FINDING OF NO SIGNIFICANT IMPACT
FOR

Food Additive Petition 6A4767, submitted by Safe Foods Corporation, to provide for the safe use of cetylpyridinium chloride (CPC) for use as an antimicrobial treatment on raw poultry carcasses.

The Environmental Review Team, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, has determined that approval of this petition will not significantly affect the quality of the human environment and therefore will not require the preparation of an environmental impact statement. This finding is based on information submitted by the petitioner in the petition, including a revised environmental assessment, dated February 6, 2007, and our supplement to the environmental record for Food Additive Petition 6A4767.

Prepared by _____ Date: March 26, 2007
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2006F-0409

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Supplement to the Environmental Record for
Food Additive Petition 6A4767

This document incorporates by reference the notifier's revised environmental assessment (EA), dated February 6, 2007.

The purpose of this supplement is to ensure the accuracy and completeness of the environmental record and to assist the public in understanding the agency's basis for preparing a finding of no significant impact (FONSI).

Environmental Introductions

As stated in the EA, most of the cetylpyridinium chloride (CPC) will be recycled in the Cecure Recycle System. When the recycle system is purged, recycled CPC is removed via a filter, which is landfilled or incinerated with municipal solid waste[1]. This filter was described on Page 10 of the revised EA as activated carbon and data supporting the ability of the filter to remove CPC from the waste water were submitted in Attachment C. Introductions of CPC as a result of landfilling and incineration do not need to be estimated because landfills and incinerators are subject to the Environmental Protection Agency's (EPA) regulations and because the approval of this use will not cause any violations of applicable regulations governing landfills and incinerators.[2]

The portion of CPC that is not recycled is the portion expected to enter the aquatic or terrestrial environment or end up in animal feed. The Environmental Review Team (ERT) assumed the amount of CPC entering the environment included the amount lost in the second minute drip, the amount lost in the potable water rinse or chiller, and the amount bound to poultry. The petitioner measured the amount of CPC lost in the second minute drip and lost in the potable water rinse with the deluge/drench methods proposed in this petition at CPC treatment concentrations of 0.6% and 1.0%. The proposed use level in the petition is at 0.8%. ERT used the highest average numbers measured in the water rinse or second minute drip in calculations because these numbers are conservative and it is reasonable that these numbers will be seen with the proposed use. The highest average numbers were obtained in the post-chill use scenario with 5.3 mg CPC measured in the second minute drip at the 0.6% treatment level and 5.5 mg CPC measured in the water rinse at the 1% treatment level with a total of 10.76 mg CPC/carcass. The numbers in the EA are slightly lower because the petitioner used the highest average total CPC measured in the water rinse plus the second minute drip for the post-chill application for a total of 8.9 mg CPC/carcass. The amount estimated to be introduced into the environment bound to carcass skin was calculated by both ERT and the petitioner to be 2.1 mg CPC/carcass.[3] These values are

[1] See page 10 of the EA dated February 6, 2007.

[2] See EPA's regulations in 40 *CFR* § 258 governing landfills and 40 *CFR* § 60.

[3] Amount CPC on carcass skin = 169.2 g skin (highest average skin weight from Page 41) x 12.40 mg/kg CPC (average CPC concentration in skin at 1% CPC application rate from Page 37 of petition) x (1 kg/1000g) = 2.1 mg CPC/carcass.

summarized in Table 1.

Table 1. Estimate of amount CPC/carcass introduced into the environment.

Pre-Chill Use	CPC (mg)
Drip	4.4
Chiller	3.37
Total	7.77
Post Chill Use	
Drip	5.3
Potable Water Rinse	5.46
Total	10.76
Carcass Skin	2.1

Total Amount of CPC Entering Environment, Market Volume, and Material Balance

In 2005, approximately 8.87 billion broilers were produced in the United States (1). Based on the estimated 20% market penetration and ERTs conservative numbers, CPC would be applied to approximately 1.78 billion broilers[4] and 22,890.8 kg CPC[5] would be introduced into the environment annually. The petitioner estimated a total market volume of CPC of 20,412 kg (45,000 pounds) on Page 20 of the revised EA. This market volume estimate appears to be low as ERTs estimates of the amount possibly entering the environment exceed the market volume and if that much is lost to the environment, then it is logical to conclude that more CPC would be needed to keep the concentrations in solution high enough to be an effective antimicrobial. However, as the environmental introductions in the EA are calculated based on a per carcass basis, this does not change the overall environmental review.

On Page 11 of the revised EA, the petitioner estimated that 77% of the market volume would not be recycled or be bound to the carcass. The number is slightly different then ERT's calculated value (94%)[6] because, as discussed above, the petitioner used the highest average total CPC measured in the water rinse plus the second minute drip.

The EA indicates on Page 21 of the revised EA that 42,500 lbs or 94% (42500/45000 = 0.94) of the market volume will enter the environment. As discussed above, ERT's calculations indicate more than the estimated market volume will enter the environment.

[4] 8.87 billion broilers x 20% = 1.78 billion broilers

[5] 1.78 billion broilers x 12.86 mg CPC/carcass x (1 kg/10^6 mg) = 22,890.8 kg CPC

[6] (8.78 x 10^9 broilers/year) x (20% of market) x (10.76 mg/bird) = 1.91 x 10^{10} mg/bird or 19,100 kg and 19,100 kg not recycled / 20,412 kg = 0.94

Summary of Introduction Routes

The total amount of CPC entering the environment is further divided into the amount entering different introduction pathways. These pathways/scenarios are used to calculate expected environmental introduction concentrations (EICs) and expected environmental concentrations (EECs). The petitioner described three scenarios for terrestrial release and one scenario for aquatic release. The first terrestrial scenario would result in releases as the chemical became a part of the poultry offal and the offal was rendered into poultry meat and bone meal (P-MBM). The P-MBM becomes part of poultry feed and CPC is not absorbed by poultry which consume it. The CPC is passed to the poultry litter and at the end of the grow-out cycle, the litter is used as an amendment in soil (offal/poultry litter EEC). The second scenario by which CPC is released to terrestrial environments is through amendment of soil with solids collected from a dissolved air floatation (DAF) system (DAF EEC). The third scenario for terrestrial release is through amendment of soil with sludge from the poultry plant wastewater treatment system (wastewater sludge EEC). The petitioner identified the only aquatic release of CPC to occur as a result of discharges of treated wastewater from the poultry plant wastewater treatment system (wastewater EEC). ERT's recommendations for review of the use of antimicrobials in poultry processing also suggest calculating introductions from the consumption of the poultry containing the CPC. In this scenario, CPC bound to poultry is ingested by humans and not absorbed. After ingestion, CPC will enter a publicly owned treatment works (POTW) and enter the aquatic environment in effluent (POTW EEC). Due to the high sorptive nature of CPC, it is more likely that CPC will bind to sludge in the POTW and soil will be amended with that sludge, resulting in a terrestrial introduction (POTW sludge EEC). Poultry that is not consumed is expected to be disposed of in municipal solid waste and ultimately to enter a landfill. Figure 1 summarizes these environmental introduction pathways.

A material balance of where CPC entering the environment will be introduced is useful to understand the fate of CPC. Approximately, 62.4%[7] of the CPC that is not recycled (8.03 mg/carcass) will be incorporated into the offal stream, 16% will bind to carcasses, and 21.2% will be applied to land as DAF.

Introductions of CPC to the Environment from Poultry Consumption (POTW EICs)

The petitioner did not calculate environmental introduction concentrations for CPC as a result of consumption of chicken bearing residual CPC. ERT calculated these values because this route represents 16% of the amount of CPC released to the environment as a result of requested use. The POTW EIC is the CPC concentration in aquatic effluent and the POTW sludge EIC reflects the concentrations in POTW sludge. The POTW EIC is estimated using the following calculation:

POTW EIC- (ppm) = A x B x C x D,

[7] 5.3 mg + 5.46 mg/2 (from DAF) = 8.03 mg /12.86 mg = 62.4%

where A = kg/year, as CPC residue on poultry
= 2.1 mg CPC mg/carcass x 1.78 billion broilers x kg $1/10^6$ mg conversion factor

= 3738 kg CPC residue on poultry
B = 1/liters per day entering POTWs (1.32×10^{11} liters per day)[8]
C = year/365 days
D = 10^6 mg/kg conversion factor.

Therefore, assuming conservatively that all CPC bound to poultry is 1) ingested evenly throughout the United States, 2) enters POTWs following consumption, and 3) remains in effluent that ultimately is released to surface waters.

POTW EIC = 3738 kg CPC x ($1/1.32 \times 10^{11}$ liters per day) x (year/365 days) x 10^6 mg/kg

POTW EIC = 0.00007752 mg/L or 77 ng/L (parts per trillion)

An EEC can be estimated simply by assuming a standard 10-fold dilution of treated effluent to a receiving water body.[9] Subsequently, the EEC would be 7.7 ng/L.

The POTW sludge EIC is calculated using the following calculation:

POTW sludge EIC = A x B x C,

Where, A = kg/year as CPC residue on poultry = 3738 kg (calculated above)
B = 1/kg sewage sludge entering POTW per year (6.8×10^9 kg sludge/year)[10]
C = conversion factor kg/10^6mg

Therefore, assuming conservatively that all CPC bound to poultry is 1) ingested evenly throughout the United States, 2) enters POTWs following consumption, and 3) it all binds to sewage sludge and is ultimately applied to land.

POTW sludge EIC = 3738 kg CPC x ($1/6.8 \times 10^9$ kg sludge/year) x 10^6 mg/kg
= 0.55 mg/kg

The estimated EECs calculated in the EA and by ERT are shown in Table 2 and available

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[8] The flow of wastewater to POTWs in the United States is 34,899 million gallons per day (1.32×10^{11} liters per day). Table C-3, Appendix C, Clean Watersheds Needs Survey 2000, U.S. Environmental Protection Agency, viewed on the Internet at http://www.epa.gov/owm/mtb/cwns/2000rtc/cwns2000-appendix-c.pdf on March 1, 2007 (2).

[9] ERT has examined dilution factors (DF) at poultry processing plants and found that 71% of facilities had DFs greater than 100 and 96 percent had a DF of 20 or greater (3). A DF of ten for all food processing facilities is assumed to be a conservative DF for the majority of food processing facilities.

[10] The volume of biosolids from POTWs was projected to be 7.6 million tons, or about 6.8×10^9 kg, for the year 2005 (4).

toxicity endpoints in Table 3. Table 3 was reproduced from the Table of "Aquatic Toxicity Data on Cetylpyridinium Chloride (CPC)" submitted as an attachment to the EA and the Ecotox Database (5). The conservative estimates of the terrestrial introductions exceed the toxicity endpoints for soil dwelling organisms estimated in the supplement to the environmental record for FAP 2A4736 and in the EA for this petition. However, as discussed below, we do not anticipate toxicity to occur.

The revised EA estimates that the bioavailable CPC present in soil would be 1/100th of the environmental introduction concentration (see Page 41 of the revised EA). As stated by Mackay, "A calculation of the distribution in the environment...cannot be performed, due to the saline character of the compound."(6). This is the case because the environmental fate will depend on characteristics of the environment CPC is introduced to such as the acidity and the organic carbon content of the soil and not only on the physical/chemical properties of the FCS itself. However, the introduction route (e.g. wastewater, poultry litter, sludge, DAF, and bone meal) and studies on the sorption of CPC and other alkyl pyridinium chlorides to these materials[11] indicate that CPC will be bound to the media (e.g. poultry offal, DAF, and sludge) with which it is introduced into the environment, making it unavailable to organisms. Evidence of decreased bioavailability of cationic surfactants is also shown by the decrease in toxicity seen when aquatic organisms were exposed in systems with sediments present in the exposure (6).[12]

Table 2. Comparison of expected environmental concentrations (EECs) and lowest estimated toxicity endpoints.

Environmental Introduction Route	EEC Calculated by ERT	EEC Calculated in EA	Lowest Toxicity Endpoint
Aquatic	**µg/L**	**µg/L**	**µg/L**
POTW	0.08	---	2[a]
Wastewater	0.058	0.047	2[a]
Terrestrial	**µg/kg**	**µg/kg**	**µg/kg**
POTW Sludge	14	---	not available
Offal/Poultry Litter	16	17	not available
DAF	33	27.5	not available
Wastewater Sludge	3.1	2.5	not available

[a] This value is based on the lowest measured aquatic toxicity endpoint (a no observable effects level) of 50 µg/L for the giant river prawn and an estimated acute-to-chronic ratio of 25.

The previous estimate of 10 to 31 ppb for soil dwelling organisms was extrapolated from aquatic toxicity data by applying a safety factor of 100. An additional acute to chronic ratio of ten was used to estimate chronic toxicity in the EA for this petition,[13] resulting in a value of 1 to 3.1 ppb.

[11] Appendix 1 to FAP 2A4736 contains data from experiments on the sorption of CPC to poultry offal, DAF, sludge, and soil.

[12] See Table 9 and discussion by R. S. Boethling (7).

[13] See page 41 of revised EA.

We have re-evaluated our approach in using aquatic toxicity data to predict toxicity to soil dwelling organisms because aquatic toxicity data are not typically used to estimate toxicity to soil-dwelling organisms. ERT agrees with the petitioner that the estimated terrestrial toxicity

Table 3. Aquatic toxicity data on cetylpyridinium chloride (CPC).[a]

Scientific Name (Common Name)	Endpoint	Duration	Concentration (µg/L)
Macrobrachium rosenbergii (Giant river prawn)	LC50[b]	24 Hours	130 (100-170)
	100% Mortality	24 Hours	470
	0% Mortality	24 Hours	50
Metapenaeus ensis (Greasyback shrimp)	LC50[b]	24 Hours	2100 (1700-2700)
	100% Mortality	24 Hours	4500
	0% Mortality	24 Hours	520
Penaeus japonicus (Kuruma shrimp)	LC50[b]	24 Hours	3100 (2000-4900)
	100% Mortality	24 Hours	13900
	0% Mortality	24 Hours	200
Penaeus monodon (Jumbo tiger prawn)	LC50[b]	24 Hours	800 (600-1000)
	100% Mortality	24 Hours	1950
	0% Mortality	24 Hours	150
Penaeus penicillatus (Redtail prawn)	LC50[b]	24 Hours	560 (420-720)
	100% Mortality	24 Hours	1500
	0% Mortality	24 Hours	100
Penaeus semisulcatus (Shrimp)	LC50[b]	24 Hours	1000 (700-1500)
	100% Mortality	24 Hours	4400
	0% Mortality	24 Hours	100
Australorbis sp. (Snail)	100% Mortality	48 Hours	5000
	Mortality	48 Hours	2500
	Mortality	48 Hours	1000
Mercenario mercenaria (Clam)[c]	Larval growth and development	14 Days	10-250
Crassostrea virginica (Oyster)[c]	Larval growth and development	14 Days	10-250

[a] This Table was reproduced from the Attachment 3 of FAP 2A4736 and the Ecotox Database (5).

[b] Median lethal concentration (LC50) is a statistically estimated concentration that is expected to be lethal to 50% of organisms tested.

[c] Results are first observed effect concentration (FOEC) determined on alkyl (C_{12}) pyridinium chloride which can be found in Boethling et al. (7).

endpoints are very conservative. Risk to soil dwelling organisms cannot be assessed at this time due to the lack of toxicity endpoints for these organisms. However, based on the low exposure and expected bioavailability, we do not anticipate that toxicity to soil dwelling organisms will occur.

Comments by ERT on Specific Items in the EA.

Item 4. Description of the Proposed Action.

The EA states on Page 2, "The concentration of CPC in the solution applied to the carcasses shall not exceed 1.0 percent by weight." The petition was amended to allow a maximum use level of 0.8% CPC.

Item 6.2.3. Terrestrial Environments.

The EA states on Page 20, "The new application conditions require a relatively small increase in the total mass of CPC to be used because of the capture and recycle system, which permits the re-use of the Cecure® treatment solution many times over the course of a day." The EA also estimates the market volume at 45,000 pounds CPC per year in this section. As mentioned above, we do not completely agree with the estimated market volume. However, the environmental conclusion is not affected because ERT's assessment of the environmental impact was independent of the market volume and based on the use rate in a typical poultry plant.

Item 8.2. Terrestrial Environments.

The EA states, on Page 41, "For example, the 14-day LC_{50} for 2-chloroethyltrimethylammonium chloride in earthworms has been determined to be greater than 1000 mg/kg in soil. This is 5 orders of magnitude greater than the minimum terrestrial LC_{50} of 10 ppb (0.01 mg/kg) estimated by FDA." We note that a more suitable compound to predict the toxicity of CPC would be an alkyl pyridinium chloride.

Literature Cited

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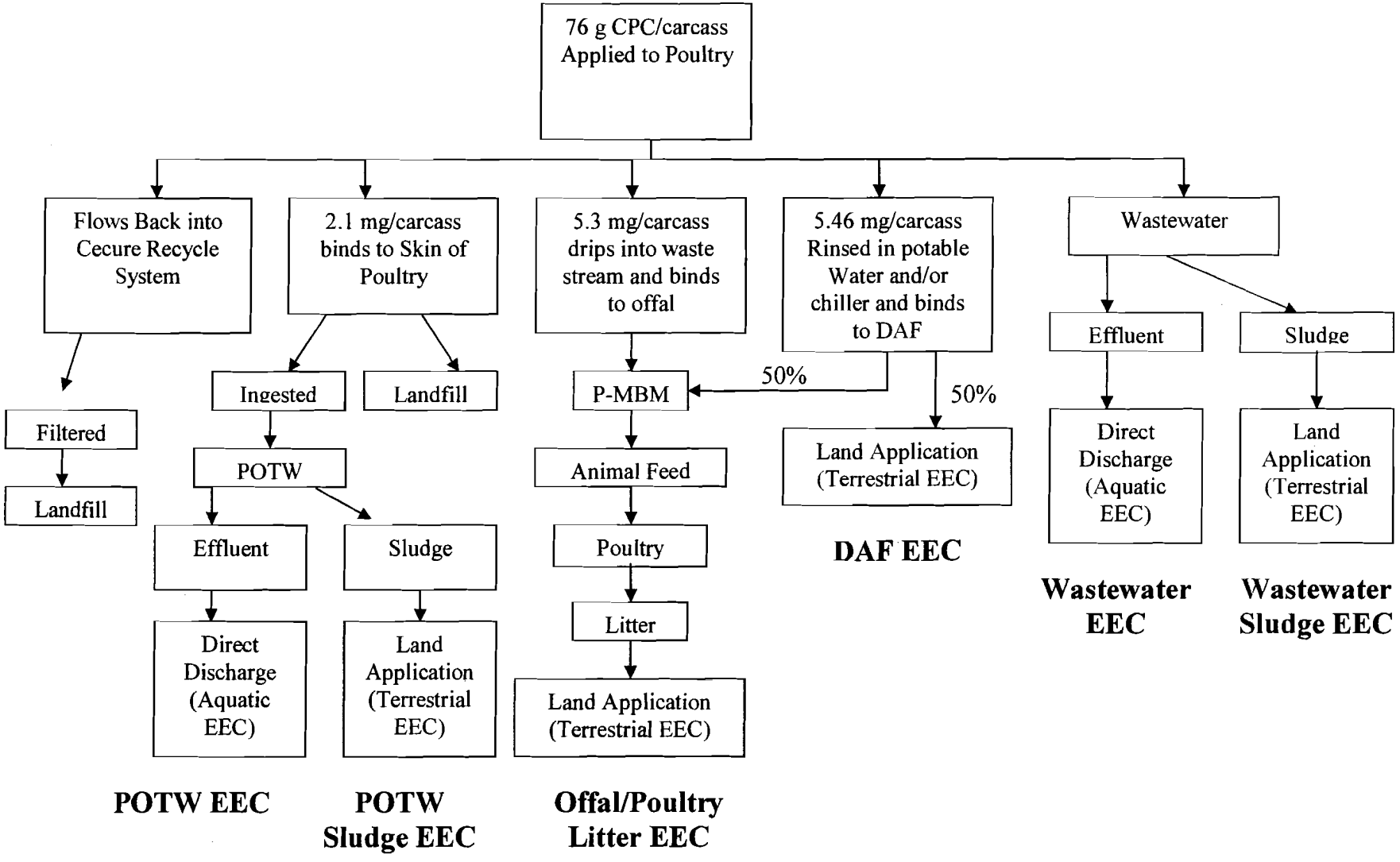
Figure 1. Summary of the Environmental Introductions of CPC from the Proposed Use.