

April 23, 2010

**MEMORANDUM FOR THE CHAIRMAN OF THE NATIONAL ORGANIC
STANDARDS BOARD**

FROM: Miles McEvoy
Deputy Administrator
National Organic Program



SUBJECT: National Organic Standards Board Recommendations (November 2009)

ISSUE:

The National Organic Standards Board (NOSB) made recommendations in November 2009 that addressed the following: renewal and rejection of materials on the National List used in crop production and handling; annotation changes for materials used in livestock production; vaccination allowances; standards for aquaculture; regulations for heightened animal welfare practices; classification of materials according to a defined, predictable standard; changes to the NOSB Policy Manual; and retail certification.

SUMMARY:

The National Organic Program (NOP) generally supports the recommendations made by the NOSB and plans to pursue actions accordingly, as specified in the discussion below.

DISCUSSION:

1. Sunset 2011 - Crop production

The NOSB reviewed the following material on the National List for use in organic crop production, due to sunset in 2011, and recommended continued listing on the basis that no new information was presented to support removal. The NOP concurs with the November 2009 NOSB recommendations to renew the following listing for crop production substances, and any restrictive annotations, that are due to sunset in 2011:

§ 205.601

Seed preparations. Hydrogen chloride (CAS #7647-01-0)-for delinting cotton seed for planting

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2. Sunset 2011 - Handling

The NOSB reviewed the following materials on the National List for use in organic handling, due to sunset in 2011, and recommended continued listing on the basis that no new information was presented to support removal. The NOP concurs with the November 2009 NOSB recommendations to renew the following listings for handling substances, and any restrictive annotations, that are due to sunset in 2011:

§ 205.605(a)

Egg White Lysozyme (CAS # 9001-63-2)

L-Malic acid (CAS # 97-67-6)

Microorganisms

§ 205.605(b)

Activated charcoal (CAS # 7440-44-0; 64365-11-3)—only from vegetative sources; for use only as a filtering aid.

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.

Peracetic acid/Peroxyacetic acid (CAS #79-21-0)-for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.

Sodium acid pyrophosphate (CAS # 7758-16-9)—for use only as a leavening agent.

Tetrasodium pyrophosphate (CAS # 7722-88-5)—for use only in meat analog products.

3. Crop Production Substances - Peracetic acid

The NOSB rejected the petition to expand the use of peracetic acid for plant disease control. The NOSB made an alternative recommendation to amend the annotation for peracetic acid to read –

§ 205.601(a)(6) Peracetic acid- for use in disinfecting equipment, seed, and asexually propogated planting material. Permitted in hydrogen peroxide formulations at concentration of no more than 5%.

§ 205.601(i)(7) Peracetic acid- for use to control fireblight bacteria. Permitted in hydrogen peroxide formulations at concentration of no more than 5%.

The NOP concurs and will propose changes to the annotation as recommended by the NOSB.

4. Livestock Substance – Eprinomectin

The NOSB rejected the petition to add eprinomectin to the National List. The NOP will not pursue rulemaking to add eprinomectin to the National List.

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5. Livestock Substance - Xylazine

The NOSB recommended that the annotation be amended to remove the words “the existence of an emergency” thereby allowing xylazine to be used during both non-emergencies and emergencies. The livestock committee presented this recommendation to align with the usage practices by veterinarians for sedation during non-emergency procedures. The NOP concurs and will propose changes to the annotation as recommended by the NOSB.

6. Livestock Substance - Excipients

- a. The NOSB approved a recommendation to amend the current listing for excipients to include a reference to drugs approved by APHIS. The current listing, which was intended to include excipients in all animal drugs used to treat organic livestock only referenced those approved by FDA, but omitted APHIS approved drugs. The NOP concurs with the NOSB recommended correction and will propose the addition of “or approved by APHIS” to the current listing.
- b. The NOSB also recommended expanding the allowance for excipients to “animal health care products.” The livestock committee has a recommendation pending for review at the April 2010 NOSB meeting. The NOP finds “animal health care products” to be a vague term and awaits the recommendation for a definition before proceeding with rulemaking.

7. Livestock Substance - Chlorhexidine

The NOSB has recommended that the annotation be amended to not limit the use of this substance to veterinarians, as follows –

Chlorhexidine – Allowed as a germicide for medical and surgical procedures. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

The NOP concurs and will propose changes to the annotation as recommended by the NOSB.

8. Vaccines

On November 5, 2009, the NOSB made a recommendation to clarify that vaccines produced through excluded methods (i.e., genetically engineered) are allowed under § 205.603 and do not need to be individually petitioned for allowance on the National List. Further, the NOSB recommends that vaccines produced from non-excluded methods be located and used before those produced by excluded methods.

The NOSB recommendation to the rule with regards to vaccines reads as follows:

§ 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

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To be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” the product must be produced and handled without the use of:

(e) Excluded methods, except for vaccines: *Provided*, That, ~~the vaccines are approved in accordance with §205.600(a)~~ vaccines made from non-excluded methods are used if commercially available;

Vaccines are listed as allowed under § 205.603 –

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(4) Biologics—Vaccines

The NOP is seeking legal review from USDA’s Office of General Council to determine whether vaccines produced through excluded methods (i.e., genetically engineered) are currently allowed under § 205.603(a)(4). The NOP will also conduct a technical review to report on the status of genetically modified vaccines and the economic impact of using commercial availability criteria for vaccines.

9. Molluscan Shellfish (bivalves)

In November 2009, the NOSB completed a recommendation on Molluscan Shellfish (bivalves). This is the third and final recommendation in the series for aquaculture standards. The NOP accepts the recommendation and will begin rulemaking for aquaculture standards as resources allow.

10. Animal Welfare

On November 5, 2009, the NOSB approved a rulemaking action recommendation to create more explicit rules for the care and handling of livestock that would heighten animal welfare practices of organic livestock production. The NOSB recommended revised regulatory language for sections § 205.238 (Livestock health care practice standard) and § 205.239 (Livestock living conditions).

The NOP appreciates NOSB’s focus on animal welfare and agrees that rulemaking action on this matter is warranted to foster the natural behavior of organic livestock.

While the NOSB presented the animal welfare recommendation as a final recommendation, the NOP finds that several significant topics have yet to be fully addressed. The recommendation did not include stocking density and spacing requirements, which are to be discussed at the April 2010 NOSB Meetings. Also since then the NOSB has proposed clarifications and revisions to the recommendation. The final recommendation does not include animal welfare requirements for livestock transport to the slaughter facility or upon arrival at the slaughter facility. Additionally, the Access to Pasture Final Rule was published on February 17, 2010, and the NOP anticipates that it will impact parts of the animal welfare recommendation.

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Questions for the NOSB:

Further NOSB guidance is needed before NOP can proceed with rulemaking on animal welfare. NOP asks that the NOSB consider the following questions while discussing the details of the animal welfare recommendation. Clarifications would facilitate and strengthen the rulemaking process:

- What impact will the recently published Access to Pasture rule have on the proposed animal welfare recommendations, specifically on stocking density? How will the adoption of intensive rotational grazing systems impact the NOSB recommendations on stocking density requirements?
- What are the economic and record keeping burdens on organic livestock producers to comply with the animal welfare requirements?
- Would the NOSB consider amending the rule to include broad principles of animal welfare and require each livestock operation to have routine animal welfare audits conducted by organizations recognized and deemed appropriate by the NOP and NOSB?
- What impact will the recommendations have on other livestock (e.g., bison, ratites, and other domesticated game)? Will there be stocking density and spacing requirements for all types of livestock (e.g., bison, ratites, and other domesticated game)?
- How will the animal welfare requirements be monitored and enforced?
- What resources were used during the decision making process for the recommendation? How were the recommendations derived?

11. Classification of Materials

The NOSB has done some excellent work on the issue of classifying materials. Developing a classification system that makes decision-making determinable and predictable is a challenging task. There is a wide range of materials from natural to synthetic and from raw agricultural ingredients to highly processed agricultural products.

Definitions and classifications are important components of the National Organic Standards due to the way the Organic Foods Production Act (OFPA) is constructed. Nonsynthetic materials are allowed and synthetic materials are prohibited. The regulations do not provide a comprehensive list of allowed and prohibited materials. For many substances the classification as synthetic or nonsynthetic is clear; however, other materials are not straightforward resulting in inconsistencies. Some materials could be considered synthetic due to minor chemical changes which occur during manufacturing, others may be considered synthetic due to addition of small amounts of synthetic ingredients. Under OFPA, they are all treated the same: if the material is synthetic then the substance is prohibited unless it is added to the National List.

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Because of the importance that OFPA places on the determination of synthetic vs. nonsynthetic, the NOP supports the NOSB taking two votes on each material – the first vote to decide whether the substance is synthetic or natural, the second to decide whether to allow the substance. It is also especially important for the NOSB to clarify the use of the substance. Annotations may be necessary to clarify the specific substance that is allowed as well as what use is specifically allowed.

The NOP does not intend to pursue rule changes based on the NOSB November 2009 recommendations at this time. The recommendation needs further attention before it is ready for proposed rulemaking.

The definitions in the NOSB's recommendation need to be further refined to be applicable to all of the various uses of materials in organic agriculture including crop production, post harvest handling, livestock feed and healthcare, and food processing.

12. Policy Manual Changes

The NOP recognizes the amendments to the NOSB Policy Manual. The changes to the manual will be incorporated into the official NOSB Policy Manual.

13. Retail Certification

The NOSB has done some excellent work on retail certification. The NOP is not planning on doing any rulemaking or guidance development at this time on the NOSB retail certification recommendation. The NOP encourages the NOSB to continue to develop recommendations on retail certification.