National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal - Ammonium Hydroxide
November 18, 2014

Summary of Proposed Action:
Ammonium hydroxide is petitioned to be added to the National List at §205.605 as a boiler water additive. Ammonium hydroxide is a synthetic substance manufactured from natural gas; natural gas is used to convert atmospheric nitrogen to ammonia to which, water is added. The Handling Subcommittee proposes not to add ammonium hydroxide to the National List.

Background:
Ammonium hydroxide has been on the National Organic Standards Board (NOSB) Work Agenda on and off for several years; review of this proposal should be considered in light of that history and changing trends in processing over the intervening years.
* The NOSB Organic Good Manufacturing Practices of 1995 did not include boiler additives.

* In 2001 ammonium hydroxide was petitioned for addition to the National List. The lengthy TAP Review (2/15/01) included many appendices and a Steam Paper which analyzes and compares all the boiler additives. This report included a recommendation to prohibit ammonium hydroxide. In August 2001 there was also a lengthy analysis submitted to the NOSB comparing all the boiler additives.

* NOSB Recommendation dated October 2001 was to approve limited use of three boiler additives, cyclohexylamine, diethylaminoethanol and octadecylamine, and to approve ammonium hydroxide "for use as a boiler additive only, with removal from the National List October 21, 2005. If Office of General Counsel says no to shorter sunset date, the material remains prohibited." Vote: 10 in favor, 3 abstentions 1 no

* The Final Rule of NOP dated September 2006 (71 FR 53299) concluded that while most commenters wanted the chemical included some did not, however, the expiration date recommended by the NOSB had lapsed. Therefore, it was not added to the list.

* A new petition was submitted on 10/30/12 to add ammonium hydroxide to the National List "solely for use as a boiler water additive, to neutralize carbon dioxide in steam condensate." Petitioner suggests that addition of ammonium hydroxide as a boiler additive would allow elimination from the National List of the three synthetic volatile amines, cyclohexylamine and diethylaminoethanol, two neutralizing amines, and octadecylamine, a filming amine – these are approved for the limited use of packaging sterilization.

* The petition was determined to be sufficient and on 2/19/13 the Handling Subcommittee voted not to add ammonium hydroxide to the National List (6:0 with two absences).. However, there was some public comment suggesting that ammonium hydroxide may be able to replace the three boiler additives scheduled for sunset discussion in October 2014, so this proposal was posted with a request for further public comment a vote by the full NOSB was deferred pending additional public comment on all boiler additives.

Discussion
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. 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 that can be used instead of boiler additives. The alternatives 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. Petitioner also suggested that the form of ammonium hydroxide in steam condensate is ammonium carbonate, which is on the National List at §205.605(b). However, ammonium carbonate is allowed for use "only as a leavening agent."

Public comment was received in Fall 2013, Spring and Fall 2014 from several commenters, including the petitioner. The majority of the public comments recommended not adding ammonium hydroxide to the National List. There were no comments from any processor or handler asking for addition of this chemical. There was no evidence provided that ammonium hydroxide could replace the three other boiler chemicals under sunset discussion.

Public comment did not indicate a demand for ammonium hydroxide, and there are many alternative practices that can be used instead of ammonium hydroxide as a boiler additive.

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: 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

Recommended Committee Action & Vote

Classification Motion: Ammonium hydroxide (CAS # 1336-21-6) as petitioned is synthetic
Motion by: Jean Richardson
Seconded by: Zea Sonnabend
Yes: 6 No: 0 Abstain: 0 Absent: 2 Recuse: 0

Listing Motion: To add ammonium hydroxide (CAS # 1336-21-6) to the National List Section 205.605(b)
Motion by: Jean Richardson
Seconded by: Tracy Favre
Yes: 0 No: 5 Abstain: 0 Absent: 3 Recuse: 0

Approved by Harold Austin, Subcommittee Chair, to transmit to NOSB December 16, 2015

NOSB Evaluation Criteria for Substances Added To the National List

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

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			Toxic to environment if spilled or volatized to atmosphere (TAP 2001 and petition pages 8, 9, and 10)
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§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. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	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 List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	X			Ammonium hydroxide dissolves copper and zinc (Petition page 8 and TAP 2001)
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X			Petitioned substance is intended for use in handing facilities, not land application, but spills would have negative impacts. Ammonia is used in conventional fertilizer but not permitted in organic agriculture.

7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			Yes, (petition page 10)
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			Yes if spilled, or released into air
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]	X			When released into air the gas contributes to greenhouse gases.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]	X			Yes, toxic if inhaled, ingested, or dermal contact
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]	X			Yes, if inhaled, ingested, or dermal contact
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			
13. 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?
Substance: Ammonium hydroxide

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			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).
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		
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		
4. Is there a natural source of the substance? [§205.600 b.1]		X		
5. Is there an organic substitute? [§205.600 b.1]		X		

6. 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, page9)
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		X		
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		
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			There are a number of alternative practices that can be used. (Petition page11) These include pre-treating water, replacing steam pipelines with stainless steel etc.

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

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		As a general rule ammonia products are not considered compatible with organic production or handling (TAP 2001, page 7, page 9)
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X		See 1 above
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		See 1 above
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]		X		
5. Is the primary use as a preservative? [§205.600 b.4]		X		
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when		X		

	required by law, e.g., vitamin D in milk)? [205.600 b.4]				
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		

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 Ammonium Hydroxide**

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	Not an agricultural substance
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: 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	