



Memorandum

Date: March 31, 2026

From: Biologist, Office of Pre-Market Additive Safety, Environmental Review Team

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2506

Notifier: Enviro Tech Chemical Services, Inc.

To: Stevie N. Walters, Ph.D., Consumer Safety Officer, Office of Pre-Market Additive Safety, Division of Food Contact Substances

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

ANTONETTA THOMPSON-WOOD -S Digitally signed by ANTONETTA THOMPSON-WOOD -S
Date: 2026.03.31 15:59:49 -0400'

Attached is the FONSI for FCN 2506, which is for the use of 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) (CAS Reg. No. 77-48-5) optionally containing up to 0.5 weight percent 1,3-dibromo-5-ethyl-5-methylhydantoin (DBEMH) (CAS Reg. No. 82925-96-0) as an antimicrobial agent in process water and ice for meat products. 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 March 2, 2026, 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.

Denis Wafula -S Digitally signed by Denis Wafula -S
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Denis Wafula, Ph.D.

Attachments: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2506, submitted by Enviro Tech Chemical Services, Inc. for the use of 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) (CAS Reg. No. 77-48-5) optionally containing up to 0.5 weight percent 1,3-dibromo-5-ethyl-5-methylhydantoin (DBEMH) (CAS Reg. No. 82925-96-0) as an antimicrobial agent in process water and ice for meat products. The FCS is for use at a level not to exceed that needed to provide 900 parts per million (ppm) available bromine in water or ice applied to meat products. The FCS is not for use in contact with infant formula 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 March 2, 2026. The EA was prepared in accordance with 21 CFR 25.40. The EA is incorporated by reference in this Finding of No Significant Impact and is briefly summarized below.

The antimicrobial agent is needed to help control or reduce the presence of pathogenic and spoilage microorganisms on meat products. The use of the FCS provides processors with an effective bromine-based alternative to traditional oxidizing agents such as chlorine and peracetic acid. Wastewater from the above-described uses will be either discharged to a publicly owned treatment works (POTW), or, if in possession of a National Pollutant Discharge Elimination System (NPDES) permit, directly to surface waters after onsite treatment.

In aqueous solution, the FCS hydrolyzes to form hypobromous acid (HOBr), the active antimicrobial species, and 5,5-dimethylhydantoin (DMH), a stable byproduct. HOBr is highly reactive and short-lived, rapidly degrading in the presence of organic matter to form bromide ion (Br^-) and trace amounts of trihalomethanes (e.g., bromoform). The resulting degradation products—primarily bromide ion, DMH, and bromoform—are expected to be present in wastewater effluent and subsequently introduced into POTWs, where additional dilution, biodegradation, and other attenuation processes occur.

Using conservative assumptions including maximum antimicrobial treatment levels (900 ppm available bromine), maximum facility throughput (4,500 head/day), and a 10-fold dilution factor upon discharge to surface waters, the maximum predicted concentrations in receiving waters are approximately 3.8 ppm for bromide ion, 1.5 ppm for DMH, and 0.081 ppb for bromoform. These concentrations are well below established toxicity endpoints:

- Bromide ion: The predicted concentration of 3.8 ppm is more than 100-fold lower than the most conservative acute toxicity benchmark of 500 mg/L (LC_{50} for *Daphnia magna*).
- DMH: The predicted concentration of 1.5 ppm is more than two orders of magnitude lower than the lowest reported acute toxicity values (LC_{50} and EC_{50} ranging from 920 to 14,000 mg/L).
- Bromoform: The predicted concentration of 0.081 ppb is more than four orders of magnitude lower than the lowest reported acute toxicity value (96-hour LC_{50} values ranging from 7,100 to 18,000 $\mu\text{g/L}$ for fish species).

Therefore, no toxicity is expected from discharge to surface waters of effluent containing these degradation products.

Use of the FCS is not expected to cause a significant impact on resources or energy. The incremental energy required to support the proposed use of the FCS is minimal, as the components used to manufacture DBDMH are standard industrial chemicals already produced at commercial scale. DBDMH would replace antimicrobial

treatments that are already approved for use in meat applications and would not result in an overall increase in resource or energy consumption.

No mitigation measures are needed since no significant adverse impacts are expected from use of the FCS. The alternative to not allowing the FCN to become effective would be continued use of currently approved antimicrobial agents; such action would have no significant environmental impact.

As evaluated in the EA, the use of the FCS as described in FCN 2506 is not expected to significantly affect the human environment, and therefore an EIS will not be prepared.

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Prepared by

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