Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date: April 11, 2013

Subject: Petition to add 1, 3-Dibromo-5,5-dimethylhydantoin (DBDMH) to Section 205.605(b)

Chair: Mac Stone

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: ☐

Guidance Statement: ☐

Other: ☐

Statement of Recommendation: (Motion # 1) Passed

Motion to classify 1, 3-Dibromo-5,5-dimethylhydantoin (DBDMH) CAS # 77-48-5 as synthetic

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

As stated in the technical report (line 201) DBDMH is synthetic

Committee Vote:

Moved: John Foster

Seconded: Harold Austin

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse 0

Statement of Recommendation: (Motion # 2) Failed

Motion to list 1, 3-Dibromo-5,5-dimethylhydantoin (DBDMH) CAS # 77-48-5 on section 205.605(b).

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

DBDMH has been petitioned for use as an antimicrobial treatment for beef carcasses and parts but fails the evaluation criteria of essentiality & availability, as well as compatibility and consistency with organic principles. DBDMH is not recognized by other organic programs, and although it has the advantage of being less corrosive to concrete and equipment, more cost-effective, and less sensitive to pH variability. there are several other materials that are currently in use in organic meat handling. Additionally, there were few or no comments from potential users indicating a need for this substance.

Committee Vote:

Moved: John Foster

Seconded: Jean Richardson

Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
1,3-dibromo-5, 5-dimethylhydantoin (DBDMH) CAS No. 77-48-5

January 14, 2013

Summary of Proposed Action:
1,3-Dibromo-5,5-dimethylhydantoin (DBDMH) is an organic compound and is widely used as a disinfectant used for drinking water purification ,recreational water treatment, as a bleaching agent in pulp and paper mills, and for treating industrial/commercial water cooling systems. 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).

DBDMH has been petitioned for use as an antimicrobial treatment for beef carcasses and parts. 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. 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).

It is not recognized by other organic programs. There are several other materials that are in current use in organic meat handling, this material has the advantage of being less corrosive to concrete and equipment, more cost-effective, and less sensitive to pH variability.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see "B" below)**
1. Impact on Humans and Environment	☐ Yes x No ☐ N/A
2. Essential & Availability Criteria	☐ Yes x No ☐ N/A
3. Compatibility & Consistency	☐ Yes x No ☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	☐ Yes ☐ No x N/A

Substance Fails Criteria Category: [ ] **Comments:**

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Subcommittee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Move to classify 1,3-dibromo-5, 5-dimethylhydantoin as synthetic.
Motion by: John Foster Seconded by: Jean Richardson
Yes: 7 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Listing Motion: Move to list 1,3-dibromo-5, 5-dimethylhydantoin as petitioned on section 205.605 (b) of the National List
Motion by: John Foster Seconded by: Harold Austin
Yes: 0 No: 7 Absent: 1 Abstain: 0 Recuse: 0

Crops	☐		☐		
Livestock	☐		☐		

Handling	X		☐		
No restriction	☐		☐		

Approved by Subcommittee Chair to Transmit to NOSB

John Foster, Subcommittee Chair **January 15, 2013**

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? **Substance: DBDMH**

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		X		TR 344+
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		TR 344+
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		TR 344+
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		TR
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]			X	Not for use in farming
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			X	Not for use in farming
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	Not for use in farming
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		Not applied in environment, None noted, TR 344+
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		Not applied in environment, None noted, TR 344+
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		X		DMH may be concerning if inappropriately managed. 361-362
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		Not for petitioned use 79
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]		X		TR 216-218
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		TR 271. No identified reports.

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production? Substance: DBDMH

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X			TR 193+
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		X		TR 193
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		TR 193
4. Is there a natural source of the substance? [§205.600 b.1]		X		TR 208
5. Is there an organic substitute? [§205.600 b.1]	X	X		Alcohol may be produced organically, but generally, no, as listed in TR 397-498
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		Some means of microbial control is needed to meet FDA handling standards (even pre-FSMA)
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		X		TR 193
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		
9. Is there any alternative substances? [§6518 m.6]	X	X		Alcohol, lactic acid, chlorine, ozone, hydrogen peroxide, eperoxyacetic acid, hot water, and others that may be costly due to temp requirements, chemical costs. TR 397-498. however, some forms of chlorine are less effective and are more corrosive than this material. These alternatives are also reported by the petitioner to be less economically feasible.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			As per TR 397-404 and other practices as noted.

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices? Substance:

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]	X	X		Meets some criteria for compatibility but not others.
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X	X		Meets some criteria for compatibility but not others.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	Not used in farming.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			TR 240-253 is noncommittal. Alternatives do have negative NQ effects.
5. Is the primary use as a preservative? [§205.600 b.4]		X		TR 47 and 244. Used as an antimicrobial, not a preservative.
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		X		TR 47 and 244. Used as an antimicrobial, not a preservative.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;			X	
b. toxins derived from bacteria;			X	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	
d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]
Substance: Name

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?			X	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?			X	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?			X	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			X	
a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			X	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.