EN

APPENDIX J

ENVIRONMENTAL ASSESSMENT

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1. **DATE:** August 29th, 2002

2. **NAME OF NOTIFIER:** Dr. Kareem I. Batarseh

3. **ADDRESS:** P.O. Box 34007
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USA

4. **DESCRIPTION OF PROPOSED ACTION**

a. ***Intended Action:***

The present notification requests from FDA to permit the use of which is an anti-microbial solution comprising of phosphoric acid, hydrogen peroxide, silver nitrate, tartaric acid, glutamic acid, and sodium tripolyphosphate as an anti-microbial agent for whole and parts of chicken, and whole and cut raw fruits and vegetables to reduce the level of microbial contamination in accordance with the current industry practices. is used on raw agricultural commodities in preparing, packing or holding of fruits and vegetables for commercial purposes. Treatment of of fruits and vegetables can be followed by a potable water rinse, though it is not necessarily due to its safety and low residual concentrations on food of chemicals comprising and low toxicity. This solution is applied directly on these food items through dipping or immersion. For fruits and vegetables processing, can be applied directly after harvesting, after washing with water, and after peeling, cutting, or paring.

b. ***Need For Action:***

The main purpose of this anti-microbial solution is to reduce the count of pathogenic bacteria present on whole and parts of chicken, and whole and cut raw fruits and vegetables. This is taken in an effort to reduce the level of contamination so as to make these food items safer and extend their shelf life.

vegetables. This is taken in an effort to reduce the level of contamination so as to make these food items safer and extend their shelf life.

c. ***Location of Use and Disposal:***

The anti-microbial solution will be used in food processing facilities. Specifically, in poultry plants, and in fruits and vegetables processing plants. The disposal of this anti-microbial will be through either on site of wastewater treatment plant or through discharge to a POTW.

5. CHEMICAL IDENTITY OF THE SUBJECT FOOD CONTACT SUBSTANCE

The finished concentrated anti-microbial solution consists of chemicals listed in Table 1, below; thus,

Table 1. Chemical constituents of anti-microbial solution]

Name	CAS #	Lewis Structure	MW	Physical Form
Water	7732-18-5	H–O–H	18	Colorless liquid
Phosphoric acid	7664-38-2	O || HO–P–OH | OH	98	Clear liquid
Hydrogen peroxide	7722-84-1	H–O–O–H	34	Clear liquid
Silver nitrate	7761-88-8	O || AgO–N–O	170	Colorless crystals
Tartaric acid	133-37-9	O OH OH O || | | || HO–C–CH–CH–C–OH	150	White crystalline powder
Glutamic acid	56-86-0	O NH_2 O || | || HO–C–$(CH_2)_2$–CH–C–OH	147	White crystals
Sodium tripolyphosphate	7758-29-4	O O O || || || NaO–P–O–P–O–P–ONa | | | ONa ONa ONa	368	White granular powder

6. INTRODUCTION OF SUBSTANCES INTO THE ENVIRONEMENT

a. *As a Result of Manufacture*:

No extraordinary circumstances pertain to the location of manufacture of the components of the solution that would require discussion of introduction into the environment. Very little, if any, introductions are expected into the environment as a result of manufacture of the solution itself since the manufacturer will minimize the loss of substances to reduce cost. The manufacturing process involves only mixing of ingredients in a closed system at room temperature. Phosphoric acid and hydrogen peroxide have vapor pressures that might produce very small losses to air. Since every batch reactor is equipped with scrubber, eliminating virtually any vapors escaping to the surrounding air. Hence, the total loss to the air is of no concern. If there is the need for maintenance of the batch reactors, any residual of present will be collected during wash in specialized tanks, and will be used in the next batch. OSHA's (Occupational Safety and Health Administration) regulations and industrial hygiene practices will be followed such as ventilation, and personal safety equipment.

Silver nitrate dusts resulting from manufacturing will be minimized through industrial hygiene practices and OSHA regulations such as proper handling and personal safety equipment.

b. ***<u>As a Result of Use and Disposal</u>:***

Introduction of substances into the environment as a result of use and disposal will be at the use site in poultry and in fruits and vegetables processing plants. This anti-microbial agent is designed to be applied directly on these food items through immersion or dipping as they move down the processing plants. Following is a discussion of how much of each of the components of the solution is expected to be introduced into the environment. These estimates are based on an average size of poultry and fruits and vegetables processing plants.

1. Poultry Plant: After the carcasses have been defeathered, eviscerated and sprayed, they will be carried by a paddle to be submersed into a chilling tank which contains diluted to achieve the technical effect of

microbial reduction. The carcasses are then carried by a conveyor and exit the chiller tank for further processing. Carcass parts and organs can also be submerged in the chilling tank. The present in the chilling tank along with other poultry wastes and blood will ultimately run into drains and be collected by the poultry plant water-treatment facility prior to disposal to POTW. Typical immersion time is about 5 minutes.

The total number of chicken being processed, the application rate, the number of processing lines, and the number of hours the facility is being operated will determine the total amount of solution used. Therefore, it is somewhat difficult to give *a priori* estimate of how much of will be used in a typical poultry-processing plant. Nonetheless, rough estimates can be deduced. The proceeding estimates are for daily production.

Typical values for average size poultry processing plant are:

Chilling tank capacity ≈ 95, 000 liters

Fresh water will be added to chilling tank at ≈ 2liters/bird

Total number of processed birds ≈ 200, 000/day

Total water used: 95,000+(200, 000) x 2 = 495,000 liters

2. Fruits and vegetables plant: After the raw fruits and vegetables have been cleaned from debris, they will be carried by a conveyor to be dipped into a tank which contains solution to achieve the technical effect of microbial reduction. The raw commodities are then carried by a conveyor and exit the tank for further processing. The present in the tank

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along with other wastes will ultimately run into drains and be collected by the fruit and vegetable plant water-treatment facility prior to disposal to POTW. The processed fruits and vegetables are immersed for less than 5 minutes.

The weight of raw agricultural commodities, the application rate, the number of processing lines and the number of hours the facility is being operated will determine the total amount of solution KB-00 used. Therefore, it is somewhat difficult to give *a priori* estimate of how much of will be used in a typical processing plant. Nonetheless, rough estimates can be deduced. The proceeding estimates are for daily production.

Typical values for average size fruits and vegetables processing plant are:

Tank capacity ≈ 75, 000 liters

Fresh water will be added to tank at ≈ 1.0liter/kg of fruits and vegetables

Total processed ≈130,000kg/day

Total water used: 75,000 + (130, 000) x 1 = 205,000 liters/day

In the following calculations, it is assumed that all the used will reach the drain and be discharged to a POTW, though this is untrue since each poultry or fruits and vegetables processing plant has its own treatment facility (Freedom of Information-Ecolab: FAP 1A4728 and 5A4459). Thus, these calculations represent "worst case" scenario. Assuming 95% degradation and 100 million liters of load to a typical POTW (Freedom of Information-Ecolab: FAP 1A4728 and 5A4459)-for silver, if we also assume 95% removal, Ratte (1999)-the calculations are given in Table 2, below.

<u>Table 2. POTW Discharge Values Resulting From Use in Poultry "P", and Fruits and Vegetables "FV" Processing Plants.</u>

Component	Effluent from POTW (ppb) "P"	Effluent from POTW (ppb) "FV"
Water	4930	2040
Phosphoric acid	0.32	0.13
Hydrogen peroxide	244.5	101.5
Silver*	0.14	0.055
Nitrate	0.085	0.035
Tartaric acid	0.8	0.32
Glutamic acid	1.65	0.65
Sodium tripolyphosphate	2.0	0.8

* Silver will be removed as silver sulfide and as complexes with other organic materials-see Item 7 **"ENVIRONMENTAL FATE OF EMITTED SUBSTANCES" Subtitle Silver.**

<u>BILBIOGRAPHY:</u>

Ecolab: FAP 1A4728. 2001. Regarding the use of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide,, peroxyoctanoic acid, and 1-hydroxyethylidene-1, 1-diphosphoric acid as a antimicrobial agent on poultry carcasses, poultry carcasses parts, and poultry organs.

Ecolab: FAP 5A4459. 1995. For the safe use of a mixture of peroxyacetic acid, acetic acid, and hydrogen peroxide to reduce the microbial load in water used to wash certain fruits and vegetables.

Ratte, H.T. 1999. Bioaccumulation and toxicity of silver compounds: A review. *Environmental Toxicology and Chemistry*. **18**, No. 1, pp 89-108. "See Supplementary Appendix Page 73"

<u>Conclusions:</u>

Accordingly, with the aid of Table 2 above, it can be, therefore, concluded that virtually all of the will be significantly diluted, and should not adversely affect the environment. It is important to note here that the levels of silver (0.14 and 0.055 ppb) are insignificant when compared with the average concentration of silver present in potable water (2.68 ppb, USEPA). In addition, it is extremely minute when compared with the USEPA limit of silver in drinking water (100 ppb).

7. ENVIRONMENTAL FATE OF EMITTED SUBSTANCES

Phosphoric acid: Phosphoric acid will present in an exceptionally low level in the discharge stream as a result of solution use (see Table 2 above). It will be in the form of $H_2PO^-_4$ which is not-toxic, and it can be used as a source of phosphate for living matters.

Hydrogen peroxide: This substance is readily degraded by organic molecules and sunlight to harmless moieties (water and oxygen); consequently, it will not persist or accumulate in the environment.

Silver: Silver will present in an exceptionally low level in the discharge stream as a result of solution use (see Table 2 above). Almost all the silver discharged will precipitate as insoluble salts such as silver chloride complexes, sulfate, carbonate and sulfide and settle into the sediment layer (Boyle, 1969). Hence, this should not constitute any toxicological effects since these salts are present naturally in the strata.

Form values of the solubility constants of these salts, one can determine the amounts of ionic silver present in the discharge water. Values of solubility constants, K_{sp} (Harris, 1986), for AgCl, Ag_2SO_4, Ag_2CO_3, and Ag_2S are $1.8x\ 10^{-10}$, 1.5×10^{-5}, 8.1×10^{-12}, and 8×10^{-51}, respectively. Therefore, by comparing these values, one can virtually see that all of the silver will be present in the form of Ag_2S. Hence,

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$$Ag_2S_{(s)} \rightleftarrows 2Ag^+_{(aq)} + S^=_{(aq)}$$

for which

$$K_{sp} = [Ag^+]^2[S^=]$$

If the concentration of dissolved $S^=$ is y M, then the concentration of Ag^+ is 2y; thus,

$$y = (K_{sp}/4)^{1/3}$$

$$y = 1.26 \times 10^{-17} \text{ M}$$

The concentration of Ag^+ is therefore $2y = 2.52 \times 10^{-17}$ M or 2.72×10^{-9} ppb.

It is important to note here that the above value does not consider the amount of Ag^+ already present in the effluent water (the common ion effect) which can be approximated as 2.68 ppb or 2.48×10^{-8} M (USEPA) in potable water. If one considers this value then,

$$Ksp = (2y + 2.48 \times 10^{-8})^2\, y$$

$$y = 1.3 \times 10^{-35} \text{ M}$$

and

$$2y = 2.6 \times 10^{-35} \text{ M or } 2.81 \times 10^{-27} \text{ ppb.}$$

Accordingly, since the amount of Ag^+ in the above calculations is << than the values given in Table 2 above (0.14 and 0.055 ppb), all of the silver which results from the use of will be precipitated as silver sulfide.

In addition, the presence of organic matter complexes with silver thereby reducing its mobility (Boyle, 1969). Smith and Carson (1977) found that in the areas where

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there is an abundance of decaying animals and plant materials, silver strongly precipitates as sulfides or it can combine with humic materials. Therefore, silver in soils will be immobilized, with no significant leaching into ground water. It is important to stress the fact here that the levels of silver (0.14 and 0.055 ppb) are insignificant when compared with the average concentration of silver present in potable water (2.68 ppb, USEPA). In addition, it is extremely minute when compared with the USEPA limit of silver in drinking water (100 ppb).

BILBIOGRAPHY:

Harris, D. 1986. *Quantitative Chemical Analysis.* W.H. Freeman & Comp. pp 659-662.

Boyle, R.W. 1968. *The geochemistry of silver and its deposit: with notes on geochemical prospecting for the element.* Geological Survey of Canada. Ottawa-Canada. Department of Energy and Resources. **160**, pp1-96.

Smith, I.C., and B.L. Carson. 1977. *Trace metals in the environment.* **Vol. 2**-Silver. Ann Arbor Science Publishers, Inc., Ann Arbor, MI.

Nitrate: Some of the nitrate, NO_3^-, which is present naturally in the human diet, will be converted to nitrite, NO_2^-, under *biotic* conditions and alkalinity (Randall and Buth, 1984), and nitrate salts. The rest will remain in the water, and be absorbed by plants to be used in their diet as a source of nitrogen. It is important to keep in mind that the amount of nitrate introduced into the environment is insignificant as a result of use of solution (see Table 2 above).

BILBIOGRAPHY:

Randall, C. W. and D. Buth. 1984. Nitrate buildup in activated sludge resulting from temperature effects. *J. Water Pollut. Control Fed.*, **56** (9), pp1039-1044. "See FCN #241"

Tartaric acid: Tartaric acid is present naturally in the human diet. The amount of tartaric acid used as a result of solution use is extremely small (see Table 2 above). It will be present as tartrate and it is a part of the diet. Therefore, it is not an environmental hazardous.

Glutamic acid: Glutamic acid is an amino acid that is present naturally in the human diet, and is a part of the diet. This substance can be used to manufacture proteins in living matters. Owing to its safety, and it is present in very low concentrations in solution -Table2 above, it should not be hazardous to the environment.

Sodium tripolyphosphate: This substance is insoluble, and is a part of the human diet. Considering the low levels used in solution (see Table 2 above), it should not have adverse effects on the environment.

Conclusions:

Based on the preceding discussion, it can therefore be concluded that the components that comprise should not result in the introduction of new or otherwise unique substances to the environment that require special measures.

8. ENVIRONMENTAL EFFECTS OF EMITTED SUBSTANCES

Phosphoric acid: This substance is generally recognized as safe under 21CFR §182.1073, present naturally in the diet, and present in low concentrations in solution Thus, there should be no effects on the environment.

Hydrogen peroxide: This substance is readily degraded to harmless moieties (water and oxygen); consequently, there should be no effect on the environment.

Silver: The amount of silver resulting from the use of solution should not be of significance to the environment due to its extremely low concentration in ind of dilution in sewers before reaching the POTW. Since most of the silver discharged will precipitate as insoluble salts and settle into the sediment layer, and be immobilized, with no significant leaching into ground water, there should be no effect on the environment, especially since these salts occur naturally.

Nitrate: Considering the fact that nitrate, NO_3^-, present naturally in the diet along with its converted form, nitrite, NO_2^-, there should be no effect on the environment from the introduction of these small amounts of nitrate as a result of solution use.

Tartaric acid: This substance is generally recognized as safe under 21CFR §184.1099, present naturally in the diet, and it is present in low levels in solution therefore, there should be no effect on the environment.

Glutamic acid: This substance is generally recognized as safe under 21CFR §182.1045, and considering its presence in the normal diet, and its low levels in solution there should be no effect on the environment.

Sodium tripolyphosphate: This substance is generally recognized as safe under 21CFR §182.1810, and it is used in small quantities in solution . Consequently, there should be no adverse effect on the environment.

9. USE OF RESOURCES AND ENERGY

No significant effect in use of energy and resources is expected as a result of no objection to this notification since it will be used in place of other anti-microbial of similar use profiles. Considering the safety of use concentration of solution there should not be any adverse effects on endangered species nor impact on any property listed in the National Register of Historical Places.

10. MITIGATION MEASURES

No mitigation measures need be discussed since, as mentioned under point 8 above, no environmental effects are expected.

11. ALTERNATIVES TO THE PROPOSED ACTION

No alternatives to the proposed action need be discussed since, as mentioned under point 8 above, no environmental effects are expected.

12. PREPARER

Dr. Kareem I. Batarseh

13. CERTIFICATION

I, the undersigned, certify that, to the best of my knowledge, all information in this EA is current, accurate, and up-to-date.

Dr. Kareem I. Batarseh	10/11/2002 Date