ADDENDUM

to the

Petition to the National Organic Program to Add

Silver Dihydrogen Citrate

to the National List of Allowed and Prohibited Substances

Petitioner
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Amended Item B.4. *Intended Activities and Application Rate*	When used as an antimicrobial for food processing, the substance is an aqueous solution of silver dihydrogen citrate and is further diluted on site to achieve a target concentration of the active antimicrobial component. The target concentrations (i.e., application rate) and method of application are as follows: (1) Poultry carcasses, parts, and organs: up to 160 ppm silver as silver dihydrogen citrate, application by spray or dip only (chiller baths are not permitted). (2) Fruits and vegetables: up to 30 ppm, application by spray or dip. The substance is not for use on citrus fruit or grapes intended for winemaking. The substance may not be used in combination with any other silver-containing antimicrobial. When used for disinfection and sanitization of previously cleaned food contact surfaces and equipment, the substance is a ready-to-use aqueous solution of silver dihydrogen citrate formulated to provide 30 ppm silver as silver dihydrogen citrate. Unlike other hard surface sanitizers, silver dihydrogen citrate meets the efficacy performance standards for disinfection and sanitization at the same 30 ppm use level for the ready-to-use product.
Item B.8. *Regulatory Authority*	The use of SDC has in poultry processing at levels up to 160 ppm, increased from 30 ppm, has been reviewed and approved by the Food and Drug Administration under Food Contact Notification (FCN) 1768,[1] which became effective on May 18, 2017.[2] This increased use of SDC also has been notified to the U.S. Department of Agriculture Food Safety and Inspection Service for addition to Directive 7120.1, the List of Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products and is the subject of a May 30, 2017 No Objection Letter.[3]
Item B.10(a) *Chemical interactions with other substances, especially substances used in organic production*	The increased use level of SDC is not expected to change the conclusion that it is not anticipated to have the opportunity to react with substances currently approved for use in organic production or adversely impact the stability of the product.
Item B.10.(b) *Toxicity and environmental persistence*	There is no change to the substances of environmental toxicological concern identified in the petition.
Item B.10(c) *Environmental impacts from its use and/or manufacture*	The environmental impact of the increased use level of the SDC from its intended use in poultry processing has been evaluated by FDA as part of FCN 1768. The environmental assessment submitted to FDA for the increased use level in poultry applications is included with this Addendum. Although this FCN is not yet effective, FDA's Finding of No

[1] FDA's Acknowledgment Letter for this FCN is included as Attachment 1 to this Addendum.
[2] https://www.accessdata.fda.gov/scripts/fdcc/?set=FCN&id=1768.
[3] A copy of the No Objection Letter is included as Attachment 2 to this Addendum.

	Significant Impact (FONSI) is not yet publicly available. We have obtained from FDA its environmental review memorandum which describes the agency's basis for its FONSI, and this is included with this submission as Attachment 3. Based on a highly conservative estimate of release to surface waters, the EA demonstrated, and FDA agreed that, the release does not exceed the acute high risk level of concern for aquatic animals established by the U.S. Environmental Protection Agency. Similarly, no significant effects were expected due to potential land application of sludge containing silver. Based on its knowledge and experience with the use of SDC in food processing facilities, the information provided in the EA is very conservative and it is highly unlikely that SDC will result in significant releases to water
Item B.10 (d) *Effects on human health*	The safety of the product for use in processing of poultry has been evaluated by FDA through FCN 1768. The safety assessment for FCN 1768 was informed by testing conducted on whole poultry carcasses, in which residues were tested on skin-on and skin-off samples. This testing used a lower limit of detection than in previous testing. Using the results from the residue testing in combination with information from USDA's National Health and Nutrition Examination Survey (NHANES) 2003 – 2004 indicating that the mean intake of poultry (combined chicken and turkey) is 72 grams per day, the assessment calculated a dietary concentration for silver of 0.33 parts per billion (ppb) and for sodium lauryl sulfate of 3.98 ppb. These dietary concentrations at the 160 ppm use level were lower than those previously calculated for the 30 ppm use level, due to the improvement in the detection limit of the residual testing. At these minuscule levels of dietary exposure for silver, FDA had no concern with the increased use level of SDC from a human consumption and health perspective.
Item B.13 *Petition Justification Statement*	As discussed in the petition, SDC is a safe and effective antimicrobial for use in the processing of food to reduce populations of microorganisms that cause foodborne illnesses, resulting in safer food for consumers. The increased use level from 30 ppm SDC to 160 ppm SDC (as silver) is necessary to provide sufficient flexibility in poultry processing plants to ensure the efficacy of the product under the variable conditions found in such plants. The level of contamination in the processing water can vary significantly both from plant to plant, and even within the same plant at different points during the processing day. Therefore, the additional use level of the SDC provides flexibility to the poultry processing plant to adjust the use level of the SDC and provide sufficient efficacy. As described above, these increased exposures present no concern for the safety of human health or the environment, as established by FDA through its review of FCN 1768. This FCN represents FDA's conclusion that the intended use of SDC at 160 ppm in poultry processing is safe for human health, while FDA's environmental review concluded that this use does not significantly affect the quality of the human environment.