

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Ammonium Hydroxide**

February 19, 2013

***Revised February 18, 2014 - request for further public comment**

Summary of Proposed Action:

Ammonium hydroxide is petitioned to be added to the National List at 205.605 as a boiler water additive. The Handling subcommittee proposes not to add Ammonium hydroxide to the National List.

Ammonium hydroxide is a powerful alkali petitioned for use as a boiler additive because it neutralizes carbonic acid in condensate to prevent corrosion, reducing pH to 8.5 or 9.0. The level of ammonium hydroxide required in steam would depend on the level of carbon dioxide in the steam. Ammonium hydroxide is produced by the addition of water to Ammonia. Ammonia is produced on a large scale worldwide and one of its largest uses by production volume is as an ingredient in conventional fertilizer (prohibited in organic agriculture).

Ammonium hydroxide is a severe irritant which must be handled properly because exposure by humans and other mammals during production or use presents a serious toxicological concern. It is toxic by all routes, inhalation, dermal and ingestion and the toxicity is well documented. It is an air and water pollutant and contributes as a greenhouse gas. It is toxic to fish and other aquatic species. Spillage could cause considerable environmental damage.

There are a number of alternative practices which can be used instead of boiler additives. These include replacement of steam lines with stainless steel piping, water treatment, physical or chemical deaeration, interruption of boiler water treatment prior to organic processing runs, bleed runs, dismantling and cleaning systems prior to organic food handling, steam to steam heat exchangers, a separate secondary boiler to generate steam for direct food contact applications.

The petition requests addition of ammonium hydroxide as a "boiler additive" to neutralize carbon dioxide in order to prevent acid attack in steam condensate lines. Where steam is used in or on food it is termed "culinary steam" and used in food processing for sanitation or sterilization of food contact surfaces, including packaging sterilization.

REQUEST FOR FURTHER PUBLIC COMMENT

The National List currently includes three volatile synthetic amines as boiler additives, namely Cyclohexylamine, Diethylaminoethanol, and Octadecyclamine, listed at 205.605(b) for use only as boiler additives in packaging sterilization. These three boiler additives will be discussed in fall, 2014, as part of Sunset Review (for 2016 materials). Because of Sunset Review for the three boiler additives listed above, the NOSB seeks further public comment on essentiality of ammonium hydroxide as a boiler additive, including scope of use as culinary steam.

Evaluation Criteria (Applicability noted for each category; Documentation attached)

	Criteria Satisfied?		
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: [3] Comments:

Ammonium hydroxide has the potential to cause significant toxic damage to humans, mammals, aquatic systems and greenhouse gasses and is not essential or compatible with organic agriculture and handling.

Proposed Annotation (if any): None proposed

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

Recommended Committee Action & Vote

Classification Motion:

Motion to classify ammonium hydroxide (CAS # 1336-21-6) as petitioned as synthetic

Motion by: Jean Richardson

Seconded by: Tracy Favre

Yes: 6 No: 0 Absent: 2 Abstain: 0 Recuse: 0

Listing Motion:

Motion to list ammonium hydroxide (CAS # 1336-21-6) at § 205.605b

Motion by: Jean Richardson

Seconded by: Colehour Bondera

Yes: 0 No: 6 Absent: 2 Abstain: 0 Recuse: 0

Approved by John Foster, Subcommittee Chair, to transmit to NOSB February 19, 2013

NOSB Evaluation Criteria for Substances Added To the National List

Category1. Adverse impacts on humans or the environment? Ammonium hydroxide

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			Toxic to environment if spilled or volatized to atmosphere (TAP 2001 and petition pages 8, 9, and 10)
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			Worker injury through breathing, ingestion or dermal contact and terrestrial damage with spills during manufacture. (Petition pages 8, 9, 10, and TAP 2001).

3. Are there any adverse impacts on biodiversity? (§205.200)	X			Toxic damage will occur through spills in terrestrial or aquatic systems, and ammonia contributes to greenhouse gases (Petition pages 8-10) Fish are particularly at risk for toxic effects.
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)]	X			Yes if spilled, or released into air the gas contributes to Greenhouse gases.
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			Yes toxic if inhaled, ingested or dermal contact
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]	X			
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600(b)(5)]		X		

Category 2. Is the Substance Essential for Organic Production? Ammonium hydroxide

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			Ammonium hydroxide is manufactured from natural gas which is used to convert atmospheric nitrogen to ammonia and then water is added to produce the hydroxide form (petition page 4 and TAP 2001).
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		Processors can utilize a number of alternative practices, such as stainless steel pipelines, physical and chemical deaeration, interrupt boiler water treatment prior to organic processing etc. These alternative practices cost time and money. (petition page 11) although economic considerations are not one of the criteria for suitability of materials used in organic production systems (TAP 2001, page 9)
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
9. Are there any alternative substances? [§6518(m)(6)]	X			There are 3 boiler additives on the NL
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	X			There are a number of alternative practices which can be used (Petition page 11) These include pre-treating water, replacing steam pipelines with stainless steel etc.
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.		X		

Category 3. Is the substance compatible with organic handling practices? Ammonium hydroxide

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		As a general rule ammonia products are not considered compatible with organic production or handling (TAP 2001, page 7, page 9)
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]		X		See 1 above
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]		X		See 1 above
4. Are the ancillary substances reviewed compatible with organic handling [?]			X	
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]		X		
6. Is the primary use as a preservative? [§205.600(b)(4)]		X		
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		

This is a proposal by a Subcommittee of the National Organic Standards Board (NOSB). Proposals are posted for public comment and then may be voted upon by the full Board. They are not final Board recommendations or NOP policy.

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)] **Ammonium hydroxide**

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?			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 about unavailability include (but is 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. Other issues which may present a challenge to a consistent supply?			X	