Environmental Assessment for ™ Solution in Support of an FCN Regarding the Use of Electrochemically Generated Hypochlorous Acid to Disinfect Water Used to Crisp Vegetables with Draining

1. Date: Revised January 22, 2007

2. Name of Submitter: Sterilox Food Safety/Div.of PuriCore (Sterilox), formerly know as Sterilox Technologies, Inc.

3. Address:

Sterilox Food Safety/Div.of PuriCore
320 King of Prussia Road
Radnor, PA 19087

4. Description of Proposed Action:

a. Requested Action:

This FCN seeks approval for the following process to be used in retail and food service establishments:

- Introduction of 20 gals of a solution at up to 60 ppm available free chlorine (AFC) in a produce sink consistent with the preconditions outlined in the Food Code.
- Place 1 box of leafy greens or other whole uncut produce item in increments of five (5) pound loads into the sink to soak for 5 minutes.
- Remove produce and set aside to drain
- Test solution for AFC and if above 25 ppm charge the sink with another five (5) pounds of produce. If AFC is below 25 ppm, drain the sink and re-fill with fresh solution.
- Continue until all the produce requiring crisping is complete.
- Produce may be used for display or prepared for consumption after 10 minutes of draining.

b. Need for action:

The intended technical effect of eliminating a potable water rinse is to avoid cross contamination of re-crisped product or products. Looking specifically at lettuce re-crisping as an example, if lettuce is re-crisped or rinsed by placing fresh-cut lettuce/leafy

greens in containers with tap water or other water with a low level of chlorine, the chlorine present is quickly inactivated by the organic load presented by the lettuce/leafy greens. This will increase the potential for lettuce/leafy greens cross contamination particularly if additional lettuce/leafy greens are added to the container (Wachtel and Charkowski, 2002, Attachment A).

The ability of chlorine to prevent cross contamination in aqueous baths was illustrated with inoculated cantaloupes and Salmonella (Suslow 2004, Attachment B). This report clearly shows that Salmonella migrated when fruit was soaked in water. By analogy and experience, the treatment of lettuce will not fully disinfect the lettuce. All subsequent treatment of lettuce with water without benefit of chlorine will promote both cross contamination and spread of existing contamination within the head.

c. Locations of use/disposal:

™ lution for re-hydrating fresh produce at retail will generally be used in backroom of the store where produce is prepared. Given that crisping is done in a sink disposal will be through the sanitary sewer. The FCS is not intended for use in large food processing facilities.

5. Identification of substances that are subject to the proposed action:

solution is a hypochlorous solution made from the electrochemical activation of sodium chloride brine. Hypochlorous acid (7790-92-3) is the active component and will generally be present at between 50 and 200ppm depending on the level necessary and the tolerance of the product being treated. However, the specific FCS for FCN No. 692 is specifically limited to a maximum of 60 ppm with a nominal concentration of 50 ppm. Residual sodium chloride (7647-14-5) is also present. It provides chloride that is oxidized to yield the hypochlorous acid.

The formula for hypochlorous acid is HOCl. Its molecular weight is 52.46. Hypochlorous acid is greenish-yellow in solution. It is highly unstable and decomposes to hydrogen chloride and oxygen except in dilute solution. Historically, sodium hypochlorite has been used as a storage form to avoid this instability. solution is generated on site avoiding the need to store or transport a concentrated solution avoiding the some of the particular chemical hazards associated with the use of concentrated sodium hypochlorite.

6. Introduction of substances into the environment:

a. Introduction of substances into the environment as a result of manufacture:

No extraordinary circumstances apply to the generation of ™ olution. It is generated on site in accordance with demand. The generation process releases sodium

hydroxide in a brine solution which is discharged to the sanitary sewer. It also releases hydrogen gas due to the hydrolysis of water in the electrochemical cell. The discharged sodium hydroxide concentration is about 0.3%. A portion of the produced sodium hydroxide is used to moderate the pH of the produced hypochlorous acid. When operating, the unit produces about 7 mg of hydrogen per minute. This value was determined experimentally by water displacement and application of a higher current to produce measurable quantities of hydrogen. These values are coupled with the number of units and other operational data in the confidential business information attach

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

Using solution in the proposed re-hydration procedure introduces the same materials into the environment as the process allowed under 21 CFR 173.315. The released materials include sodium chloride brine, residual available chlorine, and low levels of by-products including chlorate, chlorite, and disinfection by-products that are associated with the use of the various forms of chlorine.

To estimate the potential discharge volumes associated with the proposed process, it is sufficient to have a projected number of units to be installed, a projected usage rate and the measured concentrations of the various components and by-products in the discharge. The calculations require a simple multiplications of the concentrations, the number of 20 gallon cycles per day (See Confidential Business Information), the number of days per year (365) and the projected number of installations (See Confidential Business Information). The calculations and results are reported in Attachment C, Confidential Business Information.

The expected concentrations of the various constituents and by-products have been measured and reported in the various studies and other information associated with this FCN. The discharged brine will be the dominant component besides water at about 0.4% sodium chloride. The brine is made at this concentration by the generator and is very consistent. Only a small portion of the chloride is converted to hypochlorous acid.

The discharged brine solutions will also contain modest levels of free available chlorine depending on the amount of treated produce ranging from essentially zero to 60 ppm if no produce is treated. The average discharge is expected to be less than 10 ppm based on the process guideline of reusing solutions greater than 25 ppm and discharges those solutions which are less than 25 ppm. This residual chlorine can be expected to rapidly react (less than 3 hours) with organic material in the waste stream producing mostly oxygen and chloride. For the minor components and by-products, the chlorite levels will be less than 0.3 ppm. This estimate is based on the detection limit as no chlorite was detected experimentally. The chlorate levels will be less than 2 ppm. And finally, the total trihalomethanes, representative of the disinfection by-products, will be between 20-50 ppb. These discharge concentrations are all based on the chemistry studies previously submitted with the original submission of FCN No. 692 (See Attachments 7, 8, 15 and

19). These concentrations are used to estimate annual discharges which are reported in Attachment C, Confidential Business Information.

Virtually 100% of these materials will enter the waste stream via the sanitary sewer at the retail store.

7. Fate of substances released into the environment:

All of the components of solution and the degradation products are well known and with the exception of the sodium chloride are at levels approximating those found in drinking water. The proposed process does not increase or decrease the discharges from the allowed process.

This said, sodium chloride is exceedingly stable in the environment. It will become part of the total dissolved solids (TDS) in the effluent stream from the wastewater treatment facility. Furthermore, because oxychlorine species (hypochlorous acid, chlorite, chlorate and chlorine dioxide) readily react with the organic matter and microorganisms in water and soil (sediments) and will undergo ultimate degradation into chloride ion, we anticipate that the expected environmental concentrations for these oxychlorine species will be very small and thus will be of no environmental concern. **(**Attachment D**,** Supplement to the Environmental Information for Food Contact Notification No. 450, October 18, 2004, Tong Zhou, Ph.D., Environmental Toxicologist Environmental Review Group Division of Chemistry Research and Environmental Review)

Given that the solutions will be discharged to a sanitary sewer after use where the total stream is generally chlorinated, the discharges from this process will rapidly be lost in these larger pools. Furthermore, when a chlorinated effluent is released into receiving waters, free residual chlorine dissipates rapidly. It has a half-life of 1.3 to 5 hours (Attachment E, EPA RED for Chlorine Gas). The ultimate fate of chlorine-containing effluent is site specific, and depends on factors such as the chemical constituents of the receiving waters, their temperature, the dilution ratio and the intensity of sunlight (Attachment E, EPA RED for Chlorine Gas). The disinfection by-products such as the trihalomethanes are the same materials found in chlorinated drinking water, at levels well within the drinking water standard and will share the same fate as these larger pools of material in the wastewater effluent.

The estimated environmental concentrations from the proposed use for all species will be many orders of magnitude less than the levels discharged to the sewer at the point of use. This estimate can be rationalized by assuming a retail store provides produce for up to 10,000 people (Estimate based on Milpitas, CA with about 70,000 people and 7 retail stores) who each use more than 50 gallons of water per day (See attachment 2 of FCN 692) that will be discharged to the sanitary sewer system. As such the discharge to the environment for the items associated with this proposed process will be almost 4 orders of magnitude less than that generated at the site of use. Alternatively, the discharge in Milpitas is 18.5 million gallon per day (Attachment F, Clean Watershed Need Survey) which is about 5 times greater than the estimate based on population.

8. Environmental effect of released substances:

Given that the effluent of the proposed process will be discharged to the sanitary sewer, the environmental effects of the released substances will be insignificant. EPA has considered the environmental effects of using chlorine and has concluded:

> "In receiving waters from facilities using chlorine, if acute levels of concern are exceeded, a significant risk to aquatic organisms and endangered aquatic organisms can be expected. Levels of concern (equaling one-half of the EC_{50}) are 0.009 ppm for aquatic invertebrates, 0.023 ppm for freshwater fish, and 0.013 ppm for estuarine organisms. Levels of concern for endangered species (equaling one twentieth of the EC_{50}) are 0.85 ppb for aquatic invertebrates, 2.3 ppb for freshwater fish, and 1.3 ppb for estuarine invertebrates.
> Uses of chlorine that are **not** regulated under the NPDES permit program, including swimming pool, aquaria and indoor use patterns (fruit and vegetable rinsing and food processing), should produce only intermittent discharges of minimal concentration into lakes or streams, resulting in minimal environmental exposure." (Attachment G EPA RED Facts Chlorine Gas)

Direct discharge of ™ lution to sensitive waterways needs to be avoided to prevent these potential environmental effects. Given the location and limited volumes involved in this application, such discharges are exceedingly unlikely. With the expected 4 or 5 orders of magnitude of dilution and the short half-life of chlorine, reaching the levels that would prove sensitive to waterways is unlikely.

For chlorite, the potential environmental effects have been extensively reviewed (Attachment H Chlorine Dioxide Final Risk Assessment). This review tabulates numerous environmental endpoints starting in Table 17. These endpoints are greatly in excess of the environmental introductions of chlorite due to the proposed process.

Chlorates and Chlorites were reviewed as part of an FCN for sodium chlorite submitted by Bio-cide International (Attachment I Sodium Chlorite Environmental Assessment). In this document, Ringo as part of the Biocide International Inc FCN submission has reviewed the literature concerning toxicological studies on chlorites and chlorates. He opines that:

- *Numerous researchers have performed a wide variety of testing, including acute toxicity, chronic toxicity, rising dose toxicity and epidemiological studies. A consistent pattern is observed that any toxic effects and alterations in hematological parameters are dose related and that significant changes occur only at chronically administered higher dosages (100 mg/l to 1,000 ml/l) in test animals or humans.*

Furthermore he reviews the literature on the toxicological impact of chlorites and chlorates and reports that:

- *Lubbers et al, conducted an extensive controlled clinical evaluation on the effects of chlorites and chlorates in Man". This double blind study was conducted in three phases: (1st) Rising dose tolerance acute toxicity study; (2nd) Chronic studies at 5 mg/l and (3rd) Administration at 5.0 mg/l to persons with G6PD deficiencies, w, sensitive to oxidant stress. They concluded that no observable undesirable sequellae were noted by participating subjects or by the observing medical team. Any treatment associated trends were judged to be of no physiological consequence.*

- *Bercz, et al , examined the subchronic toxicity of chlorites and chlorates in non-human primates, "Subchronic Toxicity of Chlorine Dioxide and Related Compounds in Drinking Water in the Nonhuman Primate". Concentrations rose from 0 to 400 mg/l over the test period. A rising dose tolerance study was performed by Lubbers, et al., as reported in "Effects of the Acute Rising Dose Administration of Chlorate and Chlorite to Healthy Adult Male Volunteers". The study was undertaken to assess the relative safety and tolerance of the acute administration of chlorites and chlorates to healthy male volunteers. Evaluation of an extensive battery of tests and vital signs showed no adverse physiological effects.*

- *Lubbers and coworkers also examined the effects of chronic administration of chlorites and chlorates on a healthy adult population A daily dose (500 ml, 5.0 ppm) was administered to the volunteers for a twelve week period. An analysis of the qualitative and quantitative parameters of an extensive body of tests showed no clinically important physiological effects.*

- *Harrington; et al., conducted a developmental toxicity study to determine the teratogenic effects of sodium chlorite on rabbits. The study concluded no maternal or fetal effects at 200 ppm of sodium chlorite.*

- *The International Research Agency for Research on Cancer (IARC) has assigned a Class 3 rating to sodium chlorite - "Not Classified As To Its Carcinogenicity To Humans". This is published in Vol. 52 of the IARC series.*

From an environmental impact standpoint, Ringo states that:

- *There was little information found in the literature concerning the potential effects of chlorite and chlorate- on non-mammalian species. However, data was found concerning the toxicity of oxychlorine species to representatives of the Classes Osteichthyes, Aves and Insecta; these are reported below;*

- *The acute toxicity of sodium chlorite to bluegill and rainbow trout was reported in, "Acute Toxicity of Sodium Chlorite to Bluegill (Leponis machrchirus) and*

Rainbow Trout (Salmo gairdneri)". The TL50 for bluegill was determined to be 208 mg/l and to be 50.6 mg/l for rainbow trout.

- *The acute oral LD50 of sodium chlorite to bobwhite quail is reported in," Acute Oral Toxicity Study With Sodium Chlorite in Bobwhite Quail". The reported LD50 of NaClO2 in quail was 660 mg/kg.*

- *Calandra reported the LD50 of sodium chlorite in mallard ducks to be 1000 mdkg in, "Acute Oral Toxicity Study with Sodium Chlorite in Mallard Ducks".*

- *The Pesticide Information Profile on sodium chlorate available from the Extension. Toxicology Network indicates a relatively low mammalian toxicity for sodium chlorite. The possible 48 hour LC50 for sodium chlorite for various fish species was 10,000 mg/l with a verbal description as considered non-toxic to fish. Additionally, sodium chlorate is considered non-toxic to bees (9). The long term toxicity to birds resulted in reduced egg production and fertility*

- *No additional information on the eco-toxicity of sodium chlorate was found in searches of EPA sources such as IRIS documents or pesticide chemical fact sheets.*

The following published studies were referred to by Ringo during this FCN submission.

- *Lubbers, J.R et al. Controlled Clinical Evaluations of Chlorine Dioxide, Chlorite and Chlorate in Man", Environmental Health Perspectives, 46, p. 57, (1 982).*

- *Bencz, J.P.et al. Subchronictoxicity of Chlorine Dioxide and Related Compounds in Drinking Water", Environmental Health Perspectives, 46, p. 47 (1 982).*

- *Lubbers, IR. Effects of the Acute Rising Dose Administration of. Chlorine Dioxide, Chlorate and Chlorite to Normal Healthy Male Adult Volunteers",Journal of Environmental Pathology, Toxicology and Oncology, 5-4/5; p. 21 5*
  (1984).

- *Harrington, et al ,Developmental Toxicity of Sodium Chlorite in the Rabbit", Journal of the American College of Toxicology, 14 (2) p. 108-1 18 (1995).*

- *Romano, R., "IARC Working Group on the Evaluation of Carcinogenic Risks To Human", Volume 52 (June 1990).*

- *Macek, K.1, "Acute Toxicity of Sodium Chlorite to Bluegill (Lepomis macrochirus) and Rainbow Trout (Alma Gairdner)", Report to Olin Water Services, Stamford, CT. (Dec., 1971).*

- *Calandra, J.C., "Acute Oral Toxicity Study With Sodium Chlorite In Bobwhite Quail", Report No. 13 IBT 0 521 19 to O h Corporation, New Haven, CT. (Jan. 9, 1973).*

- *Calandra, lC., "Acute Oral Toxicity Study With Sodium Chlorite In Mallard Ducks", Report No.1 IBT 0 521 18 to Olin Corporation, New Haven, CT. (Jan. 9, 1973).*

- *Lackett "Oxodene: Longevity of Honey Bees", Journal of Economic Entomology, 65 (l), p. 19 (1972).*

The data available strongly suggests that the amounts of the oxychlorine species which would be expected to be released into the environment as a bi-product of using solution to crisp leafy vegetables through the use and disposal would be so low as to pose no threat to either aquatic or terrestrial ecosystems.

With regard to chloride, EPA has summarized the pertinent endpoints for acute aquatic toxicity (Attachment J, Ambient Water Quality Criteria for Chloride, 1988). Although many specific values are provided, 230mg/L was set as the standard for a four day average. This standard approaches the concentration of the sodium chloride at 0.4% if the solution were discharged directly to a waterway. Given the expected dilution, the chloride levels pose no significant environmental risk.

The situation with the trihalomethanes is less clear as this is a class of compounds. The expected discharges will be lost in the pool of disinfection by products for the chlorination of the total effluent stream. EPA has summarized the pertinent endpoints for chloroform (Attachment K, Ambient Water Quality Criteria for Chloroform, 1980). If chloroform can be used as a model for this class, then again the environmental impact of these components is also unimportant.

9. Use of resources and energy:

The proposed change will essentially have no effect on resources or energy. The use of draining to remove residual chlorine will provide a very minor reduction in water use. All other factors would remain the same. Any energy savings associated with using industrially produced chlorine as opposed to generating ™ lution onsite will be lost in transportation and shipping costs given the requi shipping the hazardous concentrated materials.

10. Mitigation measures:

No adverse situations requiring mitigation have been identified.

11. Alternatives to the proposed action:

No adverse environmental impacts remain to be addressed so alternatives are not required.

12. List of preparers:

Jim Brennan, B.S., M.S., MBA
Principal Consultant
Alliance of Technical Professionals, LLC
3368 Prairie Dr.
Pleasanton, CA 94588
(925) 484-1109
Mr. Brennan has over 20 years experience in the Food, Beverage and Wine industries and has held executive positions in R&D, Engineering, and Operations. Mr. Brennan specializes in the development and commercialization of new businesses. He has successfully guided international joint ventures in the fruit and vegetable sector. The direct results of his efforts include establishment of fresh prepared salad operations in Europe, Latin America and Asia. He has also been instrumental in establishing operational infrastructures for start-up ventures in the wine, juice, and frozen desserts categories. In this area his focus is on removing the operating obstacles to change, resulting in superior ability to quickly and economical respond to market forces. Successful engagements include development of an operational restructuring strategy for a major California winery to enhance market responsiveness, product quality and operating costs and implementation of a structured Market/Development/Operations new product process for a European fresh salad operation.

As an experienced engineer and technical manager, Mr. Brennan has spearheaded complex technical programs through both early and late stage development. He has established long-term joint development efforts in bioengineering focused on alternative disease and pest control. Equally as important are his efforts to integrate microprocessor control technology into everyday agricultural practices leading to significant reductions in disease and pest control costs as well as positively impacting the environmental stewardship of the organization.

On the processing front, Mr. Brennan has extensive experience in alternative processing and packaging technologies for vegetables, fruit and juices. He has been instrumental in the commercial introduction of barrier films, aseptic packaging and shelf stable barrier plastic packages. Additionally he is well versed in implementing GMP and HACCP programs in non-traditional processing facilities (fresh fruit and vegetable facilities as well as juice and concentrate facilities). He has worked extensively with FDA to establish pilot HACCP programs in fresh salad facilities.

Education

MBA, New York University, NY, NY
MS, Chemical Engineering, Cornell University, Ithaca, NY
BS, Chemical Engineering, Cornell University, Ithaca, NY

Eric Wilhelmsen, B.S., M.S., Ph.D
Principal Consultant
Alliance of Technical Professionals, LLC
3368 Prairie Dr.
Pleasanton, CA 94588
(408) 946-4525
Dr. Wilhelmsen is a recognized world authority in food and botanical authentication and adulteration. He has been instrumental in the organization of industry collaborations, such as the Technical Committee for Juice and Juice Products effort to develop credible product profiles. His knowledge of the chemical functionality of ingredients and packaging materials has enabled him to address product and/or process performance issues in a wide range of categories including fresh and processed fruits and vegetables, fruit based beverages, botanicals, enzymes and confections. In this role, he has experience at getting company's "back into business quickly" through sound problem solving techniques to arrive at root cause determinations. Dr. Wilhelmsen has provided technical leadership to several committees of the National Food Processors Association including the Container Enhancement committee and the Juice Products Committee.

These industry-supported activities have provided food processors with greater insight into the roll of tin, lead, oxygen and nitrates in the common three-piece metal can. With over 20 years of service to the industry, his technical contributions and practical innovations have been fundamental in establishing unique new products. Dr Wilhelmsen's product portfolio includes nutritionally fortified confections, fat free analogs of fried products, membrane processing techniques for the recovery and conversion of waste materials to by-products as well as technologies to control browning reactions in fresh and processed fruit.

Before co-founding ATP, Dr. Wilhelmsen was president of Wilhelmsen Consulting and served on the faculty of San Jose State University where he taught Food Engineering and other courses in Food Science and Nutrition. Previous to this he was responsible for the Applied Technologies group of Dole Food Company. In this position he was charged with developing and commercializing new technologies for products, processes and agricultural practices. His technical support of both the processed and agricultural aspects of this multi-national's operations lead to the accreditation of a worldwide network of contract laboratories for fruit and vegetable testing of pesticides and other potential adulterants. Dr. Wilhelmsen also held post-graduate positions at UC Davis where he both lectured and conducted environmental research in the biochemistry of selenium.

Education

PhD Agricultural and Environmental Chemistry, UC Davis, Davis, CA
MS Food Science and Technology, UC Davis, Davis, CA
BS Food Biochemistry, UC Davis, Davis, CA

13. Certification:

The undersigned official certifies that the information presented is true, accurate and complete to the best of the knowledge of Sterilox Food Safety/Div.of PuriCore.

_____Jan-_____
(Date)

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(Signatu-
Tom Daniel, Vice President & General Manager

14. References:

Marian R. Wachtel and Amy O. Charkowski, Cross-Contamination of Lettuce with *Escherichia coli* O157:H7, Journal of Food Protection, Vol. 65, No. 3, 2002, Pages 465–470

Trevor V. Suslow, Minimizing the Risk of Food Borne Illness Associated with Cantaloupe Production and Handling in California, Regents of the University of California, 2004

Tong Zhou , Supplement to the Environmental Information for Food Contact Notification No. 450, October 18, 2004, Environmental Toxicologist Environmental Review Group Division of Chemistry Research and Environmental Review)

Reregistration Eligibility Decision (RED): Chlorine Gas; EPA738-R-99-001; Office of Pesticide Programs; US EPA: February 1999. http://www.epa.gov/oppsrrd1/REDs/4022red.pdf (accessed 2007).

Clean Watersheds Needs Survey – Discharge Database 2000 for Santa Clara County, Environmental Protection Agency, http://cfpub.epa.gov/cwns/rpt_discharge2_00.cfm (accessed 2007)

Reregistration Eligibility Decision (RED) Facts : Chlorine Gas, EPA-738-F-99-001, US EPA, February 1999 http://www.epa.gov/oppsrrd1/REDs/factsheets/4022fact.pdf

Chlorine Dioxide Final Risk Assessment Case 4023, Antimicrobials Division Office of Pesticide Programs, U.S. Environmental Protection Agency, August 2, 2006

James Ringo, Sodium chlorite environmental Assessment, Biocide International, August 27, 2004, http://www.cfsan.fda.gov/~acrobat2/fnea0450.pdf

Ambient Water Quality Criteria for Chloride-1988, EPA 440/5-88-001, US EPA , February 1988, http://www.epa.gov/waterscience/pc/ambientwqc/chloride1988.pdf

Ambient Water Quality Criteria for Chloroform EPA 440/5-80-033, US EPA, October 1980 http://www.epa.gov/waterscience/pc/ambientwqc/chloroform80.pdf

15. Attachments:

A. Wachtel and Charkowski, 2002,
B. Suslow, 2004
C. Confidential Business Information
D. Supplemental for FCN No. 450
E. EPA RED for Chlorine Gas is readily available on the web and is therefore not included.
F. Clean Watersheds Need - Santa Clara County
G. EPA RED Factsheet for Chlorine Gas is readily available on the web and is therefore not included
H. Chlorine Dioxide Final Risk Assessment
I. Sodium chlorite Environmental Assessment
J. Water Quality Criteria -Chloride
K. Water Quality Criteria -Chloroform