Memorandum

Date: November 25, 2024

From: Antonetta Thompson-Wood, Physical Scientist, Environmental Review Team
Office of Pre-Market Additive Safety

To: Anita Chang, Ph.D., Regulatory Review Scientist
Office of Pre-Market Additive Safety, Division of Food Contact Substances

Through: Mariellen Pfeil, Lead Biologist, Environmental Review Team
Office of Pre-Market Additive Safety

Mariellen Pfeil -S
Digitally signed by Mariellen Pfeil -S
Date: 2024.11.25 12:48:44 -05'00'

Subject: Finding of No Significant Impact (FONSI) for Food Contact Notification (FCN) 2395

Notifier: Energis Solutions

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Notification (FCN) 2395, which is for the use of chlorine dioxide (CAS Reg. No. 10049-04-4). The Food Contact Substance (FCS) is for use as an antimicrobial agent:

1) in water used in the processing of poultry, red meat, fish, and seafood.
2) in water used to wash fruits and vegetables that are raw agricultural commodities (RAC), and to wash fruits and vegetables that are not RAC.
3) as a spray on grains (wheat, barley, oats, rice, rye, corn, millet, sorghum, spelt, triticale), pulses (peas, beans, chickpeas, soybeans), edible seeds (amaranth, chia, flax, quinoa, sesame, buckwheat), and nuts (peanuts, almonds, cashews, chestnuts, Brazil nuts, hazelnuts, pecans, macadamia, pistachio, walnuts)

This FONSI explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated October 28, 2024, may be made available to the public. We will post digital transcriptions of the FONSI and the EA on the agency's public website.

Please let us know if there is any change in the identity or use of the food-contact substance.

Antonetta Thompson-Wood -S
Digitally signed by Antonetta Thompson-wood -S
Date: 2024.11.25 10:45:44

Antonetta Thompson-Wood

Attachment: Finding of No Significant Impact (FONSI)

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2395, submitted by Energis Solutions for the use of chlorine dioxide (CAS Reg. No. 10049-04-4). The FCS will be used as an antimicrobial agent, in an amount not to exceed 3 ppm residual chlorine dioxide as determined by Method 4500-ClO2-D, as follows:

(1) Treatment of poultry, red meat, fish, and seafood will be followed blanching, cooking, or canning. Treatment of seafood products that will be consumed raw shall be followed by a potable water rinse prior to consumption.

(2) When used on fruits and vegetables that are raw agricultural commodities (RAC), the FCS will be applied in the preparing, packing, or holding of food for commercial purposes, consistent with the FD&C Act section 201(q)(1)(B)(i), but not applied for use under 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III). Treatment of all fruits and vegetables shall be followed by a potable water rinse, blanching, cooking, or canning.

(3) When used on grains (wheat, barley, oats, rice, rye, corn, millet, sorghum, spelt, triticale), pulses (peas, beans, chickpeas, soybeans), edible seeds (amaranth, chia, flax, quinoa, sesame, buckwheat), and nuts (peanuts, almonds, cashews, chestnuts, Brazil nuts, hazelnuts, pecans, macadamia, pistachio, walnuts), the FCS will be applied in the preparing, packing, or holding of the food for commercial purposes, consistent with the FD&C Act section 201(q)(1)(B)(i). Treatment of all grains, pulses, edible seeds, and nuts shall be followed by a potable water rinse, blanching, cooking, or canning.

The FCS is not for use in contact with infant formula or infant formula ingredients and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

The Office of Pre-Market Additive Safety has determined that allowing this notification to become effective will not significantly affect the quality of the human environment and, therefore, an environmental impact statement (EIS) will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA), dated October 28, 2024. The EA was prepared in accordance with 21 CFR 25.40. The EA is incorporated by reference in this Finding of No Significant Impact (FONSI) and is briefly summarized below.

The FCS is an electrolytic method of generating chlorine dioxide that provides an additional resource to food processors to respond to microbial pressures present in their processing systems. The FCS reduces or inhibits the growth of pathogenic and non-pathogenic microorganisms that may be present on and in food to provide safer food for consumers.

The FCS is intended for use in processing plants and facilities throughout the United States and may also be used aboard fishing vessels to cool and process fresh-caught seafood.

Electro-BioCide produces no traditional effluent as the chlorine dioxide and any residual starting materials or byproducts formed during the manufacturing procedure are maintained within a closed system and are reincorporated into the product medium within it to enhance and stabilize the resulting chlorine dioxide solution. Air releases are negligible since the production of chlorine dioxide is confined to a closed system. Similarly, as no wastewater or discharged

processing water is involved, no chlorine dioxide nor its degradation byproducts will be present in either water source. Following use, facilities will discharge the remaining treated water to publicly owned treatment works or will discharge directly to surface waters after on-site water treatment in accordance with a permit issued under the National Pollutant Discharge Elimination System (NPDES).

The EA also provides adequate analysis describing that chlorine dioxide degrades to, predominately, chlorate when exposed to organic matter. While release of manufacturing byproduct residues is not anticipated, the EA provides an estimate of maximum environmental introduction concentrations (EICs) of the chlorine dioxide manufacturing byproducts and its possible environmental degradation products chlorite, chlorate and free chlorine. This analysis is based upon a residuals analysis of a variety of foodstuffs treated with the FCS. The estimated environmental concentrations (EECs) were then derived for each of these species by applying process-specific dilution assumptions to these values. In the worst-case scenario (i.e., poultry processing), the EECs for chlorite, chlorate and free chlorine are 0.00004 ppm, 0.083 ppm and 0.0003 ppm respectively.

Numerous environmental toxicity endpoints for terrestrial and aquatic flora and/or fauna are presented in the EA. The most sensitive endpoint, that for *Daphnia magna* (0.027 ppm EC50 sodium chlorite) is well above the 0.00004 ppm calculated EEC for chlorite. Further, the above maximum EEC values are well below the concentrations that yielded environmental toxicity for all other organisms. Therefore, the levels of chlorine dioxide, chlorite, and chlorate produced by Electro-BioCide are well below the threshold for these risks and are not a concern for terrestrial or aquatic flora and/or fauna.

Use of the FCS is not expected to cause a significant impact on resources or energy. No mitigation measures are needed since no significant adverse impacts are expected from use and disposal of the FCS, nor do we expect significant environmental impacts, which would necessitate alternative actions to the proposed use of the FCS in this FCN. The alternative to not allowing the FCN to become effective would be continued use of currently approved antimicrobial agents that the FCS would otherwise replace; therefore, this action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2395 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Antonetta Thompson-wood -S

Digitally signed by Antonetta Thompson-wood -S
Date: 2024.11.25 10:46:12 -05'00'

Prepared by

Antonetta Thompson-Wood
Physical Scientist, Environmental Review Team
Office of Pre-Market Additive Safety
Office of Food Chemical Safety, Dietary Supplements, and Innovation
Food and Drug Administration

Mariellen Pfeil -S

Digitally signed by Mariellen Pfeil -S
Date: 2024.11.25 12:49:52 -05'00'

Approved by

Mariellen Pfeil
Lead Biologist, Environmental Review Team
Office of Pre-Market Additive Safety
Office of Food Chemical Safety, Dietary Supplements, and Innovation
Food and Drug Administration