1,3-Dibromo-5,5-dimethylhydantoin (DBDMH)

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
1,3-Dibromo-5,5-dimethylhydantoin
1,3-Dibromo-5,5-dimethyl-2,4-imidazolidinedione

Other Names:
DBDMH
Dibromantin
Dibromodimethylhydantoin

Trade Names:
ALBROM 100PC
AviBrom
BoviBrom
XtraBrom 111

CAS Number:
77-48-5

Other Codes:
U.S. EPA Registration Number: 3377-61
OPP Chemical Code: 006317
EINECS Number: 201-030-9
RTECS Number: MU0686000

Characterization of Petitioned Substance

Composition of the Substance:

1,3-Dibromo-5,5-dimethylhydantoin (DBDMH) is an organic compound with the molecular formula $C_5H_6Br_2N_2O_2$. In water, DBDMH hydrolyzes to form hypobromous acid (HOBr)—a source of bromine and an active antimicrobial agent—and dimethylhydantoin (DMH) (Albemarle Corporation, 2012). Potentially hazardous decomposition products of DBDMH include nitrogen oxides, carbon monoxide, carbon dioxide, hydrogen bromide, formaldehyde, and bromine (Fischer Scientific, 2007). The chemical structure of DBDMH is provided below as Figure 1. The reaction of DBDMH and water to produce DMH is provided below as Figure 2.

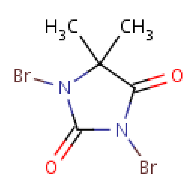

Figure 1. Chemical Structure of 1,3-Dibromo-5,5-Dimethylhydantoin
Source: ChemIDplus Lite (2012)

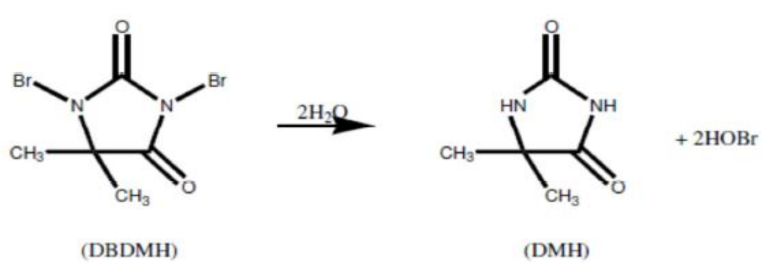

Figure 2. Hydrolysis of DBDMH in water
Source: McReynolds et al., 2011

Properties of the Substance:

DBDMH is a stable white to off-white powder with a mild halogen odor that is only slightly soluble in water. DBDMH is an oxidizer—capable of reacting with and oxidizing (i.e., removing electrons from) other substances (Fischer Scientific, 2007). Physicochemical properties of DBDMH are provided in Table 1.

Table 1. Physicochemical Properties of 1,3-Dibromo-5,5-dimethylhydantoin

Physical or Chemical Property	Value
Physical state	Solid
Appearance	White to off-white powder
Odor	Mild halogen (bromine)
Molecular weight (g/mol)	285.91
Boiling point (°C)	368−376
Melting point (°C)	187−198
Solubility in water (g/L)	60.7
Vapor pressure (mm Hg)	3.1×10^{-7}
Density (g/cm^3)	2.183 g/cm^3

Sources: Albemarle Corporation (2012); Guidechem (2012); Fischer Scientific (2007); U.S. EPA (2005)

Specific Uses of the Substance:

DBDMH in an aqueous solution is used as an antimicrobial in the post-slaughter processing and disinfection of beef and poultry products (Kalchayanand et al., 2009). AviBrom™ and BoviBrom® are two processing aids that have been developed for this purpose (Elanco Food Solutions, 2010; 2012). The reaction of DBDMH mixed with water leads to the production of HOBr, which is the active antimicrobial (see Action of the Substance). DBDMH has become a favored antimicrobial in beef and poultry disinfection processes because its efficacy is less sensitive to pH than chlorine-based disinfecting agents.[1] DBDMH is also effective in protecting food surfaces against the formation of biofilms (i.e., aggregates of microorganisms in which cells adhere to each other on a surface) (McReynolds et al., 2011).

DBDMH can also be used as a slimicide (to prevent slimy microorganism growth) in the manufacture of paper and paperboard products that come in contact with food (Albemarle Corporation, 2012; 21 CFR 176.300).

DBDMH is also used as a disinfectant in recreational water treatment (e.g., swimming pools, spas, hot tubs, and fountains (ALBROM™ 100PC; Albemarle Corporation, 2004) and as a biocide in industrial/commercial water treatment applications such as water cooling systems, brewery pasteurizers, and pulp and paper mills (XtraBrom® 111; Albemarle Corporation, 2011b).

Approved Legal Uses of the Substance:

FDA lists DBDMH as an effective food contact substance that has been demonstrated to be safe as an antimicrobial for the following intended uses (FDA, 2012):

[1]While the focus of this technical report is on the evaluation of DBDMH, alternative antimicrobial agents used in beef and poultry production and approved for use in organic handling and processing will be discussed. The purpose of this discussion is to compare DBDMH to alternative substances which are already permitted in organic handling. These alternative antimicrobial agents include: lactic acid, chlorine materials, hydrogen peroxide, peracetic acid, ozone, and organic ethanol. These substances are discussed in detail under Evaluation Question #11.

- In chiller water used during poultry processing at a level not to exceed that needed to provide the equivalent of 100 parts per million (ppm) of available bromine in the chiller water (Food Contact Substance Notification [FCN] No. 334)
- In water applied to poultry via an inside-outside bird washer and in water used for off-line reprocessing of poultry at a level not to exceed 100 ppm (FCN No. 357)
- In water used in poultry processing for disinfecting poultry carcasses and their parts and organs at a level not to exceed 100 ppm (FCN No. 453)
- In water supplied to ice machines to make ice intended for general use in the poultry processing industry at a level not to exceed 100 ppm (FCN No. 775)
- In water applied to beef hides, carcasses, heads, trim, parts, and organs at a level not to exceed 300 ppm (FCN No. 792)
- In water applied to pig, goat, and sheep carcasses and their parts and organs at a level not to exceed 500 ppm (FCN No. 1102)
- In process water for fruits and vegetables (at a level not to exceed 900 ppm) and as a component of shell egg wash solutions (at a level not to exceed 500 ppm) (FCN No. 1118)

The FDA also allows the use of DBDMH as a slimicide in the manufacture of paper and paperboard that contact food (21 CFR 176.300).

The USDA's Food Safety and Inspection Service (FSIS) directive of "Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products" lists DBDMH in its Table of Safe and Suitable Ingredients in the amounts listed above for poultry processing and meat production and specifically references FCN Nos. 334, 453, 775, 792, and 1102 (USDA, 2012).

The U.S. EPA has registered halohydantoins, including DBDMH, for microbial control in water and water systems and specifically as disinfectants in commercial and residential swimming pools, spas and hot tubs; as sanitizers for treatment of toilet bowl water in homes; and for controlling bacterial and fungal contamination in a variety of industrial water systems. The only food-use for the halohydantoins is as a slimicide in the manufacture of food-contact paper and paperboard (U.S. EPA, 2007).

DBDMH is not currently included on the National List of Allowed and Prohibited Substances (hereafter referred as the "National List") for nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" (7 CFR 205.605).

Action of the Substance:

DBDMH contains bromine, an important antimicrobial capable of reducing *Salmonella*, *Campylobacter*, and *Escherichia coli* (*E. coli*) levels. When DBDMH is mixed with water, it reacts to produce two molecules of HOBr—an active antimicrobial—as well as DMH, a reaction by-product with no antimicrobial function. DMH is described in more detail in Evaluation Questions #7 and #9.

According to the petitioner, Albemarle Corporation, HOBr kills microorganisms by inhibiting certain essential bacterial enzymes through the oxidation of sulfhydryl groups (an alkane, alkene, or other carbon-containing group of atoms bonded to sulfur and hydrogen) and the lysis (the break down) of cell walls. After this disinfection, HOBr reportedly degrades into an inactive bromide ion (Br^-) and the DMH remains (nonreactive) in the water (Albemarle Corporation, 2012; McReynolds et al., 2011).

McReynolds et al. (2011) reported the results of an investigation by McNaughton et al. (undated; internal data, peer reviewed data not located) to determine the effectiveness of DBDMH (and specifically the element bromine) in reducing poultry carcass contamination. In the McNaughton et al. study, poultry chill tanks each containing a carcass and 8 L of water were spiked with 10^7 per mL of *E. coli*, *Salmonella*, and *Campylobacter* and treated with 0, 34, 56, or 78 ppm bromine. Carcasses were removed after 80 minutes and bacteria reductions were recorded. For carcasses and chill water, dose-dependent reductions in bacteria were observed.

Kalchayanand et al. (2009) studied the effectiveness of DBDMH spray treatment on *E. coli* O157:H7 and *Salmonella* using a model beef carcass washer. A 1.1–1.9 log CFU/cm^2 reduction in *E. coli* and a 0.3–2.8 log CFU/cm^2 reduction in *Salmonella* were observed.

Combinations of the Substance:

There is no indication that DBDMH is a precursor to, component of, or commonly used in combination with any substances identified on the National List.

Status

Historic Use:

DBDMH is used to in the meat processing industry to reduce populations of organisms such as *E. coli*, *Salmonella*, and other bacteria that can contaminate meat at various points in processing. These organisms are often present on the hides of animals and can contaminate the meat when the hide is removed (Bosilevac et al., 2006). Between 1992 and 1993, a serious case of *E. coli* O157:H7 contamination in ground beef caused hundreds of illness cases and four deaths. In response, the USDA Food Safety Inspection Service declared *E. coli* O157:H7 an "adulterant" in ground beef and required meat processors to formulate plans to control microbial hazards. Since this incident, the meat processing industry has researched and implemented numerous meat and carcass disinfection techniques (Bosilevac et al., 2006), including hot water spray treatment, lactic acid spray or immersion treatment, and DBDMH spray treatment.

OFPA, USDA Final Rule:

DBDMH is not currently included on the National List for nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" (7 CFR 205.605).

International:

DBDMH is not included on the Canadian General Standards Board's (CGSB's) Permitted Substances List for processing of organic food (CGSB, 2011).

The petition states that, "The Health Products and Food Branch of Health Canada has reviewed the use of DBDMH as an antimicrobial on beef and poultry" (Albemarle Corporation, 2012); however, this could not be verified. Health Canada does allow the use of similar chemicals (1-bromo-3-chloro-5,5-dimethylhydantoin, 1,3-dichloro-5,5-dimethylhydantoin, and 1,3-dichloro-5-ethyl-5-methylhydantoin) as antimicrobials to control bacterial, fungal, and algal slimes in industrial recirculating water systems, but there was no reference to DBDMH (Health Canada, 2011).

The Codex standards for organically-produced foods do not list DBDMH as an approved additive for use in organic food handling/processing (Codex Alimentarius Commission, 2010). DBDMH does not appear in any other Codex standards for conventional food.

The European Commission Regulation EC No. 889/2008 does not list DBDMH as an allowed substance for use in production of processed organic food (European Commission, 2008a). The European Commission Regulation EC No. 681/2008 lists DBDMH as not to be included in Annexes I, IA or IB to Directive 98/8/EC, which governs the marketing of biocidal products (European Commission, 2008b). Specifically, DBDMH is not recommended for biocidal product-types 2 (private and public health area disinfectants and other biocidal products [i.e., nonfood contact surfaces such as swimming pools]); 11 (preservatives for liquid-cooling and processing systems); and 12 (slimicides) (Directive 98/8/EC). However, DBDMH is not listed as banned for product type 20—substances for the control of harmful organisms in food.

The International Federation of Organic Agriculture Movements (IFOAM) does not list DBDMH as an accepted processing aid within its "Norms for Organic Production and Processing" (IFOAM, 2010).

DBDMH does not appear on the list of approved food additives in the Japan Agricultural Standard (JAS) for Organic Processed Foods (JMAFF, 2006).

Evaluation Questions for Substances to be used in Organic Handling

<u>Evaluation Question #1:</u> Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

DBDMH can be produced by reacting sodium hydroxide, sodium carbonate, or sodium bicarbonate with the substrate 5,5-dimethylhydantoin and bromine (Markish and Arrad, 1995). No other information regarding the manufacturing processes for DBDMH could be located.

<u>Evaluation Question #2:</u> Is the substance synthetic? Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21).

DBDMH is a synthetic chemical. As discussed in response to Evaluation Question #1, DBDMH can be produced by reacting sodium hydroxide, sodium carbonate, or sodium bicarbonate with the substrate 5,5-dimethylhydantoin and bromine (Markish and Arrad, 1995).

<u>Evaluation Question #3:</u> Provide a list of non-synthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

No sources were identified to suggest that there are any natural sources of DBDMH. Sources suggest that this substance is produced through chemical synthesis using synthetic primary constituents.

<u>Evaluation Question #4:</u> Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status. What is the technical function of the substance?

DBDMH is not generally recognized safe (GRAS) by FDA (21 CFR 182, 184, and 186) nor is it self-affirmed GRAS by any producer. The technical function of DBDMH is to act as a disinfectant and kill hazardous microorganisms that may be present on food surfaces (Albemarle Corporation, 2012).

<u>Evaluation Question #5:</u> Describe whether the primary function/purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).

The primary function of DBDMH is not as a preservative. While DBDMH may delay the spoilage of meat due to its antimicrobial properties (Kalchayanand et al., 2009), its main purpose is to disinfect meat to kill bacteria and other organisms with disease-causing potential (Albemarle Corporation, 2012).

Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

No information was found to suggest that DBDMH is used to recreate or improve flavors, colors, textures, or nutritive values that are lost in processing. Its sole function in processing/handling is as an antimicrobial agent.

Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).

DBDMH decomposes when mixed with water and is not expected to be present in food at the time of consumption. In water, DBDMH hydrolyzes to form DMH and HOBr, the active sanitizing agent. The petitioner suggests that HOBr does not alter the quality or the nutritive value of the food product (Albemarle Corporation, 2012). No source of independent information was identified to verify this assertion.

DMH does not further breakdown in water, so it would be an expected residue on foods that are not washed sufficiently or processed after treatment (FAO/WHO, 2008). While DMH may exert some toxicity at very high doses, it would likely be present in food at low levels. The concentration of DMH on raw poultry is estimated to be 0.005 mg/g. The concentration of DMH in the chiller tank at any given time would be no greater than 60 mg/kg (USFDA, 2003). Therefore, the concentration of DMH in poultry would not be greater than 0.005 mg/g chicken, or 5 mg/kg chicken (FAO/WHO, 2008) [2]. The concentration of DMH on raw beef would be approximately 0.001 mg/g (FAO/WHO, 2008) [3]. It is unclear whether or not DMH would affect the nutritive value of the food. No further information was identified on DMH residues in food or their potential to affect the nutritional quality of food or feed.

The use of other food disinfecting agents, including peracetic and lactic acids and chlorine-based products, may impact the nutritional quality of food and cause bleaching in both produce and meats. Bleaching generally only impacts the aesthetic qualities of food, and a study conducted by Vandekinderen et al. (2008) determined that chlorine dioxide gas did not influence the sensorial attributes of grated carrots. However, some studies have reported that the use of chlorine products, including chlorine dioxide gas, reduces the amount of carotenoids including β-carotene in fresh-cut carrots. Liquid chlorine-based products were observed to produce less prominent effects on the nutritional quality of carrots (Vandekinderen et al., 2008). In addition, the lycopene content in tomatoes was reduced when a sanitizing solution containing peracetic acid was used (Vandekinderen et al., 2008). Bleaching has been observed when lactic acid is added to poultry disinfection washes (USDA, 2000).

[2] The amount of DMH that remains on poultry carcasses after processing was estimated using (1) the maximum use level of DBDMH in poultry chiller water (90 mg/kg), (2) the water uptake by poultry carcasses (8% by weight), (3) the assumption that DMH and other breakdown products will be absorbed by the carcass in an amount proportional to the amount of water taken up by the carcass while it is in the chiller tank, and (4) the amount of chiller water allowed to be recirculated (50% in the USA). The concentration of DMH on raw poultry is estimated to be 0.005 mg/g (FAO/WHO, 2008).

[3] The amount of DMH that remains on beef carcasses after processing can be estimated using (1) the maximum use level of DBDMH in water applied to beef as a spray (270 mg/kg), (2) the assumption that the amount of DMH absorbed by the carcass is proportional to the amount of water taken up by the carcass while it is treated with the disinfectant spray (1%), and (3) the molecular weights of DBDMH (285 g/mol) and DMH (128 g/mol) (FAO/WHO, 2008).

Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 (b)(5)).

No reports of excessive levels of heavy metals or other contaminants in DBDMH have been identified. One manufacturer, Longkou Keda Chemical Company Ltd. (2012), reports on its website that its DBDMH disinfectant tablets (450−550 mg/tablet) have <1 ppm of lead and <0.05 ppm of arsenic. Information on levels of contaminants possibly present in the petitioner's products (BoviBrom® and AviBrom™) as well as in other identified products (ALBROM™ 100PC and XtraBrom® 111) was not available.

Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

Sigma Aldrich reported in its material safety data sheet (MSDS) for DBDMH that "an environmental hazard cannot be excluded in the event of unprofessional handling or disposal" and that DBDMH is "very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment" (Sigma Aldrich, 2012). A review of DBDMH completed by the petitioner indicated that available information did not "suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of DBDBH" (Albemarle Poultry Sciences, 2004). DBDMH breaks down rapidly in water into DMH and the highly reactive HOBr. HOBr per se is not expected to survive transit in the meat processing system, especially in water contacting poultry carcasses that would contain high organic content. Therefore, it is expected that no HOBr would be released from the poultry plant into wastewater (Albemarle Poultry Sciences, 2004). According to the petitioner, DMH can be discharged into environmental media directly from wastewater streams or indirectly through wastewater treatment plants (Albemarle Poultry Sciences, 2004). DMH is expected to be degraded by the processing plant and/or the wastewater treatment plant, but the bromine ion may remain in treated wastewater unless special steps are taken to remove it. However, based on calculated maximum use levels of DBDMH containing bromine (i.e., assuming a worst-case water usage of 10 gallons per bird and DBDMH is added to all of this process water at the maximum approved level of 90 ppm), the petitioner suggested that this action might not be necessary (Albemarle Poultry Sciences, 2004). The maximum concentration at which bromide ion may be present in rivers or other bodies of water as a result of direct discharge of poultry wastewater was estimated above as 2.5 ppm or 2.5 mg/L). This maximum bromide ion level is based on worst-case assumptions which are not expected to ever occur (Albemarle Poultry Sciences, 2004).

According to U.S. EPA (2007), in the event of accidental release, DMH would likely be stable in the environment, leaching into soil and groundwater or transported via surface water runoff (U.S. EPA, 2007). The half-life of DMH in water at a pH of 7 is estimated to be 878 days. This stability in water indicates DMH could be a potential drinking water contaminant. DMH has a moderate tendency to bind to soil. DMH demonstrates low toxicity to terrestrial and aquatic animals as indicated by a number of studies in birds, freshwater fish, and invertebrates, but EPA could not make a determination of its bioaccumulative potential (U.S. EPA, 2007).

Several other substances, including lactic acid, chlorine materials, hydrogen peroxide, peracetic acid, ozone, and organic ethanol, are already permitted in organic handling for use as an antimicrobial in the post-slaughter processing and disinfection of meat products. Some of the environmental effects associated with these antimicrobial agents used in poultry and beef handling and processing are discussed below.

Although chlorine-containing compounds are generally very reactive and break down quickly in the environment, one primary product of chlorine dioxide disinfectant is chlorite (ATSDR, 2004). Chlorite may enter groundwater and contaminate drinking water. EPA has set a maximum contaminant level (MCL) of 0.8 mg/L for chlorine dioxide and an MCL 1 mg/L for chlorite. Toxic properties of chlorite include the induction of oxidative damage to red blood cells at doses as low as 10 mg/kg-body weight (bw). Toxic reaction products are not known to occur when chlorite is mixed with organic materials (U.S. EPA, 2002).

Peracetic acid has several breakdown products, including acetic acid (same acid found in vinegar at 5% level) and hydrogen peroxide that breaks down to O_2 and H_2O. These breakdown products are not expected to cause harm to the environment, and disposal of peracetic acid in a municipal sewer system could have a positive effect due to its oxidation properties. Peracetic acid kills microorganisms by oxidation and subsequent disruption of their cell membrane, via the hydroxyl radical (HO·). Peracetic acid is more persistent in the environment than chlorine-based disinfectants and can experience longer residual activity (USDA, 2000).

Ozone is a known air pollutant that causes crop damage. When plants are exposed to ozone, it elicits plant responses that are similar to plant responses to pathogens. There is evidence that ozone may reduce populations of some soil microorganisms such as nematodes. However, it is unlikely that the ozone added to disinfection washes for poultry and beef would come into contact with the soil or crop plants (USDA, 2002). The use of ozone in wastewater disinfection is increasing because ozone causes direct oxidation/destruction of the cell wall and damage to nucleic acids (EPA, 1999). Ozone is very reactive and corrosive, thus requiring corrosion-resistant material, such as stainless steel for storage. Accidental release into the environment could produce damaging effects (National Small Flows Clearinghouse, 1998).

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

No published reports on the toxicity of DBDMH in animals or humans could be identified. Data on the effects of DBDMH on human health are considered confidential business information by the petitioner. However, EPA has reported that DBDMH has an LD_{50} (the dose that causes death of 50% of test animals) between 448 and 760 mg/kg based on unpublished oral acute studies in rats. Unpublished inhalation studies in rabbits have yielded an LC_{50} (the concentration that causes death of 50% of test animals) between 0.51 and 2.02 mg/L DBDMH. Dermal studies have indicated that DBDMH is corrosive and a severe skin irritant in rabbits (U.S. EPA, 2007). It also caused somnolence (general depressed activity) and changes to sense of smell in rabbits administered dermal doses of 20 g/kg-bw (ChemIDPlus Lite, 2012). Although no corroborating information was found, a summary document reported that long-term exposure to DBDMH caused thyroid effects in rats (Ojalas et al., 1996). The DBDMH MSDS from Sigma Aldrich (2012) reported that DBDMH can cause severe skin burns and eye damage in humans. It is reportedly "extremely destructive to the tissue of the mucous membranes and upper respiratory tract." Full-face respirators are recommended for workers handling DBDMH if no other means of ventilation are in place.

Because DBDMH decomposes in water, it is not expected to be present on food at the time of consumption. According to a report from a joint FAO/WHO meeting on food disinfectants, experts agreed that, "As there is no direct dietary exposure to DBDMH, no health concern was identified" (FAO/WHO, 2008). However, authors noted that the DBDMH breakdown product, DMH, would be an expected residue on foods that are not washed sufficiently or processed after treatment. EPA has indicated, however, that the toxicological data for DMH suggests it is only nonspecifically toxic at relatively high doses in animals and that it is not developmentally toxic in animals (U.S. EPA, 2007). Other byproducts and breakdown products, including organobromine disinfection byproducts, bromide, and bromate[4], could also remain as residues on food treated with aqueous solutions of DBDMH. Specifically, bromate is a likely human carcinogen by the oral route of exposure. Insufficient data are available to evaluate the human carcinogenic

[4] Although bromate may potentially be generated in small amounts during the use of DBDMH and may migrate to poultry during processing, bromate is a strong oxidant and is expected to be reduced to bromide during cooking. Therefore, bromate is not expected to be present on food at the time of consumption (FAO/WHO, 2008).

potential of bromate by the inhalation route (HSDB, 2009). No information on the fate of formaldehyde was found.

Disinfection byproducts, like dibromoacetic acid, are formed when DBDMH is combined with chlorinated water. One study reported increased cancer in rats and mice exposed for 2 years to dibromoacetic acid in drinking water (Melnick et al., 2008). In the FAO/WHO report on the use of DBDMH as a disinfectant on food, authors ultimately concluded that it was unlikely that significant amounts of disinfection byproducts would be formed and would remain as residues on the food at the time of consumption (FAO/WHO, 2008).

Reports of irritation to the skin, eyes, and respiratory tract are commonly associated with the use of other antimicrobial agents used in poultry and beef processing including lactic acid, peracetic acid, chlorine-based materials, and ozone (USDA, 1995; 2000; 2002; 2006). Organic alcohol may cause irritation to the eyes and may cause dizziness, faintness, drowsiness decreased awareness or responsiveness, nausea, vomiting, staggering gait, lack of coordination, and coma following ingestion. Repeated ingestion of organic alcohol by pregnant mothers has been shown to adversely affect the central nervous system of the fetus, producing a collection of effects which together constitute fetal alcohol syndrome (Fairly Traded Organics, undated).

In addition, high exposures to ozone can cause a build-up of fluid in the lungs (pulmonary edema) with severe shortness of breath. Liquefied ozone on contact with skin or eyes can produce severe burns. Limited evidence indicates that ozone causes cancer in animals. It may cause cancer of the lung, mutations (genetic changes), and may damage the developing fetus (USDA, 2002). A dominant byproduct of ozonation is formaldehyde, which may be associated with various types of cancer (National Cancer Institute, 2011). With respect to carcinogenicity, peracetic acid may be a possible co-carcinogen as studies have reported that the substance may promote tumor production by known carcinogens (USDA, 2000).

Evaluation Information #11: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b)(1)).

Hot water spraying is a viable method to treat animal carcasses after slaughter to reduce microbial loads. According to a number of sources, hot water treatment is effective against pathogens and spoilage bacteria (Kalchayanand et al., 2008; 2009; Bosilevac et al., 2006; Delmore et al., 2000; Gill et al., 1999). This method generally consists of spraying water in a wash cabinet at temperatures of 165–185°F for 5.5−10 seconds (up to 28 seconds for certain organs such as beef hearts, which typically are moved at a different chain speed than the full carcasses). Hot water spraying does not damage the carcass and is chemical free; however, it uses a high volume of water and may be costly due to the high temperature requirements (Kalchayanand et al., 2009). In their experiment, Kalchayanand et al. (2009) found that spray treatments with DBDMH (treatments of 75, 175, or 270 ppm) were almost as effective as the hot water treatment in reducing *Enterobacteriaceae*, *E. coli* O157:H7, and *Salmonella*. The bacterial counts were lower on samples treated with hot water compared with DBDMH although both treatments significantly reduced bacteria compared with controls. It was also noted that DBDMH at 75 ppm was just as effective at reducing bacteria counts as the 270 ppm concentration. Three concentrations of DMDMH sprays (75 ppm, 175 ppm, and 270 ppm) were evaluated and determined to be similar in their effectiveness at reducing microbial load on treated samples.

Organic ethanol (alcohol) is an organic agricultural product that may be used as an alternative for DBDMH when used as a decontaminating wash for poultry and meat products. Some researchers have stated that 50–70% ethanol concentrations were disinfecting agents and that higher ethanol concentrations could, in some cases, desiccate cells making them more resistant to chemical and physical disinfection. Others have reported that lower concentrations of ethanol (5–20%) inhibited microbial growth by lowering water activity. The microbial population on intact chicken meat has been reduced after rinsing the meat with 70% and 50% ethanol, respectively (Keokamnerd et al., 2007). It is unclear how organic ethanol compares directly with DBDMH in its efficacy to disinfect poultry and meat.

Several other substances, including lactic acid, peracetic acid, ozone, hydrogen peroxide, and chlorine materials, are already permitted in organic handling for use as an antimicrobial in the post-slaughter processing and disinfection of meat products. Summaries of these products are provided below.

Lactic acid is a common carcass treatment solution. Nonsynthetic lactic acid is currently on the National List as a nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group[s])" (7 CFR 205.605). According to Bosilevac et al. (2006), it is the most often used organic acid for treatment of beef carcasses. In an experiment comparing the effectiveness of a 2% L-lactic acid spray treatment and a hot water spray treatment, hot water treatment was more effective than L-lactic acid. While hot water reduced *E. coli* O157:H7 counts by about 81% compared with untreated controls, L-lactic acid reduced this *E. coli* strain by only 35% (Bosilevac et al., 2006). In another study, however, Delmore et al. (2000) found that immersing a variety of meats (beef cheek, large intestine, lips, liver, oxtail, and tongue) in 2% lactic acid was among the most effective treatments (in addition to hot water spraying and acetic acid spraying) for reducing counts of *E. coli*, total coliform (common fecal bacteria), and aerobic plate counts (the level of microorganisms; sometimes used to indicate the quality and spoilage level of a product). Kalchayandand et al. (2008) found that spraying 2% DL-lactic acid resulted in a 1.4 to 2.2 log reduction in *E. coli* O157:H7 levels on beef heads, performing similarly to hot water and electrolyzed oxidizing water (ionized water; trade name FreshFx) spray treatments. Mulder et al. (1987) reported a 4 log reduction in *Salmonella* spp. in broiler carcasses following treatment with lactic acid. In similar studies, lactic acid had a slightly higher efficacy in removing *E. coli* spp. (Kalchayanand et al., 2009) than DBDMH (Kalchayanand et al., 2008; McReynolds et al., 2011) indicating that lactic acid may be a more effective beef carcass treatment.

Peracetic acid may also be used to treat animal carcasses during processing. According to 7 CFR 205.605(b), peracetic acid (CAS Number 79–21–0) is permitted for use by the USDA in wash and/or rinse water according to FDA limitations and is also permitted for use as a sanitizer on food contact surfaces. In addition, Vandhanasin et al. (2004) found that treatment with 0.5% peracetic acid was the most effective experimental antimicrobial processing treatment (compared with hydrogen peroxide and ozone treatments), reducing *Salmonella* on broiler chickens to a prevalence of 5%. It is unclear how peracetic acid compares with DBDMH in its efficacy to disinfect animal carcasses. As discussed in response to Evaluation Question #7, the use of peracetic acid may adversely influence the nutritive quality of some fruits and vegetables, including tomatoes (Vandekinderen et al., 2008).

Another potential antimicrobial treatment for meat is ozone. Synthetic ozone is currently on the National List as a nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group[s])" (7 CFR 205.605). A number of studies have found ozone treatment effective for microbial control in meat processing. Brown (1986) found that poultry carcasses chilled with ozonated water and stored at 4.4°C were more than 99% free of microorganisms with no negative effects such as skin color loss or off flavors. While not as effective as treatment with peracetic acid, ozone treatment (125 mg/L; application method unclear) was equally effective as hydrogen peroxide (30 mg/L), reducing *Salmonella* to a prevalence of 15% on broiler chickens (Vandhanasin et al., 2004). In other studies, however, researchers have found limited success with ozone treatments. Castillo et al. (2003) reported that aqueous ozone spray treatments did not achieve better results than a water wash (85°C). Kalchayandand et al. (2008) reported that ozone treatment was the least effective treatment relative to lactic acid, ionized water, hot water, acidic electrolyzed oxidizing water (60 ppm chlorine with 1,190 mV of oxidation-reduction potential), and presumably DBDMH (based on reported efficacy values in Kalchayandand et al., 2009). Only a -.07 to 0.25 log CFU/cm^2 reduction in *E. coli* was observed with the ozone treatment. Authors stated that ozone is relatively unstable in water and at pH levels above 5.0, indicating that the treatment may have failed due to the 6.5 pH of test solutions (Kalchayandand et al., 2008).

Synthetic hydrogen peroxide and chlorine materials are permitted for use by the USDA in food processing under 7 CFR 205.605(b).. Baird et al. (2006) observed a 2.9 log CFU/cm^2 reduction in *E. coli* following the treatment of cattle hides with 3% hydrogen peroxide solution. Although not as effective as peracetic acid, Vandanasin et al. (2004) reported that hydrogen peroxide reduced the prevalence of *Salmonella* on broiler chickens below the critical limit of 20%. Some products contain a combination of both peracetic acid and hydrogen peroxide. Small et al. (2005) found that this combination significantly reduced total viable bacteria counts on treated cattle hides. It is unclear how hydrogen peroxide compares directly with DBDMH in its efficacy to disinfect animal carcasses.

Chlorine was one of the first substances used for carcass decontamination of beef. It has been effective at high concentrations (200−500 ppm), but effectiveness at lower concentrations is variable. The maximum permitted level used for beef carcasses in the United States is 20−50 ppm; however, studies have shown that these levels may not be effective (Food Science Australia, 2006). Nassar et al. (1997) found that 20 and 50 ppm concentrations of chlorine in water (via calcium hypochlorite) had no significant effect on broiler carcasses inoculated with *Salmonella*. Free chlorine gas, which is used to chlorinate water, is toxic and can form toxic byproducts such as carcinogenic trihalomethanes (Food Science Australia, 2006). One advantage to using DBDMH rather than chlorine materials is the absence of toxic byproducts. McReynolds et al. (2011) discuss some additional benefits of using DBDMH in poultry disinfectant washes versus chlorine products. The microbiocidal efficacy of DBDMH is less sensitive to pH than chlorine-based disinfecting washes. Compared with chlorine products, DBDMH reaction with organics also produces lower levels of odor creating a more favorable environment for plant workers, and it is less corrosive to plant equipment and floors. DBDMH is also more effective than chlorine products in protecting against the formation of biofilms. DBDMH has been observed to be a more effective disinfectant in poultry washed compared to chlorine based disinfectants. The byproducts of the bromine chemistry (bromamines) are more biocidal than chlorine equivalents (chloramines) leading to a greater bacteriocidal compound than HOCL (McReynolds et al., 2011).

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