Environmental Assessment

1. Date	August 22, 2017
2. Name of Applicant	IET, Inc. DBA EcoloxTech
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4. Description of Proposed Action

a. Requested Action

The action identified in this food contact notification (FCN) is to provide for the use of the food contact substance (FCS) hypochlorous acid, electrolytically generated on-site at the location of intended use. The solution is generated by the electrochemical activation of a brine solution of sodium chloride. The pH at which it is generated is between 6 and 7, ensuring that hypochlorous acid is the dominant species.

The FCS is intended for use as an antimicrobial agent at a concentration up to 60 ppm of free available chlorine (FAC) in the production and preparation of whole or cut meat and poultry; processed, comminuted and preformed meat and poultry; fish and seafood; fruits and vegetables; and shell eggs, as follows:

(1) process water or ice applied as a spray, wash, rinse, dip, chiller water, immersion baths (less than 40 °C), and scalding water for whole or cut meat and poultry, including carcasses, parts, trim and organs;

(2) process water, ice, or brine used for washing, rinsing, or cooling of processed, comminuted or formed meat and poultry products;

(3) process water or ice for washing, rinsing, or cooling fruits and vegetables;

(4) process water or ice for washing, rinsing, or cooling whole or cut fish and seafood;

(5) process water for washing or rinsing shell eggs.

b. Need for Action

The antimicrobial agent reduces or eliminates pathogenic and non-pathogenic microorganisms that may be present on the food or in the process water or ice used during production.

In summary, 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 efficacious antimicrobial interventions in food processing facilities, restaurants, and grocery stores.

c. Locations of Use/Disposal

The antimicrobial agent is intended for use in fruit and vegetable, fish and seafood, meat, poultry, and egg processing plants and facilities, restaurants, and grocery stores throughout the United States. It may also be used aboard fishing vessels during initial evisceration and cleaning of fresh-caught seafood. It is expected that most of these facilities, for example, restaurants and grocery stores will discharge to publically owned treatment works (POTW); however, as some facilities will discharge directly to surface waters after on-site pre-treatment in accordance with a permit issued under the National Pollutant Discharge Elimination System (NPDES), for this assessment we will evaluate facilities will discharge directly to surface waters in accordance with NPDES regulations. During the on-site treatment process, very minor quantities of the solution are lost to evaporation. Waste water from fishing vessels is expected to be disposed in the ocean.

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

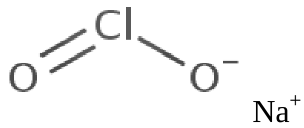
EcoloxTech hypochlorous acid solution will be generated at up to 60 ppm of free available chlorine (FAC) and at the pH of a weak acid. Relative proportions of the active chlorine species are determined by the pH of the solution.

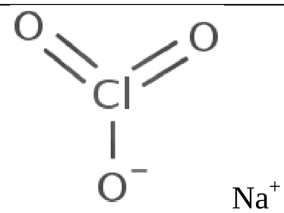
The identities are provided for the residual chemicals that may be present in the final solution, including degradation of oxychlorine species (chlorate and chlorite) and trihalomethane (THM) formation by-products (bromodichloromethane, chlorodibromomethane, bromoform, and chloroform).

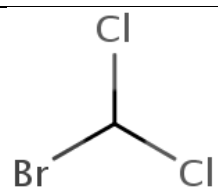
Table 1: Chemical Identity of Substances of the Proposed Action

CAS Name	Hypochlorous acid
CAS Registry Number	7790-92-3
Formula	HOCl
Structure	
Molecular weight	52.46 g/mol
Water solubility	Soluble
Comment	The primary active species in solution. Present at not more than 60 ppm.

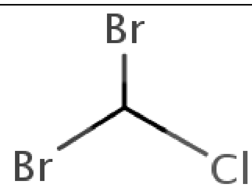
CAS Name	Chlorite
CAS Registry Number	7758-19-2 (Sodium chlorite)
Formula	ClO_2 ($NaClO_2$)

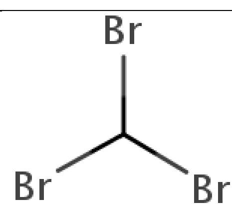
Structure	
Molecular weight	90.44 g/mol ($NaClO_2$)
Water solubility	Soluble
Comment	By-product from Ecolox hypochlorous acid solution, minimized under controlled pH environment

CAS Name	Chlorate
CAS Registry Number	7775-09-9 (Sodium chlorate)
Formula	ClO^{-}_{3} ($NaClO_3$)
Structure	
Molecular weight	106.44 g/mol ($NaClO_3$)
Water solubility	Soluble
Comment	By-product from Ecolox hypochlorous acid solution, minimized under controlled pH environment

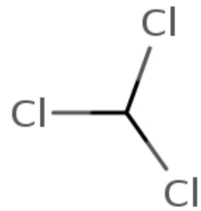
CAS Name	Bromodichloromethane
CAS Registry Number	75-27-4
Formula	$CHBrCl_2$
Structure	
Molecular weight	163.83 g/mol

Water solubility	Soluble
Comment	By-products formed in final solution

CAS Name	Chlorodibromomethane
CAS Registry Number	124-48-1
Formula	$CHBr_2Cl$
Structure	
Molecular weight	208.28 g/mol
Water solubility	Soluble
Comment	By-products formed in final solution

CAS Name	Bromoform
CAS Registry Number	75-25-2
Formula	$CHBr_3$
Structure	
Molecular weight	252.73 g/mol
Water solubility	Soluble
Comment	By-products formed in final solution

CAS Name	Chloroform
CAS Registry Number	67-66-3

Formula	$CHCl_3$
Structure	
Molecular weight	119.38 g/mol
Water solubility	Soluble
Comment	By-products formed in final solution

6. Introduction of Substances into the Environment

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

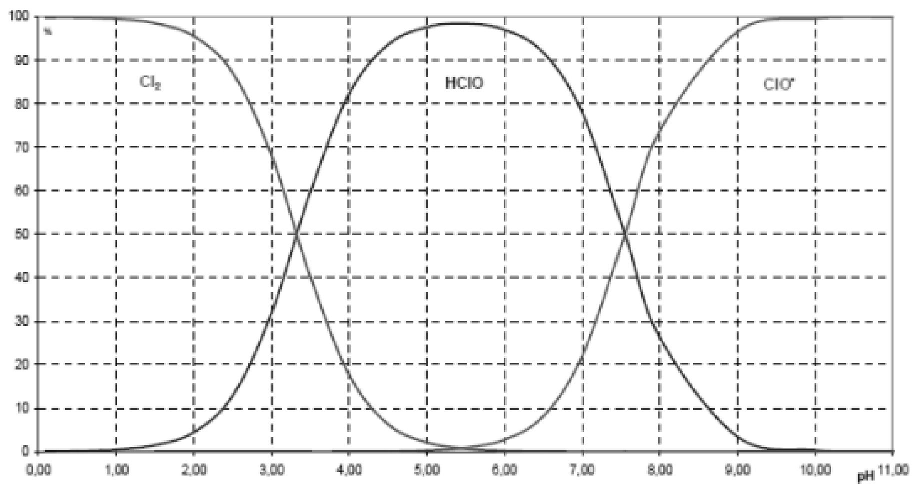
Under 21 C.F.R § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. The FCS is manufactured in plants which meet all applicable federal, state, and local environmental regulations. The notifier asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS such as: 1) unique emission circumstances that are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State, or local environmental agencies and that may harm the environment; 2) the action threatening a violation of Federal, State or local environmental laws or requirements (40 C.F.R. § 1508.27(b)(10)); or 3) production associated with the proposed action that may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in 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

Introduction of very dilute solutions of the product into the environment will take place primarily via release from wastewater treatment systems. Introduction of the components of the product into the environment will result from use of the product as an antimicrobial agent in processing water for the foods identified above, and the subsequent disposal of such water into surface waters in accordance with an NPDES permit. Most of the requested applications of the FCS will involve treatment in onsite facilities but some applications may involve drainage into POTWs. As a worst case we will consider only on site treatment prior to disposal to surface waters We expect that large processing facilities may utilize wastewater recovery systems that return the wastewater back to the EcoloxTech single cell electrolyzer for re-sterilization and re-generation of fresh EcoloxTech hypochlorous acid solution, therefore greatly limiting disposal of the FCS. However, as a conservativism, we have not assumed any water reuse in the assessment.

Hypochlorous acid exists interchangeably with other chlorine species. This is supported by the equilibrium chemistry of active chlorine. In a controlled pH environment in the range of 5 to 7.4, hypochlorous acid will exist as the dominant chlorine species.

Figure 1. Equilibrium Chemistry of Active Chlorine



The chemical species in the hypochlorous acid solution are aqueous and will be introduced into the aquatic environment via discharge to surface waters. Because the pH of EcoloxTech hypochlorous acid solution is a weak acid, the dominant oxychlorine species is hypochlorous acid. It is well understood that the primary antimicrobial activity for hypochlorous acid and hypochlorite solutions is due to the activity of the acid component and so EcoloxTech's operational parameters include operation between pH 5 and 7 to maximize available acid and the resulting antimicrobial efficacy. As we see in figure 1, at pH 7 the solution is approximately 80% HOCl and 20% ClO^- . Additionally, because oxychlorine species are strong oxidizers, they are expected to react readily with oxidizable compounds in the waste stream and be rapidly reduced to other chlorine species, primarily chlorides (ECHA 2007).[1] At a pHs between 5 and 7 the predominant reactions will be:

1. $2HClO \rightarrow 2HCl + O_2$

2. $3NaClO \rightarrow NaClO_3 + 2NaCl$ [2]

The second reaction will be favored at higher pHs but both reactions will tend to decrease the overall pH by increasing H^+ concentrations through production of HCl or through dissociation of HOCl to form OCl^- to maintain the equilibrium between those two species. Thus, although reaction 2 may occur at the operational pH range, it should not predominate as pH will be reduced through both reactions. In addition, we note that only one chlorate ion is produced for every three hypochlorite ions in reaction 2 above. Finally, chlorate ion is expected to be a

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[1] European Union Risk Assessment Report Sodium Hypochlorite, Final Report, November 2007, pg. 21.

[2] Ibid.

strong oxidizer and to react with organic matter and or metal ions in water to produce chlorite ion and ultimately chloride ion.[3,4]

Treatment facilities use chlorine as part of the wastewater treatment process, as a disinfectant (EPA 2000).[5] Because it is known that discharge of too much chlorine can have an adverse effect on aquatic life in receiving waters, prior to discharge of treated wastewater. Treatment facilities use dechlorination mechanisms such as sulfonation to remove chlorine compounds.[6] The levels of chlorine that may be discharged from treatment facilities are tightly regulated under National Pollutant Discharge Elimination System (NPDES) permits to meet established water quality standards which reflect EPA's water quality criteria for chlorine, including the Criteria Maximum Concentrations (CMCs) for acute effects and the Criterion Continuous Concentrations (CCCs) for chronic effects.[7]

Water containing hypochlorous acid may be used in the following manners.

i. Poultry Processing Facilities

Introduction of the components of the product into the environment will result from use of the product as an antimicrobial agent in processing water from spray and submersion applications for poultry carcasses, parts, organs, and trim, and the subsequent disposal of such water. In poultry processing facilities, the defeathered, eviscerated carcasses are generally sprayed before being chilled via submersion in baths. The carcass is carried on a conveyor through a spray cabinet and then submerged in the chiller baths. Parts and organs may also be chilled by submersion in baths containing the antimicrobial agent. Chiller baths typically include a "main chiller" bath and a "finishing chiller" bath, both of which may contain the FCS.

Water is used in poultry processing, in both commercial and retail settings, for scalding (feather removal), bird washing before and after evisceration, chilling, cleaning and sanitizing of equipment and facilities, and for cooling of mechanical equipment such as compressors and pumps (EPA 2004, p. 6-7).[8] Many of these water uses will not utilize the FCS, resulting in significant dilution of the FCS into the total water effluent.[9] Effluent for such facilities going to

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[3] Environmental Protection Agency Memorandum dated March 22, 2012. Product Chemistry, Environmental Fate, and Ecological Effects Scoping Document of Registration review of Sodium and Calcium Hypochlorite Salts, pg. 6.
[4] Op Cite EU 2007.
[5] U.S. Environmental Protection Agency. (2000). *Wastewater Technology Fact Sheet: Dechlorination*. Washington, D.C.: Office of Water, EPA 832-F-00-022, available at https://www3.epa.gov/npdes/pubs/dechlorination.pdf. U.S. Environmental Protection Agency. (2006b). Reregistration Eligibility Decision (RED) for Inorganic Chlorates. Washington, D.C.: Office of Prevention, Pesticides and Toxic Substances, EPA 738-R-06-014, p. 11, https://archive.epa.gov/pesticides/reregistration/web/pdf/inorganicchlorates_red.pdf
[6] Ibid. pg. 1
[7] Environmental Protection Agency. (2015). *National Recommended Water Quality Criteria – Aquatic Life Criteria Table*, available at https://www.epa.gov/wqc/national-recommended-water-quality-criteria-aquatic-lifecriteria-table.
[8] U.S. Environmental protection Agency, (2004, September 8). *Technical Development Document for the Final Effluent Limitations Guidelines and Standards for the Meat and Poultry Products Point Source Category* (40 CFR 432), EPA-821R-04-011. Available at http://water.epa.gov/scitech/wastetech/guide/mpp/upload/2008_07_15)guide_mpp_final_tddo6.pdf
[9] J. K. Northcutt and D. R. Jones: A Survey of Water Use and Common Industry Practices in Commercial Broiler Processing Facilities; 2004 Journal of Applied Poultry Research; available at http://naldc.nal.usda.gov/download/38935/PDF. This study describes 7 main uses of water in poultry facilities, of

on site treatment facilities (or any other treatment facilities) would be expected to include significant amounts of organic matter including poultry processing waste and removed soil.

ii. Meat Processing

In meat processing operations, process water containing the diluted FCS is sprayed directly on to the exposed surfaces of whole carcasses or cuts of meat. The vast majority of the solution sprayed onto the carcasses drains off the meat and enters the facility's water treatment system. Although the FCS may be used in contact with all types of meat, including pork, venison, and mutton/lamb, its use in the processing of beef constitutes the largest sector of the meat processing industry in terms of market share. The processing of pork is the sector that is expected to generate the largest amount of effluent (EPA 2004, Table 6-3, p. 6-6).[10]

Water is used in meat processing facilities in both commercial and retail settings, for purposes other than carcass and meat washing (i.e. for cleaning, boiler water, cooling waters, etc.). This additional water use will dilute the concentration of the FCS in the total water effluent to lower levels. Indeed, these other uses are reported to account for approximately 60% of the total water used in a hog slaughterhouse.[11] Based on this information, it is conservative to assume that wastewater from these facilities will reduce the FCS concentration by a factor of 0.4. Effluent for such facilities going to on site treatment facilities (or any other treatment facilities) would be expected to include significant amounts of organic matter including meat processing waste and removed soil.

iii. Fruit and Vegetable Processing Facilities

Water is used extensively in almost all aspects of processing fruits and vegetables, including during cooling, washing, and conveying of produce (FDA 2008).[12] Different methods may be used to wash different types of produce, including submersion, spray, or both (FDA 2008). Introduction of the components of the product into the environment will result from use of the product as an antimicrobial agent in the fruit and vegetable processing water and the subsequent disposal of the water. Water is used in produce processing, in both commercial and retail settings, for a variety of applications that will not utilize the FCS, including blanching, filling, cleaning and sanitizing of plant equipment and facilities, and for processed product cooling, resulting in significant dilution of the FCS into the total water effluent. Effluent for such facilities going to on site treatment facilities (or any other treatment facilities) would be expected to include significant amounts of organic matter including produce processing waste and removed soil.

iv. Fish and Seafood Processing

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which 3 (carcass washing, chilling, and movement) would be treated with HClO. Each use has been given equal weight: 3/7*100 = 43%

[10] Op Cite EPA 2004.

[11] Figure 3.2, p. 71 (summing values from the personal hygiene (~9%), cooling water (5%), knife sterilizing (5%), lairage washing (~3%), vehicle washing (~4%), and cleaning (~32%) categories, and assuming that all of the sprays and rinses are used during processing).

[12] U.S. Food and Drug Administration. (2008, February). *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables.* February 2008. Available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm#ch4 .

Water is used during many steps of seafood processing, including preparation (e.g., scaling, filleting, skinning, evisceration), inspection and trimming, product processing (e.g., pickling and brining), and further processing (e.g., freezing, canning, and bottling) (Tay 2006).[13] There are also a number of water uses in seafood processing plants that would not utilize the FCS, including equipment sprays, offal transport, cooling water, steam generation, and equipment and food cleaning (Tay 2006). The proposed use in seafood and fish processing also includes use aboard fishing vessels during the initial evisceration and cleaning of fresh-caught seafood. The wastewater from such use will be discharged directly into ocean water. The resulting dilution would make any introduction from fishing vessels negligible.

v. Processed and Preformed Meat and Poultry

The FCS is intended for use as a treatment for cooling water applied to processed and pre-formed meat and poultry products, in both commercial and retail settings. Because there are many different types of RTE meat and poultry produced using a variety of methods, it is difficult to establish water usage levels. It is expected that water not containing the FCS will be used in plants for activities such as cleaning and sanitation, resulting in significant dilution of the FCS into the total water effluent. In addition, because the application here is limited to use in cooling water relatively less of the FCS will be used compared to meat processing applications discussed above. For our purposes here, we will conservatively assume similar dilutions to that assumed for meat processing above. Effluent for such facilities going to on site treatment facilities (or any other treatment facilities) would be expected to include significant amounts of organic matter including meat poultry processing waste and soil.

vi. Shell Egg Wash

The FCS is intended for use as an antimicrobial rinse for shell eggs. Commercial washing of shell eggs is typically performed in a mechanical washer in which a series of spray nozzles mist an alkaline detergent over the eggs as flat brushes move side to side across the shells' surfaces (Northcutt 2005).[14] After washing, the final antimicrobial spray rinse is used. As with many food processing applications, estimates of water usage are difficult to compare, with reported values including 4.4 gal/min (16.6 L/min) of fresh water during washing, 2.8 gal per case (360 eggs) of eggs (10.6 L/case), and 2.5 billion gal (9.46 billion L) of wastewater each year (Northcutt 2005). No data is reported on the water usage specifically during the antimicrobial rinse. More recent water usage values have not been located, however, it is possible to estimate a dilution factor based on total water usage in typical shell egg processing plants. The U.S. Department of Agriculture has developed regulations governing the voluntary grading of shell eggs.[15] This program requires shell eggs to be washed using potable water and approved cleaning compounds.[16] This wash water must be changed at least every four hours,

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[13] Tay, J-H., Show, K-Y., and Hung, Y-T. (2006). *Seafood Processing Wastewater Treatment*, in Wang, L.K. et al. eds., *Waste Treatment in the Food Processing Industry.*

[14] Northcutt, J.K., Musgrove, M.T., and Jones, D.R. (2005). *Chemical Analyses of Commercial Shell Egg Wash Water*, Journal of Applied Poultry Research, 14: 289-295. Available at http://naldc.nal.usda.gov/download/38830/PDF .

[15] 7 C.F.R. Part 56, available at http://www.ams.usda.gov/sites/default/files/media/Regulations%20for%20Voluntary%20Grading%20of%20Shell%20Eggs.pdf.

[16] 7 C.F.R. § 56.76(f).

and replacement water is continually added.[17] In some facilities, multiple washing steps are used (Musgrove 2006).[18] There may also be a prewetting step prior to washing, which involves spraying a continuous flow of water over the eggs.[19] The antimicrobial spray rinse occurs after the various washing steps. The USDA program also requires a processing plant to clean the egg grading and packing rooms,[20] grading and candling equipment,[21] oil application equipment,[22] and cleaning equipment.[23] Water also is used for general plant operations. Effluent for such facilities going to on site treatment facilities (or any other treatment facilities) would be expected to include significant amounts of organic matter including removed soil.

vii. Introduction of Substances

All of the above intended uses of the FCS result in wastewater containing substantial amounts of soil and other organic matter before, during and after treatment. For example, significant amounts of food particles will we included in the wastewater for nearly of the above processes and soil will be present in all as all of the above uses are primarily intended to wash away soil and other materials from processed food. In addition to oxidizable organic matter numerous inorganic metal ions will also be present which may also be oxidized (e.g., $Fe^{+2} \rightarrow Fe^{+3}$) The recent European Union Risk assessment(EU 2007) for sodium hypochlorite emphasizes the reactivity of hypochlorous acid, hypochlorite ion and other associated oxychloro compounds. Because of the complexity of the potential reactions among hypochlorite, hypochlorous acid, other oxychloro compounds and organic matter including food, soil and other oxidizable matter the E.U. risk assessment has relied on kinetic modeling of the reduction of the various oxychloro compounds to chloride.[24] This kinetic model predicts that even concentrations as high as 75 ppm active chlorine result in near complete reduction of available chlorine to chloride in a matter of hours during transport, treatment and introduction into surface waters.

The rigor of the model has been tested and accepted as conservative for the EU risk assessment. The model predicts that at initial concentrations of 75 ppm sodium hypochlorite will decay to less than 4×10^{-27} ppb active chlorine in the approximately 9 hours window for use and treatment and discharge of the chemical (including 10 minutes after discharge into surface waters). In addition, the model predicts decay of any chloramines that may be produced to concentrations of 1×10^{-10} ppb as well.

With respect to halomethanes and associated compounds, the EU risk assessment estimates an overall production rate for uses of hypochlorite disinfectants of about 1.5% of total available chlorine.[25] The EU risk assessment focuses on halomethanes, and chlorinated acetic acids regarding environmental introductions. We consider the estimate of the production of

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[17] *Id*.

[18] Musgrove, M.T., et al. (2006). *Antimicrobial Resistance in Salmonella and Escherichia coli Isolated from Commercial Shell Eggs*, Poultry Science, 85: 1665-1669. Available at http://naldc.nal.usda.gov/naldc/download.xhtml?id=3896&content=PDF.

[19] 7 C.F.R. § 56.76(f).

[20] 7 C.F.R. § 56.76(b)(4).

[21] 7 C.F.R. § 56.76(c)(3).

[22] 7 C.F.R. § 56.76(e)(5).

[23] 7 C.F.R. § 56.76(f)(1).

[24] Op Cite EU Appendix 2.

[25] Ibid pg 52.

these compounds relative to available chlorine conservative for our intended use because the EU report also shows that uses including larger amounts of available organic material will reduce the residual oxidative species significantly.[26] Thus, conservatively we estimate a maximum combined concentration of trihalomethanes and other trichloroacetic and other haloacetic acids as 60 ppm x 1.5% = 900 ppb. However, the EU risk assessment estimates that trihalomethanes constitute no more than 9.6%, trichloroacetic acid constitutes no more than 3.49% and other chlorinated acetic acids constitute no more than 4% of the total oxidizable species before treatment. Thus we estimate the concentrations of trihalomethanes, trichloroacetic acid and other chloroacetic acids prior to treatment to be no more than 86.4 ppb, 31.4 ppb and 36 ppb, respectively. These concentrations would be reduced 10-fold upon dilution in surface waters. The EU assessment estimates that other species would be expected to be present at less than an order of magnitude lower than the substances of primary concern; trihalomethanes, trichloroacetic acid and other chloroacetic acids.[27] EICs for compounds for the aqueous compartment are: 4×10^{-27} ppb for HOCl, OCL^-, ClO_2^- and ClO_3^-; 1×10^{-10} ppb for chloroamines, 8.64 ppb for trihalomethanes, 3.14 ppb for trichloroacetic acid and 3.6 ppb for other chloroacetic acids. Finally, because the hypochlorous acid and its reaction and breakdown products will be ultimately reduced to chlorides, we will assume a chloride concentration of 6 ppm (mg/L), incorporating only the 10% reduction for dilution in surface waters.

7. Fate of Emitted Substances in the Environment

Adsorption and oxidation-reduction reactions will have occurred during wastewater treatment, before reaching the aquatic environment. Since oxychlorine species are strong oxidizers, they are expected to react readily with oxidizable compounds in the wastewater treatment process before discharge to surface waters. Though many of these species will have been depleted by the above stated mechanisms, some potential for exposure through air may exist.

A pH-mediated equilibrium exists between the free chlorine species. Decomposition of free chlorine species depend on a number of factors such as pH, concentration, nature of inorganic and organic matter in aquatic environment, exposure to sunlight, and temperature. The half-life of free residual chlorine in natural freshwater systems is approximately 1.3 to 5 hours (U.S. EPA, 1999).[28] There is no evidence that active chlorine species accumulate in sediment (U.S. EPA, 1999). Oxychlorine species are strong oxidizers and readily react with oxidizable organic compounds. Chlorate does not bind readily to soil or sediment particulates and is expected to be very mobile and partition predominantly into the water (EPA, 2006b).[29] However, extensive redox reactions are expected to occur in the environment, which would serve to reduce the concentration of chlorate in surface waters (EPA, 2006b). Oxychlorine species

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[26] Ibid.
[27] Ibid. pg. 54.
[28] U.S. Environmental Protection Agency. (1999). *Registration Eligibility Decision (RED) for Chlorine Gas*. Washington, D.C.: Office of Prevention, Pesticides and Toxic Substances, EPA 738-R-99-001. Available at: http://archive.epa.gov/pesticides/reregistration/web/pdf/4022red.pdf.

[29] U.S. Environmental Protection Agency. (2006b). *Reregistration Eligibility Decision (RED) for Inorganic Chlorates.* Washington, D.C.: Office of Prevention, Pesticides and Toxic Substances, EPA 738-R-06-014. https://archive.epa.gov/pesticides/reregistration/web/pdf/inorganicchlorates_red.pdf.

have low bioaccumulation potential, high mobility, and low volatility. They do not readily biodegrade under aerobic conditions (EPA, 2006a[30] and 2006b). Upon reaching surface water, the THMs are expected to transition out of the aquatic environment within hours to days[31]

Based on the above, we conclude that the primary environmental exposure will be through the aquatic compartment.

8. Environmental Effects of Released Substances

Aquatic toxicity is summarized in the following tables:

Table 3. Environmental Toxicity for Chlorine Species

Aquatic Species	**Chemical Species**	**Acute LC_{50} or EC_{50} (mg/L)**	**Source**
Freshwater fish	Chlorite	50.6-420	U.S. EPA, 2006a[32]
	Chlorate	>1,000	U.S. EPA, 2006c[33]
	Chlorine (FAC)	0.045-0.71	U.S. EPA, 2010[34]
Freshwater invertebrates	Chlorite	0.027-1.4	U.S. EPA, 2006a
	Chlorate	920	U.S. EPA, 2006c
	Chlorine (FAC)	0.017-0.673	U.S. EPA, 2010
Estuarine/marine fish	Chlorite	75	U.S. EPA, 2006a
	Chlorate	>1,000	U.S. EPA, 2006c
	Chlorine (FAC)	0.71	U.S. EPA, 2010
Estuarine/marine invertebrates	Chlorite	0.576-21.4	U.S. EPA, 2006a
	Chlorate	>1,000	U.S. EPA, 2006c

[30] U.S. Environmental Protection Agency. (2006a). *Chlorine Dioxide: Environmental Hazard and Risk Assessment Case 4023*. EPA Docket No. EPA-HQ-2006-0328.

[31] See attached extracts from the Hazardous Substance Database regarding environmental fate information for Bromoform, Chloroform, Bromodichloromethane and Chlorodibromomethane.

[32] Op Cite EPA 2006a pp. 5-11.

[33] U.S. Environmental Protection Agency. (2006c*). Environmental Fate and Ecological Risk Assessment for the Reregistration of Sodium Chlorate as an Active Ingredient in Terrestrial Food/Feed and Non-food/Non-feed Uses*. Reregistration Case Number 4049, Docket No. EPA-HQ-OPP-2005-0507.

[34] U.S. Environmental Protection Agency. (2010). *Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Chlorine Registration Review Decision Document*, Case No. 4022, EPA Docket No. EPA-HQ-OPP-2010-0242.

	Chlorine (FAC)	0.026-1.42	U.S. EPA, 2010
Aquatic plants	Chlorite	1.32	U.S. EPA, 2006a
	Chlorate	43-133	U.S. EPA, 2006c
	Chlorine (FAC)	None reported	U.S. EPA, 2010

[a] See p. 5-11.

[b] See Table 3-11, p. 47-48.

[c] Data supplied from U.S. EPA, 2010 may reflect studies for lithium hypochlorite, see p. 21.

In Table 5, the most sensitive value for environmental toxicity for oxychloro species is that for freshwater invertebrate at 17 µg/L. The EIC based on the EU risk assessment is 4×10^{-27} µg/l for HOCl, OCL^-, ClO_2^- and ClO_3^-. Thus, the EIC for oxychlorospecies is more than 25 orders of magnitude lower than the EIC.

Table 4. Environmental Toxicity for THM Species[35]

Aquatic Species	Chemical Species	Acute LC_{50} or EC_{50} (mg/L)[a]
Freshwater fish	Bromodichloromethane	--
	Chlorodibromomethane	34
	Bromoform	2.9
	Chloroform	1.24
Freshwater invertebrates	Bromodichloromethane	240
	Chlorodibromomethane	65
	Bromoform	7.8
	Chloroform	2.66
Estuarine/marine fish	Bromodichloromethane	--
	Chlorodibromomethane	--
	Bromoform	12
	Chloroform	--
Estuarine/marine invertebrates	Bromodichloromethane	--
	Chlorodibromomethane	--
	Bromoform	7
	Chloroform	2
Aquatic plants	Bromodichloromethane	--
	Chlorodibromomethane	--
	Bromoform	0.24
	Chloroform	22.86

Source: see search results from EPA Ecotox Database attached

[a] "--" No data was listed

The volatility of halomethanes will mean that most will evaporate from surface waters in a matter of hours.[36] In Table 6, the most sensitive values for environmental toxicity for THM

[35] See attached HSDB extracts for each THM.

species are for freshwater fish at 1.24 mg/L and for aquatic plants at 0.24 mg/L. The EIC estimated above of 8.6 µg/l is well below the most sensitive endpoints for aquatic toxicity.

Chloramines are chemicals commonly used in the disinfection of drinking water. We have attached data records from EPA's Ecotox database. These data records show that the most sensitive aquatic species is the water flea with an LC_{50} of 0.016 mg/L. It is expected that chloroamines will be reduced so that the EIC will be no more than 1×10^{-10} ppb (µg/l). Thus, the EIC is over 11 orders of magnitude below the lowest $LC_{50.}$

Monochloracetic acid is produced in the disinfection of drinking water and are present in drinking water at levels between 2 and 82 µg/l. WHO has performed a risk assessment of monochloramine in drinking water and estimated a tolerable daily intake for humans of 210 µg/p/d, a level which includes a 100-fold safety factor and which is still more than 60-fold larger than our EIC of 3.6 µg/l.[37] In addition, OECD SIDs has assessed the environmental safety of trichloracetic acid.[38] OECD SIDS identified the alga *Chlorella pyrenoidosa* as the most sensitive species with a NOEC of 10µg/l. Our EIC of 3.14 µg/l for trichloroacetic acid is 3-fold below the referenced no effect concentration.

Finally, as noted in section 6 above we have estimated an EIC for chloride of 6ppm. A review of ecotoxicology data on chloride ion indicate that the most sensitive species based on LC_{50}s and EC_{50}s is Cladoceron with an EC_{50} of 735 mg/L (735 ppm).[39] Thus, the EIC is over two orders of magnitude below the lowest measure of aquatic toxicity.

9. Use of Resources and Energy

The use of the FCS will not require additional energy resources for treatment and disposal of waste solution, as the wastewater system already is designed to treat the substances produced from the intended use of the FCS. The raw materials that are used in production of the mixture are commercially-manufactured materials that are produced for use in a variety of chemical reactions and production processes. Energy used specifically for the production of the mixture components is not significant.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the dilutions of antimicrobial product. Therefore, the mixture is not reasonably expected to result in any new environmental issues that require mitigation measures of any kind.

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[36] Ibid.
[37] http://www.who.int/water_sanitation_health/dwq/chemicals/monochloroaceticacid.pdf
[38] http://www.inchem.org/documents/sids/sids/76039.pdf
[39] Siegel, Lori; Hazard Identification for Human and Ecological Effects of Sodium Chloride Road Salt (6 July, 2007), State of New Hampshire, Department of Environmental services Table 4 (pp. 8-9).

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. If the proposed action is not approved, the result would be the continued use of the currently marketed antimicrobial agents that the subject FCS would replace. Such action would have no environmental impact. The addition of hypochlorous acid to the options available to food processers is not expected to increase the use of antimicrobial products.

12. List of Preparers

Dr. Scott Hartnett, IET, Inc. DBA Ecolox, 4770 Biscayne Blvd, Ph B, Miami, FL 33137.

Dr. Hartnett holds a Doctorate of Osteopathic Medicine from Nova Southeastern University. For the past year, Dr. Hartnett has been researching the application of electrolyzed water as an effective all natural disinfectant for the food industry.

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Ms. Attwood has six years of experience preparing environmental submissions to FDA for the use of peroxyacetic acid antimicrobials.

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Dr. Cheeseman holds a Ph.D. in Chemistry from the University of Florida. Dr. Cheeseman served for 18 months as a NEPA reviewer in FDA's food additive program. He has participated in FDA's NEPA review of nearly 800 food additive and food contact substance authorizations and he supervised NEPA review for FDA's Center for Food Safety and Applied Nutrition for five and a half years from 2006 to 2011 including oversight of FDA's initial NEPA review for the regulations implementing the Food Safety Modernization Act.

13. Certification

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

Date: August 22, 2017

[redacted]

Mitchell Cheeseman, PhD

14. References

ChemIDplus. Hypochlorous acid. U.S. National Library of Medicine. Accessed June 12, 2016. Available at: http://chem.sis.nlm.nih.gov/chemidplus/.

Division of Pollution Prevention and Environmental Assistance and Division of Water Resources of the North Carolina Department of Environment and Natural Resources, and Land-of-Sky Regional Council (NC DENR). (1998, August). *Water Efficiency Manual for Commercial, Industrial, and Institutional Facilities*. Available at http://www.allianceforwaterefficiency.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=1016.

Hazardous Substances Data Bank (HSDB). (Extracts attached) Available at: https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm

Musgrove, M.T., et al. (2006). *Antimicrobial Resistance in Salmonella and Escherichia coli Isolated from Commercial Shell Eggs*, Poultry Science, 85: 1665-1669. Available at http://naldc.nal.usda.gov/naldc/download.xhtml?id=3896&content=PDF.

J. K. Northcutt and D. R. Jones: A Survey of Water Use and Common Industry Practices in Commercial Broiler Processing Facilities; 2004 Journal of Applied Poultry Research; available at http://naldc.nal.usda.gov/download/38935/PDF .

Northcutt, J.K., Musgrove, M.T., and Jones, D.R. (2005). *Chemical Analyses of Commercial Shell Egg Wash Water*, Journal of Applied Poultry Research, 14: 289-295. Available at http://naldc.nal.usda.gov/download/38830/PDF.

Siegel, Lori; Hazard Identification for Human and Ecological Effects of Sodium Chloride Road Salt (6 July, 2007), State of New Hampshire, Department of Environmental Services; Table 4 (pp. 8-9).

Tay, J-H., Show, K-Y., and Hung, Y-T. (2006). *Seafood Processing Wastewater Treatment*, in Wang, L.K. et al. eds., *Waste Treatment in the Food Processing Industry*.

U.S. Environmental Protection Agency. (2015). *National Recommended Water Quality Criteria – Aquatic Life Criteria Table*. Accessed June 12, 2016. Available at https://www.epa.gov/wqc/national-recommended-water-quality-criteria-aquatic-life-criteria-table.

U.S. Environmental Protection Agency. (2010). *Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Chlorine Registration Review Decision Document*, Case No. 4022, EPA Docket No. EPA-HQ-OPP-2010-0242.

U.S. Environmental Protection Agency. (2006a). *Chlorine Dioxide: Environmental Hazard and Risk Assessment Case 4023*. EPA Docket No. EPA-HQ-2006-0328.

U.S. Environmental Protection Agency. (2006b). *Reregistration Eligibility Decision (RED) for Inorganic Chlorates.* Washington, D.C.: Office of Prevention, Pesticides and Toxic Substances, EPA 738-R-06-014. https://archive.epa.gov/pesticides/reregistration/web/pdf/inorganicchlorates_red.pdf.

U.S. Environmental Protection Agency. (2006c*). Environmental Fate and Ecological Risk Assessment for the Reregistration of Sodium Chlorate as an Active Ingredient in Terrestrial Food/Feed and Non-food/Non-feed Uses*. Reregistration Case Number 4049, Docket No. EPA-HQ-OPP-2005-0507.

U.S. Environmental Protection Agency. (2004, September 8). *Technical Development Document for the Final Effluent Limitations Guidelines and Standards for the Meat and Poultry Products Point Source Category (40 CFR 432)*, EPA-821R-04-011. Available at http://water.epa.gov/scitech/wastetech/guide/mpp/upload/2008_07_15_guide_mpp_final_tdd06.pdf.

U.S. Environmental Protection Agency. (2000). *Wastewater Technology Fact Sheet: Dechlorination*. Washington, D.C.: Office of Water, EPA 832-F-00-022. Available at https://www3.epa.gov/npdes/pubs/dechlorination.pdf.

U.S. Environmental Protection Agency. (1999). *Registration Eligibility Decision (RED) for Chlorine Gas*. Washington, D.C.: Office of Prevention, Pesticides and Toxic Substances, EPA 738-R-99-001. Available at: http://archive.epa.gov/pesticides/reregistration/web/pdf/4022red.pdf.

U.S. Environmental Protection Agency Science Advisory Board (SAB). (2007, September 7). *Review of the Estimation Programs Interface Suite (EPI Suite™).* Available at https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/CCF982BA9F9CFCFA8525735200739805/$File/sab-07-011.pdf.

U.S. Food and Drug Administration. (2008, February). *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, February 2008. Available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm#ch4.

Versar. (2007). Exposure and Fate Assessment Screening Tool (E-FAST) Version 2.0. Documentation Manual. Available at: https://www.epa.gov/sites/production/files/2015-04/documents/efast2man.pdf.

15. Attachments