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Washington, D.C. 20250-0268

September 5, 2013

MEMORANDUM TO THE NATIONAL ORGANIC STANDARDS BOARD

FROM: Miles McEvoy
Deputy Administrator
National Organic Program (NOP)

A handwritten signature in blue ink, appearing to read "Miles McEvoy", with a large, stylized flourish underneath.

SUBJECT: National Organic Standards Board Recommendations (April 2013)

This memorandum responds to National Organic Standards Board (NOSB) recommendations and other actions at the April 9-11, 2013 meeting of the NOSB in Portland, Oregon. The NOSB recommendations and other actions included the following:

- 1) The NOSB voted on a petition to extend the allowance of tetracycline beyond October 21, 2014. The current allowance of tetracycline for fire blight control in organic apples and pears is due to expire on October 21, 2014. The NOSB's motion to extend the allowance of tetracycline beyond October 21, 2014 did not receive the necessary 2/3 majority vote to pass.
- 2) The NOSB recommended that USDA should investigate the ability of the Secretary to invoke USDA's authority under the Organic Foods Production Act (OFPA) and USDA organic regulations about emergency spray to allow the emergency use of tetracycline for fire blight during the period of October 21, 2014 to October 21, 2017.
- 3) The NOSB recommended that USDA should increase support and prioritization of research into alternative practices and materials for control of fire blight on organic farms.
- 4) The NOSB recommended to add the substance taurine to the National List of Allowed and Prohibited Substances (National List) for use as a feed additive in organic pet food.
- 5) The NOSB recommended that NOP develop guidance to describe how certifying agents should verify the percentage of organic content in multi-ingredient organic products. NOSB also recommended a change to 7 CFR section 205.302(a) to correct the method of calculation so that the calculation of percentage of organic content is based on all ingredients, not the finished product.
- 6) The NOSB recommended a plan for review of ancillary substances found in generic handling materials petitioned for (or included on) the National List according to OFPA requirements as they come up in review of petitioned or sunset materials.
- 7) The NOSB recommended that the NOSB Policy and Procedures Manual be amended to describe a public communication mechanism that is available year round and implement such a



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mechanism. NOSB also recommended a revision to the New Member Guide to reflect changes in policy, subcommittee membership, and NOP staff changes.

NOP DISCUSSION AND RESPONSE:

1-3. Tetracycline.

Tetracycline is currently allowed under the USDA organic regulations solely for the treatment of fire blight in organic apple and pear production. Tetracycline is an antibiotic effective against fire blight, a bacterial disease that is ubiquitous in the environment. Under the correct moisture and temperature conditions, fire blight bacterium becomes active and affects pome fruit trees, causing extensive tree damage that can quickly spread throughout entire orchards. Based on analysis of data from the USDA's 2011 Organic Production Survey, more than half of organic apple production in Washington State and roughly 80 percent of organic pear acreage in U.S. could be highly susceptible to fire blight. In 2011, there were approximately 370 U.S. organic farms growing apples with \$122M in gross sales. There were approximately 170 U.S. organic farms growing pears with \$27.5M in gross sales. The majority of these farms are in Washington State and California.

The NOSB has long debated the suitability of this material in organic production, which resulted in two rulemaking actions that amended the listing for tetracycline on the National List (7 CFR 205.601(i)(12)):

- 1) July 6, 2010: The addition of an expiration date to October 21, 2012 (75 FR 38693).
- 2) August 2, 2012: The extension of the expiration date to October 21, 2014 (77 FR 45903).

The main reasons for adding the expiration dates for tetracycline were twofold: 1) to acknowledge research and public concern that the use of antibiotics in the environment contributes to antibiotic resistance; and 2) to prompt research and development of alternatives acceptable for use in organic production.

At the April 2013 meeting, the NOSB considered a petition requesting removal of the expiration date from its listing on the National List, which would, in effect, continue to allow tetracycline in organic apple and pear production after October 21, 2014. In response to the petition, the NOSB Crops Subcommittee put forth a proposal to extend the use of tetracycline for another two years, until October 21, 2016. This proposal was intended to address concerns of both, consumer groups who want antibiotics out of organic fruit production immediately, and organic producers who want more time to use these materials. Organic producers stated that additional time is needed to develop effective commercial alternatives to tetracycline use and posited that, without the use of tetracycline or alternatives to combat fire blight, some producers will remove their land from organic production. Before voting, NOSB members visited organic orchards in Oregon's Hood River Valley and listened to public comments.

The NOSB did not reach the two-thirds majority vote required to pass the proposal to extend the use of tetracycline. NOP has reviewed the NOSB's discussion and April 2013 vote on tetracycline. Based on this review, AMS will not take action to extend the allowance of tetracycline as a fire blight management tool after October 21, 2014.



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At the April 2013 meeting, the NOSB recommended that USDA examine whether it could use its authority to allow use of tetracycline in “emergency” situations after October 21, 2014. The NOSB speculated that the “Emergency Spray Programs” provision of the Organic Foods Production Act (OFPA, 7 USC 6518(k)(6)) and the USDA organic regulations (7 CFR 205.672) may provide this authority. If USDA had such authority and declared a Federal fire blight emergency, products from treated trees could no longer be sold as organic, but the producer would retain organic certification.

NOP Response:

NOP does not have a mechanism to establish a federal emergency spray program for fire blight on organic apple and pear orchards through OFPA or the USDA organic regulations. Federal emergency spray programs are authorized by the Animal and Plant Health Inspection Service (APHIS) under the Plant Protection Act (7 U.S.C. 7701) and associated regulations (7 CFR Part 301). In April and May 2013, NOP consulted with APHIS to understand how they establish federal emergency spray programs and determine whether USDA could implement such a program to treat fire blight on organic farms. Our understanding is that APHIS establishes these programs to address pest outbreaks or exotic plant disease emergencies for the purposes of domestic quarantine. These programs are not initiated to treat endemic pests or diseases, such as fire blight, that occur widely in the U.S. on both conventional and organic farms. Therefore, USDA would not be able to declare a federal emergency spray program for fire blight that would be limited to organic producers given that it is plant disease endemic to the U.S.

Furthermore, emergency spray programs would be difficult to implement in real time given that the threat of fire blight incidence is influenced by cultivar susceptibility, tree age, succulence of tissues and weather conditions. The window of time between when producer learns the correct weather conditions could take place and when preventive application of fire blight control materials should be applied can be as short as 24 hours.

If individual states want to pursue a state level emergency spray program, the Plant Protection Act does allow states to regulate interstate commerce for control of a specific pest if the USDA does not have a federal program established. States may also establish additional requirements for control of pests or disease in addition to any federal program if the state can demonstrate to USDA that a special need exists. However, USDA cannot mandate that states take action to establish a state program to control, eradicate or prevent introduction of plant pests in the absence of a federal program.

NOP will continue to support the development of prevention practices and effective alternatives for treating fire blight on organic farms. In May 2011, the NOP [requested](#) support for development of such alternatives from the USDA Agricultural Research Service and National Institute of Food and Agriculture (NIFA). In Fiscal Year 2011, USDA awarded a \$475,835 grant to Oregon State University to develop non-antibiotic treatments for the control of fire blight in organic apples and pears. This research was funded through NIFA’s Organic Research and Extension Initiative (OREI). In May 2013, NOP met with the Agricultural Research Service (ARS) Office of Pest Management Policy (OPMP) to ensure coordination with the Environmental Protection Agency (EPA) on the pesticide registration process for any tetracycline alternatives that would be compliant with the USDA organic regulations. The NOP believes that providing alternatives approved for use in organic production prior to the 2014 expiration date may be essential to preventing some organic apple and pear growers from dropping organic certification. Any alternatives would still require review by a certifying agent to ensure compliance with USDA organic regulations. If these alternatives contain synthetic substances that are



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not on the National List, then these substances would need to be petitioned and reviewed by the NOSB.

4. Add the substance taurine to the National List for use as a feed additive in pet food.

In response to a petition to add amino acids to the National List for use in organic pet food, the NOSB recommended adding taurine to section 205.603 of the National List as a feed additive for pet food. The NOSB recommendation states that synthetic taurine is necessary to meet the nutritional requirements for cats and for different life stages of dogs. Taurine is not readily available from agricultural sources due to degradation of this amino acid during processing. The NOSB also voted on whether to add arginine, DL-methionine, L-lysine, tryptophan, threonine, histidine, isoleucine, leucine, phenylalanine, tyrosine, and valine to the National List for use in organic pet food. The NOSB did not reach the two-thirds majority vote required to pass a recommendation to add these other synthetic amino acids to the National List. In its recommendation, the NOSB stated that manufacturers could meet the amino acid needs for pets and meet the criteria for “complete and balanced” pet food as required by Association of American Feed Control Officials (AAFCO) using organic agricultural ingredients, rather than synthetic forms, as the amino acid source.

NOP Response:

The NOP has reviewed the NOSB’s recommendation and intends to add taurine to the National List for use in organic pet food through rulemaking.

5. Calculation of percent organic content in multi-ingredient products.

The NOSB recommended that NOP develop guidance to describe how certifying agents should verify the percentage of organic content in multi-ingredient organic products. The NOSB also recommended NOP amend section 205.302(a) to correct the method of calculation so that the calculation of percentage of organic content is based on all ingredients, not the finished product.

NOP Response:

The NOP has reviewed the NOSB’s recommendation and appreciates the clarification and background information provided by the NOSB. NOP will use this information to work on revising the NOP policy memo on “Calculating the Percentage Organically Produced Ingredients (PM 11-9) with updated guidance on the topic. As we develop this guidance, NOP will evaluate whether a change in the regulation at section 205.302(a) is necessary to change the method of calculation of organic content, so that it is based on the sum of all ingredients, not the final weight or volume of the finished product.

6. Ancillary Substances used in handling materials.

On November 23, 2011, the NOP [requested](#) that the NOSB clarify whether “other ingredients” are allowed in organic processed products. The NOP stated that when used as a formulated product, some substances on the National List may contain additional “other ingredients” in various categories, including, but not limited to, carriers, stabilizers, and preservatives. The NOP requested that NOSB develop a policy on “other ingredients” for substances listed on section 205.605 and that the NOSB consider the presence of any “other ingredients” as part of their review processes as substances on the



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National List come up for sunset review, or as new petitions are considered. The NOP stated at that time that “since OFPA requires that each non-agricultural ingredient be specifically allowed, and because the National List doesn’t specifically list “other ingredients” commonly found in formulated products, the NOP is requesting that the NOSB specify whether these “other ingredients” are allowed.” In its recommendation, the NOSB references these “other ingredients” using the terminology “ancillary substances”. The NOSB recommendation outlined a plan for review of ancillary substances found in generic handling materials petitioned for (or included on) the National List according to OFPA requirements as they come up in review of petitioned or sunset materials

NOP Response:

The NOP has reviewed the NOSB’s recommendation and supports a review of these ancillary substances according to OFPA requirements. The NOP also agrees that the review does not require these substances to be individually listed on the National List, and reiterates that the NOP could communicate any restrictions or prohibitions in an annotation for the generic substance or in published guidance regarding permitted substances for organic handling.

At the April 2013 meeting, the NOP stated its concerns with NOSB recommending changes to listings or addition of annotations to substances on the National List during sunset review. This concern would also apply to any recommendation to address ancillary substances through an annotation as part of the NOSB’s sunset review. Therefore, the NOP is coordinating with the NOSB Handling Subcommittee to determine the best timing for conducting ancillary substance reviews.

7. Public communication policy for the NOSB Policy and Procedures Manual and New Member Guide update.

The NOSB recommended updates to the New Member Guide and an addition to the Policy and Procedures Manual to provide an opportunity for the public to provide communications to the NOSB year round. This would be in addition to the public comment period on specific agenda items that is solicited through www.regulations.gov in advance of the NOSB public meetings.

NOP Response:

The NOP has reviewed the NOSB’s recommendation and supports these changes. The NOP is working to evaluate the best options for implementation of a sustainable and manageable open process to receive public communications at any time.

Summary

The NOP recognizes and sincerely appreciates the number of hours and creative work each NOSB member volunteers every month during their five-year term. The NOSB plays a vital role in representing the diverse aspects of the organic community as we work collaboratively to improve the organic regulatory system and protect organic integrity from farm to table.