Attachment 9 - Environmental Assessment

1. Date: August 17, 2006

2. Name of Notifier: JohnsonDiversey, Inc.

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4. Description of Proposed Action:

The action requested in this Food Contact Notification (FCN or Notification) is to establish the clearance of the food contact substance (FCS), chlorine dioxide, that is produced using a certain sodium chlorite-based system (*i.e.*, [redacted] process) for use as an antimicrobial during processing of poultry and fruits and vegetables. The Food and Drug Administration's (FDA) food additive regulations at 21 C.F.R. § 173.300 currently provide for three alternate methods of generation of chlorine dioxide for these uses, and additional methods have been cleared via Notifications to FDA. The JohnsonDiversey [redacted] process provides another means of generating chlorine dioxide for the referenced applications.

The proposed action is needed to provide for an alternate means of generating chlorine dioxide without requiring chlorine gas or the direct mixing of a concentrated acid. The FCS produced using the [redacted] process is to be used as an antimicrobial agent in water used in poultry processing and to wash fruits and vegetables that are not raw agricultural commodities in an amount not to exceed 3 ppm residual chlorine dioxide as determined by methods described in Attachment 3 and in Form 3480, Section II D of this Notification. The [redacted] process produces a concentrated solution that contains at least 600 ppm chlorine dioxide. When used in water to wash fruits and vegetables, treatment of the fruits and vegetables by the FCS shall be followed by a potable water rinse or by blanching, cooking, or canning.

The FCS is intended to be added to process water used in poultry and fruit and vegetable plants throughout the United States. Most of the chlorine dioxide will be consumed by the oxidation of organic matter and microorganisms present in food and/or process water. Consumed chlorine dioxide is reduced to chlorite and chlorate and eventually to chloride. The expected route of disposal for waste process water from these facilities is via discharge to a local Publicly-Owned Treatment Works (POTWs) or to on-site wastewater treatment systems. Accordingly, the use of chlorine dioxide produced with this technology to control microbial growth may result in small amounts of chlorite, chlorate, and chloride being discharged at such sites.

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

The [redacted] system produces chlorine dioxide based on the following general chemical equation:

$$\mathbf{5ClO_2^-(aq.) + 4H^+(aq.) \rightarrow 4ClO_2(aq.) + Cl^-(aq.) + 2H_2O}$$

The process water will contain chlorine dioxide (CASRN 10049-04-4), chlorite ion (CASRN 14998-27-7), chlorate ion (CASRN 14866-68-3), and chloride ion (CASRN 16887-00-6). In addition, sodium ions (CASRN 7440-23-5) will be discharged after regeneration of the columns used in producing the acidified chlorite solution. The maximum concentration of the FCS, its degradates and impurities in the discharge streams are described below.

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 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 as a result of the manufacture of the FCS precursor materials. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. Introduction of substances into the environment as a result of use and disposal:

The FCS, *i.e.*, chlorine dioxide, will be produced on site within a closed system. The potential for releases of chlorine dioxide into environmental media, including air, water and soil, and the corresponding effects have been described in prior Food Additive Petitions and Notifications, which are incorporated by reference. *See, e.g.,* Environmental Assessments for FAP 7A4532, FAP 9A4692, FAP 0A4724, FAP 4A4408, and FCN 450.

Air Releases

Air releases from approved uses of chlorine dioxide are expected to be negligible. Since the production of chlorine dioxide is in a closed system, the only potential air release of chlorine dioxide is by off-gassing from the process water. FDA considered the potential for volatilization of chlorine dioxide when reviewing FAPs 4A4408 and 4A4415. JohnsonDiversey is not proposing to increase the residual chlorine dioxide used in either poultry process water or in fruit and vegetable process water. Therefore, the information in the above referenced FAPs related to air releases is incorporated by reference. Furthermore, the Notifier believes that the [redacted] Process may be used to generate chlorine dioxide at the proposed maximum application rates without exceeding worker exposure limits established by NIOSH (Short Term Exposure Limit (STEL) of 0.3 ppm (0.9 mg/m^3) during any 15-minute period of a 10-hour workday), or by OSHA (Permissible Exposure Limit (PEL) of 0.1 ppm (0.3 mg/m^3 time-weighted average over an 8-hour shift)).[1] The Material Safety Data Sheet (MSDS) for chlorine dioxide identifies potential adverse health effects, exposure limits, and workplace exposure controls. The Notifier understands that an February 4, 1994 Memorandum of Understanding between the U.S. Department of Labor Occupational Safety and Health Administration and the U.S. Department of Agriculture Food Safety and Inspection Service establishes a process and a framework for worker protection.

Water Releases

Wastewater from poultry and fruit and vegetable processing facilities that use the [redacted] Process to generate chlorine dioxide will likely be treated onsite (for certain fruit and vegetable processing facilities) or discharged to a local publicly owned treatment works

[1] *See* http://www.cdc.gov/niosh/npg/npgd0116.html

(POTW). Releases to surface water from a POTW or onsite treatment system would be subject to the terms and conditions of a National Pollution Discharge Elimination System (NPDES) permit. In some instances, discharges from fruit and vegetable processing facilities may be used as irrigation water and applied to land.[2]

Wastewater discharged to a POTW or onsite treatment system may contain chlorite, chlorate and sodium resulting from the use of chlorine dioxide generated with the [redacted] Process. **Table 1 in the Confidential Attachment to this Environmental Assessment** provides a summary of estimated concentrations of these substances in wastewater discharges to POTWs or onsite treatment systems.[3] Importantly, as discussed further below, it is expected that the organic loading of the wastewater streams present in an on-site wastewater treatment facility or POTW would cause any chlorine dioxide, chlorite, and chlorate present in process water discharged to these treatment facilities to undergo reduction to chloride ion. As a result, discharges from these facilities to surface waters or as irrigation water are not expected to contain appreciable levels of the identified substances.

With respect to discharges to POTWs, the contribution from a poultry processing facility or fruit and vegetable processing facility would represent only a portion of the wastewater being processed by the POTW. As a result, the estimated concentrations of chlorate, chlorite, and sodium referenced in **Table 1 in the Confidential Attachment to this Environmental Assessment** would likely be reduced significantly due to dilution. For example, according to an EPA report, the average flow at POTWs that treat between one and ten million gallons of wastewater per day is approximately 3.12 million gallons per day.[4] Thus, as an initial matter, the estimated concentrations of chlorite, chlorate, and sodium would be reduced by at least 50% to 10.9 mg/L, 2.25 mg/L, and 6.45 mg/L, respectively, due to dilution by the other flow into the

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2 *See, e.g.,* Carawan, R. E.; Chambers, J. V.; Zall, R. R. Fruit and Vegetable Water and Wastewater Management, http://www.p2pays.org/ref/05/04874.pdf.

3 *See* Attachment 10 to the Environmental Assessment.

4 *See* Table C-3 in U.S. EPA's Clean Watersheds Needs Survey 2000. http://www.epa.gov/owm/mtb/cwns/index.htm. Total existing flow of 8,328 divided by number of facilities in the specified range of 1 to 10 mgd = 3.12 mgd per facility.

POTW.[5] Furthermore, and of particular importance, prior to discharge from the POTW or onsite treatment facility, the chlorite and chlorate are expected to undergo reduction to chloride.

Due to the high organic loading in wastewater, the oxychlorine species associated with the FCS are expected to undergo reduction to chloride prior to release into the environment. Iron, manganese, and sulfur, which are commonly present in wastewater discharges processed at POTWs, further facilitate the degradation of chlorite and chlorate.[6] Chlorite is also reduced to chloride when exposed to light, with an increase in rate of reduction as the pH of the solution decreases.[7] Gordon *et al.* (1972) stated that 100% of an $HClO_2$ solution decomposed to chloride and oxygen in one hour.

Under anaerobic conditions, as would be present during wastewater treatment, a stoichiometric reduction of chlorate occurs, producing oxygen and chloride.[8] The reduction of chlorite to chloride is enhanced in the presence of ferrous iron (Fe^{2+}), and when Fe^{2+} is in excess, total reduction may be achieved in minutes.[9] Gordon *et al.* (1990) report that sulfite (SO_3^{-2}) reduced chlorite to chloride in minutes to a few days, depending on the pH and sulfite concentration.[10] Reduced forms of sulfur compounds, such as sulfite, are present under anoxic conditions (*e.g.*, in wastewater treatment plants using anaerobic digestion or in aquatic sediments). Gordon *et al.* also report that treatment of wastewater or drinking water with sulfur

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5 These estimates are based on the conservative assumption that discharges from the poultry processing facility account for 50% of the wastewater being treated at the POTW. As documented in the Confidential Attachment, for purposes of this Environmental Assessment, we assume that a poultry processing facility consumes approximately 1.75 million gallons of water per day. This is approximately 50% of the 3.12 million gallons per day processed by POTW. See Footnote 4 above.

6 For a discussion of the presence of these substances, see *Use of Reclaimed Water and Sludge in Food Crop Production Committee on the Use of Treated Municipal Wastewater Effluents and Sludge in the Production of Crops for Human Consumption*, Water Science and Technology Board, Commission on Geosciences, Environment, and Resources, National Research Council 1996, National Academy Press, Washington, D.C. http://www.epa.gov/owm/pipes/sludmis/mstr-ch2.pdf.

7 Gordon, G., Kieffer, R.G., and Rosenblatt, D.H., The chemistry of chlorine dioxide. *In* Progress in Inorganic Chemistry, Vol. 15 (1972), p. 224-225. S.J. Lippard (ed.). Wiley-Interscience, New York, NY.

8 Van Ginkel, C.G., C.M. Plugge and C.A. Stroo., Reduction of chlorate with various energy substrates and inocula under anaerobic conditions. Chemosphere, 31(9) (1995), p. 4057-4066.

9 *See* http://www.cdc.gov/niosh/npg/npgd0116.html.

10 Gordon, *et al.*, Minimizing chlorite ion and chlorate ion in water treated with chlorine dioxide. Research and Technology: Journal of the American Water Works Association. April, 1990, p. 160-165.

dioxide-sulfite ion removes up to 99 percent of chlorite ion in 0.34 minutes at pH 5.0 and within 15.6 minutes at pH 7.5.[11] Griese (1991) reported that sodium thiosulfate and ferrous chloride achieve greater than 80% reduction of chlorite within 60 minutes.[12] Two commonly used chemicals to aid flocculation of suspended solids in wastewater treatment are ferrous chloride ($FeCl_2$) and ferrous sulfate ($FeSO_4 \cdot 7H_2O$).[13]

Chlorate undergoes biological reduction to chloride under anaerobic conditions by denitrifying microorganisms.[14] During anaerobic digestion of wastewater, populations of denitrifying microorganisms are deliberately enhanced in order to prevent the release of nitrates into the environment. As nitrate is depleted as an electron acceptor, chlorate will be reduced to chloride. According to the ATSDR's *Toxicological Profile for Chlorine Dioxide and Chlorite*, "the rate of chlorate ion degradation appears to be rapid under anaerobic conditions in wastewater treatment facilities."[15]

Based on the above information, it is not expected that chlorite or chlorate will persist in discharges from POTWs or onsite treatment facilities, but will be reduced to chloride through chemical degradation, reaction with microbes, and photolysis. Although no specific data are available for solutions generated with the [redacted] Process, for purposes of this Environmental Assessment, we assume that one percent of the chlorite that is predicted to be discharged from poultry and fruit and vegetable processing facilities using the [redacted] Process will pass through the POTW or onsite treatment works.[16] This corresponds to the following discharge concentrations:

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11 *Id.*

12 Griese, *et al.*, Using reducing agents to eliminate chlorine dioxide and chlorite ion residuals in drinking water. Research and Technology: Journal of the AWWA. September, 1991, p. 107-113.

13 Wastewater Engineering: Treatment, Disposal, and Reuse. Third Edition, p. 488. Metcalf and Eddy, Inc. Tchobanoglous and Burton (ed.), McGraw-Hill, Inc. 1991.

14 van Ginkel, C.G., Plugge, C.M. and Stroo, C.A., Reduction of chlorate with various energy substrates and inocula under anaerobic conditions. Chemosphere, 31 (9) (1995), p. 4057-4066.

15 ATSDR Toxicological Profile for Chlorine Dioxide and Chlorite, September 2004, p. 94.

16 As the wealth of scientific literature regarding the degradation of chlorite in such systems suggests that the chlorite will completely degrade to chloride, we believe that this is a reasonable assumption. With respect to chlorate, we note that the estimated discharge concentrations are well below any toxicity endpoints without accounting for such reduction.

Source of WW Discharges	*Assumption*	**Chlorite (ClO_2^-)**	**Chlorate (ClO_3^-)**	**Sodium (Na^+)**
Poultry Processing	Prior to POTW	21.7 mg/L	4.5 mg/L	12.9 mg/L
	POTW dilution	10.9 mg/L	2.3 mg/L	6.5 mg/L
	Degradation	0.1 mg/L	0.02 mg/L	6.5 mg/L (none assumed)
Fruit & Vegetable Processing	Prior to POTW	3.7 mg/L	0.8 mg/L	2.2 mg/L
	POTW dilution	1.9 mg/L	0.4 mg/L	1.1 mg/L
	Degradation	0.02 mg/L	0.004 mg/L	1.1 mg/L (none assumed)

Soil Releases

Use of fruit and vegetable process water for irrigation of crops is employed as a method of final treatment to remove excess organic material and nutrients (notably nitrogen), and as a beneficial recycling of a scarce resource. Fruit and vegetable processors may dispose of up to 100% of the process water by irrigation, once primary onsite treatment is completed. The volume of water used for irrigation on a daily basis, and number of acres on which it is applied are quite variable, depending on the soil texture, depth to groundwater, crops grown, and climate. However, groundwater protection regulations do not permit a processor to apply more nutrients to irrigated crop than they are capable of using during the growing season.[17]

7. Fate of Emitted Substances in the Environment

As noted above, chlorine dioxide is reduced primarily to chlorite and chloride, with the introduction of low levels of chlorate during generation of the FCS. Both chlorite and chlorate are further reduced to chloride.

With respect to air releases, chlorine dioxide in air will undergo rapid photochemical decomposition. As a result, while air releases from the approved uses of chlorine dioxide are expected to be negligible, even if a small amount of chlorine dioxide were to volatilize out of solution, it would decompose and dissipate rapidly.

[17] *See, e.g.,* http://www.swrcb.ca.gov/rwqcb5/available_documents/waste_to_land/FoodProcessingInfoItem/

With respect to water releases, any chlorite or chlorate that survives the POTW or onsite treatment processes is expected to undergo substantial degradation to chloride in the environment. In particular, as noted elsewhere in this Environmental Assessment and as discussed in FCN 450, reactions of chlorite with inorganic and organic compounds are well documented. We note that no adsorption/desorption constants have been reported for chlorite or chlorate, but these ions are mobile and can travel from surface to groundwater.[18] However, chlorite ions will undergo oxidation-reduction reactions with components in soils, suspended particles, and sediments containing ions such as Fe^{2+} and Mn^{2+} and S^{-2}.[19] Thus, the concentration of any chlorite will be reduced.

To account for the expected reduction in the environment (including dilution in the receiving water body), an additional environmental dilution factor of 10 is applied to the expected concentrations of substances introduced into the environment (EICs) that are shown in Item 6, above. This results in an expected environmental concentrations (EEC) of 0.01 mg/L Chlorite for discharges from poultry processing facility and 0.002 mg/L Chlorate. Sodium is not expected to degrade during primary or secondary wastewater treatment. It may be removed partially during flocculation and filtration processes. Sodium is soluble in water, however, and a portion is expected to be discharged into the receiving waters. The U.S. EPA has established a drinking water equivalency level of 20 mg/L for sodium.[20] The U.S. Geological Survey reports widely variable concentrations for sodium in ground water and drinking water, ranging from a few parts per million to over 100 ppm. Based on this information, it is unlikely that the addition of sodium, from sodium discharge during column regeneration, would result in adverse effects on the environment.

With respect to soil releases, it is not expected that irrigation water would be applied at rates that result in significant or frequent introduction of process water into natural bodies of water by runoff, as the intent is to maximize an available resource. Chlorite in the process water is expected to undergo decomposition upon exposure to sunlight, forming oxygen and chloride ion. Chlorite also would undergo degradation in soil due to the presence of organic matter and certain inorganic material. Chlorate is stable under aerobic conditions, but will be reduced to

18 ATSDR Toxicological Profile for Chlorine Dioxide and Chlorite, September 2004, p. 89.

19 *Id.*

20 http://www.epa.gov/ogwdw000/ccl/sodium.html.

chloride in anaerobic sediments. Therefore, neither degradate of chlorine dioxide is expected to persist in the environment and accumulate in soil or in the irrigated crops. Furthermore, the USDA recognizes chlorine dioxide as a disinfectant with potential to treat large quantities or irrigation water without damaging plants.[21] The predicted environmental exposure concentrations would be well below the most conservative end point for avian species (see table in Item 8 below).

8. Environmental Effects of Released Substances

The U.S. Environmental Protection Agency recently released its draft environmental risk assessment for chlorine dioxide and chlorite, and for sodium chlorate. In these drafts, the following endpoints for aquatic and terrestrial toxicity were summarized.

Organism	Test	ClO_2^-	ClO_3^-
Bluegill sunfish	LC_{50}	244-420 ppm	> 1000 ppm
Rainbow trout	LC_{50}	203-360 ppm	> 1000 ppm
Daphnia magna	EC_{50} (48 hr.)	27 - 390 ppb	920 ppm
Mysid shrimp	EC_{50} (96 hr.)	576 ppb	> 1000 ppm
Eastern Oyster	EC_{50} (96 hr.)	21.4 ppm	> 1000 ppm
Sheepshead minnow	EC_{50} (96 hr.)	75 ppm	133 ppm
Aquatic plants (green algae)	EC_{50}	1.32 ppm	133 ppm
Northern bobwhite quail	LC_{50}	> 5000 ppm	> 5000 ppm
Northern bobwhite quail	LD_{50}	390 – 797 mg/kg	No data
Mallard duck	LC_{50}	> 5000 ppm	> 5000 ppm
Mallard duck	LD_{50}	>31 mg/kg	>2510 mg/kg

Based on the low levels of chlorite, chlorate and sodium estimated to be released into the environment, no adverse effects to aquatic organisms, including fish and invertebrates, are anticipated from the proposed use of the FCS. The predicted EECs are below each of the above-listed toxicity endpoints.

21 Copes, W.E., Chastaganer, G.A., Hummel, R.L. 2004. Activity of Chlorine Dioxide in a Solution of Ions and pH Against *Thielariopsis basicola* and *Fusarium oxysporum*.. Plant Disease. 88:188-194.

9. Use of Resources and Energy

The generation of the FCS using the method that is the subject of this Notification will replace existing methods of generation. No appreciable impact on the use of natural resources and energy will occur.

10. Mitigation Measures

No adverse environmental effects are anticipated if this Notification becomes effective; therefore, mitigation measures are not required.

11. Alternatives to Proposed Action

No alternative actions are necessary.

12. List of Preparers

This assessment was prepared by: Ralph A. Simmons, Counsel for Notifier
Elizabeth A. Heger, Staff Scientist
Trent M. Doyle, Associate Counsel

13. Certification

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

Name: Ralph A. Simmons

Title: Counsel for Notifier

Signature:

Date: August 17, 2006

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