Attachment #11

Environmental Assessment

1. Date: October 26, 2010 (revision #1)

2. Name of Applicant: Enviro Tech Chemical Services, Inc

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4. Description of the Proposed Action:

The action requested is the establishment of a clearance to permit the use of hypobromous acid as an antimicrobial additive in general process water for use on meat (<900 ppm as Br_2). The product will be added to process water to reduce the numbers of and inhibit the growth of pathogens and other microorganisms for purposes of food safety.

Hypobromous acid can be made on-site in a number of ways in this FCN. Typically, the hydrogen bromide precursor (HBr) is blended with sodium hypochlorite bleach (NaOCl) in the process water to form hypobromous acid:

$$HBr + NaOCl \longrightarrow HOBr + NaCL$$

Another alternative method of creating on-site HOBr is blending hydrogen bromide (HBr) with potassium hypochlorite bleach (KOCl):

$$HBr + KOCl \longrightarrow HOBr + KCL$$

Another alternative method of creating on-site HOBr is blending hydrogen bromide (HBr) with calcium hypochlorite bleach Ca(OCl)2:

$$2HBr + Ca(OCl)2 \longrightarrow 2HOBr + CaCl_2$$

After undergoing chemical oxidation during use in the process water, the hypobromous acid converts to bromide ion (Br^-).

Estimates of water usage in the meat processing industry vary. It has been reported that water usage, primarily from carcass washing and process clean-up during meat processing, is in the range

of 150-450 gal/animal processed[1]. The U.S. EPA has reported the rate of wastewater generated at three hog and three cattle processing facilities ranged from 291-442 gal/1,000 lbs live weight killed[2]. The FDA has also examined dilution factors (DF) at poultry processing plants and found that 71% of facilities had DF's >100, and 96% had a DF of 20 or greater[3]. In a letter dated October 27, 2010, page 4 (g), the Agency noted "…the Agency generally allows a dilution factor (DF) for the EIC to be 10 to obtain the EEC in receiving water…" Therefore, this revised report will use the DF factor of 10[14].

Additionally, at 19 medium and large complex slaughterhouses, wastewater flows ranged from 435-1,500 gal/1,000 lbs live weight killed, with a mean value of 885 gal/1,000 lbs live weight killed[4]. The International Finance Corporation has published industry benchmarks of 1.62-9 m^3 water per ton of slaughtered cattle. This corresponds to approximately 190-1077 gal/1,000 lbs live weight killed[4]. The USDA has reported that the average live weight of commercial cattle, calf, hog, sheep and lamb slaughtered ranges from 137-1,275 lbs[5]. Therefore, based on water use ranging from 885-1,077 gal per 1000 lbs live weight, the *average* discharge for (cattle) meat plant would be 981 gal per head.

The primary route of disposal for water that has been treated with hypobromous acid is through the processing plant wastewater treatment facility. A majority of beef and poultry processors treat their wastewater on site and ultimately discharge directly into receiving bodies of water or via land application or as pretreated wastewater to a local sewer district. The plant processing water effluent empties into drains and may contain fat, blood, excrement and other organics and solids which may be fugitive from carcasses as they are washed, trimmed and further processed. The effluent stream is screened or filtered to remove gross solids and particulates prior to being sent to the Dissolved Air Floatation (DAF) systems. These combined systems are called the "pretreatment" system. This pretreated water is then sent to either a conventional aerobic wastewater treatment system or, in some cases, to anaerobic lagoon/digester system, both of which digest the balance of the soluble fats, proteins, and other organic constituents of the wastewater stream. Many if not most meat and poultry plants use the anaerobic digestion method of wastewater treatment[2]. It should be noted that during several stages of wastewater pretreatment and subsequent digestion, the solids are removed from the wastewater by using several common techniques, but the great majority of the FCS would remain in the water phase due to the fact the FCS is water soluble (hydrophilic) as opposed to fat soluble (lipophilic) in nature.

The Agency is well aware of the substantial amount of scientific data available for the chemistry and environmental toxicology of sodium hypochlorite and hypochlorous acid, and the hypochlorites in general. The subject of this FCN is hypobromous acid, which also proportionally reverts to hypobromite at pH values above 8.5. However, the chemistry and environmental toxicology of hypobromous acid is substantially similar or equivalent to hypochlorous acid, so the great majority of data for hypochlorous acid would be substantially identical to that of hypobromous acid[8].

5. Identification of Substances that are the subject of the Proposed Action:

The subject of this FCN is the on-site generation and use of hypobromous acid. In this case, hypobromous acid is generated by reacting (blending) pre-diluted hydrogen bromide (HBr), CAS #10035-10-6, with a hypochlorite source. The following equations would predominate:

a. $HBr + NaOCl \longrightarrow HOBr + NaCL$ (sodium hypochlorite activator)

b. $HBr + KOCl \longrightarrow HOBr + KCL$ (potassium hypochlorite activator)

c. $2HBr + Ca(OCl)_2 \longrightarrow 2HOBr + CaCl_2$ (calcium hypochlorite activator)

The above reactions are very fast and require no resonance (holding) time. In all cases the reaction products are hypobromous acid and varying degrees of salt.

6. Introduction of Substances into the Environment

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

Under 21 CFR §25.40(a), an environmental assessment ordinarily should focus on relevant issues relating to use and disposal from use, rather than the production of the FCS. However, the <u>precursor</u> to the FCS (hydrogen bromide) is a highly specialized chemical that is not ordinarily sold to commercial markets. It is typically a by-product of bromine manufacturing and is often reused at the point of origin by recycling the HBr through the bromine manufacturing process, as illustrated by the following reaction:

$$Br_2 + H_20 \longrightarrow HOBr + HBr$$

Thus, the HBr would not create any extraneous or additional changes in the manufacturing of this chemical, other than less HBr would be used to recycle through the initial bromine manufacturing system.

In terms of hypochlorite manufacturing, this use would be an insignificant side-stream use for long-standing and mature manufacturing processes throughout the United States. It should be further noted that the subject of this FCN, hypobromous acid, is made *in situ* (on

site) and therefore no substantive manufacturing data is available for this substance at or from remote locations.

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

The use of the FCS, hypobromous acid, will not exceed 900 ppm as available bromine (Br_2) in the process water for meat processing. This equates to 450 ppm as bromide ion (Br-). It should be noted here that Br_2 has a mole wt of 159.8 gms/mole and bromide ion is one half of this amount, with an atomic weight of 79.904 gms/mole.

Hypobromous acid is a highly unstable and reactive oxidizing compound and is not expected to survive the transition through meat processing due to the high organic demand which is inherent in these facilities[11, 12, 13]. The half-life of hypobromous acid in low-demand tap water has been estimated by the EPA to be 125 hrs[7]. Hypobromous acid, being an unstable and reactive compound will decay to bromide ion (Br-) very quickly in the presence of organic matter and ammonia, similar to hypochlorous acid [8, 11, 12, 13].

Although not part of the current petition, the hypochlorite activators used to convert the HBr into HOBr create inert by-products that should be noted (see equations above in Sec. 5). Each mole or ppm of HBr converted by a hypochlorite source will yield a finite amount of salt relative to each source of hypochlorite. Based on mole weights of each compound, the following amounts of salt for each source of hypochlorite will be created in the process and wastewater:

Each mole of HBr consumed in the hypobromous acid reaction will yield one mole of sodium chloride salt. The results can also be expressed in terms of ppm vs. ppm of Br-. Thus, salt production below is based on the equations listed in section 4:

a) 58.5 g NaCl / 80.9 g HBr = 0.772 g NaCl vs. 1 g of HBr
b) 74.6 g KCl / 80.9 g HBr = 0.992 g KCl vs. 1 g of HBr
c) 111 g CaCl2 / 80.9 g HBr = 0.686 g CaCl2 vs 1 g of HBr

There are numerous environmental advantages to using several hypochlorite sources as the "activator" of the hydrogen bromide. Potassium hypochlorite and calcium hypochlorite may be preferred due to their innocuous environmental profile, and would undoubtedly be chosen by the processor who may be restricted on sodium discharge by their facility discharge permit, or perhaps a processing facility may land apply wastewater and would therefore

choose a earth metal cation that does not leach through the soil zone or has beneficial effects on an agricultural crop. Bromide ion is negatively charged, and would slowly leach through a soil zone if land applied. Note that the potassium ion (K+) is also a fertilizer and an essential plant nutrient, and does not leach through the root zone, as does sodium.

In Section 4, pg 67, this applicant estimated the water use at a meat plant to be about 981 gal per average head of meat, with each head using about 98.1 gal of water [(14)].
For a meat plant, 2000 head/day is a reasonably sized processing facility. An Agricultural Marketing Report, published in 2004, estimated that a small facility processed 20,000 head/year, a medium facility processed 480,000 head/year, and a large facility processed 1.5 million animals per year[(9)]. This results in approximately 77 head/day in the small facility, 1846 head/day at a medium facility, and 5769 head/day at a large facility (based on normal hours @ 250 days).
In the revised Form 3480 (V2) , in Part II, #3 (page 9) this applicant explains how the FCS will be used in a meat processing facility:

"The intended use is addressed in several efficacy studies that are included as an attachment(s) to this Form 3480 (See Attachment #7 & #9). Attachment #8 deals specifically with the estimated amount of bromide ion (the degradation product) that would be expected with the use of the FCS. Furthermore:

In many meat establishments the carcass rinse system is one of the most important HACCP points. These systems often consist of two or three separate operations. Typically, the first wash cabinet uses high flows and pressures with the FCS listed in FCN 994. Then the half carcass may *go into a hot water cabinet at 180 F. Most spray exposures are short (7-10 seconds) in this treatment train. Subsequently the carcasses are often passed through another cabinet using acidified sodium chlorite (chlorine dioxide) at high concentration and low pressure. Typically, this treatment uses the FCS at 1,000-1,200 ppm. The carcass is then diverted to further processing. This applicant has personally witnessed this use, where the processor uses about 2 gal of low-pressure spray with the high level of the FCS per each half carcass.*

We believe the amount of FCS the processor will use is economically self-limiting, and will NOT be used for general plant use at these high levels, but may be appropriate for certain specific uses, such as the secondary low-volume high ppm carcass spray. It is important to achieve good microbial kill prior to further processing to prevent contamination, and this is the reason the 1,000-1,200 ppm rang of sodium chlorite is used in this final stage. It is impossible for the current FCS listed in FCN #944 to be efficaciously equivalent to sodium chlorite due to the concentration differential (300 ppm bromine vs. 1,200 ppm acidified sodium chlorite).

Sodium chlorite is problematic in a plant environment due to the corrosion and odor problems it creates. Our internal lab testing shows that the efficacy of 900 ppm of available bromine is essentially equal to the 1,000-1,200 ppm of acidified chlorite. It is also about 3 times less corrosive and exhibits far less odor potential to workers than acidified sodium chlorite (chlorine dioxide). Thus, the product is safer, less corrosive, performs equivalently

and is less expensive than acidified sodium chlorite in the meat washing environment of the process plant.

The FCS is intended to be used at a maximum level of 900 ppm as total available bromine (Br_2) for meat processing. Therefore, the estimated discharges of the bromide and by-product salts are as follows (assuming all the water is treated with the FCS):

a. MEAT PROCESSING: FCN #1036

981 gal/head x 2,000 head/day = 1,962,000 gal total water discharged.

i. If 4 gal of the 900 ppm solution were used per head, the total FCS discharge would be 4 gal x 2,000 head = 8,000 gal

ii. 1,962,000 gal / 8,000 gal = 245:1 dilution factor

iii. Since 900 ppm Br_2 = 450 ppm as bromide (Br-), then the resultant bromide discharge into a receiving body of water would be: 450 ppm / 245 = 1.84 ppm Br

iv. In terms of salt, this level of bromide would equal (a) 1.84 x 0.72 = 1.33 ppm (as NaCl); (b) 1.84 x 0.92 = 1.69 ppm (as KCl); or (c) 1.84 x 0.68 = 1.25 ppm (as $CaCl_2$). See equations in #4 above.

b. Using the above assumptions, if the balance of the processing plant used the FCN #944 substance at its maximum use level for general process water, it would contribute the following amounts of the substance:

i. A 300 ppm available bromine (Br_2) rinse would contain 150 ppm as bromide ion. Using a DF of 10 as suggested by the Agency, this would result in a maximum discharge of 15 ppm as bromide ion. *(One should note here that a FCN is never used at its maximum ceiling limits, to allow for processing, testing and sampling variables.)*

ii. The combined effluent for the uses of FCN 944 and FCN 1036 would therefore become: 15 ppm + 1.84 ppm = 16.84 ppm as bromide. The most sensitive aquatic organism listed in the chart in #8 below is NOEC <3-19 mg/L for Daphnia magna.

iii. Total salt discharges, based on 16.84 ppm as Br-, would therefore be (a) 12.1 ppm as NaCl; (b) 15.5 ppm as KCl; and (c) 11.5 ppm as CaCl2.

7. Fate of Emitted Components in the Environment

As explained above, this applicant would estimate the degradate product, bromide ion (Br-), to be present in the wastewater at the level of <17 ppm in meat processing facilities.

The bromide (Br-) ion would be expected to remain in the wastewater process system and would further be diluted in the receiving body of water. The chemistry would be substantially similar or identical as those for the chloride (Cl-) ion.

This applicant believes that, based on the vast amount of information available for chloride, the bromide ion at the proposed use levels would not create an undue burden on the environment. Both anions are naturally occurring and have a well known and mostly benign toxicology profile.

In 2005 the EPA[15] stated that (pg 19): "These results indicate that (sodium) bromide can be used at typical sites without impact most of the time. Since the discharge of hypobromous acid is limited by the NPDES permit program administered by EPA's Office of Water, the Agency will be able to control the discharge of hypobromous acid on a site-by-site basis, so that toxic levels are avoided."

8. Environmental Effects of the Released Substance(s):

Bromide ion (Br-) is of low toxicity to aquatic organisms, which would be the target group, assuming most of the bromide in wastewater would be released into other bodies of water.

Most of the available data on bromide ion comes from extensive studies from the U.S. EPA. Sodium bromide is the source of the bromide ion environmental data, which was submitted to the FDA in support of an application which became FCN No. 792. The target FCS was DBDMH, di-bromo-dimethyl hydantoin. This compound hydrolyzes into hypobromous acid and di-methyl hydantoin when dissolved in water. The hypobromous acid is identical to the end-product that is created with this FCN application, namely, blending a hypochlorite source with hydrogen bromide to obtain hypobromous acid. Since sodium bromide is also 'activated' with a hypochlorite source and creates hypobromous acid, it could be considered identical to the current FCS. However, on the other hand, if sodium bromide is released into the environment, it could still be considered identical to the bromide ion (degradate product), due to the fact that sodium bromide dissociates in water to yield free sodium and free bromide ions.

Without burdening the Agency with duplicate data submissions, this applicant will cite by reference the data in Appendix 1 of the Environmental Assessment submitted in support of FCN 792, which was obtained from the U.S. EPA's ECOTOX Ecotoxicity Database, located at http://www.epa.gov/ecotox/.

Of particular importance, 3 of these studies include specific aquatic acute toxicity assays conducted by an industry task force to support a pesticide re-registration for sodium bromide used in the generation of hypobromous acid[10]. However, this applicant agrees with the EA Notifier for FCN 792, page No. 415 of the FCN application, "Thus, the data obtained in these studies are not directly relevant to the current Environmental Assessment, as hypobromous acid is not expected to be released as a result of the proposed use of DBDMH". This applicant would also note that activated hydrogen bromide with a hypochlorite source (typically sodium hypochlorite), both the sodium and bromide ions would be discharged into the wastewater streams, so the toxicology profile of sodium bromide, contrasted with the current FCS, would logically be a substantially identical mixture, and the sodium bromide data would directly apply. It should be noted, however, that the current FCS precursor, hydrogen bromide, does not contain the additional sodium burden associated with sodium bromide as an alternative precursor.

Therefore, the following table is a summary of the data presented to the Agency for the aquatic toxicity of sodium bromide that was submitted by the Notifier of FCN 792, as presented in Appendix 1, 2 and 3 of the Environmental Assessment submission:
Aquatic Toxicity Data Summary From EPA's ECOTOX for Sodium Bromide (Br-)

Test Organism	Endpoint	Duration	Concentration
Daphnia magna	NOEC-behavior	21 days	91 mg/L
Rotifer	NOEC-reproduction	48 hrs	1000 mg/L
Green algae	NOEC-population/growth	3-4 months	>500 mg/L
Daphnia magna	EC_{50}	24 hrs	500 mg/L
Daphnia magna	NOEC-reprod. viability	21 days	7.5 mg/L
Daphnia magna	NOEC-general reprod.	19 days	<3 to 19 mg/L
Bluegill	LC_{50}	96 hrs	>1000 ppm
Rainbow trout	LC_{50}	96 hrs	>1000 ppm
Medaka, high eyes	LC_{50}	34 days	1500 mg/L
Medaka, high eyes	LC_{50}	72 hrs	24,000 mg/L
Medaka, high eyes	NOEC-multiple	34 days	250 mg/L
Fathead minnow	LC_{50}	96 hrs	16479 mg/L
Guppy	LC_{50}	124 days	7900 mg/L
Guppy	LC_{50}	96 hrs	16,000 mg/L
Guppy	NOEC-reproduction	124 hrs	78 mg/L

Note: mg/L = ppm
NOEC = No Observable Effects Concentration

The lowest acute toxicity EC_{50} or LC_{50} given in the table summary is 500 mg/L, for Daphnia magna. However, some other values for EC_{50} cited in the ECOTOX database reports

concentrations >6100 mg/L. Thus, the lowest reasonable estimate for Daphnia magna EC_{50} at 500 mg/L clearly represents a conservative estimate of the toxicity of bromide ion to this species.

A very wide range of NOEC are reported in the ECOTOX database. The value shown in the above table, <3-19 mg/L, is reported by Soares, et al (1992, ref 5857 in ECOTOX database, FCN 792 EA Appendix 3. Nine different clones were tested to evaluate interclonal and environmental variation in the results by obtained in the assay. For four of the clones, the NOEC was reported at <3.0 mg/L, for two clones the NOEC was 3 mg/L, and the remaining 3 clones the NOEC varied from 7.5-19 mg/L. Considering the variability of NOEC's, the entirety of the available data, and given the variability within daphnid clones, we submit that the use of a NOEC of <19 mg/L is a reasonably conservative number for estimating a safe level of bromide ion in bodies of water receiving the FCS effluent when considering one of the more sensitive species. We would also suggest here that the upper limit of <19 mg/L for daphnids may be appropriate, as there are no meat processing plants that operate under 24 hour per day processing (discharge) conditions. Most operations process for about 16 hrs and clean the facility for 8 hrs, typically on a 5 days/week basis. Obviously, the FCS would not be in operation nor discharged during these periods, allowing the organisms large periods of time without exposure to the FCS. Thus, it would be rational and reasonable for one to use the upper end of the range given for the most sensitive species.

The EPA has assessed the ecological effects risk assessment for freshwater and estuarine environments relative to hypobromous acid from activated sodium bromide used in industrial applications[11].

> *"As discussed earlier, EPA conducted a Tier 1c EEC screening model for hypobromous acid to estimate the maximum concentration that occurs immediately downstream from an industrial point source discharge site. The results for the high exposure case are comparable to the amounts detected in the two Potomac River aquatic residue studies, one of which showed high concentrations of hypobromous acid as far downstream as 80 meters. Based on these studies, the Agency presumes risk to freshwater and estuarine fish and invertebrates at the point of discharge and downstream at 80 meters. However, the modeling results for "typical" sites are well below the levels of concern for fish and invertebrates. These results indicate that (activated) sodium bromide can be used at typical sites without impact most of the time. Since discharge of hypobromous acid is limited by the NPDES permit program administered by EPA's Office of Water, the Agency will be able to control the discharge of hypobromous acid on a site-by-site basis so that toxic levels are avoided.*

Based on this modeling, EPA also presumes a risk to endangered freshwater and estuarine/marine organisms in "worst case" situations. However, "typical" discharge levels are below those of concern for endangered species"

The use of inorganic halides in poultry processing is listed as a use pattern subject to U.S. EPA re-registration with use levels ranging from 150-300 parts per million in the facility (page 25 of the RED document[12]). Additionally, the U.S. EPA published a Tolerance Reassessment Decision Document (TRDD). The Ecological Risk Characterization was based on the documents published in the RED for Inorganic Halides[13]. The EPA concluded:

> "*The current uses of sodium and potassium bromide have been evaluated and it is concluded that there is a reasonable certainty that the use of products…will not pose harm to the general population or any population subgroup. It is further acknowledged that additional uses for these products do exist and that the RED for bromide should be consulted for additional information on quantitative risks associated from the use of other bromide-containing products."*

Considering that bromide ion, derived from the degradation of hypobromous acid in the presence of organic matter, has a relative benign environmental profile as established by the U.S. EPA, and that discharges will be controlled with an NPDES permit, we submit there will be no adverse environmental impact associated with its use and discharge.

9. Use of Resources and Energy:

The use of the proposed FCS will not require additional energy resources to manufacture. The fact of the matter is that energy will be *saved* by the use of this product. As explained in section 6(a) above, the source material, HBr, is a by-product in the manufacturing process of elemental bromine (Br_2). The HBr is not reactive for any other manufacturing processes, and must be recycled through the Br_2 manufacturing process, which is very energy intensive. The proposed FCS, hypobromous acid, is derived directly from HBr, which will reduce the amount of HBr to be recycled, and reduce any further reprocessing energy demands or costs at the point of manufacturing. We would not anticipate any further resource demands.

10. Mitigation Measures:

The proposed FCS is not reasonably expected to result in any new or extraordinary environmental problems that would require mitigation measures of any kind. The FCS is a relatively benign

compound that may replace other more toxic compounds in use presently at the use sites. In addition, discharge permits are mandated by the National Pollutant Discharge Elimination System (NPDES), in which all pollutants or components of discharges are reported by the discharger, and each location's discharge permit is then monitored and controlled by each state and region within a state.

11. Alternatives to the Proposed Action:

No potential adverse environmental effects are identified herein that would necessitate alternative actions to the proposed use of the FCS. Conversely, the alternative of not approving the action proposed herein would result in the continued use of other products by the beef and poultry industry, and such action would have no environmental impact. On the other hand, the use of the FCS would reduce the dependence on sodium hypochlorite bleach, which would have the net result of lower salt discharges into the environment, which would be a positive result.

12. List of Preparer(s):

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