Wolf DiMatteo + ASSOCIATES

The Organic Specialists

## MARCH 2016 NOSB Preview

***In this issue:***



*"If you're going to play the game properly, you'd better know every rule."*
**Barbara Jordan**

## PRESIDENT'S MESSAGE

**From Expo West to NOSB**
***Market and regulatory forces keep us on our toes***

Natural Products Expo West is now one of the largest conference and trade shows in North America. I hadn't been in a few years so the shock of its size and how organic branding is dominating every category was quite palpable for me. Organic products dominated the new products display cases, and the event's tenor was incredibly upbeat and lively. The 3200+ exhibitors no longer fit in the Anaheim Convention Center and have spread to the Anaheim Hilton, Arena, and tents. Some of the 77,000 attendees have to stay miles away. The organic seminars co-sponsored by the Organic Trade Association (OTA) were packed, even the ones two days before the main tradeshow opened. The Organic Center dinner was sold out with 650 folks listening to Alice Waters and guest chef Matthew Raiford, who created the dinner's menu and runs a restaurant and farm in Georgia.

I couldn't get to every exhibit this year, but what I did see was quite impressive nonetheless. In decades past, I would walk the exhibit floor and see lots of faulty organic labels, but this year it was hard to find many problems, which is extraordinary considering organic labels dominated among the food, nutraceutical, and cosmetics categories, and even household products and clothing. Although a few newly launched products made organic claims without being certified, label information and accuracy has improved markedly from five or six years ago.

So, what does this have to do with the content of today's newsletter about current NOSB recommendations? The decisions made at the upcoming NOSB meeting and subsequent meetings will determine whether this growth will continue. I encourage you to pay attention to these issues and participate in the public comment process directly, through one of the associations you belong to, or with our help.

In closing, I can't help but express my disappointment that the NOSB won't be voting in April to correct the NOP memo blocking usage of Biodegradable Mulch Film. Although it looks like we're not going to have that valuable tool available for organic farmers for the 2016 season, I remain optimistic that it will get fixed soon. You may want to weigh in on this issue when you are writing your comments. Let us know if you need details.

***Bill Wolf***
***President***
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**Wolf, DiMatteo + Associates delivers the strategic expertise to help organic, socially, and Environmentally responsible products and projects reach their full potential—and flourish.*

## ORGANIC REGULATORY AND MARKET UPDATES

### NATIONAL ORGANIC STANDARDS BOARD SPRING 2016 MEETING

**Comment by April 14**

The National Organic Standards Board meeting will take place April 25-27 at the Omni Shoreham Hotel, 2500 Calvert Street, NW, Washington, DC. In order to be considered during the Spring 2016 meeting, written public comments or requests for oral comment speaking slots must be received by 11:59 pm April 14. Use docket number AMS-NOP-15-0085 at www.Regulations.gov for comments, and sign up to request a comment slot.

Once again, there will be a webinar in advance of the meeting which offers extended time for comments (4 minutes versus 3 minutes during the in-person meeting) and will be part of the meeting record. The webinar will be Tuesday, April 19 from 1-4 p.m. EDT. Speakers can have only one comment slot, during a webinar or in-person at the meeting. To listen to the webinar, either call 866-740-1260 or go to http://www.readytalk.com and enter participant code 7202000.

Along with materials review and discussions brought forward by subcommittees, the agenda includes presentations from NOP staff, an update from the Hydroponics Task Force and a panel on emerging technologies. Meeting documents can be found here.

### Handling Subcommittee

***Petitions:*** *(page 235 of the meeting material document)*

Sodium & Potassium lactate: These materials were originally petitioned in 2004, and a decision by NOP that a petition was not necessary since the components of the substances were already included on the National List. Subsequently, this decision was deemed inconsistent with previous NOSB materials classification recommendations. The original petition asked that sodium and potassium lactate be added to the National List for use in meat processing as a pathogen inhibitor. However, public comment indicates these materials are being used for additional purposes in organic products, such as

a pH regulator. The Subcommittee voted in favor of the petition and recommends addition to the National List.

Classification: Classify both sodium lactate and potassium lactate as synthetic. Vote: Yes 6; No 0; Abstain 0; Absent 2; Recuse 0.
Listing motion: list Sodium Lactate and Potassium Lactate at §205.605(b) of the National List with the following annotation: for use as an antimicrobial agent and pH regulator only. Vote: Yes 5; No 0; Abstain 1; Absent 2; Recuse 0.

Oat beta-glucan: This material is used to supplement fiber content in processed foods including biscuits, cakes, breads, cereals, bars, soups, and smoothies. Other common names for oat beta glucan include oat bran soluble fiber, oat fiber, oat soluble fiber, and oat bran fiber. The petition would add it to the National List in §205.606. The Subcommittee felt that other alternatives and sources were available to fill the need and voted against the petition.

Classification: Classify Oat Beta Glucan as agricultural. Vote: Yes 4; No 0; Absent 2; Recuse 0.
Motion: List Oat Beta Glucan at §205.606. Vote: Yes 0; No 4; Abstain 0; Absent 2; Recuse 0.

Hypochlorous acid: Petitioned as a result of the NOP policy memo on Electrolyzed Water for use as an antimicrobial/sanitizer for use on equipment and raw agricultural products. Also, petitioned for addition to the List at §205.601 - Synthetic substances allowed for use in organic crop production. Because of the way it is produced (generally on site, therefore reducing transportation risks), as well as its lower concentration of chlorine, hypochlorous acid (EW) is a safer product for the environment and for human health, than chlorine sanitizer materials currently on the National List. The Subcommittee voted in favor of the petition and recommends addition to the National List.

Classification: Classify hypochlorous acid as synthetic. Vote: Yes 6; No 0; Abstain 0; Absent 2; Recuse 0.
Motion: List hypochlorous acid at §205.605(b), chlorine materials. Vote: Yes 6; No 0; Abstain 0; Absent 2; Recuse 0.

Sodium dodecylbenzene sulfonate (SDBS): Petitioned for listing at §205.605 - Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)) (b) Synthetics Allowed. SDBS is petitioned for use as one of two active ingredients (the other is lactic acid) in an antimicrobial formulation for treating fruits and vegetables at organic food retail establishments, such as restaurants, cafeterias, etc. Although the Food and Drug Administration has cleared the material for use as an antimicrobial agent in produce wash water, it is not listed as GRAS. Alternatives include: lactic acid, citric acid, acidified sodium chlorite, and peracetic acid. The Subcommittee did not recommend SDBS for addition to the National List.

The Subcommittee seeks comment on what retailers are currently using to address these food safety concerns; if any of the alternatives are used at the retail level and if they are effective; and what levels of impurities (such as neutral oil, arsenic, iron and lead), if any, are found in SDBS made with current production methods.

Classification: Classify SDBS as synthetic. Vote: Yes 7; No 0; Abstain 0; Absent 1; Recuse 0.
Motion: List SDBS at at §205.605 - Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)) Vote: Yes 1; No 5; Abstain 1; Absent 1; Recuse 0.

***Proposal: Ancillary Substances Procedure*** *(page 263 of the meeting materials document)*
In order to clarify tools certifiers and suppliers can use to ensure compliance with the ancillary substances policy passed in 2014, the Subcommittee is proposing a definition of Ancillary Substance; criteria both NOSB and certifiers could use to review ancillary substances; NOSB procedures for review of materials that may have ancillary substances, and a list of information certifiers could use to develop a compliance template.

The proposed definition of Ancillary Substance:

> "Additives intentionally added to a non-organic substance on the National List that are not removed and have a technical or functional effect on the non-organic substance, not on the final organic product that the non-organic substance is used in. Ancillary substances may be present in the final organic product but only in insignificant amounts. Ancillary substances fall under the FDA definition and labeling regulations for "incidental additives," which do not need to be declared on the label of the final food (including organic product) (CFR Title 21 101.22(h)(3) and 101.100 (a)(3 i to iii4). To illustrate: Enzymes are listed on 205.605(a). The enzymes might contain the following additives, which are considered by the organic industry as "ancillary ingredients": calcium silicate (anticaking agent), calcium phosphate (carrier and/or filler), stearic acid (preservative), sorbitol (stabilizer), sodium citrate (pH control, buffer)."

The proposed Criteria for Compliance:
At least one must apply:

1. The ancillary ingredient was considered part of the manufacturing process that has already been reviewed by the NOSB.
2. The ancillary ingredient is certified organic, on the National List 205.605 or 205.606, or is agricultural (e.g., sugars as standardizing agents in pectin).
3. The ancillary ingredient is approved by FDA as GRAS for the particular use.
4. The ancillary ingredient is approved by FDA as a direct food additive or incidental additive for the particular use.
5. The ancillary ingredient is approved by FDA as a food contact substance for the particular use, as evidenced by a Food Contact Notification (FCN).

Additionally, the ancillary ingredient cannot be a known or probable carcinogen according to the International Agency for Research on Cancer (IARC) or the National Toxicity Program (NTP). A compiled list is published by the American Cancer Society.

The proposed Procedure for NOSB review of ancillaries would add the following criteria to those already in place:

- The vote to approve a new substance will be considered to also approve the ancillaries that are associated with that substance unless the NOSB specifically states that one is not approved. Similarly, the vote to finalize the sunset review after the second posting will be considered to also approve ancillaries unless one is pulled out as not approved.

- Any ancillary substances that the NOSB wishes to prohibit (that are not already on the IARC and NTP lists) will have to come before the board in a separate proposal that can be voted on at the same meeting or a subsequent meeting of the board.

Motion: Adopt the definition, criteria and procedure. Vote: Yes 6; No 0; Abstain 0; Absent 2; Recuse 0

***Discussion: Nutrient Vitamins and Minerals §205.605(b) Annotation Change*** *(page 267 of the meeting materials document)*

The listing for nutrient vitamins has needed to change since the rule was first published in 1995. The current annotation has been in place since 2012 as an interim rule in section 205.605(b): ''Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods.''

The Subcommittee offers two options for changing the annotation, since the regulatory reference is incorrect and confusing. The first would consist of three separate annotations:

1. Allow synthetic minerals (including trace elements), vitamins and similar isolated ingredients for food (labeled 'organic' and 'made with organic') if their use is required by law or to meet an FDA standard of identity; and
2. Allow food products in the 'made with organic' category to use synthetic vitamins and minerals (including trace elements) if those nutrients are identified as essential in 21 CFR 101.9, or in the case of infant formula required by 21 CFR 107.100 or §107.10; and
3. Non-synthetic vitamins and minerals (including trace elements) would be allowed for food labeled as 'organic' products, and limited to use for only those determined as essential in 21 CFR 101.9, or in the case of infant formula required by 21 CFR 107.100 or §107.10.

The second option proposed that the following annotation be adopted for both 'organic' and 'made with organic' food products:

> Synthetic vitamins and minerals (including trace elements) identified as essential in 21 CFR 101.9, or in the case of infant formula required by 21 CFR 107.100 or §107.10.

Read the proposed annotations and the advantages of each starting on page 268 of the meeting materials document.

The Subcommittee seeks input on which option is preferred, other options that should be considered and any mandatory international fortification requirements that should be taken into consideration, and how to do so.

***2018 Sunset Review*** *(page 215 of the meeting materials document):*
This is the first or preliminary comment period. It is important to comment and provide evidence at this time since your comments will be considered by the subcommittee during their discussion and vote. The second comment period comes in conjunction with the subcommittee's recommendation for removal or continued use of the material. *An * indicates NOSB requested comments on specific topics*. Unless otherwise noted, sunset date is November 3, 2018.

7 CFR 205.605(a) Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as ‘‘organic’’ or ‘‘made with organic (specified ingredients or food group(s)).’’
*Agar-agar
*Animal enzymes
Calcium sulfate-mined
*Carrageenan: In particular, the subcommittee asks if ‘sensitivity’ to a food ingredient is enough of a reason to prohibit a substance in organic products if it is clearly listed as an ingredient on a food label.
*Glucono delta-lactone
*Tartaric acid

7 CFR 205.605(b) Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as ‘‘organic’’ or ‘‘made with organic (specified ingredients or food group(s)).’’
*Cellulose
*Potassium hydroxide (Sunset date: May 29, 2018)
*Silicon dioxide

7 CFR §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”
*Colors: Beta-carotene extract (Sunset date: May 29, 2018)

## Crops Subcommittee

***Petitions:*** *(page 279 of the meeting materials document)*

Ash from manure burning — The petition requests revision of 7 CFR 205.602(a), Ash from Manure Burning, to include the following annotation: “except where the combustion reaction does not involve the use of synthetic additives and is controlled to separate and preserve nutrients.” The petitioner, which operates a facility that processes poultry manure in such a manner, argues that annotation approval will provide the following benefits: will generate renewable electricity; will prevent excess nutrients in the environment; and will increase development of similar commercial processing facilities throughout the US. The Subcommittee noted: “Utilizing ash from manure burning in order to assist CAFOs in their reduction of environmental and human health contamination is not a compelling argument for consideration for addition to the National List.”

Motion: Annotate ash from manure burning as proposed. Vote: Yes 0; No 5; Abstain 0; Absent 0; Recuse 0

Squid and squid byproducts — The petition seeks to add “Squid and Squid Byproducts” to the National List of Allowed and Prohibited Substances section 205.601(j)(7) for use as a fertilizer since the technical definition of fish in the United States does not include squid. The Subcommittee recommends approval of the petition.

Classification: Classify squid and squid byproducts as synthetic. Vote: Yes 6; No 0; Abstain 0; Absent 1; Recuse 0

Motion: List Squid & Squid Byproducts at §205.601(j) of the National List – with the annotation – can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5. Vote: Yes 6; No 0; Abstain 0; Absent 1; Recuse 0

Hypochlorous acid — Petitioned for use in organic crop production as a post-harvest sanitizer for raw herb and spice materials (<60ppm) and as an equipment and cold room sanitizer (<200ppm). (See notes about this material in the Livestock and Handling Subcommittees.) The Subcommittee recommends approval of this petition.

Classification: Classify hypochlorous acid as synthetic. Vote: Yes 7; No 0; Abstain 0; Absent 0; Recuse 0
Motion: List hypochlorous acid at §205.601 of the National List: Synthetic substances allowed for use in organic crop production. §205.601(a) As algicide, disinfectants, and sanitizer. (2) chlorine materials (iv) Hypochlorous acid. Vote: Yes 7; No 0; Abstain 0; Absent 0; Recuse 0.

Soy wax — Petitioned for use in mushroom production as an alternative to microcyrstalline cheesewax, which is made from petroleum. Soy wax from non-GMO soy is available. The Subcommittee recommends approval of the petition

Classification: Classify soy wax as synthetic. Vote: Yes 4; No 0; Abstain 0; Absent 1; Recuse 0
Motion: List soy wax at §205.601 of the National List (o) - As production aids. Soy wax (CAS # 8016-70-4) - for use in log grown mushroom production. Must be made from non-GMO soybeans. Vote: Yes 4; No 0; Abstain 0; Absent 1; Recuse 0

***Discussion: EPA List 4 on §205.601(m) Annotation Change (Prohibition of Nonylphenol Ethoxylates (NPEs) in inerts)*** *(page 301 of meeting materials document)*

The discussion document and proposed annotation change are designed to raise awareness that within 3-4 years NPEs will no longer be allowed in materials used for organic production, and to encourage formulators and suppliers to take action now to rework their products without it. The proposed annotation is: §205.601(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances. Except for inerts from the group known as Nonylphenol Ethoxylates.

The proposed annotation will circulate for discussion and comment until Fall 2016, when NOSB will vote on it. Then expect 18 months for rule change, including comment period, and perhaps a grace period, resulting in 3-4 years notice of this change.

The Subcommittee seeks input on the suggested timeline, and if it is enough time to reformulate products; how many products certifiers and materials review organizations have approved with NPEs and what categories they fall into; and suggestions for reaching those who may be affected by this change.

***2018 Sunset Reviews*** *(page 271 of the meeting materials document)*
This is the first or preliminary comment period. It is important to comment and provide evidence at this time as your comments will be considered by the subcommittee during their discussion and vote. The second comment period comes in conjunction with the subcommittee's recommendation for removal or continued use of the material. *An * indicates NOSB requested comments on specific topics*. Unless otherwise noted, sunset date is November 3, 2018.

7 CFR §205.601 Synthetic substances allowed for use in organic crop production:
*Copper sulfate
*Ozone gas
*Peracetic acid (sunset date May 29, 2018)
EPA List 3 - Inerts of unknown toxicity: This listing will be superseded by the annotation change approved by the NOSB for EPA List 4 and List inerts (§205.601(m)(1)). The NOSB is continuing the sunset review process for these EPA List 3 inerts in case that change cannot be implemented through rulemaking before the 11/03/2018 sunset of EPA List 3 inerts.

7 CFR §205.602 Nonsynthetic substances prohibited for use in organic crop production:
Calcium chloride

## Materials/GMO Subcommittee

***Proposal: Excluded Methods Terminology*** *(page 1 of the meeting materials document)*
The current definition of 'excluded methods' is inadequate to cover rapidly developing technologies and several vexing issues such as GMO vaccines, the use of cell fusion within plant families, genetically engineered insects, and more. After a few rounds of discussion and public comment, the Subcommittee proposes using NOP Guidance on Excluded Methods (rather than rule-making) to provide definitions of newer methods as they are developed, outline principles and criteria that will be used to evaluate new technologies, and provide a chart which lists terminology and if that term represents an excluded method.

Key definitions included in the proposal include:

- Genetic engineering (GE) – A set of techniques from molecular biology (such as recombinant DNA and RNA) by which the genetic material of plants, animals, micro-organisms, cells and other biological units are altered and recombined
- Genetically Modified Organism (GMO) – A plant, animal, or microorganism that is transformed by genetic engineering as defined here. This term will also apply to products and derivatives from genetically engineered sources
- Modern Biotechnology – (i) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in conventional breeding and selection.
- Non-GMO – The term that is used to describe or label a product that was produced without any of the excluded methods defined here. It is consistent with the NOP process-based standard

that does not imply freedom from GMOs but does indicate that processes to prevent GMO contamination have been used
- Synthetic Biology – A further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems.

The principles and criteria for evaluating additional methods draw on the IFOAM-Organics International Principles of Organic Agriculture and the NOSB Principles of Organic Production and Handling. As such, the proposal would review biotechnology processes based on the following criteria:

- The genome is respected as an indivisible entity and technical/physical invasion into the plant genome is refrained from (e.g. through transmission of isolated DNA, RNA, or proteins). In vitro nucleic acid techniques are considered to be invasion into the plant genome.
- The ability of a variety to reproduce in species-specific manner has to be maintained and technologies that restrict the germination capacity of seed-propagated crops are refrained from (e.g. Terminator technology).
- Novel proteins must be prevented from being introduced into the soil and water ecosystems and into the organic food supply.
- The exchange of genetic resources is encouraged and any patenting of living organisms, their metabolites, gene sequences or breeding processes are refrained from

The terminology chart groups technologies by the tasks the methods accomplish and the types of changes to the genetically engineered organism. The chart has several terms listed that have not yet been evaluated; the discussion document below looks at technologies, terms, and issues that are still obscured, either from lack of agreement within the subcommittee, lack of information or due to challenges that have not been addressed.

<u>The Materials/GMO Subcommittee accepts all three sections (definitions, principles/criteria, terminology chart) of the proposal. Motion to approve: Yes 5; No 0; Abstain 1</u>

***Discussion: Excluded Methods Terminology***

The discussion document below looks at technologies, terms, and issues that are still obscured, either from lack of agreement within the subcommittee, lack of information or due to challenges that have not been taken up. The Subcommittee is bringing these issues forward for public input:

Additional criteria for evaluating technologies need to be considered:

- How to detect those technologies that are excluded but may not provide detectable genetically engineered DNA when tested.
- Enforcement of the excluded method provisions of the rule when they are not traceable and undetectable.
- Additional technologies and terms that may not be clearly prohibited as excluded methods.
- Whether the concepts adopted in the proposal should or could lead to Organic Plant Breeding standards and the regulation of the term "Organically Bred Variety (or Animal)"

In particular, the subcommittee seeks comment on: What, if any, additional criteria for evaluating technologies that need to be considered; insights on detecting technologies that are excluded but may not have detectable genetically engineered DNA; suggestions on how to enforce excluded method provisions; and opinions on parts of the terminology chart that are marked 'TBD.' Read more details on page 13 of the meeting materials document.

***Discussion Document: Next Steps for Improving Seed Purity*** *(page 19 of the meeting materials document)*

Several clear themes about protecting organic seed purity have emerged from the public comment received over the past several years of discussions and the expert panel from the Spring 2015 NOSB meeting. Those themes include: the need for more data; the responsibility for genetic contamination should lie with the polluters; all crops species are not the same; let the marketplace guide the way; and thresholds and testing are tools to be used responsibly. The subcommittee seeks comment on solution-oriented suggestions (and any new ideas), which will assist in setting priorities and move the organic community toward consensus on NOSB's next steps.

Ideas include:

- Enabling data collection, perhaps via accredited certifiers by collecting seed purity declarations from non-organic seed of high risk crops planted on organic farms. There would be no threshold, the test results would not be made public except as compiled anonymous data, nor would the certifiers take any action concerning any level stated in the test. Crops grown from those reported seeds could also be tested in the marketplace and then matched (by ID number) in the data collection system. This would enable buyers who test to turn in some of their data anonymously also so that it could be correlated with seed.
- USDA Task Force: NOSB could recommend that USDA form a Seed Purity Advisory Task Force, which could then design a feasibility study for evaluating realistic, but rigorous crop-specific thresholds, based on testing that USDA would administer and pay for.
- Strengthening the Organic Seed requirement: NOSB can continue to work on is strengthening the organic seed provisions in the regulation through the guidance process. For example, encouraging continuous improvement in organic seed use by, changing the 'three seed source' guidance into something more specific, or asking for more measurable progress in the Organic System Plan; or making handlers who require contracted growers to use certain seed subject to the organic seed requirements and procurement efforts.
- Start with a Soybean testing Project: NOSB could advance a soybean testing mandate for both organic and non-organic seed to the proposal level at the next meeting. The experience could be useful for other proposals in the future.

Specifically, the Subcommittee seeks feedback on the workability of these suggestions and how they could be better; other new ideas; if data collection is workable, where would data be collected and complied; if NOSB should strengthen organic seed requirements, what parts of the seed guidance should be strengthened; if a soybean testing project is feasible, what sample size and testing protocols should be used.

## Livestock Subcommittee

***Petitions:*** *(page 27 of the meeting materials document)*
Hypochlorous Acid — Submitted in response to a policy memo issued by the NOP on Electrolyzed Water, this material (CAS #7790-92-3) is being petitioned for use as an antimicrobial/sanitizer for use on equipment and raw agricultural products. As an alternative to other chlorine disinfectants and sanitizer, EW could potentially be used for fresh fruits and vegetables, poultry carcasses, shell eggs, cutting boards, and food processing surfaces. Because of the way it is produced (generally on site), as well as its lower, yet equally effective, concentration of chlorine, hypochlorous acid (EW) is a safer product, for the environment and for human health, than chlorine sanitizer materials currently on the National List. The Subcommittee recommends approval of this petition.

Motion to classify hypochlorous acid as synthetic: Yes 8; No 0.
Motion to list hypochlorous acid as petitioned at §205.603 of the National List (a) As disinfectants, sanitizer, and medical treatments as applicable. (7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act. (iv) hypochlorous acid: Yes 7; No 0; Abstain 1.

***Proposal: Annotation Change for Lidocaine and Procaine Use in Livestock Production***
Local anesthetics, Lidocaine and Procaine, used to reduce or prevent pain during de-budding horns in livestock or for general minor surgery on mature livestock require withholding the animal from production for 90 days, which may discourage timely humane treatment of animals. The proposal would reduce the withholding period to 8 days for slaughter stock and 6 days for dairy animals.

Motion: To amend Section 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days 8 days after administering to livestock intended for slaughter and 7 days 6 days after administering to dairy animals
(7) Procaine —as a local anesthetic. Use requires a withdrawal period of 90 days 8 days after administering to livestock intended for slaughter and 7 days 6 days after administering to dairy animals.

The vote was the same for both materials: Yes 6; No 0; Abstain 0; Absent 0; Recuse 0.

***Proposal: Amend Use of Parasiticides in Organic Livestock Production***
Three substances are currently approved for use as paraciticides in organic livestock: ivermectin, moxidectin and fenbenzadole. Their use is confined to emergencies, as routine use of paraciticides is prohibited in organic production. Furthermore, all three materials have additional annotations and limitations on use. The proposal recommends that:

- Parasiticides continue to be prohibited in slaughter stock.
- The milk withholding period after treatment with fenbenzadole or moxidectin be changed from 90 days to 2 days for dairy cows, and 36 days for goats and sheep.
- The listing for ivermectin remains as presently listed, with a 90-day withdrawal period.
- Moxidectin be allowed for both internal and external use.

- Fleece and wool from fiber bearing animals be allowed to be certified organic even if use of parasiticides was necessary at some time in the animal's life.
- Fenbenzadole be allowed without written order of a veterinarian.

In five motions, the Subcommittee recommends the changes to §205.238 Livestock Health Care Practice Standard – see page 47 of the meeting materials document for details on additions and deletions to the current language of the NOP Regulations.

All five motions had the following votes: Yes 6; No 0; Abstain 0; Absent 0; Recuse 0.

## Policy Development Subcommittee

***Proposal: Policy and Procedure Manual Revisions*** *(see page 51 of the meeting materials document)*
The subcommittee is recommending updates throughout the NOSB's Policies and Procedures manual to reflect current board practices. The manual has not been updated since April 2012. See the list of changes and read the proposed manual starting at page 55 of the meeting materials document.

Motion: Approve the Feb. 23, 2016 draft manual as presented.
Vote: Yes 5; No 0; Abstain 0; Absent 1; Recuse 0.

***Discussion: Sunset Review Efficient Work Load Reorganization*** *(page 201 of the meeting materials document)*
In order to better balance the workload of the NOSB and other stakeholders, the Subcommittee is seeking comment on a potential plan to rearrange the timing of sunset evaluations.

Of the four options presented (including the status quo), the preferred option is to conduct reviews of like items, regardless of listing section in the National List (i.e. chlorine materials on 205.601, 205.603 and 205.605 are all grouped together), and adjust the timing of the reviews based on the year the materials first appear on the list starting at 205.601(a). This results in reviews of 17-53 materials each year, instead of as many as 187 reviews in the years ending with 2 and 7. Only materials currently slated for sunset in years ending in 2 or 7 would be reviewed early, and items reviewed early under the reorganization plan would be allowed to sunset on their original timeline. In other words, only the reviews are moved up; not the dates of removal from the National List, if removal is the outcome of the review. See a chart of when materials would be reviewed if the preferred option is adopted, starting on page 205 of the meeting materials document.

The Subcommittee seeks comments on which option for reorganization is the most advantageous, and how items for review, especially in the preferred reorganization option, should be grouped together.

## How to comment on materials slated for sunset

Clearly indicate your position about the material, and explain your reasons for or against using relevant information and data (e.g., scientific, environmental, manufacturing, industry impact information, etc.). Keep in mind that materials allowed in organic production must be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly non-synthetic alternatives, and (3) consistent and compatible with organic practices, and use information that addresses these points. Focus on providing new information about a substance since its last NOSB review. Mention your continuing need for a substance or whether the substance is no longer needed or in demand.

If you have information about other methods or practices that could be effectively substituted for the material, mention those and include supporting information or data. Address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Unless the alternative is already on the National List, include the name and address of the manufacturer of the alternative. Include a copy or the specific source of any supportive literature, such as product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; or an itemized comparison of the function and effect of the proposed alternative(s) with substance under review.

For nonorganic agricultural substances on section 205.606, include current information regarding availability of and history of unavailability of an organic form of the substance in the appropriate form, quality, or quantity of the substance. Mention if there is a change in supply of organic forms of the substance or demand for the substance (i.e. is an allowance for the nonorganic form still needed), as well as any new information about alternative substances.

Wolf, DiMatteo + Associates has expertise in preparing effective comments and petitions. Contact us if you need assistance.

## USDA AND OTHER REGULATORY NEWS

**Help set workable produce safety requirements**
**Comment to FDA by May 3**
In order to make well-informed policy decisions regarding produce grown using untreated biological soil amendments of animal origin (such as raw manure), the Food and Drug Administration (FDA) is requesting scientific data, information, and comments as part of a risk assessment. The risk assessment also will evaluate the impact of certain interventions, such as use of a time interval between application of the soil amendment and crop harvest, on the predicted risk. The risk assessment is intended to inform policy decisions with regard to produce safety. Comment on docket number FDA-2016-N-0321 by May 3, 2016 here.

**NASS to work with certifiers on organic data collection**
The National Agriculture Statistics Service will be collecting organic operation data from certifiers as an interim step before the National Organic Program takes over this data collection via the Organic INTEGRITY database. The compiled data is expected for release mid-December.

**NOP updates National List Petition Guidelines**
Based on recent recommendations form the National Organic Standards Board, the National Organic Program updated its petition guidelines. Check for criteria used to evaluate petitions, types of information to include, typical timelines, and more. Note that it is no longer acceptable to include confidential business information; all petitions are part of an open evaluation process. *(Need help preparing a petition? Contact Wolf, DiMatteo + Associates for expert advice and assistance.)*

**Learn about continued improvement of natural resources on your organic operation**
A new on-demand webinar discussing NOP's recent guidance for natural resources and biodiversity conservation and opportunities for USDA Natural Resources Conservation Service to support producers as they implement these conservation practices will be available online around March 24 here.

**USDA staff updates to note**

- Elanor Starmer is the new Acting Administrator at the Agricultural Marketing Service. Her focus throughout her work at USDA has been to create new market opportunities for farmers, ranchers and food businesses of all sizes.
- Valerie Frances has returned to the Standards Division after a long-term detail with NRCS in the Office of the Chief.
- John Reid joined the Organic Integrity Database team as a Program Analyst to provide data analysis and reporting support, and to assist external users of INTEGRITY.
- Graham Davis joined the Accreditation and International Activities Division as an Accreditation Manager.
- Mary Lou Croisetiere retired from the Accreditation and International Activities Division (AIA) at the end of February after 24 years of service.

## WHERE TO FIND WOLF, DIMATTEO + ASSOCIATES

**April 25-28, 2016:** NOSB meeting, Washington, DC. Bill Wolf to attend.

**May 6-13, 2016:** Codex Committee on Food Labeling, Ottawa, Canada. Katherine DiMatteo to attend.

**May 24-26, 2016:** OTA Policy Conference and Hill Visit Days, Washington, DC. WDA staff to attend.