

Environmental Assessment

- 1. Date:** March 3, 2017
2. Name of Applicant/Petitioner: Pure Bioscience, Inc.
3. Address:

Pure Bioscience
1725 Gillespie Way
El Cajon, CA 92020

Agent: Mitchell Cheeseman, Ph.D.
Steptoe & Johnson LLP
1330 Connecticut Ave. NW
Washington, DC 20036

4. Description of Proposed Action:

a. Requested Action

The action requested in this Notification is the establishment of a clearance to permit the use of a solution of silver dihydrogen citrate (SDC) stabilized with sodium lauryl sulfate and citric acid as an antimicrobial solution applied to reduce the pathogen populations on poultry carcasses, parts and organs. The maximum use level requested for this use will be 160 ppm as silver.

b. Need for Action

SDC solutions reduce populations of pathogenic and nonpathogenic microorganisms that may be present on poultry carcasses parts and organs. SDC is expected to be an important preventive control in providing safer poultry products for consumers.

The present application is in response to the changing needs of the food processing industry. Many antimicrobials previously approved for use in poultry processing have physical and chemical properties which make them more challenging to use and, therefore, less desirable for our intended use. In addition, the increasing pressure by Federal authorities to continue to improve control of foodborne pathogens in poultry processing makes it necessary to use antimicrobials such as SDC in order to achieve needed reductions in microbial populations without undesirable side effects related to worker exposure and the quality of processed poultry.¹

c. Locations of use/disposal

This product is for use in poultry processing plant(s) throughout the United States. The expected route of disposal for waste solution is the processing plant wastewater treatment facilities. The FCS will be limited to use in facilities that have either on-site waste water treatment facilities or that discharge to publically owned treatment works (POTW). It is

¹ See USDA FSIS Federal Register Notice, *New Performance Standards for Salmonella and Campylobacter in Young Chicken and Turkey Slaughter Establishments: Response to Comments and Announcement of Implementation Schedule*, 76 Fed. Reg. 15282; see also FSIS Notice 54-12, *New Performance Standards for Salmonella and Campylobacter in Chilled Carcasses at Young Chicken and Turkey Slaughter Establishments*, dated 9/11/12, available at <http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/54-12.pdf>.

expected that, as a worst-case, on-site waste water treatment facilities will discharge directly to surface waters.

The antimicrobial will be applied to the surfaces of poultry carcasses, parts, organs or trim in a cabinet or line by spray or dip. Based on our understanding of typical water use in the poultry industry and our anticipated market, we expect a volume of 0.75 to 1 gal per minute of our diluted antimicrobial will be used for a 4 to 6 nozzle spray cabinet that serves to coat the surfaces of the carcasses, parts or organs. The antimicrobial is not intended for use in chilling baths.

After the diluted product is sprayed onto the poultry, the bulk of the solution drains off the product. The waste solution ultimately runs into drains and enters the poultry processing plant water treatment facility. The treatment facility will receive water used throughout the plant for scalding (feather removal), bird washing before and after evisceration, chilling, cleaning and sanitizing of equipment and facilities, and for cooling of mechanical equipment such as compressors and pumps.² All of this water is collected and treated by the facility prior to release to surface waters. Very minor quantities are lost to evaporation into the air.

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

The raw materials used in this product are silver, citric acid, sodium lauryl sulfate, and water. The result of the reaction of silver and citric acid in the presence of SLS is to form an equilibrium stabilized complex of SDC. When the mixture is diluted for use on poultry carcasses, poultry parts and organs, the solution contains no more than 160 ppm silver as SDC. To attain 160 ppm silver in the water, the concentrated solution containing 0.24% silver would be diluted 15-fold. The product may be further diluted up to 160-fold for a minimum silver use level of 15 ppm.

Complete Name	CAS No.	Molecular Weight	Molecular Formula
Silver	7722-84-1	34.01	Ag
Citric acid	64-19-7	60.05	C ₆ H ₈ O ₇
Sodium Lauryl Sulfate	79-21-0	76.05	NaC ₁₂ H ₂₅ SO ₄
Water	7732-18-5	18.01	H ₂ O

6. Introduction of Substances into the Environment:

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

The FCS is manufactured in plants which meet all applicable Federal, State and local environmental regulations. Pure Bioscience also asserts that there are no extraordinary

² U.S. Environmental Protection Agency (EPA), *Technical Development Document for the Final Effluent Limitations Guidelines and Standards for the Meat and Poultry Products Point Source Category (40 CFR 432)*, EPA-821R-04-011, p. 6-7 (September 8, 2004) (“MPP ELG TDD”), available at https://www.epa.gov/sites/production/files/2015-11/documents/meat-poultry-products_tdd_2004_0.pdf.

circumstances pertaining to the manufacture of the FCS such as 1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; 2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27(b)(10)); and 3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

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

Introduction of dilute solutions of the product into the environment will take place primarily via release in wastewater treatment systems. Introduction of the components of the product into the environment will result from use of the product as an antimicrobial agent for spray or dip application onto poultry carcasses, parts and organs, and the subsequent disposal of such water and spray drainage into the processing plant wastewater treatment facility. The total amount of product used at a typical facility can be estimated based on the parameters of a typical plant processing scenario based on the knowledge and experience of the notifier.

Our expectation, based on our understanding of poultry processing and our market predictions,³ is that a typical poultry plant will use an antimicrobial spray or dip, at a maximum rate of 1 gal/min, or 480 gallons per 8 hr. shift, and 960 gallons for a plant processing for 16 hr/day. For the larger 16 hr plants, a total of $960/12 = 80$ gallons of SDC concentrate would be consumed per day.⁴

Northcutt & Jones have published an analysis of survey data regarding increased water use in the poultry industry as a result of HACCP requirements.⁵ Northcutt & Jones report water use data before and after HAACP. Northcutt and Jones report a minimum water use level from before HACCP of 15 L/bird.⁶ In addition, Northcutt & Jones report an average increase in water use after HACCP implementation for small facilities of <3.8 L/bird.⁷ A small facility is described in this article as one that processes no more than 125,000 birds per day and represents a worst case regarding the ratio of water use to antimicrobial use. Therefore, we will base our estimates of environmental introductions on the processing of 125,000 carcasses per day using 15 L plus 3.8 L or 18.8 L of water per bird. Thus, we will assume our model plant generates at least

³ See confidential attachments including estimates by industry expert consultants.

⁴ As a worst case, we have applied the dilution rate of 1:15 even though in some cases a dilution rate as large as 1:160 may be used. The higher dilution rate would reduce the amount of the FCS introduced into the environment.

⁵ Northcutt J.K. & D.R. Jones. A survey of water use and common industry practices in commercial broiler processing facilities. *Journal of Applied Poultry Research* 13:48-54 (2004), available at <https://naldc.nal.usda.gov/download/38935/PDF>.

⁶ *Ibid.* pg. 48.

⁷ *Ibid.* pg. 50, Table 2.

2.35 million L of waste water per day.⁸ The maximum concentration of each component in the SDC concentrated product is:

- Silver 0.24%
- Sodium Lauryl Sulfate $\leq 0.45\%$
- Citric acid 20%

The concentrated product is 9.11 pounds per gallon, so 64 gallons would be 583.0 pounds or 264.4 kg.⁹

The total amount of each component present in 64 gallons is

- Silver: 0.24% of 264.4 kg = 0.63 kg.
- SLS 0.45% of 264.4 kg = 1.2 kg.
- Citric acid 20% of 264.4 kg = 52.9 kg.

Assuming that 100% of these chemicals are discharged to an on-site waste water treatment facility each day in a total waste water discharge of 2.35 million liters from the poultry plant, the maximum concentration of these components in waste water would be:

- Silver: 630 g / 2.35 million liters = 268 $\mu\text{g/liter}$ (ppb).
- SLS: 1200 g / 2.35 million liters = 511 $\mu\text{g/liter}$ (ppb).
- Citric acid: 52,900 g / 2.35 million liters = 22.5 mg/liter (ppm).

Treatment of the process water at the on-site wastewater treatment plant is expected to result in near complete biodegradation of the organic components of the SDC solution (citric acid, citrate, and sodium lauryl sulfate). This expectation is based on the available data on the biodegradability of SLS¹⁰ and citric acid¹¹ which establish a biodegradation rate of 93% for citric acid and 90% for SLS before entry into surface waters. If we assume that level of biodegradation and use a dilution factor of 1/10 for discharge to surface waters,¹² worst case discharges of 0.16 mg/L (160 $\mu\text{g/L}$) for citric acid¹³ and 5.1 $\mu\text{g/L}$ for SLS¹⁴ can be estimated.

⁸ 18.8 L \times 125,000 birds = 2,350,000 L/day.

⁹ See SDS Sheet provided; 9.11 lbs/gal \times 64 gals = 583 lbs, or 264.4 kg.

¹⁰ OECD SIDS, *Sodium Dodecyl Sulfate* (1995), pg. 8, <http://webnet.oecd.org/Hpv/UI/handler.axd?id=498ea9e0-5478-42ad-8fce-c44fcaeda38e>.

¹¹ OECD SIDS, *Citric Acid* (2000), and included references from that document, <http://www.inchem.org/documents/sids/sids/77929.pdf>. Specifically, Gericke, Fischer: *A correlation study of biodegradability determinations with various chemicals in various tests*. Ecotox. Environm. Safety 3: 159-173 (1979). See specifically Table 3 Page 165.

¹² Rapaport, Robert A., 1988. *Prediction of consumer product chemical concentrations as a function of publically owned treatment works treatment type and riverine dilution*. Environmental Toxicology and Chemistry, 7(2), 107-115. Found online at: <http://onlinelibrary.wiley.com/doi/10.1002/etc.5620070204/abstract>.

¹³ 22.5 mg/L \times (100% - 93%) \div 10 = 0.16 mg/L.

¹⁴ 511 $\mu\text{g/L}$ \times (100% - 90%) \div 10 = 5.1 $\mu\text{g/L}$.

If we apply the estimate by Ratte et al. that >94% of the silver will partition to sludge during treatment at the on-site facility¹⁵ to the concentration exiting the processing facility (268 µg/L), then the EIC for silver in water released from the on-site treatment facility would be 16.1 µg/L and the concentration in sludge generated at the on-site treatment facility would be 251.9 µg/L, the terrestrial EEC.¹⁶ With respect to silver partitioning to sludge, EPA's Reregistration Eligibility Decision (RED) document for silver concludes that silver partitioning to sludge during wastewater treatment will be in the form of silver sulfides.¹⁷ The silver in the water released from the on-site treatment facility will be further diluted either because it is released to surface waters after treatment at the on-site facility or processed in a POTW. In either case, the concentration of silver in the aquatic compartment will be further diluted 10-fold to produce an EEC of 1.6 µg/L.¹⁸ The EEC's for silver, SLS and citric acid are summarized below:

- Silver_(aq): 268 µg/L (ppb) × 6% partitioning to water = 16.1 µg/L (ppb);
16.1 µg/L (ppb) ÷ 10 (dilution in POTW or surface water) = 1.6 µg/L (ppb)
- Silver_(terr): 268 µg/L (ppb) × 94% partitioning to sludge = 251.9 µg/L (ppb)
- SLS: 511 µg/L (ppb) × 10% ÷ 10 = 5.1 µg/L (ppb)
- Citric acid: 22.5 mg/L (ppm) × 7% ÷ 10 = 0.16 mg/L = 160 µg/L (ppb)

Pursuant to 40 C.F.R. § 261.24, silver is a toxic hazardous waste - carrying a waste code of D011—if detected at 5 mg/L by Toxicity Characteristic Leaching Procedure (TCLP) - EPA Method 1311. Accordingly, if not sent for silver recovery, sludge containing more than 5 mg/L silver by TCLP must be managed and disposed of as a hazardous waste. However, we have estimated a concentration of silver in sludge of 251.9 µg/L. This concentration is ~20-fold lower than the level requiring disposal of the sludge as toxic waste. Therefore, EPA's limits should be no issue with respect to disposal of sludge even from an onsite treatment facility.

7. Fate of Emitted Components in the Environment:

Only insoluble silver salts, and very minor amounts of silver ion, citric acid and SLS are expected to survive treatment at the on-site water treatment facilities at poultry processing plants. Silver is naturally present at low levels in the environment in surface waters at concentrations between 0.2-0.3 µg/L.¹⁹ We reference EPA's reregistration review²⁰ which considers LC₅₀s for freshwater fish which range from 3.9 to 280 µg/L. In addition, EPA references EC₅₀s for freshwater invertebrates of 0.25 to 4500 µg/L. Finally, EPA references EC₅₀s for marine/estuarine invertebrates of between 5.8 and 150 µg/L.

¹⁵ Ratte, Hans Toni, *Bioaccumulation and toxicity of Silver Compounds: A Review, Environmental Toxicology and Chemistry*, Vol. 18, no.1, pp 89-108 (1999) (specifically p. 89).

¹⁶ 268 µg/L × 6% = 16.1 µg /L; 268 µg /L × 94% = 251.9 µg /L

¹⁷ EPA Reregistration Eligibility Decision ("EPA Silver RED") on Silver (1992) p. 16 of RED document (page 37 of the PDF document). Available Online at:

<https://archive.epa.gov/pesticides/reregistration/web/pdf/silver.pdf>.

¹⁸ Op Cite Rapaport.

¹⁹ WHO, 2003, Silver in Drinking Water: Background document for development of WHO Guidelines for Drinking-water Quality, p 1.

²⁰ Op Cite EPA Silver RED pp. 16-17.

The above referenced data are substantially similar to what EPA reviewed in order to establish water quality criteria for silver, including the National Recommended Water Quality Criteria-Aquatic Life Criteria for Silver, which establishes a criterion maximum concentration (CMC) of 3.2 µg/L (acute).²¹ This criterion is an acute concentration of silver in surface waters which is not expected to pose a significant risk to the majority of species in a given environment. We believe that our EEC of 1.6 µg/L establishes a suitable margin of safety for our intended use. The acute risk quotient (RQ) for fish and invertebrates, using the acute silver CMC as the endpoint, would be calculated as (peak water concentration) ÷ (acute silver CMC): $1.6 \div 3.2 = 0.5$. This is not greater EPA's Level of Concern (LOC) of 0.5 for acute high risk presumptions for aquatic animals.²²

Moreover, silver and silver compounds are specifically considered in NPDES permitting as a designated toxic pollutant²³ and priority pollutant²⁴ under the Clean Water Act. NPDES permits generally specify an acceptable level of a pollutant or pollutant parameters in a discharge of water, where the discharge occurs from either an industrial use site using pre-treatment or a POTW, and the permittee may choose which technologies to use to achieve that level. A poultry processing facility that is a "direct discharger," meaning that it directly releases wastewater to surface waters of the United States (e.g., lakes, rivers, oceans) is subject to national effluent limitations guidelines and standards and new source performance standards in their NPDES permit, while an indirect discharger (meaning a facility that discharges to a POTW) must comply with pretreatment standards.²⁵ Silver is not regulated by EPA under the national effluent guideline for meat and poultry products²⁶ and is instead regulated by the relevant permitting authority, usually a state authority, although EPA issues NPDES permits for some states.²⁷

In this regard, EPA develops, using the latest scientific knowledge, the National Recommended Water Quality Criteria, to assist NPDES permitting authorities with determining levels of pollutants that are unsafe for people and wildlife.²⁸ As discussed above, EPA has developed an aquatic life water quality criterion for silver. State and tribal governments may use this criterion or use it as guidance in developing their own standard. Under the NPDES program, limits must be included in permits where pollutants will cause, have reasonable potential to cause, or contribute to an exceedance of the State's water quality standards, and the final calculated limit placed in the permit must be protective of water quality standards.²⁹ Because

²¹ <https://www.epa.gov/wqc/national-recommended-water-quality-criteria-aquatic-life-criteria-table>.

²² <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/technical-overview-ecological-risk-assessment-risk>.

²³ 40 C.F.R. § 401.15(57).

²⁴ 40 C.F.R. Part 423, Appendix A, also available at <https://www.epa.gov/sites/production/files/2015-09/documents/priority-pollutant-list-epa.pdf>.

²⁵ Op cite MPP ELG TDD, p. 2-1.

²⁶ EPA decided to not regulate metals, including silver, under the effluent guidelines for meat and poultry processing facilities. MPP ELG TDD, p. 7-25.

²⁷ EPA has a reference table indicating which states have NPDES permit program and pretreatment program authorities at <https://www.epa.gov/npdes/npdes-state-program-information>.

²⁸ <https://www.epa.gov/wqc/basic-information-water-quality-criteria>.

²⁹ EPA, *Central Tenets of the National Pollutant Discharge Elimination System (NPDES) Permitting Program*, <https://www3.epa.gov/npdes/pubs/tenets.pdf>, p. 3.

silver is a toxic pollutant under the Clean Water Act and subject to a water quality criterion, we would expect monitoring to be required either by the permitting authority and/or the POTW to which a facility discharges (assuming no on-site waste water processing).

Pure Bioscience intends to include the following information in product labeling, which is required for EPA-registered products as a result of EPA's most recent reregistration decision on silver antimicrobials. This label information will alert Pure Bioscience's customers as to the need for appropriate coordination with the NPDES permitting authority, as needed.

"This product is toxic to fish and aquatic invertebrates."

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the provisions of a National Pollution Discharge Elimination Permit (NPDES) permit and the permitting authority has been notified in writing prior to discharge."

There are various methods used to monitor and enforce NPDES permit conditions. The permit will require the facility to sample its discharges and notify EPA and the state regulatory agency of these results or if the facility determines it is not in compliance with the requirements of a permit.³⁰ EPA and state regulatory agencies also will send inspectors to companies in order to determine if they are in compliance with the conditions imposed under their permits. The facility monitoring reports are public documents, and the general public can review them.³¹ If violations of permits occur, EPA can take enforcement action, including imposition of significant monetary penalties.³²

We have estimated an EEC of 251.9 µg/L of silver for the terrestrial compartment and expect that this silver will be present as silver sulfides.³³ The equivalent concentration of silver sulfide would be 578.7 µg/L.³⁴ Ratte (1999) reports a NOEC for earthworms for silver sulfide of 62 mg Ag/Kg soil.³⁵ If we assume a density of soil of 1.5 g/cm³,³⁶ and use that as an approximation of the density of sludge, this NOEC would translate to 93 mg/L,³⁷ a value which would represent a margin of safety compared to our terrestrial EEC of ~161-fold.³⁸ This is a sufficient safety margin given that our estimate of silver concentration assumes that sludge from onsite treatment facilities at a poultry facility will not be diluted by other sludge if applied to agricultural or other lands. In addition, Ratte (1999) reports NOECs for multiple terrestrial

³⁰ <https://www.epa.gov/npdes/npdes-permit-basics>, see response to "How are the conditions in NPDES permits enforced by EPA and the states?"

³¹ <https://echo.epa.gov/>.

³² See generally, EPA Office of Water, *The Enforcement Management System National Pollutant Discharge Elimination System (Clean Water Act)*, (1989), <https://www.epa.gov/sites/production/files/documents/emswa-jensen-rpt.pdf>.

³³ Op Cite EPA Silver RED, p. 16.

³⁴ $(251.9 \text{ } \mu\text{g/L silver}) \times ((247.8 \text{ g/mole silver sulfide}) \div (107.868 \text{ g/mol silver})) = 578.7 \text{ } \mu\text{g/L silver sulfide}$

³⁵ Op Cite Ratte, pg. 97.

³⁶ Donahue, Roy Luther; Miller, Raymond W.; Shickluna, John C. (1977). *Soils: An Introduction to Soils and Plant Growth*. Prentice-Hall pg. 60. ISBN 0-13-821918-4.

³⁷ $62 \text{ mg/kg} \times 1.5 \text{ g/cm}^3 = 93 \text{ mg/L}$.

³⁸ $93 \text{ mg/L} \div 0.5787 \text{ mg/L} = 160.7$

plants of 771 mg/Kg (the highest level tested).³⁹ All of these referenced experiments demonstrate no toxic effect for silver sulfide in sewage sludge at exposure levels much higher than our worst-case estimates of EECs. Therefore, we conclude that the requested use of the FCS will not result in any significant environmental impact from increased introductions of silver.

Remaining citric acid⁴⁰ and SLS⁴¹ concentrations would be expected to continue to biodegrade in the environment.

8. Environmental Effects of Released Substances:

In the use scenario described above, waste antimicrobial solution (from application and drainage) will be directed to an on-site wastewater treatment facility. Water from such a facility will be discharged to surface waters or to a POTW. In addition, sludge from such an on-site treatment facility is expected to be applied to agricultural or other lands in combination with sludge from other sources.

Citric acid appears to be of low acute toxicity to fish, daphnia and algae.⁴² The HERA project 2005 environmental risk assessment for citric acid derived a predicted no effect concentration (PNEC) of 0.8 mg/L based on toxicity data of sodium citrate on fish, daphnia and algae.⁴³ This very conservative PNEC is four-fold above our worst case estimate of introductions (0.16 mg/L) for citric acid.

SLS also appears to be of low toxicity to aquatic organisms.⁴⁴ The OECD SIDS report references a lowest LOEC of 0.02 mg/L in *Scenedesmus quadricauda*. This LOEC is 4-fold higher than our worst case estimated level of introduction for SLS (5.1 µg /L) for the proposed use.

EPA has thoroughly considered the toxicity of silver processed in wastewater facilities and concluded that no significant environmental risk of aquatic toxicity exists at levels at or below 3.2 µg/L,⁴⁵ EPA's National Recommended Water Quality Criteria-Aquatic Life Criteria for silver. We believe that our aquatic EEC of 1.6 µg/L establishes a suitable margin of safety for our intended use compared to the above aquatic life criteria for silver. This EEC is based on small processing facilities (125,000 birds per day or less) with lower dilution rates. We expect that use of a silver based antimicrobial at such facilities would be prohibitively expensive as well. Therefore, we believe that our EEC is quite conservative.⁴⁶ Moreover, silver and silver compounds are specifically considered in NPDES permitting and EPA's silver water quality criterion would be the basis for state NPDES permitting authorities to establish local limits.

³⁹ Op Cite Ratte pg. 98.

⁴⁰ OECD SIDS, *Citric Acid*, 2000.

⁴¹ OECD SIDS, *Sodium Dodecyl Sulfate*, 1995.

⁴² Op Cite to OECD SIDS, *Citric Acid*, 2000.

⁴³ HERA, *Substance: Citric Acid and Salts (CAS # 77-92-9; 5949-29-1; 6132-04-3)* (2005), http://www.heraproject.com/files/37-F-05-HERA_citricacid_version1_April05.pdf.

⁴⁴ Op Cite OECD SIDS, *Sodium Dodecyl Sulfate* (1995), pp. 21-23.

⁴⁵ <https://www.epa.gov/wqc/national-recommended-water-quality-criteria-aquatic-life-criteria-table>.

⁴⁶ See confidential attachments including estimates by industry expert consultants.

Therefore, we would expect monitoring to be required either by the permitting authority and/or the POTW to which a facility discharges (assuming no on site waste water processing). Moreover, the label for this product advised facilities that coordination with the NPDES permitting authority is needed.

9. Use of Resources and Energy

The use of the Pure Bioscience product will not require additional energy resources for treatment and disposal of waste solution, as the components are adequately dealt with through existing infrastructure. The raw materials used in the production of the mixture are commercially-manufactured materials that are produced for use in a variety of chemical reactions and production processes. Energy used specifically for the production of the mixture components is not significant.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the dilutions of this antimicrobial product. Thus, the use of the subject mixture is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this exemption request. The alternative of not approving this exemption request would simply result in a delay in beginning SDC use at 160 ppm in poultry processing facilities; such action would therefore have no significant environmental impact.

12. List of Preparers

Dr. Mitchell Cheeseman, Steptoe & Johnson LLP, 1330 Connecticut Ave. NW, Washington DC, 20036

Dr. Cheeseman holds a Ph.D. in Chemistry from the University of Florida. Dr. Cheeseman served for 18 months as a NEPA reviewer in FDA's food additive program. He has participated in FDA's NEPA review of nearly 800 food additive and food contact substance authorizations and he supervised NEPA review for FDA's Center for Food Safety and Applied Nutrition for five and a half years from 2006 to 2011 including oversight of FDA's initial NEPA review for the regulations implementing the Food Safety Modernization Act.

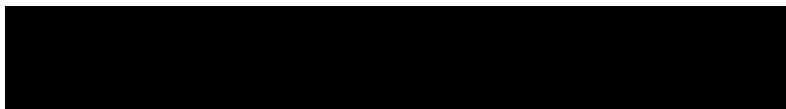
Deborah C. Attwood, Steptoe & Johnson, LLP, 1330 Connecticut Avenue NW, Washington DC, 20036

Ms. Attwood has eight years of experience preparing environmental submissions to FDA for the use of antimicrobials in food processing.

13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: March 3, 2017



Mitchell Cheeseman Ph.D.

14. References

Donahue, Roy Luther; Miller, Raymond W.; Shickluna, John C. (1977). *Soils: An Introduction to Soils and Plant Growth*. Prentice-Hall pg. 60. ISBN 0-13-821918-4.

EPA, *Central Tenets of the National Pollutant Discharge Elimination System (NPDES) Permitting Program*.

Environmental Protection Agency, *National Recommended Water Quality Criteria*.

Environmental Protection Agency, *Reregistration Eligibility Decision: Silver* (1992).

Environmental Protection Agency (September 8, 2004) *Technical Development Document for the Final Effluent Limitations Guidelines and Standards for the Meat and Poultry Products Point Source Category (40 CFR 432)*, EPA-821R-04-011.

EPA Office of Water, *The Enforcement Management System National Pollutant Discharge Elimination System (Clean Water Act)* (1989).

Safety Data Sheet for Pure Control. 2016.

Gericke, Fischer: *A correlation study of biodegradability determinations with various chemicals in various tests*, *Ecotox. Environm. Safety* 3: 159-173 (1979).

HERA, 2005, *Substance: Citric Acid and Salts (CAS # 77-92-9; 5949-29-1; 6132-04-3)* (2005).

Northcutt J.K. & D.R. Jones. *A survey of water use and common industry practices in commercial broiler processing facilities*. *Journal of Applied Poultry Research* 13:48-54 (2004).

OECD SIDS, *Sodium Dodecyl Sulfate* (1995).

OECD SIDS, *Citric Acid CAS No. 77-92-9* (2000).

Rapaport, Robert A., *Prediction of consumer product chemical concentrations as a function of publically owned treatment works treatment type and riverine dilution*. *Environmental Toxicology and Chemistry*, 7(2), 107-115 (1988).

Ratte, Hans Toni, *Bioaccumulation and toxicity of Silver Compounds: A Review*, *Environmental Toxicology and Chemistry*, Vol. 18, no.1, pp 89-108 (1999).

USDA FSIS Federal Register Notice, *New Performance Standards for Salmonella and Campylobacter in Young Chicken and Turkey Slaughter Establishments: Response to Comments and Announcement of Implementation Schedule*, 76 Fed. Reg. 15282 (March 21, 2011).

USDA FSIS Notice 54-12, *New Performance Standards for Salmonella and Campylobacter in Chilled Carcasses at Young Chicken and Turkey Slaughter Establishments* (9/11/12).

WHO, *Silver in Drinking Water: Background document for development of WHO Guidelines for Drinking-water Quality* (2003).