HS Comments

Ammonium Hydroxide

Summary
Support listing: Richard Theuer, petitioner
Oppose listing: 10 individuals, plus Cornucopia, CU, and BP.

1. Cornucopia Institute “recognizes that ammonium hydroxide is the most cost-effective method to prevent corrosion in boilers. It is also a safer alternative to the toxic amine boiler additives currently on the National List. However, our position remains that if ammonium hydroxide is approved it should be considered for sunset in five years if adequate research concludes corrosion can be prevented by altering production practices, such as filtering and pre-treating water and maintaining steam lines.”

2. Consumers Union urges the Board to reject the petition to add ammonium hydroxide to the National List. “Ammonium hydroxide is a toxic synthetic substance that is hazardous to human health and the environment. It does not appear to be essential to organic handling, as numerous alternatives preventing corrosion and “acid attack” exist; these alternatives have been used by organic processors for years.” Also, they state that the petitioner was not forthright about the material as the FDA does not allow volatile amines for milk pasteurization.

3. Lynn Magnuson supports “the Handling Subcommittee's proposal to reject Ammonium Hydroxide for inclusion on to the National List. In addition, since the NOP has reversed the meaning of sunset, if the HS chooses to support this substance, it should attach an annotation with a 5-year expiration date.”

4. Alice McGough supports “the Handling Subcommittee's proposal to reject Ammonium Hydroxide for inclusion on to the National List. In addition, since the NOP has reversed the meaning of sunset, if the HS chooses to support this substance, it should attach an annotation with a 5-year expiration date.”

5. L Schwartzman, Ph.D. supports “the Handling Subcommittee's proposal to reject Ammonium Hydroxide for inclusion on to the National List. In addition, since the NOP has reversed the meaning of sunset, if the HS chooses to support this substance, it should attach an annotation with a 5-year expiration date.”

6. Terry Shistar of Beyond Pesticides “supports the Handling Subcommittee recommendation to deny the petition for use of ammonium hydroxide as a boiler additive to prevent corrosion. We agree with the Handling Subcommittee that ammonium hydroxide meets none of the OFPA criteria of human and environmental health impacts, essentiality, and compatibility with organic production.” “Since the new NOP process requires a two-thirds majority to prevent a material from being relisted after five years—as opposed to the former policy of requiring a two-thirds majority to relist—the only way to apply the same threshold for allowance as is required by the petition process is through the Board adoption of a five-year expiration date as an annotation to the listing.”
7. **Richard Theuer** is the petitioner. He views ammonium hydroxide as a “consumer-friendly alternative to enable removal of the three synthetic amines currently on the National List – cyclohexylamine, dimethylaminoethanol, and octadecylamine.” “If you believe that potable water treated with ammonia and chlorine is okay to be part of an organic food, using ammonia in steam generation that adds a few ppm of ammonium carbonate to condensate water should be equally acceptable.”

8. **Vivian Valtri Burgess** supports “the Handling Subcommittee’s proposal to reject Ammonium Hydroxide for inclusion on to the National List. In addition, since the NOP has reversed the meaning of sunset, if the HS chooses to support this substance, it should attach an annotation with a 5-year expiration date.”

9. **Susan Brown** agrees with the Subcommittee's assessment of Ammonium Hydroxide and urges it be rejected as an addition to the National List because it meets none of the OFPA criteria of human and environmental health impacts, essentiality, and compatibility with organic production.

10. **Patricia Toolan** supports “the Handling Subcommittee's proposal to reject Ammonium Hydroxide for inclusion on to the National List. In addition, since the NOP has reversed the meaning of sunset, if the HS chooses to support this substance, it should attach an annotation with a 5-year expiration date.”

11. **David Osterhoudt** supports “the Handling Subcommittee’s proposal to reject Ammonium Hydroxide for inclusion on to the National List. In addition, since the NOP has reversed the meaning of sunset, if the HS chooses to support this substance, it should attach an annotation with a 5-year expiration date.”

12. **Allan Peterson** says “Alternatives exist. There is no need to use a recognized threat to human, fish and other species. It meets none of the criteria under the Organic Foods Production Act. I agree with the Subcommittee’s recommendation to reject.”

13. **Frances Dunham** says, “Ammonium Hydroxide is too toxic to humans, animals and the environment to be used in organic production. Safer alternatives are available for corrosion prevention. I urge its rejection. The new rules improperly prejudice the process in favor of synthetics, so it is critical that no new synthetics be listed.

14. **Tom Caine** “supports the Handling Subcommittee's proposal to reject Ammonium Hydroxide for inclusion on to the National List. As the subcommittee notes, the substance is a "severe irritant," and presents a "serious toxicological concern." The substance is toxic to fish and other aquatic species, and is also a greenhouse gas. Ammonium Hydroxide meets none of the criteria under the Organic Foods Production Act in terms of human health and environmental impacts and compatibility with organic. Moreover, the product is not essential, as there are a number of viable alternatives that could be used instead of boiler additives. In addition, since the NOP has reversed the meaning of sunset, if the HS chooses to support this substance, it should attach an annotation with a 5-year expiration date.”

**Ancillary Substances**

1. **Liana Hoodes of NOC** considers the presence of ancillary substances in a material that is submitted for review by the NOSB to be in direct contradiction to the legal and regulatory requirement that the National List contain only single substances, as opposed to formulated
multi-ingredient products. NOC recommends that, at whatever stage in the review process that it becomes apparent that a material is not a single substance, but rather a substance that contains multiple components, the petition be returned to the petitioner with an explanation that “only single substances may be petitioned for evaluation: formulated products cannot appear on the National List.” NOC supports a review of the current entries on the National List to identify all of the currently listed materials that contain ancillary substances, coupled with a plan for reframing each of these listings to conform to the “single-substance listing” principle.... All non-organic ingredients and synthetic ingredients must be on the National List. Sunset Review is a method for correcting identified problems in the National List. If an organic handler believes that a material on the National List cannot be sourced without a particular synthetic and unapproved ancillary substance then that ingredient should be petitioned to be added to the National List with an annotation restricting its use to the materials for which it is needed.

Glycerin

Summary
Support delisting petition: 3 individuals, plus Cornucopia, CU, BP
Oppose delisting: none.
Other: Retain on 605(b) with commercial availability clause and add to 606: OTA, QAI, California Natural Products.
Other: OMRI warns about availability of flavors, etc.

1. Cornucopia Institute supports the petition to remove glycerin as an allowed synthetic material as organic glycerin can now be produced in sufficient quantities with only the ‘mechanical and biological processes.’ Additionally, “The transition from synthetic glycerin to organic glycerin is an example of organic regulations pushing industry toward safer practices. Removing synthetic glycerin from the National List (i.e., glycerin produced by hydrolysis of fats and oils) will encourage additional glycerin production consistent with organic principles

2. Consumers Union supports the petition to remove glycerin from the List. “When companies develop organic alternatives to the non-organic or synthetic materials on the National List, their commitment to developing organic versions should be rewarded with a removal of the material from the National List”

3. Organic Trade Association “In response to a petition presenting the commercial availability of organic glycerin in the marketplace, the Handling Subcommittee is to proposing to remove glycerin from the National List as an allowed non-agricultural synthetic for use in or on processed products labeled “organic” or “made with organic (specified) ingredients.” OTA supports the National List process and the recommendation to remove glycerin from the National List provided there is a sufficient quantity of organic glycerin in the quality and form needed for all applications. However, it’s our understanding that the supply is not adequate. There is also lack of clarity on the classification of glycerin produced from hydrolysis of fats and oils. NOP guidance on classification of materials may clear up this issue, but final guidance is
pending. One solution would be to retain glycerin on § 205.605(b) (non-agricultural synthetic) with an annotation requiring organic forms in organic products unless commercially unavailable, and add to § 205.606 (non-organic agricultural ingredients allowed in organic products when organic forms are unavailable) of the National List. This would recognize agricultural forms of glycerin and accordingly allow for the use of non-organic agricultural glycerin in “made with products.” At the same time, it would require the use of organic glycerin in “organic” products unless commercially unavailable.”

4. **Terry Shistar of Beyond Pesticides** “supports the Handling Subcommittee’s (HS) proposal to remove synthetic glycerin from the National List §205.605(b), given that there are organic nonsynthetic forms of glycerin available. This is the kind of progress anticipated by the authors of the Organic Foods Production Act in designing a National List with mechanisms for reconsideration and removal. We urge the NOSB and NOP to develop process-based standards for ingredients that are products or byproducts of microbial fermentation.”

5. **OMRI** warns that removing glycerin from §205.605(b) may have implications for natural flavors and colors that use glycerin –there may not now be enough of those ingredients made with organic glycerin.

6. **John Ashby of California Natural Products** supports OTA comments.

7. **Susan Brown** supports the decision to remove synthetic glycerin from the National List, given that there are organic nonsynthetic alternatives available. This is positive development that shows the value of organic regulations to encourage safer products on the marketplace. We hope to see the industry transition towards this process.

8. **QAI** supports the OTA’s suggested options.

9. **Allan Peterson** supports the removal of glycerin because organic glycerin is available.

10. **Frances Dunham** says, “Synthetic Glycerin should be delisted in favor of organically produced glycerin, which is compatible with organic standard.”

**PGME**

**Summary**

Support listing: none.

Oppose listing: 3 individuals, BP, Cornucopia, CU.

1. **Terry Shistar of Beyond Pesticides** says “The subcommittee determined, based on the non-volatility of PGME at the boiling point of water, that under its petitioned use, PGME “does not come into direct contact with processed organic products,” and was thus not eligible or required to be listed in the National List of approved and prohibited substances. We disagree with the Handling Subcommittee (HS) conclusion that PGME will not come into direct contact with organic products. In addition, we believe that the HS errs in saying that because PGME “does not come into direct contact” with food to be labeled organic in the organic production process in which it would be used, that somehow PGME “is not required to be on the National List.” In fact, we believe this
conclusion requires public comment and consideration of the NOSB because it is based on a misreading of the Organic Foods Production Act (OFPA) and the requirement of the Board to consider this material for listing on the National List.”

2. **Consumers Union** believes that PGME needs to be petitioned, reviewed and approved before it can be allowed in organic feed production. According to the Technical Evaluation Report (TR), PGME is synthesized from butanol, propylene oxide and ethylene oxide. It is a synthetic made from toxic starting materials, and should be prohibited in organic production unless added to the National List.” They do not think it should be removed from the agenda; organic certification is systems based and all synthetic inputs need to be assessed. Consumers Union does agree that PGME may not be appropriate for 205.605 and suggests the petitioner be instructed to petition PGME for 605.603.

3. **Cornucopia Institute** opposes the use of PGME in organic food without adding it to the National List. “The Handling Subcommittee’s recommendation to allow the use of PGME without adding it to the List is based on a potentially flawed Technical Review. The TR states that PGME when used as a boiler additive does not come into contact with food. The Cornucopia Institute documents evidence below indicating that PGME likely contacts food when used as a boiler additive and therefore must be approved by the full NOSB through the petition process.

   §205.605 of the National List includes synthetic materials “allowed as ingredients in or on processed products...” Polyalkylene glycol monobutyl ether was petitioned to be added to the National List, based on the petitioner’s assumption that it may be present in organic foods when used as a boiler additive. However, the authors of the TR indicated that PGME will not be present in organic food when used as a boiler additive...

   The petition, submitted by a manufacturer of a product containing PGME designed to be used in livestock food mills, states that the mode of action is through direct contact of the product with food. The TR states this does not occur, but does not provide a citation for this assertion that can be independently verified.”

4. **Susan Brown** believes that although PGME is non-volatile, contact with organic food is possible under this use through entrainment in water droplets. It should be evaluated through the petition process for its appropriateness for use in organic production. PGME is made from highly toxic ethylene dioxide, and the TR identifies alternative production practices that do not require an additive like PGME.

5. **Allan Peterson** opposes the relisting of PGME because alternative production methods are available that do not require such an additive.

6. **Frances Dunham** says, “Given that PGME is derived from toxic source materials and given that alternatives are available, a technical report on its use and potential contact with food must be generated before NOSB considers it for organic production.”

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**Gellan Gum**

**Summary**
Support relisting: CROPP, Hain-Celestial, CP Kelco.
Oppose relisting: 3 individuals, plus Cornucopia, BP.
Unsure: CU

1. **Cornucopia Institute** does not support the continuation of Gellan Gum substances on the List because: Technical Reports are either missing or inaccurate and gellan gum should be considered a synthetic substance. They recommend allowing only high-acyl native form gellan gum. The Committee should propose not to relist so that the full NOSB can consider these issues with public comment. Also “The Cornucopia Institute considers the public debate and the involvement of the full NOSB in decision-making to be a cornerstone of organic regulations and critical to maintaining public trust in the label. **All materials scheduled for relisting should be voted on by the full NOSB.** We urge the Handling Subcommittee to vote not to relist materials as long as this new policy is in effect so that a full and open debate can take place.”

2. **Consumers Union** is concerned with the possible use of excluded methods and “other ingredients” to manufacture the ingredient gellan gum, and urges careful review by the Board to ensure that the gellan gum currently used in organic foods is fully compliant with all requirements in the organic law and regulations. If excluded methods are found to be used anywhere in the process, we would oppose relisting gellan gum.

3. **Terry Shistar of Beyond Pesticides** opposes the relisting of gellan gum on §205.605(a). Gellan gum is synthetic and should have been considered for listing on §205.605(b). Furthermore, under the new sunset policy announced by the NOP, unless the Handling Subcommittee proposes not to relist gellan gum, it will not be reviewed and considered by the full board as required by OFPA.

4. **Beth Unger of CROPP** supports the listing of gellan gum on 205.605(a). Organic Valley has several products that include gellan gum -- chocolate milk, eggnog, and soy beverages, and it could be used as an ingredient in future products. OV has “removed carrageenan from our products, replacing it with gellan gum for its properties as a stabilizer that suspends particles and acts as a thickening agent. Gellan gum provides a comparable alternative in body and flavor to current consumer expectations of product performance Studies have demonstrated that gellan gum is safe for human consumption (FAO testing [http://www.inchem.org/documents/jecfa/jecmono/v28je17.htm])**

5. **Herman Zareb of Hain-Celestial** supports gellan gum because it is necessary, safe, and meets OFPA criteria.

6. **Cheryl Van Dyne of CP Kelco** supports continued listing of gellan gum because it has unique properties which lend themselves to specific food applications such as suspension of particulates in beverages, and providing heat stability to confections and water gels.

7. **Susan Brown** opposes the relisting of gellan gum on §205.605a because gellan gum is synthetic. Furthermore, under the new sunset policy announced by the NOP, unless the Handling Subcommittee proposes not to relist gellan gum, it will not be reviewed and considered by the full board as required by OFPA, and the NOSB would be acting without adequate transparency and public input.

8. **Allan Peterson** says, “The sunset policy must be reinstated before consideration of Gellan Gum.”
Frances Dunham says, “My family relies on the OFPA and its original provisions for sunsetting synthetic materials unless individually evaluated and approved by NOSB for provisional 5 year terms. New data and conclusions from credible sources must be weighed in these evaluations. We were distressed to learn that USDA is now bypassing both the NOSB and the public to relist substances that might not pass NOSB under the OFPA. This only damages the integrity and reputation of the “USDA Organic” label. Gellan gum should not be relisted until the sunsetting policy is reversed.”

Sherry and Marsala

Summary
Support relisting: None.
Oppose relisting: 3 individuals, plus Cornucopia, Beyond Pesticides.
Other: OMRI warning.

1. **Cornucopia Institute** does not support the continuance of marsala and sherry on the List. Although they were the original petitions, the company Fairfield Farm Kitchens is no longer using these in their products. Therefore they should be relisted since they are no longer essential and organic alternatives are available. “If marsala and sherry are relisted, Cornucopia recommends an annotation to prohibit fortified wines that contain added sulfites such as sulfur dioxide or potassium metabisulfite.” Also “The Cornucopia Institute considers the public debate and the involvement of the full NOSB in decision-making to be a cornerstone of organic regulations and critical to maintaining public trust in the label. All materials scheduled for relisting should be voted on by the full NOSB. We urge the Handling Subcommittee to vote not to relist materials as long as this new policy is in effect so that a full and open debate can take place.”

2. **Terry Shistar of Beyond Pesticides** opposes the relisting of marsala and sherry on §205.606, made from chemical-intensive grape production. Non-organic grape production involves the use of many toxic chemicals. There is no evidence of essentiality. Furthermore, under the new sunset policy announced by the NOP, unless the Handling Subcommittee proposes not to relist marsala and sherry, they will not be reviewed and considered by the full board as required by OFPA.

3. **OMRI** says that if there is a shortage of organic sherry or marsala and processors use instead sherry or marsala “made with organic grapes,” that the added sulfites may cause a violation or because of exceeding the 5% limit on nonorganic ingredients.

4. **Allan Peterson** asks that sherry and marsala not be relisted because they are not essential and non organic grape production uses many toxics.

5. **Susan Brown** opposes the relisting of sherry and marsala on §205.606. Non-organic grape production involves the use of many toxic chemicals. There is no evidence of essentiality. Furthermore, under the new sunset policy announced by the NOP, unless the Handling Subcommittee proposes not to relist marsala and sherry, they will not be reviewed and considered by the full board as required by OFPA.

6. **Frances Dunham** urges the delisting of conventional sherry and marsala because both can be made organically, and they have no place in organic food.
Tragacanth Gum

Summary
Support relisting: None.
Oppose relisting: 3 individuals, plus Cornucopia, CU, BP.

1. **Cornucopia Institute** does not support the continuation of tragacanth gum on the List because organic gum is readily available and it is therefore not essential. Also “The Cornucopia Institute considers the public debate and the involvement of the full NOSB in decision-making to be a cornerstone of organic regulations and critical to maintaining public trust in the label. **All materials scheduled for relisting should be voted on by the full NOSB.** We urge the Handling Subcommittee to vote not to relist materials as long as this new policy is in effect so that a full and open debate can take place.”

2. **Consumers Union** supports the sunset of tragacanth gum as it is essentially identical to gum Arabic, which is available organically.

3. **Terry Shistar of Beyond Pesticides** opposes the relisting of tragacanth gum on §205.606. There are potential health effects that have not been taken into account. Furthermore, under the new sunset policy announced by the NOP, unless the Handling Subcommittee (HS) proposes not to relist tragacanth gum, it will not be reviewed and considered by the full board as required by OFPA.

4. **Vivian Valtri Burgess** opposes “the relisting of tragacanth gum on §205.606. The HS has not previously investigated the impacts of nonorganic production of tragacanth gum on consumers, workers, or the environment. Furthermore, under the new sunset policy announced by the NOP, unless the Handling Subcommittee (HS) proposes not to relist tragacanth gum, it will not be reviewed and considered by the full board as required by law.

5. **Allan Peterson** opposes the relisting of tragacanth gum because it can cause severe allergic reactions.

6. **Frances Dunham** says, “Tragacanth gum should not be relisted until the sunsetting policy is reversed, especially since some members of the public are very sensitive to this nonorganic food additive and the full range of its effects have not been investigated.”

7. **Susan Brown** opposes the relisting of tragacanth gum on §205.606. There are potential health effects that have not been taken into account. Furthermore, under the new sunset policy announced by the NOP, unless the Handling Subcommittee (HS) proposes not to relist tragacanth gum, it will not be reviewed and considered by the full board as required by OFPA and basic standards of transparency.

NOP-NOSB Collaboration
1. Terry Shistar of Beyond Pesticides addresses recent USDA actions that usurp and deny the authority of the NOSB granted to it under the Organic Foods Production Act (OFPA). We believe these actions endanger public trust in the organic label. We urge the NOSB to: not abdicate its responsibilities under OFPA; support motions to delist sunset materials in subcommittee; support a motion on every petition to add an annotation
calling for an expiration date in 5 years; and disclose interests fully on every issue, and ask others to do so.

Sunset

1. Terry Shistar of Beyond Pesticides asks that the NOP place a moratorium on changes announced in the September 16, 2013 Federal Register until the changes are announced with an opportunity for public comment. OFPA gives the NOSB responsibility for managing the National List. The NOP has usurped that authority. The NOSB should use every opportunity to assert its authority. This includes refusing to approve petitions because they may prove to be irretractable and unmodifiable in the near future.

Other

1. Dana Perls of Friends of the Earth asks that ingredients including flavors and fragrances derived from synthetic biology be prohibited in organic food.