

Environmental Assessment

1. **Date:** 3/2/2026
2. **Submitter:** Enviro Tech Chemical Services, Inc.
3. **Address:** 500 Winmoore Way, Modesto, CA. 95358
4. **Description of Proposed Action:**
 - a. **Description of the Requested Action:** This Food Contact Notification (FCN) proposes the use of 1,3-dibromo-5,5-dimethylhydantoin (DBDMH, CAS Reg. No. 77-48-5) as a food contact antimicrobial agent. The substance will be used in water or ice that comes into direct contact with food, specifically meat products, to reduce or eliminate microbial contamination. The FCS will be used in food processing facilities as an antimicrobial agent in:

The FCS is intended for use at concentrations not to exceed those necessary to achieve 900 parts per million (ppm) of available bromine in water or ice applied to meat products.
 - b. **Need for the Action:** The FCS is being proposed as an antimicrobial intervention to help control or reduce the presence of pathogenic and spoilage microorganisms on raw meat products. The use of DBDMH provides processors with an effective bromine-based alternative to traditional oxidizing agents such as chlorine and peracetic acid.
 - c. **Locations of Use and Disposal:** The FCS will be used at food processing facilities throughout the United States. Following use, any remaining FCS in solution will be discharged along with facility process water. In facilities permitted for direct discharge under the National Pollutant Discharge Elimination System (NPDES), wastewater will be treated on-site prior to discharge into surface waters. In facilities classified as indirect dischargers, wastewater will

be conveyed through municipal sewer systems to Publicly Owned Treatment Works (POTWs), where standard treatment processes will degrade the active components before final environmental release.

5. Identification of Substance:

The food contact substance is a solid brominated hydantoin, chemically identified as 1,3-dibromo-5,5-dimethylhydantoin. It is typically supplied in granular, tablet, or powder form and dissolves in water to release hypobromous acid (HOBr), the primary antimicrobial agent.

Ingredients:

Chemical Name	CAS#
1,3-Dibromo-5,5-dimethylhydantoin (DBDMH)	77-48-5

Molecular Formula: $C_5H_6Br_2N_2O_2$

Molecular Weight: 285.91 g/mol

In aqueous solution, DBDMH hydrolyzes to release active bromine species and hydantoin byproducts. The hydrolysis and antimicrobial activity occur rapidly and are pH dependent, with optimum efficacy observed under slightly acidic to neutral conditions.

6. Introduction of Substance into the Environment:

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

Under 21 C.F.R. § 25.40(a) an environmental assessment (EA) ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production of, FDA-regulated articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any significant adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. Introduction from Use and Disposal:

The subject FCS, 1,3-dibromo-5,5-dimethylhydantoin (DBDMH, CAS Reg. No. 77-71-4), is intended for use as an antimicrobial agent in meat processing facilities, where it is applied to meat through spray application. In water, DBDMH hydrolyzes to form hypobromous acid (HOBr) and 5,5-dimethylhydantoin (DMH). HOBr is the active antimicrobial species, while DMH is a stable byproduct. The reaction is as follows: $C_5H_6Br_2N_2O_2 + 2H_2O \rightarrow C_5H_8N_2O_2 + 2HOBr$

As HOBr is highly reactive and short-lived, it further degrades rapidly in the presence of organic matter to form bromide ion (Br^-) and can also form halomethanes (e.g. bromoform).

The maximum application level is 900 ppm available bromine (as Br_2), which equates to approximately 450 ppm bromide ion when fully reduced. HOBr and related bromine species (Br_2) are not expected to persist in the environment due to their rapid decomposition in the presence of organic load and ammonia, which are inherent in meat processing wastewater facilities^{1,2,3}. The EPA has recognized this behavior in related assessments, noting half-lives for HOBr in low-demand waters of up to 125 hours¹, with significantly faster degradation expected under high organic conditions typical of food processing effluents.

The resulting degradation products, primarily bromide ion and DMH, are expected to be present in wastewater effluent. These compounds are subsequently introduced into publicly owned treatment works (POTWs), where additional dilution, biodegradation, and other attenuation processes occur.

¹ RED Facts: Inorganic Halides, EPA-738-F-93-015; U.S. EPA, Washington, D.C., 2007; <http://www.epa.gov/oppsrrd1/REDs/factsheets/4051fact.pdf>

² Re-registration Eligibility Decision: Inorganic Halides, List D, Case 4051; U.S. EPA, Washington, D.C., 2007; http://www.epa.gov/oppsrrd1/REDs/old_reds/inorganic_halides.pdf

³ Morrow, M.S., Potassium Bromide and Sodium Bromide Tolerance Reassessment Decision Document (CAS numbers 7758-02-3 and 7647-15-6, DP Barcode 321794); Docket No. EPA-HQ-OPP-2006-0143-004; U.S. EPA, Washington D.C., Sept 20, 2005.

Bromide Ion (Br⁻):

This inorganic ion is naturally occurring in the environment and is not known to bioaccumulate. Bromide is commonly present in drinking water at levels up to 1 mg/L and is considered low in toxicity⁴.

Dimethylhydantoin (DMH):

DMH is a stable compound with moderate water solubility and low volatility. Based on its structure and previous assessments by the EPA⁵, it is not expected to bioaccumulate or persist in the environment. DMH is ultimately mineralized through biological treatment processes.

Trihalomethanes (THMs, e.g. Bromoform):

Bromoform (a trihalomethane) demonstrates minimal potential for bioaccumulation, as supported by the U.S. Environmental Protection Agency's Update of Human Health Ambient Water Quality Criteria: Bromoform (EPA 820-R-15-021)⁶. In this document, EPA develops chemical-specific bioaccumulation factors (BAFs) for bromoform, and these BAF values are low, reflecting the compound's physicochemical characteristics, including low to moderate hydrophobicity and rapid volatilization, which inherently limit tissue uptake and retention in aquatic organisms. The inclusion of bromoform in EPA's BAF framework, and the assignment of low BAF values, supports the conclusion that bromoform does not significantly bioaccumulate or biomagnify in the environment. Therefore, introduction of these substances into the environment from the use and disposal of the FCS will occur primarily via wastewater from meat processing facilities. This wastewater is expected to undergo standard treatment at POTWs before discharge to surface waters.

⁴Bromine Summary Document: Registration Review Preliminary Work Plan. Docket Number; EPA-HQ-OPP-2009-0167. March 2009. US EPA.

<https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwjfu8bq04uTAxWWkIkEHarbJ1EQFnoECBEQAQ&url=https%3A%2F%2Fdownloads.regulations.gov%2FEPA-HQ-OPP-2009-0167-0004%2Fcontent.pdf&usg=AOvVaw1IqUVbTgidjIhWLgUAICFj&opi=89978449>

⁵Draft Risk Assessment for the Halohydantoins Registration Review, January 24, 2020, EPA-HQ-OPP-2013-0220-0019, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, WASHINGTON, D.C. 20460.

<https://www.regulations.gov/document/EPA-HQ-OPP-2013-0220-0019>

⁶Update of Human Health Ambient Water Quality Criteria: Bromoform. EPA 820-R-15-021. June 2015. US EPA.

No significant introduction of the parent FCS (DBDMH) itself is expected in effluent due to its rapid hydrolysis. Likewise, no extraordinary environmental exposures are anticipated from its degradation products. The levels of these substances introduced into the environment are not expected to cause significant adverse environmental impacts.

7. Fate of Emitted Components in the Environment:

Estimates of water usage in the meat processing industry vary depending on facility size, species processed, and operational practices. Reported values indicate that total water usage during meat processing operations ranges from approximately 150 to 450 gallons per animal processed⁷. The U.S. Environmental Protection Agency (EPA) reported that wastewater generation rates at three hog and three cattle processing facilities ranged from 291 to 442 gallons per 1,000 pounds live weight killed⁸.

Additional EPA-reviewed data from 19 medium- and large-scale slaughter facilities reported wastewater generation rates ranging from 435 to 1,500 gallons per 1,000 pounds live weight killed, with an average value of 885 gallons per 1,000 pounds live weight killed⁵. The International Finance Corporation (IFC) has established industry benchmarks for water consumption in cattle slaughter operations of 1.62 to 9 cubic meters per metric ton, which corresponds to approximately 190 to 1,077 gallons per 1,000 pounds live weight killed⁸.

⁷Water and Wastewater Use in the Food Processing Industry - Meat and Poultry Processing, North Carolina Division of Environment and Natural Resources (July 6, 2010), available at [http://www.nwfpa.org/nwfpa.info/component/content/article/372-water-and-wastewater-use-in-the-food-processingindustry?](http://www.nwfpa.org/nwfpa.info/component/content/article/372-water-and-wastewater-use-in-the-food-processingindustry?start=2)

⁸Environmental Health and Safety Guidelines for Meat Processing; International Finance Corporation, WorldBank Group., April 30, 2007. <https://www.ifc.org/content/dam/ifc/doc/2023/ifc-general-ehs-guidelines.pdf>

According to data published by the U.S. Department of Agriculture (USDA), the average live weight of commercially slaughtered cattle, calves, hogs, sheep, and lambs ranges from 137 to 1,275 pounds. Using the average wastewater generation rate of 885 gallons per 1,000 pounds live weight killed and a conservative worst-case live weight of 1,275 pounds per animal, the estimated water usage per carcass is calculated as follows:

$$885 \text{ gal} / 1,000 \text{ lb} \times 1,275 \text{ lb} = 1,128 \text{ gallons per head}$$

Industry data provided by Tyson Fresh Meats (2007) indicate that approximately 18% of total water used in meat processing is treated with an antimicrobial agent⁹. For conservatism, it is assumed that 25% of the total water used per carcass is treated with the food contact substance (FCS). Therefore, the volume of water treated with the FCS per head is estimated to be:

$$1,128 \text{ gal} \times 25\% = 282 \text{ gallons per head}$$

An Agricultural Marketing Report estimated that small, medium, and large meat processing facilities process approximately 20,000, 480,000, and 1.5 million animals per year, respectively¹⁰. Assuming 52 weeks of operation at five processing days per week, this corresponds to approximately 77 head/day (small), 1,846 head/day (medium), and 5,769 head/day (large). A value of 4,500 head/day is used as a reasonable estimate for a typical large meat processing facility.

Accordingly, the total volume of water treated with the FCS per day is:

$$4,500 \text{ head/day} \times 282 \text{ gal/head} = 1,269,000 \text{ gallons/day}$$

$$1,269,000 \text{ gal/day} \times 3.785 \text{ L/gal} = 4,800,000 \text{ L/day}$$

$$(\text{assumed density} = 1.0 \text{ kg/L} \rightarrow 4,800,000 \text{ kg/day})$$

⁹Environmental Assessment for FCN 792, Section 6.b., pages 7-8, available at <http://www.fda.gov/downloads/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/UCM147199.pdf>, and included as Attachment B.

¹⁰ Koontz, SR; Hoag, DL, Community Development and the Profitability of Value-Added Meat Production and Processing; February/No 99-01; Colorado State University; Cooperative Extension; Feb, 1999; <http://dare.colostate.edu/csuaecon/extension/docs/agmarketing/amr99-01.pdf>.

Bromide Ion

1,3-Dibromo-5,5-dimethylhydantoin (DBDMH) generates hypobromous acid (HOBr) as the active antimicrobial species, which is subsequently reduced to bromide ion (Br^-). Based on stoichiometric considerations, bromide ion formation represents approximately 50% of the available bromine concentration when expressed as Br_2 .

Assuming a maximum antimicrobial treatment level of 900 ppm available bromine, the total bromide ion discharged per day is calculated as follows:

$$\begin{aligned} &4,800,000 \text{ kg/day} \times 900 \text{ mg/kg} \times 1 \text{ kg} / 10^6 \text{ mg} \\ &= 4,320 \text{ kg bromide/day} \end{aligned}$$

Dimethylhydantoin (DMH)

DBDMH also yields 5,5-dimethylhydantoin (DMH) as a non-halogenated breakdown product. Assuming a conservative maximum DMH concentration of 360 ppm, the total DMH discharged per day is calculated as follows:

$$\begin{aligned} &4,800,000 \text{ kg/day} \times 360 \text{ mg/kg} \times 1 \text{ kg} / 10^6 \text{ mg} \\ &= 1,728 \text{ kg DMH/day} \end{aligned}$$

Trihalomethanes (THMs)

Among trihalomethanes, bromoform has typically been the only compound detected in wastewater associated with bromine-based antimicrobial systems¹¹. Bromoform levels were therefore estimated using data presented in attachment 2 of Albemarle Corporation's revised environmental assessment¹¹. In that assessment, rinsate collected from three beef flank samples treated at 300 ppm available bromine contained bromoform at concentrations of <5 ppb, <5 ppb, and 6.4 ppb¹¹.

For conservatism, the highest detected value (6.4 ppb) was linearly extrapolated to the proposed maximum treatment level of 900 ppm available bromine, yielding an estimated bromoform concentration of 19.2 ppb in treated water. This linear extrapolation is intentionally conservative because bromoform becomes the dominant THM under bromine-rich conditions, and its formation does not increase proportionally at higher bromine levels. Studies show that elevated bromide shifts THM formation strongly toward bromoform dominance, not linear total THM growth, meaning a straight-line projection overestimates actual bromoform formation and therefore provides a protective upper-bound estimate¹².

¹¹Protocol for Determining Byproducts after Beef Meat is sprayed with 300 ppm available bromine from DBDMH. Albemarle Corporation, Eric Liimatta, Ph.D., September 24, 2007. FCN 1190 EA Attachment C. <https://wayback.archiveit.org/7993/20170606192306/https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/EnvironmentalDecisions/UCM323186.pdf>

¹²Integrated Risk Information System (IRIS), Chemical Assessment Summary, Bromoform; CASRN 75-25-2. US EPA. https://iris.epa.gov/static/pdfs/0214_summary.pdf

The total bromoform discharged per day is therefore calculated as follows:

$$\begin{aligned} &4,800,000 \text{ kg/day} \times 19.2 \text{ } \mu\text{g/kg} \times 1 \text{ kg} / 10^9 \text{ } \mu\text{g} \\ &= 0.092 \text{ kg bromoform/day} \end{aligned}$$

Wastewater Dilution and Environmental Introduction

As calculated above, the total daily water usage at a facility processing 4,500 head/day is:

$$1,128 \text{ gal/head} \times 4,500 \text{ head/day} = 5,076,000 \text{ gallons/day}$$

$$5,076,000 \text{ gal/day} \times 3.785 \text{ L/gal} = 19,200,000 \text{ kg/day}$$

To account for additional dilution, wastewater discharge to a publicly owned treatment works (POTW) with a typical daily flow of 25 million gallons/day (approximately 94,600,000 kg/day) is assumed. For conservatism, wastewater discharge is assumed to enter a publicly owned treatment works (POTW) with a representative flow of approximately 25 million gallons per day (MGD), a value within the range of flows reported for municipal wastewater treatment plants in the United States (U.S. EPA, 2000)¹³. Thus, the total daily dilution volume is:

$$19,200,000 \text{ kg} + 94,600,000 \text{ kg} = 113,800,000 \text{ kg/day}$$

¹³U.S. Environmental Protection Agency (EPA). Progress in Water Quality: An Evaluation of the National Investment in Municipal Wastewater Treatment. EPA-832-R-00-008. June 2000.

The resulting environmental concentrations are calculated as follows:

Bromide ion:

$$4,320 \text{ kg/day} \div 113,800,000 \text{ kg/day} = 38 \text{ ppm}$$

DMH:

$$1,728 \text{ kg/day} \div 113,800,000 \text{ kg/day} = 15 \text{ ppm}$$

Bromoform:

$$0.092 \text{ kg/day} \div 113,800,000 \text{ kg/day} = 0.81 \text{ ppb}$$

The actual concentrations at which the byproducts may be present in receiving waters into which POTW effluent is discharged will be even lower due to the dilution effect of mixing effluent with the water flowing through the receiving river or other body. Assuming that the effluent concentrations are diluted by as little as 10-fold, the maximum concentrations of DMH, bromide ion, and bromoform in the receiving water will be 1.5 ppm, 3.8-ppm, and 0.081-ppb respectively. Following treatment at a publicly owned treatment works (POTW), effluent discharged to receiving surface waters is expected to undergo additional dilution. Consistent with assumptions commonly used in environmental exposure assessments and FDA environmental assessments, a conservative 10-fold dilution factor was applied to estimate concentrations in receiving waters¹⁴.

To summarize, the worst-case release of wastewater to the environment resulting from the intended use of 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) as an antimicrobial in meat processing may contain dimethylhydantoin (DMH), bromide ion (Br^-), and bromoform at maximum concentrations of approximately 1.5 ppm, 3.8 ppm, and 0.081 ppb, respectively. These values were calculated using

¹⁴Rapaport, Robert A., 1988. Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution. *Environmental Toxicology and Chemistry* 7(2), 107-115. Found online <http://onlinelibrary.wiley.com/doi/10.1002/etc.5620070204/abstract>

highly conservative assumptions, including maximum antimicrobial treatment levels, maximum facility throughput, and complete transfer of all degradation products to wastewater without loss during onsite treatment or publicly owned treatment works (POTW) processing.

It is important to note that bromide ion formation was conservatively assumed to be equivalent to the full available bromine concentration expressed as Br₂. Because bromide ion has half the molecular weight of Br₂, the actual bromide concentration formed would be approximately 50% lower than the values calculated. This reduction, however, was not applied in order to maintain a conservative environmental exposure assessment.

Releases of treated wastewater from meat processing facilities are regulated under the terms and conditions of National Pollutant Discharge Elimination System (NPDES) permits, whether discharged directly or indirectly through a POTW. Therefore, any discharge of wastewater containing DBDMH degradation products would be subject to applicable federal, state, and local effluent limitations and monitoring requirements

8.) Environmental Effects of Released Substances:

As discussed in Sections 6 and 7, the use of 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) as an antimicrobial agent in meat processing is expected to result in the release of dimethylhydantoin (DMH), bromide ion (Br⁻), and trace levels of bromoform to wastewater streams. The parent compound (DBDMH) and the active antimicrobial species, hypobromous acid (HOBr), are not expected to be present in effluent due to rapid hydrolysis and reduction reactions occurring during use and wastewater treatment.

Dimethylhydantoin (DMH)

According to information published by the U.S. Environmental Protection Agency (EPA) under the High Production Volume (HPV) Chemical Challenge Program, DMH is slightly toxic to aquatic organisms, with reported acute toxicity values (LC_{50} and EC_{50}) ranging from approximately 920 mg/L to 14,000 mg/L, depending on species and test conditions¹⁵. ECOSAR modeling data similarly indicate a 96-hour LC_{50} of approximately 1,252 mg/L for fish¹⁶.

As calculated in Section 7, the maximum predicted concentration of DMH in receiving waters following POTW treatment and conservative dilution assumptions is approximately 1.5 mg/L. This concentration is more than two orders of magnitude lower than the lowest reported acute toxicity values for DMH. Therefore, DMH released as a degradation product of DBDMH is not expected to result in adverse environmental effects to aquatic organisms.

Bromide Ion (Br^-)

Bromide ion is an inorganic ion naturally present in surface waters and is not known to bioaccumulate. Toxicity data for bromide ion are commonly derived from studies conducted using sodium bromide, which dissociates in water to yield free sodium and bromide ions and therefore provides relevant information for assessing bromide ion toxicity.

A substantial body of aquatic toxicity data for sodium bromide is available in the EPA's ECOTOX database. Reported acute toxicity values (LC_{50} or EC_{50}) for freshwater and marine organisms range widely, with the lowest reported LC_{50} value of 500 mg/L observed in

¹⁵ U.S. EPA. High Production Volume (HPV) Chemical Challenge Program: 5,5-Dimethylhydantoin

¹⁶ U.S. EPA. ECOSAR v2.0: Fish Acute Toxicity Estimates for 5,5-Dimethylhydantoin.

*Daphnia magna*¹⁷. Other reported LC₅₀ values for bromide ion typically exceed 1,000 mg/L, with many values in the several-thousand mg/L range¹⁸.

As calculated in Section 7, the maximum predicted concentration of bromide ion in receiving waters following POTW treatment and dilution is approximately 3.8 mg/L. This value is more than 100-fold lower than the most conservative acute toxicity benchmark of 500 mg/L. Accordingly, bromide ion released from the proposed use of DBDMH is not expected to pose an environmental risk to aquatic organisms.

Bromoform

Bromoform formation associated with the proposed use is expected to be minimal. As discussed in Section 7, the maximum predicted concentration of bromoform in receiving waters following POTW treatment and dilution is approximately 0.081-µg/L (0.081-ppb).

Available aquatic toxicity data indicate that bromoform is slightly to moderately toxic to aquatic organisms at concentrations orders of magnitude higher than those predicted here. Reported 96-hour LC₅₀ values for fish species such as sheepshead minnow range from approximately 7,100 to 18,000 µg/L¹⁹. The predicted environmental concentration is therefore more than four orders of magnitude lower than the lowest reported acute toxicity value.

¹⁷ U.S. EPA. ECOTOX Ecotoxicology Database - Sodium Bromide aquatic toxicity data.

¹⁸ Ecological Hazard and Environmental Risk Assessment of Bromine and Sodium bromide for the reregistration eligibility decision (RED) document. June 30, 2005. US EPA.
<https://nepis.epa.gov/Exe/ZyPDF.cgi/P101CMQP.PDF?Dockkey=P101CMQP.PDF>

¹⁹https://www.cluin.org/contaminantfocus/default.focus/sec/Dense_Nonaqueous_Phase_Liquids_%28DNAPLs%29/cat/Toxicology/p/2/n/1

In addition, bromoform is volatile and subject to degradation in surface waters and the atmosphere, further reducing the potential for environmental exposure. Consequently, bromoform formed as a result of the proposed use of DBDMH is not expected to pose an environmental concern.

9.) Use of Resources and Energy

Use of DBDMH is not expected to result in increased energy demand for wastewater handling or disposal because its primary reaction byproduct, DMH, readily undergoes hydrolysis. The components used to manufacture DBDMH are standard industrial chemicals that are already produced at commercial scale for a wide range of established applications. The incremental energy required to support the proposed use of DBDMH is therefore minimal. In addition, because DBDMH would replace antimicrobial treatments that are already approved for use in meat application and its use would not result in an overall increase in resource or energy consumption.

10.) Mitigation Measures

Based on the information presented above, the intended use of DBDMH is not anticipated to result in significant adverse effects on the environment. Accordingly, the proposed use of this food-contact substance is not expected to introduce new environmental concerns or require the implementation of mitigation measures.

11.) Alternatives to the Proposed Action

The environmental review conducted for this notification did not identify any adverse impacts that would warrant consideration of alternatives to the proposed action. If the proposed use were not approved, meat processing facilities would continue relying on antimicrobial treatments that are already in use, and this outcome would not result in a meaningful change to environmental conditions. Given the demonstrated effectiveness of DBDMH for the intended antimicrobial applications, the associated benefits to food

safety, and the lack of any significant environmental effects identified in this assessment, approval of the proposed use of DBDMH is considered both environmentally acceptable and appropriate.

12.) List of Preparers:

- a. Joseph Donabed, B.Sc., Cal. State Stanislaus University, 14-years of experience preparing EPA and FDA regulatory submissions
- b. Deanna Mansueto, B.Sc., The Pennsylvania State University, MBA, Montclair State University, 5 years of experience preparing EPA regulatory submissions and 7-years preparing FDA regulatory submissions

13.) Certification:

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Enviro Tech Chemical Services, Inc.

Date: March 2nd, 2026

Signature: Name and Title: Joseph Donabed, Director, R&D



Deanna Mansueto, Senior Regulatory Affairs Associate

