ENVIRONMENTAL ASSESSMENT

1. Date:	03.04.2008
2. Name of Applicant:	Xyrex Ltd
3. Address:	Willowburn Road, Willowyard Industrial Estate, Beith, North Ayrshire, KA15 1LN

All correspondence should be sent to the above address marked FAO Patrick McTurk or Dr. Sabita Srivastava.

Tel: 0870 161 0103

Fax: 0870 161 0104

Email: patrick@xyrex.com

4. Description of the proposed action:

a. Requested Action:

The action requested in this Notification is to establish the clearance of the food-contact substance (FCS) sodium chlorite as a quality enhancing processing aid in water or ice that is used to rinse, wash, thaw, transport or store seafood in accordance with current industry standards of good manufacturing practice. The FCS is produced by diluting an aqueous solution of sodium chlorite at pH 12.0 -13.0 with water to achieve an actual use concentration of up to 50 parts per million (ppm) or <100ppm sodium chlorite. Any seafood that is intended to be consumed raw shall be subjected to a portable water rinse prior to consumption.

b. Need for action:

The purpose of the proposed Food Contact Notification (FCN) is to demonstrate Xyrex® as a quality enhancing processing aid for seafood. It is applied to seafood to extend the shelf life of the fish by controlling the growth of bacterial degradation by 3 methods; enzymatic, oxidative and biostatic nature.

The mechanism whereby sodium chlorite acts is that in acid solution (from e.g. naturally produced acids in degrading fish) it rapidly decomposes to chlorine dioxide/chlorous acids which can act by slowing the growth of naturally occurring bacteria.

In biochemical systems, it is hypothesised that the uncharged chlorous acid is able to penetrate bacterial cell walls disrupting protein synthesis and thus preventing proliferation and growth of bacteria.

c. Locations of use/disposal:

Once the FCS is approved, the substance will become available to all processors of seafood and freshwater fish. The FCS may be used throughout the United States as many states produce fish and seafood. However, geographically, the substance is more likely to be used in those states known to produce fish and seafood e.g. Coastal states, the states bordering the Great Lakes, the states of Alabama, Arkansas, Louisiana, and Mississippi (major catfish producers), and Idaho (major trout producer) (1,2). The FCS may also be used by major fishing operators in the processing of fish and seafood on-board fishing vessels at sea (3). A large portion of sea-harvested product is processed or pre-processed soon as caught.

The primary method of disposal of the FCS will be into the wastewaters of fish and seafood processors. Wastewaters from processors may be directly discharged into surface waters, indirectly discharged into publicly owned treatment works, or discharged directly off fishing vessels into surface waters. Wastewater effluents from fish and seafood processing facilities may also be applied to land (4 , 5).

5. Composition

Chlorite solution is the base product that is used in the formulation of each individual XyRex® product. The dilutions and manufacture of each individual XyRex® product are confidential.

CAS registry number and chemical properties

CAS Number	CAS 7758-19-2
Molecular Formula	$NaClO_2$
Molecular Weight	90.44
Physical Description	White flakes

6. Introduction of substances into the environment:

a. As a result of manufacturing

Under 21CFR25.40 (a) an Environmental Assessment (EA) should focus on relevant environmental issues relating to the use and disposal of the FCS (Food Contact Substance) rather than their production. Therefore, this report does not include any information on production of chlorite solution as no extraordinary circumstances were found to arise from the manufacture of the substance. With regards to its use, the FCS causes no unique emissions or threatens any endangered species.

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

21CFR25.40 (d) states, "Consistent with 40 CFR 150 0.4(j) and 1502.21, EA's may incorporate by reference information presented in other documents that are available to FDA and the public." Information incorporated by reference should be summarized in the EA, as the EA should be a stand alone document.

The Food and Drug Administration recently reviewed submissions similar to this FCN for the use of sodium chlorite and chlorine dioxide in the processing of fish and seafood. The discussions on the environmental fate and effects of substances in these document s are relevant to this FCN and we are including them in this EA by reference.

The environmental record for Food Additive Petition (FAP) 3A4743 discusses environmental impacts resulting from the use of 40 to 50 parts per million (ppm) sod ium chlorite as an in water and ice that are used to rinse, wash, thaw, transport, or store seafood or freshwater fish in accordance with current industry standards of good manufacturing practice.[1] The final EA was dated May 28, 2004. The EA for this petition indicates that all fish and seafood processing facilities will discharge effluents into a publicly owned treatment works (POTW). We note that some fish and seafood processing facilities are expected to discharge effluent directly to surface waters and the dilution in a POTW will not always occur (7). Therefore, this dilution step should not be included in estimates of environmental introduction concentrations. All facilities discharging directly in surface water must have an EPA permit to do so.

The environmental record for FCN 668 discusses environmental impacts resulting from the use of chlorine dio xide as an antimicrobial agent to be applied to red meat (including meat parts and organs), raw agricultural commodities, processed, comminuted or formed meat products, and seafood. The environmental record for this FCN is the most current EA for sodium chlorite with a similar use. The EA was dated Novem ber 13, 2006, and is available along with the finding of no significan t impact and supplement to the environmental record at http://www.cfsan.fda.gov/~rdb/opa-envt.html.

The environmental introductions from the proposed action will be very similar to those discussed in the previously accepted EA's. These documents are incorporated by reference into the environmental record for this FCN and shoul d be consulted for more complete discussions on these topics. We have only included a brief summary here.

[1] The most recent environmental documents for this petition are availab le at FDA dockets (docket number 03F-0128) and may also be obtained with a freedom of information (FOI) request. These documents will also be made available on the Office of Food Additive Safety (OFAS) environmental website after this notification becomes effective.

Additionally, the United States Environmental Protection Agency (EPA) recently published a Re-eligibility Decision and risk assessments for the use of sodium chlorite and chlorine dioxide (see docket number EPA-HQ-OPP-2006-0328, at www.regulations.gov, for all associated documents).

c. Water Releases

The primary concerns for environmental introductions from the proposed use are possible releases of sodium chlorite and its byproducts into surface waters. Sodium chlorite will dissolve in water into sodium and chlorite ions. The chlorite ion and its other byproducts (chlorine dioxide, chlorate, chlorous a cid, etc.) are transformed to the chloride ion and oxygen via oxidation-reduction reactions in the presence of Fe(II), Mn(II), I^- and S^{-2} (8). Chlorite and its byproducts also readily react with organic materials to form chloride (9). Effluents associated with fish and seafood processing are known to have high concentrations of organic materials that would react with the chlorite to form chloride (7). The sodium chlorite concentrations are low enough (@<100 parts per million) and organic content high enough that almost all chlorite will be transformed to chloride (7).[2]

d. Air Releases

The potential for air releases of chlorites and associated byproducts may occur primarily during use of the product. When used as directed by the Material Safety Data Sheets and other labels, occupational exposures are not expected to be a concern (10).

e. Terrestrial Releases

Any chlorite still present in effluent applied to land is expected to rapidly undergo degradation to chloride through oxidation-reduction reactions (9). The U.S. EPA states, "The rapid degradation of the chemicals, coupled with the generally low toxicity of chlorine dioxide and sodium chlorite to birds and mammals, make risk to these organisms unlikely. The very limited data available to assess the phytotoxicity of chlorine dioxide/sodium chlorite make it difficult to determine the risk to terrestrial/semi-aquatic plants" (10). Rapid degradation of chlorite and its byproducts is also expected to prevent toxicity to soil dwelling organisms such as earthworms.

7. Fate of substances released into the environment

The environmental fate of sodium chlorite is well-characterized in the published literature and has been covered in the previously mentioned petitions and FCNs. The possible introductions resulting from the proposed use include releases of sodium chlorite and it s byproducts, including chlorate, chlorous acid, chlorine dioxide, and chloride (10). In brief, chlorite and its intermediates will react with the organic materials in the effluent to form the chloride ion (9,10). The primary introductions into the environment will be the sodium and chloride ions.

The maximum use level of sodium chlorite ($NaClO_2$) is 25 mg/L. Sodium is approximately 25 weight percent of the FCS and chlorine is approximately 39 weight percent of the FCS.

[2] Fish and seafood processing waters contain fat, oil, grease, blood, and small pieces of fish that all contribute to the organic content of the effluent (3,7). The organic materials present are expected to exceed that needed to degrade all sodium chlorite used *(7)*.

Using these numbers, the maximum amount of sodium in the water used will be 6.25 mg/L (25 mg/L x 0.25= 6.25 mg/L) and the maximum amount of chloride will be 9.75 mg/L (25 mg/L x 0.39 = 9.75 mg/L).

8. Environmental effects of released substances Aquatic Environments

As stated previously, only very small amounts of chlorite and its byproducts are expected to be introduced into the environment. We did not calculate environmental introduction concentrations for chlorite. However, based on the high organic content in wastewater, we do not expect significant exposure to occur. Environmental toxicity endpoint s for chlorites and chlorates are summarized below. Complete discussions of the toxicity data are available in the Environmental Hazard and Risk Assessment and Final Risk Assessments written by the EPA (13,14).

Table 1. Summary of environmental toxicity endpoints fo r chlorite.[ab]

Species	LC50 or EC50 (mg/L)	NOEC or NR (mg/L)
Freshwater Fish	75 - 600	Not available
Phytoplankton	2 - 5	1.18 – 1.47
Estuarine/Marine Fish	75	13.9
Estuarine/Marine Invertebrates	0.576 - 21.4	14.3
Aquatic Plants	1.32	<0.62

[a] The substance tested was sodium chlorite with approximately 80% active ingredient.

[b] All data from: Chlorine Dioxide: Final Risk Assessment Case 4023; Docket ID No. EPA -HQ-OPP-2006-0328; U.S. Environmental Protection Agency, Antimicrobials Division: Washington D.C., Aug 2, 2006 (14).

Table 2. Summary of environmental toxicity endpoints for chlorate. [a]

Species	LC50 or EC50 (mg /L)	NOEC (µg/L)
Freshwater Fish	7.3 - 4000	5 - 60
Phytoplankton	21 - 4100	52 - 1000
Aquatic Plants	Not available	1000

[a] All data from: Anderson, B.; Hetrick, J. A.; Nelson, H. Environmental Fate and Ecological Risk Assessment for the Reregistration of Sodium Chlorate as an Active Ingredient in Terrestrial Food/Feed and Non-food/Non-feed Uses. Reregistration Case Numb er 4049 (18).

The Median Effective Concentration (EC50) is the concentration that causes a specified effect in 50% of the organisms tested.

The Median Lethal Concentration (LC50) is a statistically estimated concentration that is expected to be lethal to 50% of organisms tested.
The No Observable Effect Concentration (NOEC) is the highest concentration that did not produce an effect.

All data relating to the toxicology of Chlorate and Chlorite was extracted from the: PAN Pesticides Database - Chemical Toxicity Studies on Aquatic Organisms at

http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC34363

As stated previously, the primary materials introduced into the environment are sodium and chloride ions. The salinity in freshwater systems is lower than that found in estuaries and other marine environments. Therefore, environmental effects of sodium and chloride ions will be greatest in freshwater systems and we have only discussed freshwater systems here.

Chloride concentrations are not expected to result in toxicity. The EPA has established national recommended water quality criteria for the non priority pollutant chloride for the protection of aquatic life in fresh water. The EPA determined the Criteria Maximum Concentration and Criterion Continuous Concentration and defines them as, "The Criteria Maximum Concentration (CMC) is an estimate of the highest concentration of a material in surface water to which an aquatic community can be exposed briefly without resulting in an unacceptable effect.

The Criterion Continuous Concentration (CCC) is an estimate of the highest concentration of a material in surface water to which an aquatic community can be exposed indefinitely without resulting in an unacceptable effect" (15). The CMC for chloride in freshwater is 860 mg/L and the CCC is 230 mg/L (15). The maximum amount of chloride from the proposed use possible is 9.75 mg/L and is well below, approximately 24 times lower, than the CCC (230 mg/L / 9.75 mg/L = 24) Therefore, we do not expect that the proposed use will result in significant environmental effects.

The concentration of sodium will be lower than what occurs naturally in the environment. Concentrations of sodium in freshwater systems in the United States are approximately 6 – 7 mg/L (16). However, concentrations may be much higher as there are many natural sources (16). The environmental concentrations will be lower than naturally occurring concentrations because the effluent will be diluted with other sources of water used in processing and with the surface water into which effluent is released. Therefore, the proposed use will not result in significant introductions of sodium.

We note that fish and seafood processing waters are known to sometimes be high in salinity (7). Point source discharges of sodium chlorite and chlorine dioxide solutions require a National Pollutant Discharge Elimination System (NPDES) permit which would mitigate any possible environmental effects (10).

Atmosphere and Terrestrial Environments

Potential effects from air and terrestrial releases are discussed under Format Item 6.

Sodium chlorite is highly stable and is a dissolved solid no higher than 12.5% with maximum saturation of approx. 40%.

There is no vapor pressure as this is a dissolved solid.

The degradation products of Xyrex are sodium chloride .

Sodium chlorite is also reduced very rapidly in organic load burdened solutions or waste streams (with iron, manganese, reduced sulfur species, microbial populations etc. that are present) again principally through reduction to form chlorite. The by-product is chloride.

PHYSICAL/CHEMICAL CHARACTERIZATION	
Water Solubility	39 g/100 ml (17 °C)
Dissociation Constant(s)	Not applicable
Octanol/Water Partition Coefficient (Log K_{ow})	Not applicable
Vapor Pressure or Henry's Law Constant	Not applicable
DEPLETION MECHANISMS	
Absorption/Desorption (K_{oc})	No data
Hydrolysis	No data
Aerobic Biodegradation	No data
Soil Biodegradation	No data
Photolysis	No data
Metabolism	No data
ENVIRONMENTAL EFFECTS	
Microbial Inhibition	No data
Acute Toxicity	No data
Chronic Toxicity	No data

While the major residue component that is formed from a Xyrex sodium chlorite (SC) solution is chloride ions, the added impact of these treatment-derived chloride ions on the typical background levels of sodium chloride found in all foods is not measurable or detectable with current test sensitivities. Since toxicologically these chloride ions are not of concern at the typical levels found in the foods, there is not an impact from any “added” chloride deriving from a Xyrex SC treatment.

9. Use of resources and energy

The use of the food contact substance is intended to compete with and replace acidified sodium chlorite and chlorine dioxide, which are already used in the production/processing of food such that there is essentially no effect on the use of natural resources and energy. Our justification is that the energy consumption for the production of chlorite for acidified sodium chlorite, chlorine dioxide or Xyrex would be essentially the same. The raw materials for the production of both materials are of a common nature and therefore readily available internationally and supplied globally.

The application is new to the seafood industry. However, as volumes of seafood consumed increase, the levels of Xyrex applied proportional to seafood shipments is negligible. In addition, the increased benefit of reducing the amount of wastage lost due to degradation by using Xyrex will result in less transport and resources required within the industry as a whole. Furthermore, due to the reduction in wastage there is the added benefit that customers effectively need to buy less fish, reducing transportation, energy consumption etc again outweighing the energy consumption created by Xyrex.

For further information please see the attached risk assessment carried out by the Norwegian Scientific Committee for Food Safety.

10. Mitigation measures

The United States EPA recently published the "Reregistration Eligibility Decision (RED) for Chlorine Dioxide and Sodium Chlorite (Case 4023)"(10). The RED gives a comprehensive review of the use of chlorine dioxide and sodium chlorite as an antimicrobial and this review is applicable to the proposed use in this FCN and also helps to support a finding of no significant impact (FONSI). The risk assessment was conducted for the "once-through cooling tower use of chlorine dioxide/sodium chlorite...because out of all the uses of these chemicals, it is the one expected to have the most potential for environmental exposure" (13). Excerpts from the risk assessment summarize acute and chronic risk findings below.

> "Acute risk is anticipated for aquatic organisms from the use of chlorine dioxide/sodium chlorite in once-through cooling towers. At the highest doses on current labels (25 ppm), there is risk to freshwater and marine/estuarine fish and invertebrates and aquatic plants, and at the lowest doses there is risk only to freshwater invertebrates."

To mitigate this risk, the maximum application rate for this use pattern must be reduced from 25 ppm to 5 ppm for intermittent applications" (10).

> "Chronic risk to aquatic organisms cannot be assessed at this time due to the lack of chronic toxicity endpoints for fish and aquatic invertebrates. When the required aquatic chronic toxicity testing described above is submitted, chronic risk to these organisms will be assessed. All other exposure and risk estimates are below the Agency's level of concern" (10).

As stated by EPA, "The generic database supporting the re-registration of chlorine dioxide and sodium chlorite has been reviewed and determined to be substantially complete" (10).
The EPA determined that, "chlorine dioxide and sodium chlorite are eligible for re-registration provided that: (i) additional data that the Agency intends to require confirm this decision; and (ii) the risk mitigation measures outlined in this document are adopted, and (iii) label amendments are made to reflect these measures" (10). The risk mitigation measures and label amendments are listed and clearly identified in the RED and include requiring the following statement on the label in the ecological effects language:

> "This product is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA" (10).

The risk mitigation measures and label requirements identified in the RED will also be required for use of chlorine dioxide and sodium chlorite as an antimicrobial in food processing facilities and fishing vessels and will help to mitigate any adverse environmental impact from the proposed uses (17)

11. Alternatives to the proposed action

Alternatives to the proposed action need not be considered because no potential adverse effects a re expected to occur

12. List of preparers:

Dr . Sabita Srivastava
Technical Research Director
BSc Biochemistry
BSc Applied Biology & Clinical Chemistry (H onours)
PhD Bioengineering (1988)

Mr. Patrick McTurk
Managing Director
B.Eng. Dipl Eng Engineering (1993)

Miss Audrey J Gr ieve
Quality Manager
BA with Merit (English with Environmental Science) (1999)
SCQF 10 (Level 4) Quality Auditing (2007)

13. Certification:

The undersigned official certifies that the information presented is true, accura te, and complete to the best of the knowledge of XyRex®.

4th March 2008
(Date)

(Signature of responsible official)

Dr Sabita Srivastava, Technical Research Director

(Name and title of responsible official, printed)

References

1. Catfish Production; National Agricultural Statistics Service; U.S. Department of Agriculture: Washington, D.C., Jul 26, 2007. http://usda.mannlib.cornell.edu/usda/current/CatfProd/CatfProd-07-26-2007.pdf (accessed Aug. 30, 2007).

2. Trout Production; National Agricultural Statistics Service; U.S. Department of Agriculture: Washington, D.C., Feb 26, 2007. http://usda.mannlib.cornell.edu/usda/current/TrouProd/TrouProd-02-26-2007.pdf (accessed Aug. 30, 2007).

3. Jespersen, C.; Christiansen, K.; Hummelmose, B. Overview of Fish Processing. In Cleaner Production Assessment in Fish Processing, United Nations Environment Programme; Danish Environmental Protection Agency: 2007; pp 7-19. http://www.agrifood-forum.net/publications/guide/f_chp2.pdf (accessed Sept. 7,2007).

4. Overcash, M. R.; Pal, D. Characterization and land application of seafood industry wastewaters; UNC-WRRI-80-142; Water Resources Research Institute of the University of North Carolina: Raleigh, NC, Aug, 1980. http://www.p2pays.org/ref/15/14395.pdf (accessed Sept. 7, 2007).

5. News Release: To protect the environment, Ecology orders seafood company to stop surimi wastewater discharge; Washington State Department of Ecology: Aug 25, 1995. http://www.ecy.ecy.wa.gov/news/1995news/95-134.html (accessed Sept. 7, 2007).

6. Memorandum to Agencies: Forty Most Asked Questions Concerning CEQ's National Environmental Policy Act Regulations; Federal Register, Vol. 46, 18027; Council on Environmental Quality: Washington, D.C., Mar 21, 1981. http://www.eh.doe.gov/nepa/tools/guidance/volume1/4-1-40_questions.html (accessed Aug. 24, 2007).

7. Islam, M. S.; Khan, S.; Tanaka, M. Waste loading in shrimp and fish processing effluents: potential source of hazards to the coastal and near shore environments. Marine Pollution Bulletin 2004, 49, 103-110.

8. Shamim, A. N. Chlorine Dioxide: Environmental Fate and Transport Assessment; Docket ID Number EPA-HQ-OPP-2006-0328-0005; Office of Pesticide Programs; U.S. Environmental Protection Agency: Feb 23, 2006.(accessed Sept. 7, 2007).

9. Toxicological Profile for Chlorine Dioxide and Chlorite; Agency for Toxic Substances and Disease Registry; U.S. Department of Health and Human Services: Sep, 2004. http://www.atsdr.cdc.gov/toxprofiles/tp160.pdf (accessed June 4, 2007).

10. Reregistration Eligibility Decision (RED) for Chlorine Dioxide and Sodium Chlorite (Case 4023); EPA 738-R-06-007; U.S. Environmental Protection Agency; Prevention, Pesticides and Toxic Substances: Washington D.C., Aug, 2006. http://www.epa.gov/oppsrrd1/REDs/chlorine_dioxide_red.pdf (accessed Jan. 25, 2007).

11. Reregistration Eligibility Decision (RED) for Inorganic Chlorates; EPA 738-R-06-014; U.S. Environmental Protection Agency: Washington, D.C., Jul, 2006. http://www.epa.gov/pesticides/reregistration/REDs/inorganicchlorates_red.pdf (accessed June 4, 2007).

12. ECOTOX Database, http://www.epa.gov/ecotox/ecotox_home.htm (accessed Feb. 6, 2007).

13. Angle, G. Chlorine Dioxide: Environmental Hazard and Risk Assessment; Docket Document Number EPA-HQ-OPP-2006-0328-0020; U. S. Environmental Protection Agency; Office of Pesticide Programs: Washington, D.C., Jul 13, 2006.

14. Chlorine Dioxide: Final Risk Assessment Case 4023; Docket ID No. EPA -HQ-OPP-2006-0328; U.S. Environmental Protection Agency, Antimicrobials Division: Washington D.C., Aug 2, 2006.

15. Current National Recommended Water Quality Criteria, http://www.epa.gov/waterscience/criteria/wqcriteria.html (accessed Feb. 13, 2007).

16. Baird, C. The Chemistry of Natural Waters. In Environmental Chemistry, Second ed.; Julet, M., Ed.; W. H. Freeman and Company: New York, 1999; pp 421 -459.

17. Development of Clean Water Act National Pollutant Discharge Elimination System Permits for Discharges Incidental to the Normal Operation of Vessels; Federal Register, Vol. 72, No. 119, June 21, 2007.; U.S. Environmental Protection Agency: Washington D.C., Jun 21, 2007. http://www.epa.gov/fedrgstr/EPA -WATER/2007/June/Day-21/w12022.pdf (accessed Sept. 7, 2007).

18. Anderson, B; Hetrick, J,A; Nelson, H. Environmental Fate and Ecological Risk Assessment for the Reregistration of Sodium Chlorate as an Active Ingredient in Terrestial Food/Feed and Non -feed Uses. Reregistration Case Number 4049; Docket ID No. EPA -HQ-OPP-2005-0507;US. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances: Washington, D.C, Jan 31, 2005.