release of aluminum nitrate is not expected when the sludge is used as a soil amendment in land application. Nonetheless, simply for the sake of completeness, a set of calculations relating to aluminum nitrate in sludge also are included below.

The concentration of aluminum nitrate in sludge can be estimated by assuming a sludge production rate based on the effluent flow rate. *Wastewater Engineering: Treatment and Reuse* provides a dry solids production rate of 150 kilograms of dry solids per 1,000 cubic meters of effluent.¹⁴ The solids increase to 450 kilograms dry solids per 1,000 cubic meters of effluent with the addition of water treatment chemicals.¹⁵ The average flow to the WWTP (shown in above Table 2 titled “Flows and Concentrations From Point of Application to Discharge to Receiving Waters”) is 14,453 liters per hour. If the facility runs 24 hours a day, 7 days a week, the total flow would be 126,606,002 liters per year, which could produce 56,970 kilograms of sludge per year.

¹¹ Time Average Release = $0.091 \text{ mg/L} \times (1 \text{ hour}/240 \text{ hours}) + 0.00125 \times (239 \text{ hours}/240 \text{ hours}) = 0.00162 \text{ mg/L}$

¹² It should further be noted that all tabulated and calculated concentrations are based on the level of aluminum nitrate, nonahydrate used in the FCS. Aluminum nitrate, *per se*, comprises only 57% of the total mass contributed by the nonahydrate form of this substance. Thus, any actual level of aluminum nitrate, *per se*, is approximately 57% of the tabulated/calculated values above. This mass fraction is calculated as follows:

$$212.99 \text{ g/mol aluminum nitrate} \div 375.13 \text{ g/mol aluminum nitrate, nonahydrate} = 57\%$$

¹³ See OECD SIDS Initial Assessment Profile of the nitrates category, available at: http://webnet.oecd.org/hpv/ui/SIDS_Details.aspx?id=3d9eafad-49b1-42ff-96c9-f40f0ff36aa3.

¹⁴ Metcalfe and Eddy, Inc., *Wastewater Engineering: Treatment and Reuse*, McGraw-Hill, New York, 4th Ed. 2003, Chapter 14, pp. 1456.

¹⁵ 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.

Using the average values from the bottle-rinsing table above, it is possible to calculate the amount of aluminum nitrate introduced into the sludge from the bottling process and from the periodic draining of the spent sterilant baths as follows:

Table 4

Annual Contribution of Aluminum Nitrate to Sludge (Bottle Rinsing)	
Total aluminum nitrate in effluent to WWTP (mg/L)	0.0094
Aluminum nitrate to sludge (assuming 100% is adsorbed to sludge) (mg/L)	0.0094
Effluent (L/hr)	14,453
Aluminum nitrate to sludge (mg/hr)	136
Aluminum nitrate to sludge (kg/day)	0.00326
Aluminum nitrate to sludge (kg/yr)	1.19

Table 5

Annual Contribution of Aluminum Nitrate to Sludge (Tank Draining)	
Total Aluminum nitrate in effluent to WWTP (mg/L)	60
Aluminum nitrate to sludge (100% of DPS will be adsorbed to sludge) (mg/L)	60
Effluent (L/tank)	144
Aluminum nitrate Adsorption to Sludge (mg/tank)	8640
Aluminum nitrate Adsorption to Sludge (kg/day) ^a	0.00086
Aluminum nitrate Adsorption to Sludge (kg/yr)	0.31

^a Tank drained once every 10 days

Table 6

Total Aluminum Nitrate in Sludge (Bottle Washing + Tank Draining)	
Non-degraded aluminum nitrate (bottle washing) (kg/yr)	1.19
Non-degraded aluminum nitrate (tank draining) (kg/yr)	0.31
Non-degraded aluminum nitrate aluminum nitrate (bottle washing + tank draining) (kg/yr)	1.50
Effluent (bottle washing + tank draining) (1000 cu meters/yr)	126.6
Sludge Generation/Removal Rate (450 kg sludge/1000 cu meters flow) (kg/year)	56,970
Aluminum nitrate Concentration in sludge (mg/kg)	26
After land application and incorporation (2.5% dilution factor provided by Harrass) mg/kg	0.65

As noted above, because of the good water solubility of aluminum nitrate, is it unlikely that the sludge would contain any aluminum nitrate. Nonetheless, the above calculations demonstrate that if the sludge were to contain aluminum nitrate, concentrations of aluminum nitrate in land applied effluent and sludge are below the level of concern for this material for the most sensitive terrestrial species described in Section 8 of the EA (i.e., the 13.6 mg/L 96 hr EC50 for *Bufo americanus* (toad)).¹⁶

¹⁶ It should further be noted that all tabulated and calculated concentrations are based on the level of aluminum nitrate, nonahydrate used in the FCS. Aluminum nitrate, *per se*, comprises only 57% of the total mass contributed by the nonahydrate form of this substance. Thus, any

A quantitative evaluation of phosphoric acid is not included in this assessment because phosphate is an essential element for all life forms. Phosphate, therefore, is ubiquitous in the environment at levels far above the levels that could be introduced into the environment due to its use as a stabilizer for this FCS. Specifically, phosphoric acid is used in the FCS solution at 70% of the level at which aluminum nitrate is used. Thus, the phosphoric acid introductions will be 70% of the aluminum nitrate introductions, or a time-averaged value of 0.0011 mg/L (70% of 0.00162 mg/L), for example. Average phosphate concentrations in the environment have been reported to be 0.2 mg/L based on data from monitoring 132 stream sites.¹⁷ Thus, the introduction of phosphoric acid into the environment due to the proposed use of the FCS will not change the background levels of this important nutrient in the receiving streams in any measurable way.

7. Fate of Emitted Components 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.¹⁸ 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.¹⁹

The maximum concentration of stabilizer release to the environment via WWTP effluent discharged to receiving water is calculated above as 0.0125 mg/L from the bottle washing application and 0.91 mg/L from the combined bath disposal and bottle washing, assuming the entire contents of the batch was discharged over a one hour period. These values reflect the stabilizer concentration before dilution by receiving waters. Because bath disposal is assumed to occur less frequently than once a week, the maximum effluent concentration represents at maximum, a one-hour load in any seven-day period.

Although, we do not think that food processors operating under this FCN would discharge their wastewater in land applications, we have, nevertheless, calculated the maximum concentration of stabilizer released to the environment if the WWTP effluent were directly discharged to land to be 0.0125 mg/L from the bottle washing application and 0.91 mg/L from

actual level of aluminum nitrate, *per se*, is approximately 57% of the tabulated/calculated values above. This mass fraction is calculated as follows:

$$212.99 \text{ g/mol aluminum nitrate} \div 375.13 \text{ g/mol aluminum nitrate, nonahydrate} = 57\%$$

¹⁷ Mueller, D.K., and N.E. Spahr. 2005. Water-quality, streamflow, and ancillary data for nutrients in streams and rivers across the nation, 1992-2001: U.S. Geological Survey data series 152. <http://pubs.usgs.gov/ds/2005/152/>. (Follow the link in the Contents (left sidebar) labeled Data Files, then click on the link labeled Summary Data for individual measurements.

¹⁸ Hydrogen Peroxide. JACC No. 22. European Centre for Ecotoxicology and Toxicology of Chemicals, January 1993.

¹⁹ *Ibid.*

the combined bath disposal and bottle washing, assuming the entire contents of the bath were discharged over a one hour period. 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.

The primary environmental function of nitrate ion (NO_3^-) is as a source of nitrogen for the nutrition and growth of plants and water- and soil-based microorganisms. More specifically, nitrogen-fixing bacteria in the soil and root nodules of many plants transform atmospheric nitrogen gas to ammonium ion. Nitrifying soil bacteria in turn convert ammonium ions to nitrite ions. In the presence of oxygen, nitrite is readily oxidized to nitrate by *Nitrobacter* bacteria. For this reason, nitrate is the ion predominantly found in groundwater and surface waters. Nitrate in the ground is taken up by plants and converted to organic forms to build constituent plant tissues. Once the plants die, aerobic and anaerobic bacterial decomposers and fungi in the soil convert the organic nitrogen in the plant tissues back into ammonia and the cycle begins anew.

One consequence of this nitrogen cycle is that nitrate ions are ubiquitous in the environment. Nitrate concentrations in natural ground waters are typically on the order of 2 mg/L.²⁰ In agricultural areas, where fertilizer runoff can occur, levels can fluctuate seasonally around 18 mg/L.²¹ By comparison, we have estimated a total maximum concentration of aluminum nitrate nonahydrate upon release to the receiving water is 0.091 mg/L. This concentration corresponds to 0.045 mg nitrate ion/L. Importantly, this level occurs only during the one-hour period out of every ten days when the sterilant bath is emptied. While the sterilant bath is in use, the environmental releases arise only from bottle washing; a maximum level of 0.00125 mg/L (0.00062 mg/L nitrate ion).

The estimated nitrate ion concentration released into the environment from the proposed use of the FCS is far below naturally occurring background levels that are necessary for life and are therefore too low to perturb this natural nitrogen cycle. Although human activities can sometimes increase the amount of nitrogen cycling between the living world, soil and the water, the activities leading to eutrophication conditions are those involving the discharge excessive quantities of phosphorous- and nitrogen-based fertilizer runoff or sewage into an aquatic system, typically in an estuary, where land-derived nutrients are channeled from a much larger watershed to a single confined channel and then pour into low-flow water such as a bay where they can concentrate.

Importantly, nitrates (NO_3^-) are an oxidized form of nitrogen and are formed when *Nitrobacter* bacteria combine oxygen with nitrites (NO_2^-). Eutrophication is the process by which a body of water acquires a high concentration of nutrients, especially phosphates and nitrates, which promote excessive algae growth. As the algae die and decompose, high levels of

²⁰ Mueller, David K., Hamilton, Pixie A., Helsel, Dennis R., Hitt, Kerie J., and Barbara C. Ruddy, "Nutrients in Ground Water and Surface Water of the United States--An Analysis of Data Through 1992," U.S. Geological Survey Water Resources Investigations Report 95-4031, 1995.

²¹ Nitrate and nitrite in drinking-water, Background document for development of WHO Guidelines for Drinking-water Quality, World Health Organization 2011.

organic matter and the decomposing organisms deplete the water of available oxygen, causing anoxia which may lead to the death of other organisms, such as fish. The lack of oxygen also reduces the capacity of the natural nitrogen cycle to oxidize nitrite ions to nitrate. Further, dissimilatory nitrate reduction (DNR), or nitrate/nitrite conversion, is an anaerobic respiration process possessed by certain bacteria that reduces nitrate to nitrite *in the absence of oxygen*. Thus, nitrites are implicated as a consequence of eutrophication, not a cause.

Bioaccumulation occurs when the rate of intake of a substance exceeds the rate of metabolism and/or excretion. Because the estimated environmental introduction of nitrate due to the proposed use of the FCS is far below naturally occurring background levels in the environment, and because the preferred metabolic path in the presence of oxygen (normal environmental conditions) is the conversion of nitrite to nitrate, bioaccumulation of nitrite is not expected to occur under the intended conditions of use.

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 the hydrogen peroxide 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.

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.

Stabilizer: A summary of the ecotoxicity data on the stabilizer is provided as follows:

Aluminum Nitrate: According to an OECD SIDS document,²² “Based on the available data, members of the nitrate category are not considered toxic to aquatic organisms.” This OECD SIDS document has summarized the aquatic and terrestrial toxicity of nitrates. The available data are shown below:

Toxicity of the nitrate group to fish

Organism	Salt	Exposure	LC ₅₀ (mg/L) (nominal)
Bluegill (<i>Lepomis macrochirus</i>)	Sodium nitrate	96 hrs	12,000
Bluegill (<i>Lepomis macrochirus</i>)	Sodium nitrate	96 hrs	9,000; 9400; 10,000 (different sizes of fish used)
Rainbow trout (<i>Oncorhynchus mykiss</i>)	Sodium nitrate	96-hrs	8,226 (TL _m) (analytical not specified)

²² See OECD SIDS Initial Assessment Profile of the nitrates category, available at: http://webnet.oecd.org/hpv/ui/SIDS_Details.aspx?id=3d9eafad-49b1-42ff-96c9-f40f0ff36aa3.

Organism	Salt	Exposure	LC ₅₀ (mg/L) (nominal)
Rainbow trout (<i>Oncorhynchus mykiss</i>)	Sodium nitrate	96 hrs	1685
<i>Oncorhynchus tshawtscha</i> (Chinook salmon)	Sodium nitrate	96 hrs	5,800 (freshwater) 4400 (15 ppt salinity)
Anemone fish (<i>Amphiprion ocellaris</i>)	Sodium nitrate	3 months	NOEC = 97.8
Mosquitofish (<i>Gambusia affinis</i>)	Sodium nitrate	96 hrs	6650
Black sea bass (<i>Centropristes striata</i>)	Sodium nitrate	96 hrs	2240
Bluegill (<i>Lepomis macrochirus</i>)	Potassium nitrate	96 hrs	3,000 (analytical not specified)
Guppy (<i>Poecilia reticulata</i>)	Potassium nitrate	96-hrs	1378
Mosquitofish (<i>Gambusia affinis</i>)	Potassium nitrate	96-hrs	162
Rainbow trout (<i>Oncorhynchus mykiss</i>)	Potassium sodium nitrate	96 hrs	>98.9 (measured concentration; OECD TG 203)
Chinook salmon, rainbow trout and bluegill	Ammonium nitrate	96 hrs	420 to 1360 mg NO ₃ /L depending on the species tested (analytical not specified)
Rainbow trout (<i>Oncorhynchus mykiss</i>)	UAN (nitrogen solution)	96 hrs	>103
<i>Barilius barna</i>	Urea	96 hrs	> 9100
<i>Leuciscus idus melanotus</i> (Golden orfe)	Urea	96 hrs	LC ₀ > 10,000
<i>Tilapia mossambica</i> (tilapia)	Urea	25 days	22,500

TL_m = median tolerance limit

Toxicity of the nitrate group to *Daphnia magna* and other invertebrates

Organism	Salt	Exposure	EC ₅₀ (mg/L)
<i>Daphnia magna</i>	Sodium nitrate	48 hrs	TL _m = 3,581 (analytical not specified)
<i>Crassostrea virginica</i>	Sodium nitrate	96 hrs	15,810 (adult); 23,040 (juvenile)
<i>Mercenaria mercenaria</i>	Sodium nitrate	96 hrs	> 19,840 (adults and juveniles)

Organism	Salt	Exposure	EC ₅₀ (mg/L)
<i>Pseudacris regilla</i>	Sodium nitrate	96 hrs	1749.8
<i>Xenopus laevis</i>	Sodium nitrate	96 hrs	1655
<i>Daphnia magna</i>	Potassium nitrate	48 hrs	TL _m = 490
<i>Daphnia magna</i>	Ammonium nitrate	up to 7 days	EC ₅₀ = 555
<i>Bufo americanus americanus</i> (toad)	Ammonium nitrate	96 hrs	13.6 – 39.3 (from different ponds)
<i>Bufo bufo</i> (common or European toad)	Ammonium nitrate	96 hrs	1704
<i>Pseudacris regilla</i> (Pacific chorus frog)	Ammonium nitrate	96 hrs	135.4
<i>Pseudacris triseriata</i> (Western chorus frog)	Ammonium nitrate	96 hrs	17
<i>Rana clamitans melanota</i> (frog)	Ammonium nitrate	96 hrs	32.4
<i>Rana pipiens</i> (Leopard frog)	Ammonium nitrate	96 hrs	22.6
<i>Xenopus laevis</i> (African clawed frog)	Ammonium nitrate	96 hrs	100.7
<i>Daphnia magna</i>	Urea	24 hrs	> 10,000

TL_m = median tolerance limit

Toxicity of the nitrate group to aquatic plants

Organism	Salt	Exposure (days)	ErC ₅₀ (mg/L) based on growth rates
<i>Scenedesmus quadricauda</i>	Ammonium nitrate	7	83 (EC ₃)
<i>Navicula arenaria</i>	Potassium nitrate	10	> 1700
<i>Nitzschia c.f. dissipata</i>	Potassium nitrate	10	> 1700
<i>Nitzschia dubiformis</i>	Potassium nitrate	10	Could not be determined
<i>Nitzschia closterium</i>	Potassium nitrate	10	> 1700
<i>Amphiprora c.f. paludosa</i>	Potassium nitrate	10	Could not be determined
<i>Stauroneis constricta</i>	Potassium nitrate	10	> 1700
<i>Navicula cryptocephala</i>	Potassium nitrate	10	> 1700
<i>Navicula salinarum</i>	Potassium nitrate	10	> 1700
<i>Gyrosigma spencerii</i>	Potassium nitrate	10	> 1700
<i>Nitzschia sigma</i>	Potassium nitrate	10	> 1700
<i>Scenedesmus quadricauda</i>	Urea	8	> 10000

No data are available on toxicity to terrestrial organisms.

The calculated environmental exposure to stabilizer from effluent release from a WWTP to receiving waters is 0.0125 mg/L from the bottle washing application and 0.091 mg/L from the combined bath disposal and bottle washing, assuming the entire contents of the bath were discharged over a one-hour period, and that the stabilizer concentration was diluted 10-fold upon discharge to the receiving waters. This level of exposure is well below the levels of concern reflected in the available aquatic toxicity data.

If effluent from the WWTP were discharged directly to land rather than to receiving waters, the maximum short-term effluent concentration of 0.91 mg/L stabilizer present in the surface water is not expected to have any significant adverse environmental impact based on the toxicity endpoints available for plants, as reflected above.

Because of the good solubility of the stabilizer, it is expected that it would not be adsorbed to sludge during treatment in the WWTP. Thus, it is unlikely that sludge from treatment in the WWTP would contain stabilizer and, hence, an environmental release of stabilizer is not expected when the sludge is used as a soil amendment in land applications.

As indicated above, hydrogen peroxide is not expected to survive the treatment processes at the wastewater treatment facility.

9. 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 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 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 significant environmental impact.

12. List of Preparers

Mark A. Hepp, Ph.D., Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001. Dr. Hepp has a Ph.D. in chemistry with 21 years of experience in reviewing and preparing food-contact notifications and environmental assessments.

Devon Wm. Hill, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001. J.D. with 21 years of experience with FCN submissions and environmental assessments.

13. Certification

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



Devon Wm. Hill
Counsel for Notifier

DWH/BPS/MAH

4822-4515-4137, v. 1