

Environmental Assessment

1. Date	December 29, 2021
2. Name of Applicant	Bioionix Inc.
3. Address	Agent for Notifier Mitchell Cheeseman, Ph.D. Decernis 1250 Connecticut Ave. NW Suite 200 Washington, DC 20036

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 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 and preformed meat and poultry; fish and seafood; fruits and vegetables; plant-derived protein products used as meat replacements (such as meatless burger, sausage, and bacon, etc); shell eggs; and cheese, where the FCS is limited to a concentration of 6 ppm in cheese salt brining processes as follows:

- (1) in 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) in process water, ice, or brine used for washing, rinsing, or cooling of processed and preformed meat and poultry defined in 21 CFR 170.4(n)(29) and 21 CFR 170.3(n)(34), respectively.
- (3) in process water or ice for washing, rinsing, or cooling fruits and vegetables;
- (4) in process water or ice for washing, rinsing or cooling whole or cut fish and seafood;
- (5) in process water for washing, rinsing or cooling plant-based proteins used as meat substitutes (such as meatless burger, sausage, bacon, etc.);
- (6) in process water for washing, rinsing, or cooling cheese and in brine for producing cheese; and
- (7) in 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 in 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. Location of Use/Disposal

The antimicrobial agent is intended for use in fruit and vegetable, fish and seafood, meat, poultry, cheese, plant-based protein, 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 publicly 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 for facilities who 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. Wastewater from fishing vessels is expected to be disposed in the ocean in accordance with regional fisheries rules and regulations (i.e., the Maritime Protection, Research and Sanctuaries Act (MPRSA) or International Maritime Organization (IMO) recommendations).

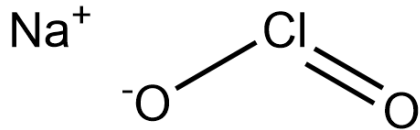
5. Identification of Substances that are Subject of Proposed Action

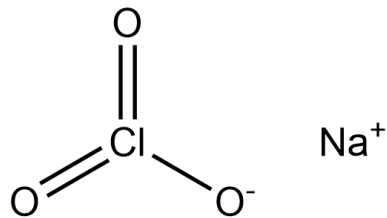
Bioionix’s hypochlorous acid solution will be generated at up to 60 ppm of free available chlorine (FAC) and at the pH of a weak acid. Relative proportions of the active chlorine species are determined by the pH of the solutions.

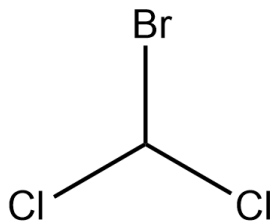
The identities are provided for the residual chemicals that may be generated in the final solution, including degradation of oxychlorine species (chlorate and chlorite) and trihalomethane (THM) formation by-products (bromodichloromethane, chlorodibromomethane, bromoform, and chloroform).

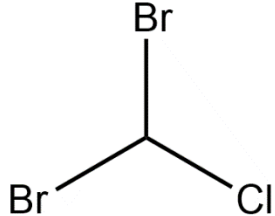
Table 1: Chemical Identity of Substances of the Proposed Action

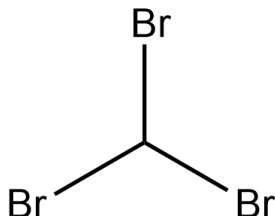
<i>Parameter</i>	<i>Specification</i>
CAS Name:	Hypochlorous Acid
CAS Registry Number:	7790-92-3
Formula:	HOCl
Structure:	HO — Cl
Molecular weight:	52.46 g/mol
Water solubility:	Soluble
Comment:	The primary active species in solution. Present at not more than 60 ppm.

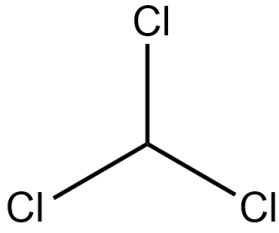
CAS Name:	Chlorite
CAS Registry Number:	7758-19-2 (Sodium chlorite)
Formula:	ClO_2^- (NaClO_2)
Structure:	
Molecular weight:	90.44 g/mol (NaClO_2)
Water solubility:	Soluble
Comment:	By-product from Ultra-Lyte® hypochlorous acid solution

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 Ultra-Lyte® hypochlorous acid solution, mineralized 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-product formed in final solution

CAS Name:	Chlorodibromomethane
CAS Registry Number:	124-48-1
Formula:	CHBr ₂ Cl
Structure:	
Molecular weight:	208.28 g/mol
Water solubility:	Soluble
Comment:	By-product 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-product 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-product formed in final solution

6. Introduction of Substances into the Environment

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

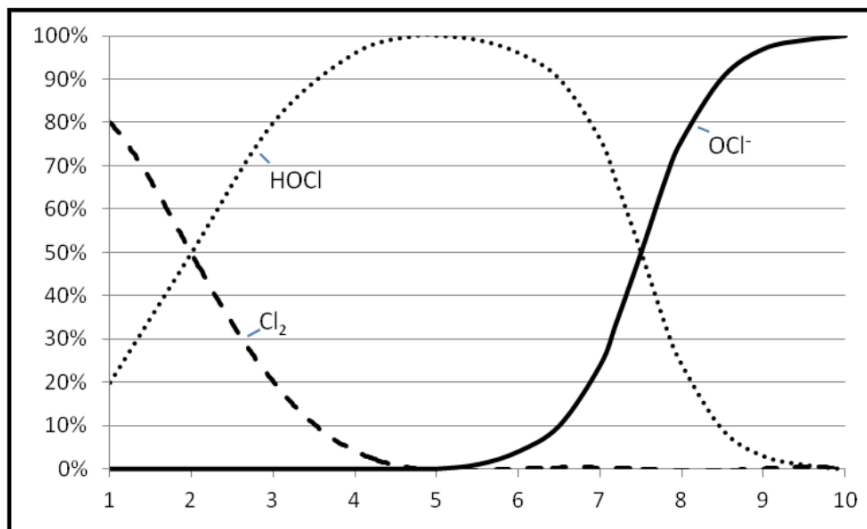
Under 21 C.F.R. § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. The FCS is manufactured in plants which meet all applicable federal, state and local environmental regulations. The notifier asserts 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 the 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 products 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 the use of the product as an antimicrobial agent in processing water for the foods identified above, and the subsequent disposal of such water 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. To be conservative, 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 controlled pH environment in the range of 3.4 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 the surface waters. Because the pH of the Bioionix hypochlorous acid 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 Bioionix'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 pHs between 5 and 7 the predominant reactions will be:

1. $2\text{HClO} \rightarrow 2\text{HCl} + \text{O}_2$
2. $3\text{NaClO} \rightarrow \text{NaClO}_3 + 2\text{NaCl}$ ²

The second reaction will be favored at higher pHs but both reactions will tend to decrease overall by pH increasing H⁺ concentrations through production of HCl or through dissociation of HOCl to form OCl⁻ to maintain 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,

¹ European Union Risk Assessment Report, *Sodium Hypochlorite Final Report*, November 2007, pg. 29, <https://echa.europa.eu/documents/10162/330fee6d-3220-4db1-add3-3df9bbc2e5e5>.

² Ibid.

we note that only one chlorate ion is produced for every three hypochlorite ions in reaction to above. Finally, the chlorate ion is expected to be a strong oxidizer and to react with organic matter and/or metal ions in water to produce chlorite ions and ultimately chloride ions.^{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 dichlorination 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 Systems (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 the process 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. 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 poultry processing waste and removed soil.

ii. Meat Processing

³ Environmental Protection Agency, *Product Chemistry, Environmental Fate, and Ecological Effects Scoping Document of Registration Review of Sodium and Calcium Hypochlorite Salts* (March 22, 2012), pg. 6, available at: [Regulations.gov - Supporting & Related Material Document](https://www.epa.gov/regulations-supporting-related-material-document)

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, pg. 11, https://archive.epa.gov/pesticides/reregistration/web/pdf/inorganicchlorates_red.pdf.

⁶ Ibid EPA 2000, 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-life-criteria-table>.

⁸ 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: <https://www.semanticscholar.org/paper/A-Survey-of-Water-Use-and-Common-Industry-Practices-Northcutt-Jones/29bd184cbe5f2ff4f465d05fd47592b265f2c4f8>.

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 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).⁹

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.¹⁰ 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 facility) would be expected to include significant amounts of organic matter including meat processing waste and removed soil.

iii. Fruit and Vegetable Processing

Water is used extensively in almost all aspects of processing fruits and vegetables, including during cooling, washing and conveying produce (FDA 2008).¹¹ 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 fruits and vegetable processing water and the subsequent disposal of water. Water is used in produce processing, in both commercial and retail settings, for a variety of applications that will not utilize the FCS, to include blanching, filling, cleaning and sanitizing the 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 facility) would be expected to include significant amounts of organic matter including produce processing waste and removed soil.

iv. Fish and Seafood Processing

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).¹² There are also a number of

⁹ 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-821-R-04-011. Available at: https://epa.gov/sites/production/files/2015-11/documents/meat-poultry-products_tdd_2004_0.pdf.

¹⁰ Wang, L.K. et al. eds., *Waste Treatment in the Food Processing Industry*, 2006, 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).

¹¹ 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: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-cut-fruits-and-vegetables>.

¹² Tay, J.H., Show, K.Y. (2006). *Seafood Processing Wastewater Treatment*, in Wang, L.K. et al. eds., *Waste Treatment in the Food Recovery Industry*.

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 the use aboard fishing vessels during the initial evisceration and cleaning of fresh-caught seafood. The wastewater from such a use will be discharged directly into the 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 ready to eat (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 and poultry processing waste, and soil.

vi. Cheese Processing

The FCS is intended for use as an antimicrobial in the treatment of brining solution used in cheese production. Because there are many different types of cheese produced using a variety of methods, it is difficult to establish water usage levels. Cheese whey wastewater (CWW) is highly variable due to raw milk used, the fraction of non-valorized cheese whey and the amount of cleaning water used. CWW generation is roughly four times the volume of processed milk.¹³ 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. Effluent for such facilities going to on-site treatment facilities (or any other treatment facility) would be expected to include significant amounts of organic matter, including whey.

vii. Plant-based Protein Processing

Plant based processing would be largely similar to fruit and vegetable processing in terms of environmental entry. Introduction of the components of the product into the environment will result from use of the product as an antimicrobial agent in the processing and rinse water and the subsequent disposal of water. Water is used in plant protein processing for a variety of applications that will not utilize the FCS, including, cleaning and sanitizing the plant equipment and facilities resulting in significant dilution of the FCS into the total water effluent. Effluent for such facilities going to on-site treatment facilities would be expected to include significant amounts of organic matter including plant protein processing waste. Treatment will only be done in a commercial setting where onsite effluent treatment would be expected.

viii. Shell Egg Wash

¹³ Carvalho, F., Prazeres, A., Rivas, J, *Cheese whey wastewater: Characterization and treatment*, Science of The Total Environment, 15 February 2013, pages 385-396. Available at: [Cheese whey wastewater: Characterization and treatment - ScienceDirect](#)

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 use are difficult to compare, with reported values including 4.4 gal/min (16.6 L/min) of fresh water during washing, 2.8 gal/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 a typical shell egg processing plant. 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 with potable water and approved cleaning compounds.¹⁶ This wash water must be changed at least every four hours, 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 other treatment facilities) would be expected to include significant amounts of organic matter including removed soil.

ix. 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 be included in the wastewater for nearly all the above processes, and soil will be present 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., $\text{Fe}^{+2} \rightarrow \text{Fe}^{+3}$). The European 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 reaction among hypochlorites, hypochlorous acid, other oxychloro compounds, and organic matter including food, soil and other oxidizable matter, the EU 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.

¹⁴ Northcutt, J.K., Musgrove, M.T., and Jones, D.R. (2005). *Chemical Analysis 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 [2019-20123.pdf \(govinfo.gov\)](http://www.gpo.gov/dp/d19-20123.pdf)

¹⁶ 7 C.F.R. § 56.76(f).

¹⁷ *Ibid.*

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://handle.nal.usda.gov/10113/3896>.

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. Cit. EU Appendix 2

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 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, trichloroacetic acid and other haloacetic acids as $60 \text{ ppm} \times 1.5\% = 900 \text{ ppb}$. 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 after treatment.²⁷ Thus, we estimate the concentrations of trihalomethanes, trichloroacetic acid and other chloroacetic acids prior to treatment to be not 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. EECs for compounds for the aqueous compartment are: 4×10^{-27} ppb for HOCl, ClO₂⁻ and ClO₃⁻; 1×10^{-10} ppb for chloramines; 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, incorporating only the 10% reduction for dilution in surface waters.

7. Fate of Emitted Substances in the Environment

Atmospheric Compartment

According to the 2007 European study on sodium hypochlorite solutions, the hypochlorite solutions are non-volatile. However, depending on the pH of the solution, different chlorine species may be present.²⁸ However, the information on the relative abundances of species and information on the volatility of those species only very low concentrations of any species will be available in the atmospheric compartment, and so effect assessment is not applicable in this case.²⁹ In addition, the atmospheric compartment was determined to be of no risk concern for exposure to other halogenated byproducts, such as haloacetic acids and trihalomethanes.³⁰

Aquatic Compartment

²⁵ Ibid pg. 52.

²⁶ Ibid.

²⁷ Ibid. pg. 53-54.

²⁸ European Union Risk Assessment Report, *Sodium Hypochlorite Final Report*, November 2007, pg. 74. Available at: <https://echa.europa.eu/documents/10162/330fee6d-3220-4db1-add3-3df9bbc2e5e5>.

²⁹ Ibid. pg. 102.

³⁰ Ibid. pg. 116.

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 free chlorine species. Decomposition of free chlorine species depends on several factors such as pH, concentration, nature of inorganic or organic matter in the 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).³¹ There is no evidence that active chlorine species accumulate in sediment (U.S. EPA, 1999). Oxychlorine species are strong oxidizers and readily react with organic compounds. Chlorate does not bind readily to soil or sediment particulates and is expected to be very mobile and partition predominately into the water (EPA, 2006a)³². However, extensive redox reactions are expected to occur in the environment, which would serve to reduce the concentration of chlorate in surface water (EPA 2006b). Oxychlorine species have low bioaccumulation potential, high mobility, and low volatility. They do not readily biodegrade under aerobic conditions (EPA, 2006b³³ and 2006a). Upon reaching surface water, the THMs are expected to transition out of the aquatic environment with hours to days³⁴ (HSDB, 2009c-e; HSDB 2006).

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

8. Environmental Effects of Released Substances

In addition to the information listed in the table in section 11 of this EA, the EU risk assessment model (discussed in Section 6, subsection vii of this EA) predicts the environmental impact concentration (EIC) of sodium hypochlorite will decay to less than 4×10^{-27} ppb active chlorine in approximately 9 hours. This EIC includes all breakdown products, including hypochlorite, chlorate and chlorite. Aquatic toxicity is summarized in the following tables:

³¹ 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>.

³² U.S. Environmental Protection Agency. (2006a) *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.

³³ U.S. Environmental Protection Agency. (2006a) *Chlorine Dioxide: Environmental Hazard and Risk Assessment Case 4023*. EPA Docket No. EPA-HQ-OPP-2006-0328.

³⁴ See attached extracts from the Hazardous Substance Database regarding environmental fate information for Bromoform, Chloroform, Bromodichloromethane and Chlorodibromomethane.

³⁵ Op cite EPA 2006b, see p. 5-11

Table 2. Environmental Toxicity for Chlorine Species

Aquatic Species	Chemical Species	Acute LC50 or EC50 (mg/L)	Source
Freshwater Fish	Chlorite	50.6 – 420	U.S. EPA, 2006a ³⁵
	Chlorate	> 1,000	U.S. EPA, 2006c ³⁶
	Chlorine (FAC)	0.045 – 0.71	U.S. EPA, 2010 ³⁷
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
	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

In Table 2, the most sensitive value for environmental toxicity for oxychloro species is that for freshwater invertebrates at 17 µg/L. The EIC based on the EU risk assessment is 4×10^{-27} µg/L for HOCl, OCl⁻, ClO₂⁻ and ClO₃⁻. Thus, the EIC for oxychlorospecies is more than 25 orders of magnitude lower than the EIC.

³⁶ 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 Users*. Reregistration Case Number 4049, Docket No. EPA-HQ-OPP-2005-0507.

³⁷ 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.

³⁸ See attached HSDB extracts for each THM.

Table 3. Environmental Toxicity for THM Species³⁸

Aquatic Species	Chemical Species	Acute LC50 or EC50 (mg/L) ^a	Source
Freshwater fish	Bromodichloromethane	--	HSDB, 2009c
	Chlorodibromomethane	53 – 250 ^b	HSDB, 2006
	Bromoform	29	HSDB, 2009d
	Chloroform	0.185 ^b – 133	HSDB, 2009e
Freshwater invertebrates	Bromodichloromethane	--	HSDB, 2009c
	Chlorodibromomethane	--	HSDB, 2006
	Bromoform	46 – 56 ^b	HSDB, 2009d
	Chloroform	29 – 353	HSDB, 2009e
Estuarine/marine fish	Bromodichloromethane	--	HSDB, 2009c
	Chlorodibromomethane	--	HSDB, 2006
	Bromoform	7.1 – 29	HSDB, 2009d
	Chloroform	--	HSDB, 2009e
Estuarine/marine invertebrates	Bromodichloromethane	--	HSDB, 2009c
	Chlorodibromomethane	--	HSDB, 2006
	Bromoform	1.0 – 24.4	HSDB, 2009d
	Chloroform	81.5	HSDB, 2009e
Aquatic plants	Bromodichloromethane	--	HSDB, 2009c
	Chlorodibromomethane	--	HSDB, 2006
	Bromoform	--	HSDB, 2009d
	Chloroform	437 – 950	HSDB, 2009e

^a “—” No data was listed

^b Non-standard test duration

The volatility of halomethanes will mean that most will evaporate from surface waters in a matter of hours.³⁹ In Table 3, the most sensitive value for environmental toxicity for THM species is that for freshwater fish at 185 µg/L. The EIC estimated above of 8.6 µg/L is well below the most sensitive endpoint 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 LC₅₀ of 0.016 mg/L. It is expected that the chloramines will be reduced so that the EIC will be no more than 1 x 10⁻¹⁰ ppb (µg/L). Thus, the EIC is over 11 orders of magnitude below the lowest L₅₀.

Monochloroacetic 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

³⁹ Ibid.

3.6 µg/L.⁴⁰ In addition, OECD SIDS has assessed the environmental safety of trichloroacetic acid.⁴¹ OECD SIDS identified the alga *Chlorella pyrenoidosa* as the most sensitive species with a NOEC of 10 µg/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 6 ppm. A review of the ecotoxicology data on chloride ion indicates that the most sensitive species based on LC50 and EC50 is *Cladoceron* with an EC50 of 735 ppm (mg/L).⁴²

The lowest endpoint is 17 ppb (Chlorine-FAC, *Daphnia magna*, LC₅₀). The EIC of 4x10⁻²⁷ ppb is far below this endpoint. The concentration of chloride will be reduced to 6 ppm when discharged into the environment. This concentration is much lower than the endpoint of the most sensitive species (735 ppm, *Cladoceron sp.*, EC50). According to the calculations, any chloramines produced during the process will decay to 1x10⁻¹⁰ ppb, well below the lowest endotoxicity endpoint of 0.016 ppm (*Daphnia magna*, LC₅₀).

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 by-products generated 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 expected to be significant.

10. Mitigation Measures

As discussed above, no significant adverse environmental effects are identified herein that would require mitigation in this Food Contact Notification.

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 anticipated significant environmental impact. The addition of hypochlorous acid to the options available to food processors is not expected to increase the use of antimicrobial products.

In summary, the food contact substance and all of its reaction and breakdown products will ultimately be reduced to chloride at a concentration of 6.0 ppm after a 10% reduction for dilution in surface waters. In addition, the EIC of the total organohalogens was calculated to be 900 ppb. The EIC and EEC of the individual organohalogens can be seen in the table below.

⁴⁰ World Health Organization, *Monochloroacetic Acid in Drinking-water, Background Document for development of WHO Guidelines for Drinking-water Quality* (2004). Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/monochloroaceticacid.pdf.

⁴¹ See Attachment: EAReference_OECD_trichloroacetic acid.pdf

⁴² 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).

Organohalogen	% of total Organohalogen	EIC Calculation (ppb)	EEC (ppb)
Trihalomethanes	9.6	0.096 x 900 ppb = 86.4	8.64
Trichloroacetic acid	3.5	0.035 x 900 ppb = 31.4	3.14
Other trichloroacetic acids	4.0	0.040 x 900 ppb = 36.0	3.60

EEC = EIC / 10 for dilution factor after release to surface water

12. List of Preparers

Mr. Matthew Parker, Decernis, 1250 Connecticut Avenue, NW, Washington, DC 20036

Mr. Parker holds a BS in Chemistry from Ball State University. Mr. Parker has thirteen years of experience as a regulatory affairs manager for food contact packaging. Specifically, in the plastic closures and bottles markets.


Dr. Mitchell Cheeseman, Decernis, 1250 Connecticut Avenue, NW, Washington, DC 20036

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 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: December 29, 2021



Mitchell Cheeseman, PhD

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