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October 3, 2014

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Re. HS: Boiler Chemicals: Octadecylamine, Diethylaminoethanol, Cyclohexylamine

These comments to the National Organic Standards Board (NOSB) on its Fall 2014 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and groups around the world.

Beyond Pesticides opposes the relisting of the boiler chemicals octadecylamine, diethylaminoethanol, and cyclohexylamine because they fail the OFPA criteria for health and environmental impacts, essentiality, and compatibility with organic handling practices. Documents prepared for the NOSB include TAP reviews for each chemical and a paper on "Steam Generation in Organic Processing."

1. Health and Environmental Impacts

In terms of environmental impacts, the Technical Advisory Panel reviews of three chemicals found them to be toxic, volatile, and carried in the steam, so the local environment is likely to be affected, especially in the case of a boiler blowout. All are manufactured by chemical processes using toxic precursors and high energy inputs. They are all considered hazardous enough to require special precautions in the case of spills.

All three chemicals are moderately to highly toxic by multiple routes of exposure and severe irritants. The chemicals cannot be separated from the steam, so they are carried by the steam into the materials being sterilized, and can therefore end up in organic food products.

The NOSB has not determined the extent to which these amines, which are known to be carried in the steam, are present on sterilized containers and in processed food. This is a critical piece of information that is necessary to support the compromise annotation, "for use only as a boiler water additive for packaging sterilization." In addition, the TAP reviews did not consider

information relating to worker exposure, including occupational illness and asthma caused by exposure to the chemicals.[1]

2. Essentiality

The TAP studied these chemicals and their uses. The panel's conclusions were adamantly opposed to their use in organic processing, citing both hazards and lack of essentiality. Some quotations will convey their conclusions regarding essentiality:

> "Justification of the [substances' use] by the petitioners is based on the constraints of their particular boiler and steam systems as they currently exist, and on the financial and/or logistical challenges involved with changing those systems so as to avoid contact of the organic food by [the substance]. However, economic considerations are clearly not one of the criteria (either in OFPA or the final NOP rule) for determining the suitability of materials used in organic production systems.
>
> "History shows that quite often it has been the case that an organic operator (producer or handler) has had to make substantial changes to their system in order to be compliant with organic standards. These changes often involved redesigning of systems, practices, and techniques. In many cases, such changes resulted in the need for financial investment, as well as an investment in time. Some creativity on the part of the operator was often needed, to devise a new system. This has indeed been the case for certain processors, who made adjustments to their boiler systems or manufacturing practices in order to comply with the prohibition of contact of organic foodstuffs by synthetic boiler chemicals. The inconvenience of having to retool or readjust systems should not be the determining factor in whether or not such materials are added to the National List." (TAP reviewer #2)
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> "The justification for use of [the materials] is no different than trying to justify the use of a synthetic herbicide like Round-Up for organic farming, just because it provides a cheaper alternative to weed control and does not leave any detectable residue." (TAP reviewer #3)

3. Compatibility

The use of these synthetic amines as boiler chemicals is not compatible with organic processing. Again, we cite the TAP review:

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[1] Gadon, Margaret E. MD; Melius, James M. MD; McDonald, Gerald J. AS; Orgel, David MD, 1994. New-Onset Asthma after Exposure to the Steam System Additive 2-Diethylaminoethanol. Journal of Occupational Medicine 36(6); Centers for Disease Control and Prevention, 1990. Workplace Exposures to Corrosion-Inhibiting Chemicals from a Steam Humidification System -- Ohio, 1988. Morbidity and Mortality Weekly Report 39(47);863-865.

> "Organic principles are precautionary when evaluating synthetic substances used in food. Volatile amines in general do not appear to be compatible with the principles of organic handling…Food processors generated and used steam for a long time without these chemicals."

4. Ancillary Substances

According to the recommendation passed by the NOSB in the spring of 2013, the board defined "ancillary substances" as "additives added during the manufacturing of a non-organic substance and ***not*** removed."

The NOSB went on to recommend the following policy:

> The NOSB intends to review ancillary substances found in substances on and petitioned for the National List in accordance with OFPA criteria. Comprehensive review does not require these substances to be individually listed on the National List, however. The Board intends to follow the request by NOP to consider ancillary ingredients contained in substances as they come up for review or as new petitions are considered.
>
> In each NOSB review checklist and recommendation cover sheet there will be a clear space to indicate what other ingredients are being reviewed and what restriction if any are placed on them as a result of the review. Restrictions on other ingredients will be included in an annotation and may be for specific individual components, for functional classes of ingredients, or by regulatory reference to another governmental agency such as FDA. The other ingredients restrictions may be incorporated into a permitted substances database for Handling, such as the one that is coming out for crops.
>
> The NOSB recommendation will include a note that the other ingredients were reviewed and accepted. The review of other ingredients will distinguish between synthetic and nonsynthetic ones, as well as agricultural ingredients that might be able to be organically produced. Any additional restrictions will be specified in an annotation.
>
> Ancillary substances in general product categories that are currently on §205.605 and §205.606 and currently used in certified organic processed product will continue to be allowed until they go through their next sunset review and subsequent Rule amendment.

The ancillary substances associated with these materials have not been reviewed or even listed. This is an important piece that needs to be incorporated into the review of every material during sunset.

5. Conclusion

Beyond Pesticides opposes the relisting of the boiler chemicals octadecylamine, diethylaminoethanol, and cyclohexylamine because they fail the OFPA criteria for health and environmental impacts, essentiality, and compatibility with organic handling practices.

We have attached a checklist in which we provide the Board with answers to questions, based on available TAP reviews, which are required to be considered as a part of a sunset review that is in compliance with the Organic Foods Production Act (OFPA) and the implementing regulations. We believe that an up-to-date Technical Review should have been available and critiqued for this meeting. Since the Fall 2014 meeting is scheduled to be the only public NOSB meeting during which the Handling Subcommittee and Board members can share their thinking and receive "timely" public comment on the checklist and assessment of the material in accordance with OFPA criteria, the lack of any updated technical information and prepared written analysis by the subcommittee for this meeting makes for an incomplete and truncated assessment process. Under the current process, information brought to the Board at the Spring 2015 meeting will be considered "untimely."

We appreciate the subcommittee's questions about use and essentiality of the materials, but believe that the subcommittee and Board have a responsibility to bring to the public a comprehensive set of questions that address all OFPA criteria with a preliminary assessment of the data it has –along the lines of the checklist that we have attached. While we recognize that the Board has embarked on a new two-stage process, the first stage, or first meeting on sunset materials, must be a more robust review process if the Board's assessment of exempt prohibited materials, like these, on the National List is to be viewed by the public, including users and consumers, as credible. The process requires this if there is to be continuing and building public trust in the process and the organic food label.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors

National Organic Standards Board
Handling Subcommittee
Petitioned Material Checklist
Amine Boiler Chemicals
(Octadecylamine (ODA), Diethylaminoethanol (DEAE), Cyclohexylamine (CEA))

[Date of Vote]

Summary of Proposed Action:
Cyclohexylamine (CAS # 108-91-8)—for use only as a boiler water additive for packaging sterilization.
Diethylaminoethanol (CAS # 100-37-8)—for use only as a boiler water additive for packaging sterilization.
Octadecylamine (CAS # 124-30-1)—for use only as a boiler water additive for packaging sterilization.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?
1. Impact on Humans and Environment N/A	☐ Yes ☐ No ☐
2. Essential & Availability Criteria N/A	☐ Yes ☐ No ☐
3. Compatibility & Consistency N/A	☐ Yes ☐ No ☐
4. Commercial Supply is Fragile or Potentially Unavailable N/A as Organic (only for §205.606)	☐ Yes ☐ No ☐

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

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

Classification Motion: Move to classify [substance] as [synthetic, nonsynthetic, agricultural]
Motion by:
Seconded by:
Yes: # No: # Absent: # Abstain: # Recuse: #

Listing Motion: Move to list [substance] on section **205.6xx** of the National List [with the annotation]
Motion by:
Seconded by:
Yes: # No: # Absent: # Abstain: # Recuse: #

Proposed Annotation (if any):

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

Approved by Subcommittee Chair to Transmit to NOSB

Name , Subcommittee Chair **Date**

NOSB Evaluation Criteria for Substances Added To the National List
Handling

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

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]	X			They are toxic, volatile, and carried in the steam, so the local environment is likely to be affected, especially in the case of a boiler blowout.
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]	X			All are manufactured by chemical processes using toxic precursors and high energy inputs. They are all considered hazardous enough to require special precautions in the case of spills.
3. Are there any adverse impacts on biodiversity? (§205.200)	X			Toxic by multiple routes if spilled.
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]			X	
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]				No information about persistence or concentration, but all are highly volatile.
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c))(1)(A)(i); 6517 (c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]	X			All three are moderately to highly toxic and severe irritants. Nothing is known about ancillary substances.

7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]		X		None of the substances is GRAS. Ancillary substances are unknown.
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 (b)(5)]	?			

NOSB Evaluation Criteria for Substances Added To the National List
Handling

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

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			
3. 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		
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		
6. Is there an organic substitute? [§205.600(b)(1)]		X		
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]		X		The TAP reviews for all three substances, and the Steam paper all agree that they are not essential.
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
9. Are there any alternative substances? [§6518(m)(6)]	X			See review “Steam Generation in Organic Processing.”
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	X			See review “Steam Generation in Organic Processing.”
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.		X		Ancillary substances unknown.

NOSB Evaluation Criteria for Substances Added To the National List
Handling

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

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]		X		"Organic principles are precautionary when evaluating synthetic substances used in food. Volatile amines in general do not appear to be compatible with the principles of organic handling…Food processors generated and used steam for a long time without these chemicals."
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]		X		"Justification of the [substances' use] by the petitioners is based on the constraints of their particular boiler and steam systems as they currently exist, and on the financial and/or logistical challenges involved with changing those systems so as to avoid contact of the organic food by [the substance]. However, economic considerations are clearly not one of the criteria (either in OFPA or the final NOP rule) for determining the suitability of materials used in organic production systems. "History shows that quite often it has been the case that an organic operator (producer or handler) has had to make substantial changes to their system in order to be compliant with organic standards….The inconvenience of having to retool or readjust systems should not be the determining factor in whether or not such materials are added to the National List." (TAP reviewer #2)
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]		X		"The justification for use of [the materials] is no different than trying to justify the use of a synthetic herbicide like Round-Up for organic farming, just because it provides a cheaper alternative to weed control and does not leave any detectable residue." (TAP reviewer #3)
4. Are the ancillary substances reviewed compatible with organic handling [?		X		Ancillary substances not reviewed.
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]		X		Amines will be in steam, and hence in contact with food. All are toxic.
6. Is the primary use as a preservative?		X		

	[§205.600(b)(4)]				
7.	Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]		X		

NOSB Evaluation Criteria for Substances Added To the National List
Handling
Category 4. Is the commercial supply of an organic agricultural substance fragile or potentially unavailable? [§6610, 6518, 6519, §205.2, § 205.105(d), §205.600(c)] **Substance:**

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?				
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?				
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?				
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?				
5. Does the industry information about unavailability include (but is not limited to) the following?: a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;				
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;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or				
e. Other issues which may present a				

challenge to a consistent supply?				