



**Albemarle Corporation**

451 Florida Street

Baton Rouge, LA 70801-1765

Telephone: 800-535-3030

Facsimile: 225-388-7686

March 13, 2013

To Whom It May Concern,

Recently, Albemarle Corporation was notified that our petition requesting the addition of 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) to section 205.605 of the National Organic Program's National List of Allowed and Prohibited Substances has been added to the agenda for the NOSB meeting scheduled for April 9-11, 2013. In review of the Handling Subcommittee's Petitioned Material Proposal, the recommended action is to not add DBDMH to the National List of Allowed Substances. We respectfully disagree with the recommendation of the Subcommittee and we appreciate being allowed to make the following comments on the petition proposal prior to the board NOSB meeting in April. Our comments are provided in table format along with the National Organic Program's evaluation criteria for allowed and prohibited substances.

Albemarle Corporation's Food Safety Initiative is dedicated to delivering safe and effective antimicrobials to food processors, ensuring that they are able to comply with rigorous food safety standards proposed by the USDA's Food Safety and Inspection Service. As the global food supply diversifies, Albemarle is committed to increasing public and industry awareness of effective new technologies.

The top beef and poultry processors in the U.S. are recognizing hypobromous acid as a highly effective antimicrobial which is approved for use in multiple applications. Hypobromous acid can be generated safely via hydrolyzing DBDMH (1,3-Dibromodimethylhydantoin) in water. Hypobromous acid is the active antimicrobial agent applied to meat via process water and its oxidizing action has proven to be effective at reducing food-borne pathogens such as *E. coli*, *Salmonella*, *Listeria* and *Campylobacter*. After undergoing chemical reduction during use, the hypobromous acid converts to an inactive bromide ion. The DMH by-product from hydrolysis remains in the water, serves no function, and does not react further.

DBDMH has been reviewed and approved for use as an antimicrobial processing aid on beef by the FDA (FCN 792, FCN 1190). That FCN included a TBA analysis determining the extent of lipid oxidation and fatty acid profiles of treated and untreated beef. This study demonstrated that there was no significant change to the beef upon treatment with DBDMH. Therefore, we expect that the nutrition of the meat is not compromised.

The USDA also reviewed FCN 792 and FCN 1190 and DBDMH was added to the USDA's directive 7120.1 Safe and Suitable ingredients used in the production of Meat, Poultry and Egg products.

DBDMH is safe for workers and the environment. It is less sensitive to pH in water and less corrosive to plant equipment and floors than the current chlorine and acid treatments. DBDMH has been successfully used without meat discoloration and without carcass damage, effects associated with high-temperature washes. Furthermore, DBDMH treated water can be recycled or discharged into public sewer systems

We look forward to our petition being approved and DBDMH being added to the National Organic Program's National List of Allowed Substances.

Respectfully,  
Albemarle Corporation

Requirement	Response
<b>Title 7 – Agriculture, C.F.R. 205.600, Subpart G, National List of Allowed Substances and Prohibited Substances</b>	
(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:	
(1) The substance cannot be produced from a natural source and there are no organic substitutes;	DBDMH cannot be produced from a natural source. Wholly organic substitutes, as well as synthetics on the National Organic Program List of Approved Substances, are either not as efficacious against <i>E. coli</i> or as cost effective as DBDMH.
(2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;	<p>The manufacture of Albemarle's DBDMH is performed at an ISO 9001 certified facility. The by-product of the reaction used to manufacture DBDMH is a salt solution. This salt solution is utilized in the preparation of another compound.</p> <p>The use of DBDMH requires no manual mixing of raw materials by plant workers, no mixing or heating of the solution, no daily monitoring or adjustment beyond testing of the final solution, and no on-site chemical reaction.</p> <p>While we do not anticipate any disposal of DBDMH, as the product is loaded into a feeder and then hydrolyzed to prepare hypobromous acid. However, in the event of accidental release, DMDMH can be swept up and shoveled into suitable containers for disposal in an approved landfill.</p>
(3) The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations;	<p>When used as directed, dilute solutions prepared from DBDMH did not result in meat discoloration or carcass damage that is often associated with high-temperature washes.</p> <p>DBDMH has been reviewed and approved for use as an antimicrobial processing aid on beef by the FDA (FCN 792). That FCN included a TBA analysis* determining the extent of lipid oxidation and fatty acid profiles of treated and untreated beef. This study demonstrated that there was no significant change to the beef upon treatment with DBDMH. Therefore, we expect that the nutritional qualities of the meat remain unchanged.</p> <p>*Although confidential, a copy of the above mentioned study can be made available to the NOSB, for review, upon request.</p>
(4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;	DBDMH is an antimicrobial processing aid, which provides a one-time reduction in the microbial load of the meat but does not have an ongoing antimicrobial effect and does not affect the characteristics of the meat.

(5) The substance is listed as generally recognized as safe (GRAS) by Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; and	DBDMH is listed on the USDA's directive 7120.1 Safe and Suitable ingredients used in the production of Meat, Poultry and Egg products. As DBDMH does not remain with the food and is not considered a direct food additive, it is not listed as GRAS. However, the FDA has deemed DBDMH safe when used as directed and within the limits established in FCN1190. DBDMH contains no residues or other heavy metals in excess of tolerances set by the FDA. This was confirmed by Inductively Coupled Plasma analysis of several lots of DBDMH
(6) The substance is essential for the handling of organically produced agricultural products.	DBDMH reduces the microbial load and therefore makes food safer for human consumption.
<b>7 U.S.C., United States Code, 2011 Edition, Title 7 – Agriculture, Chapter 94 - Organic Certification, Section 6517 - Nation List, (c) Guidelines for prohibitions or exemptions</b>	
<b>(1) Exemption for prohibited substances in organic production and handling operations,</b> The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter only if—	
(A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances—	
(i) would not be harmful to human health or the environment;	The FDA has thoroughly evaluated the potential environmental and health effects of a DBDMH solution up to a concentration of 900 ppm. Environmental Decision Memo for Food Contact Notification 1190, dated July 9, 2012, states the following: The Office of Food Additive Safety has determined that allowing this notification to become effective will not significantly affect the quality of the human environment and, therefore, will not require the preparation of an environmental impact statement. This finding is based on information, including an environmental assessment, dated June 21, 2012, in the notification submitted by the notifier, and other information known to the agency. The on-line FDA decision memo can be viewed at: <a href="http://www.fda.gov/Food/FoodIngredientsPackaging/EnvironmentalDecisions/ucm323188.htm">http://www.fda.gov/Food/FoodIngredientsPackaging/EnvironmentalDecisions/ucm323188.htm</a>
(ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products; and	Wholly organic substitutes, as well as synthetics on the National Organic Program List of Approved Substances, are either not as efficacious against <i>E. coli</i> or as cost effective as DBDMH.
(iii) is consistent with organic farming and handling;	DBDMH is an antimicrobial intervention used in processing meat and poultry.
(B) the substance—	

(i) is used in production and contains an active synthetic ingredient in the following categories: copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or	N/A
(ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern; and	DBDMH is not listed on the EPA's List of Inerts of Toxicological Concern. Nor is it included on the EPA's List for Potentially Toxic Inerts/High Priority for testing.
(C) the specific exemption is developed using the procedures described in subsection (d) of this section.	Petition submitted according to Subsection D
<b>7 U.S.C., United States Code, 2011 Edition, Title 7 – Agriculture, Chapter 94 - Organic Certification, Section 6518 - National Organic Standards Board</b>	
<b>(m) Evaluation,</b> In evaluating substances considered for inclusion in the proposed National List or proposed amendment to the National List, the Board shall consider—	
(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;	N/A
(2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;	As has been mentioned previously, the molecule DBDMH hydrolyzes in water to form hypobromous acid or what is referred to as "bromine" and the carrier DMH. From a historical perspective, no adverse effects have been observed or reported on the waste treatment systems at several different beef processing plants using DBDMH. Bromine residuals have been monitored periodically in the water leaving the plant prior to entering the anaerobic sludge lagoon. At no time was a significant bromine residual measured. This is expected as the wastewater in the plant contains a substantial organic load which will reduce the bromine levels in the wastewater. The

	mode of action of bromine is similar to "chlorine" (sodium hypochlorite) as both are oxidizers. Bromine acts through lysis of the cell walls and the inhibition of certain enzymes essential to life. As for the carrier DMH, it is ultimately biodegradable. After an acclimation period, bacteria typically found in a waste treatment plant can degrade it. (US EPA 40 CFR 796.340 September 27, 1985. Inherent biodegradability: Modified SCAS Test, Study number 86-1449-11 Hill Top Labs).															
(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;	<p>Please see our comment to C.F.R. 205.600 G(b)(2) above which addresses the manufacture, use and disposal of DBDMH.</p> <p>While we feel the misuse of DBDMH would be difficult due to the nature of the reaction and the efficient application systems, any resulting reaction products formed from the inadvertent mixing of DBDMH and incompatible material would ultimately not be harmful to the environment.</p>															
(4) the effect of the substance on human health;	<p>The maximum level at which the by-products of DBDMH may enter the diet is calculated by multiplying the worst-case residue levels in the beef by the applicable consumption factor. FDA has established a daily intake value for beef of 50 grams per person per day (g/p/d) for the 90th percentile consumer of beef. This is equivalent to a CF of 0.017 (1.7% of the diet) based on the standard diet of 3000 g/p/d. On this basis, the dietary concentrations and EDI's for DMH and bromide from the intake of beef are calculated as follows:</p> <table><tr><th>Compound</th><th>Conc. in Beef (ppm or ppb)</th><th>Conc. in Diet (ppm or ppb)</th><th>EDI (mg/p/d or ug/p/d)</th><th>ADI *</th></tr><tr><td>DMH</td><td>1.21 ppm</td><td>0.0206 ppm</td><td>0.062 mg/p/d (62 ug/p/d)</td><td>.30 mg/p/d</td></tr><tr><td>Bromide ion (from DBDMH)</td><td>1.55 ppm</td><td>0.0264 ppm</td><td>0.079 mg/p/d (79 ug/p/d)</td><td>1.0 mg/kg/w/d</td></tr></table> <p>*The chart above shows that the estimated daily intakes (EDI) from consuming beef treated with DBMDH is approximately 5 times lower than the acceptable daily intake (ADI) for DMH.</p> <p>An analysis of rinsate from 1000 ppm DBDMH solution applied to beef meat did not detect the presence of bromate (detection level 10 µg/L), Using a level of 10 µg/L an EDI for bromate was calculated to be &lt;0.19µg/p/d. As no ADI exists for bromate, this analysis was compared to the National Drinking Water Standards which list the maximum contaminant level as 10µg/L. Estimating the typical water consumption per person at 2 liters, bromate consumption would be 20µg, 100 times higher than the calculated EDI. Reference FCN792.</p>	Compound	Conc. in Beef (ppm or ppb)	Conc. in Diet (ppm or ppb)	EDI (mg/p/d or ug/p/d)	ADI *	DMH	1.21 ppm	0.0206 ppm	0.062 mg/p/d (62 ug/p/d)	.30 mg/p/d	Bromide ion (from DBDMH)	1.55 ppm	0.0264 ppm	0.079 mg/p/d (79 ug/p/d)	1.0 mg/kg/w/d
Compound	Conc. in Beef (ppm or ppb)	Conc. in Diet (ppm or ppb)	EDI (mg/p/d or ug/p/d)	ADI *												
DMH	1.21 ppm	0.0206 ppm	0.062 mg/p/d (62 ug/p/d)	.30 mg/p/d												
Bromide ion (from DBDMH)	1.55 ppm	0.0264 ppm	0.079 mg/p/d (79 ug/p/d)	1.0 mg/kg/w/d												

	<p>Halogenated acetic acids (HAA) like dibromoacetic acid typically form during the disinfection of water containing bromide ions, natural organic matter, and chlorine. Since the water used to prepare hypobromous acid in the processing plants is potable, one would expect the water to contain minimal amounts of organic matter and chlorine. Thus one would expect minimal or no HAA formation to occur in the water applied to product in the processing plants.</p> <p>Furthermore, laboratory tests of meat treated with DBDMH show no levels of concern for residues of any component or by-product of DBDMH.</p> <p>The concentration of the antimicrobial solution will have similar properties to chlorine solutions that are currently employed in the meat processing industry. The hazards and precautions necessary for the safe handling and use of dilute bromine solutions are not expected to be any greater than those that exist for chlorine. Dermal irritation is not expected at these dilute levels. However, as a precaution, rubber gloves, and if necessary, a waterproof apron are recommended to prevent dermal and body contact. In addition, it is good industrial hygiene practice and it is recommended that eye protection be employed to prevent splashes to the eye. In the event of exposure, the affected area should be rinsed/flushed with plain water.</p>
(5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;	<b>N/A</b>
(6) the alternatives to using the substance in terms of practices or other available materials; and	Wholly organic substitutes, as well as synthetics on the National Organic Program List of Approved Substances, are not as efficacious against <i>E. coli</i> or as economically feasible as DBDMH.
(7) its compatibility with a system of sustainable agriculture.	<b>N/A</b>

Due to a comment in the NOSB Technical Evaluation Report, we are providing Health Canada and Canadian Food Inspection Agency letters allowing use of BoviBrom as separate files with these comments.