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1400 Independence Avenue, S.W.
Room 2642-S, Mail Stop 0268
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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 at the end.

SUBJECT: National Organic Standards Board Recommendations (April 2015)

Background

The National Organic Standards Board (NOSB) is a 15-member Federal Advisory Committee comprised of organic community and stakeholder representatives. The Board was established by the Organic Foods Production Act of 1990 and charged with the following:

- Providing advice to the USDA about whether substances should be allowed or prohibited in organic production and/or handling
- Assisting with the development of standards for organic production, and
- Advising the Secretary on other aspects of the implementation of the Organic Foods Production Act.

The NOSB advises USDA on which substances should be allowed or prohibited in organic farming and processing, based on criteria under the Organic Foods Production Act. The NOSB must also review each substance on the National List every five years to confirm that it continues to meet all required criteria; this is referred to as the “sunset” review.

This memorandum responds to National Organic Standards Board (NOSB) recommendations at the April 27–30, 2015 meeting of the NOSB in La Jolla, California. The NOSB provided a series of recommendations to USDA at the meeting. All motions by the NOSB require a 2/3 majority to pass.

Summary of Recommendations from April 27-30, 2015 NOSB Meeting

- 1. Petitioned Substances.** The NOSB recommended four amendments to the National List of Allowed and Prohibited Substances (National List). This section of the USDA organic regulations includes synthetic substances allowed in crop and livestock production, nonsynthetic substances prohibited in crop and livestock production, and all substances allowing in handling of organic products.

Substance	Section	Action Considered by NOSB and the NOSB Recommendation
Glycerin produced by hydrolysis of fats and oils	§205.605(b)	The motion to remove this substance from the National List passed
Glycerin, when derived from agricultural source material and processed using biological or mechanical/physical methods described under §205.270(a)	205.606	The motion to add this substance to the National List at 205.606 as an agricultural substance passed
Acidified Sodium Chlorite (ASC) (CAS # 7758-19-2 (sodium chlorite) and CAS # 14998-27-7 (chlorous acid))	§205.603(a)	The motion to add this substance to the National List passed with the following annotation: allowed for use on organic livestock as a pre and post teat dip treatment. The substance was classified as synthetic.
Zinc Sulfate	§205.603(b)	The motion to add this substance to the National List passed with the following annotation: for use as a foot or hoof treatment only. The substance was classified as synthetic.
DL–Methionine, DL–Methionine—hydroxy analog, and DL–Methionine—hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9) -	§205.603(d)	<p>The motion to amend the listing for methionine passed as follows: for use only in organic poultry production at the following maximum average pounds per ton of 100% synthetic methionine in the diet over the life of the flock: Laying chickens – 2 pounds; Broiler chickens – 2.5 pounds; Turkeys and all other poultry – 3 pounds.</p> <p>Motion to adopt the following resolution passed: The National Organic Standards Board is committed to the phase-out of synthetic methionine for organic poultry production, and encourages aggressive industry and independent research on natural alternative sources of methionine, breeding poultry that perform well on less methionine, and management practices for improved poultry animal welfare.</p>

2. 2016 Sunset Review: The NOSB completed the 2016 sunset review for two substances used in crop production and ten substances used in organic handling.

The NOSB considered motions to remove each of the following substances from the National List. The NOSB recommended five substances for removal: egg white lysozyme, cyclohexylamine, diethylaminoethanol, octadecylamine, and tetrasodium pyrophosphate (TSPP).

Substance	Section	Action Considered by NOSB NOSB Recommendation
Ferric Phosphate	§205.601(h)	The motion to remove the following substance from the National List failed. The NOSB completed its sunset review.
Hydrogen Chloride	§205.601(n)	The motion to remove the following substance from the National List failed. The NOSB completed its sunset review.
Egg White Lysozyme	§205.605(a)	The motion to remove the following substance from the National List passed. The NOSB recommended removal from the National List as a result of its sunset review.
L-Malic Acid	§205.605(a)	The motion to remove this substance from the National List failed. The NOSB completed its sunset review.
Microorganisms	§205.605(a)	The motion to remove this substance from the National List failed The NOSB completed its sunset review.
Activated Charcoal	§205.605(b)	The motion to remove this substance from the National List failed. The NOSB completed its sunset review.
Peracetic Acid	§205.605(b)	The motion to remove this substance from the National List failed. The NOSB completed its sunset review.
Cyclohexylamine	§205.605(b)	The motion to remove this substance from the National List passed. The NOSB recommended removal from the National List as a result of its sunset review.

Diethylaminoethanol	§205.605(b)	The motion to remove this substance from the National List passed. The NOSB recommended removal from the National List as a result of its sunset review.
Octadecylamine	§205.605(b)	The motion to remove from the National List passed. The NOSB recommended removal from the National List as a result of its sunset review.
Sodium Acid Pyrophosphate (SAPP)	§205.605(b)	The motion to remove from the National List failed. The NOSB completed its sunset review.
Tetrasodium Pyrophosphate (TSPP)	§205.605(b)	The motion to remove from the National List passed The NOSB recommended removal from the National List as a result of its sunset review.

3. Other Recommendations

Peer Review Recommendation

The NOSB passed a recommendation for the National Organic Program Accreditation Peer Review Process.

NOP Discussion and Response

The NOP reviewed the NOSB's final recommendations and has provided a response of intended actions.

1. Petitioned Substances

Glycerin

At the April 2015 meeting, the NOSB recommended removing glycerin from §205.605(b). The NOSB proposed the listing of glycerin at §205.606 and removal of glycerin from §205.605(b). The proposed annotation for glycerin listed on §205.606 is: Glycerin, when derived from agricultural source material and processed using biological or mechanical/physical methods described under §205.270(a).

Glycerin is currently listed at §205.605(b) with the annotation "produced by hydrolysis of fats and oils." Per the Technical Review for glycerin and the petitioner, there are a variety of methods to manufacture glycerin. Among them include, saponification of natural fats and oils, a process of hydrolyzing the agricultural products fat or oil with water (steam) under pressure or with a solution of sodium carbonate, sodium hydroxide, or potassium hydroxide to produce synthetic glycerin and fatty acids. The agricultural forms of glycerin would be those produced from agricultural source material and processed using biological (microbial fermentation) or

mechanical/physical methods (steam or pressure). Additionally, according to the Technical Review Report, glycerin can be produced organically by the process of microbial fermentation using mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List.

The petitioner requested removal of glycerin from §205.605(b), stating that there is now sufficient quantity of organically produced glycerin and that synthetic glycerin is no longer required. The NOSB proposed the listing of some forms of glycerin at §205.606 and removal of glycerin from §205.605(b).

NOP Response:

The NOP has reviewed the NOSB's recommendation and plans to initiate rulemaking for public comment to add agricultural forms of glycerin to the National List, §205.606, for use in organic handling. If finalized, the use of glycerin as included at §205.606 would be limited to those forms derived from agricultural source material and processed using biological or mechanical/physical methods described under §205.270(a).

Acidified Sodium Chloride

The NOSB considered a petition for Acidified Sodium Chlorite (ASC), which was petitioned to be added to the National List at §205.603(a) as a disinfectant, sanitizer and medical treatment, and at §205.603(b) for use as a topical treatment, for the intended use on organic livestock as a pre and post teat dip. The NOSB found it to be an important ingredient in teat dips and recommended its addition to the National List at §205.603(a).

ASC, also listed as Sodium Chlorite, Acidified, is currently on the National List as an allowed disinfectant for direct food contact under §205.605(b). Over the course of several NOSB meetings and much discussion, the NOSB has determined that ASC satisfies the criteria related to impact on human health and the environment, and is compatible with organic agriculture. NOSB received a number of public comments indicating a strong need for ASC as an effective alternative teat dip that could be used in cases of microbiological resistance to teat dips currently listed.

The NOSB recommended adding this material at §205.603(a) as follows: Acidified Sodium Chlorite, allowed for use on organic livestock as a pre and post teat dip treatment.

NOP Response:

The NOP has reviewed the NOSB's recommendation and plans to initiate rulemaking for public comment to add acidified sodium chlorite (ASC) to the National List for use in organic livestock production. If finalized, the use of ASC would be limited for use on organic livestock as a pre and post teat dip treatment.

Zinc Sulfate

The NOSB considered a petition to add zinc sulfate to §205.603(b) for use as a foot or hoof treatment and recommended to add it to the National List as petitioned. The recommended annotation is: for use as a foot or hoof treatment only.

The petition supported the allowance of zinc sulfate to be used as a footbath for control of foot rot in livestock, particularly dairy cattle, sheep and goats. Commercially, zinc sulfate is manufactured from zinc ore mined from underground or open pit mines. Zinc ores are extracted in more than 50 countries and zinc sulfate is most commonly produced by the interaction of zinc salts and sulfuric acid.

The NOSB supported the recommendation based on evidence that adding zinc sulfate would provide a tool for treating foot diseases in livestock and would therefore promote animal welfare.

NOP Response:

The NOP has reviewed the NOSB's recommendation and plans to initiate rulemaking for public comment to add zinc sulfate to the National List for use in organic livestock production. If finalized, the use of zinc sulfate would be limited for use as a foot or hoof treatment only.

DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium

DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine-hydroxy analog calcium is currently listed on the National List, §205.603(b) as:

DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine-hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following maximum levels of synthetic methionine per ton of feed: Laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds.

The regulations currently express a total maximum limit of pounds of methionine (MET) per ton of feed. Over the course of several meetings, the NOSB considered the proposal which requests that MET rates be expressed as an average per ton of feed over the life of the flock. After much review, debate, and public comment, the NOSB recommended at the April 2015 meeting to accept the following amendment at §205.603(d):

DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9) -for use only in organic poultry production at the following maximum average pounds per ton of 100% synthetic methionine in the diet over the life of the flock: Laying chickens – 2 pounds; Broiler chickens – 2.5 pounds; Turkeys and all other poultry – 3 pounds.

The NOSB also recommended a phasing-out of synthetic methionine for organic poultry production and encouraged industry and independent research on natural alternative sources of

methionine, breeding poultry that perform well on less methionine, and management practices for improved poultry animal welfare.

MET is classified as an essential amino acid because it cannot be biologically produced by poultry and is necessary to maintain viability. MET is required for proper cell development and feathering in poultry. Natural feed sources with a high percentage of MET include blood meal, fish meal, crab meal, corn gluten meal, alfalfa meal, and sunflower seed meal. Synthetic MET is also used in poultry feed. The dietary demand for total MET declines with age for broilers and turkeys, and while there is a decline during the early stages of pullet development, it increases just before laying begins and trails off as the birds age.

Prior to the April 2015 meeting, the NOSB studied the commercial availability and/or development status of any non-synthetic alternatives to synthetic MET, the impact the stepped down rates have had on animal welfare, and what role outdoor access has on naturally available sources of MET, i.e., insects and worms that might be foraged by pastured chickens. Comments from a variety of stakeholders in organic poultry production, including both smaller and larger producers, university researchers, poultry nutritionists and agronomists were received. While there was some debate around the timeline for commercial availability of non-synthetic alternatives, there was consensus that as long as consumers have the expectation of all-vegetarian diets for poultry (laying hens, in particular) methionine will continue to be needed.

The levels of MET put forth in this proposed annotation change reflect the NOSB's Livestock Subcommittee's understanding of the minimum average levels of MET that organic producers need in order to effectively balance the nutritional needs of their flocks with consumer preference for vegetarian poultry diets.

NOP Response:

The NOP has reviewed the NOSB's recommendation and plans to initiate rulemaking for public comment to amend the listing at §205.603(d) of the National List for DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium. If finalized, the use of DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium would be limited for use only in organic poultry production at the following maximum average pounds per ton of 100% synthetic methionine in the diet over the life of the flock: Laying chickens – 2 pounds; Broiler chickens – 2.5 pounds; Turkeys and all other poultry – 3 pounds.

NOP will continue to encourage the research and development of natural alternative sources of methionine, breeding poultry that perform well on less methionine, and management practices for improved poultry animal welfare.

2. 2016 Sunset Review

The NOSB completed the sunset review for ferric phosphate, hydrogen chloride, L-malic acid,

microorganisms, activated charcoal, peracetic acid, egg white lysozyme, cyclohexylamine, diethylaminoethanol, octadecylamine, sodium acid pyrophosphate (SAPP), and tetrasodium pyrophosphate (TSPP).

During their review of egg white lysozyme, the NOSB determined that its use in organic handling operations is not essential. The NOSB received no public comments supporting the need for this material, and therefore recommended removal from the National List.

During their review of the boiler chemicals, cyclohexylamine, diethylaminoethanol, and octadecylamine, the NOSB requested information regarding the continued use of these boiler chemicals in boiler systems. The information received suggested that most manufacturers have already begun to move away from these materials. In addition, these materials are suspected to be toxic to humans and the environment. The NOSB recommended removing these three materials from the National List.

During their review of tetrasodium pyrophosphate, the NOSB determined that due to historical concern over the use of this material, information provided in the 2014 Technical Report, the lack of public support, and the ample alternatives that exist to TSPP, it should be removed from the National List.

This action completes the NOSB's responsibility to review substances scheduled for the 2016 sunset review, according to the Organic Foods Production Act's (OFPA) sunset provision (7 U.S.C. 6517(e)).

NOP Response:

The NOP accepts the NOSB's completed 2016 Sunset review. NOP intends to publish a proposed rule requesting comments on the removal of egg white lysozyme, cyclohexylamine, diethylaminoethanol, octadecylamine, tetrasodium pyrophosphate (TSPP) from the National List. AMS also intends to publish a notice to renew the seven substances (ferric phosphate, hydrogen chloride, L-malic acid, microorganisms, activated charcoal, peracetic acid, sodium acid pyrophosphate (SAPP)) on the National List for another five years.

3. Peer Review

In a memorandum dated November 19, 2014, the NOP asked the NOSB's Certification, Accreditation and Compliance Subcommittee (CACS) to review a 'Peer Review of National Organic Program (NOP) Accreditation' process. Furthermore, the NOP requested that the (CACS) provide feedback to the NOSB during the spring 2015 NOSB meeting and that the feedback be in the form of a proposal, which might include (1) support for the NOP's peer review process and/or (2) any recommendations for how the process should be changed to be successful, and/or (3) any suggestions the NOP should consider in its implementation.

The NOSB reviewed the peer review program and supports: 1) the concept and practice of a formal Peer Review Panel (PRP) process and 2) the general direction of the process outlined by

the NOP. In addition, the NOSB's proposal suggested modifications which relate to the number, composition, and experience of the PRP members:

1. The number of PRP members: NOP draft suggests a minimum of 3; the NOSB feels that 5 members are more appropriate. The NOSB also recommends that one of the 5 should be an ex officio member of NOSB, to serve at discretion of NOP Deputy Administrator, and to have organic certification and/or inspection experience, and suggests that this be the chair or vice-chair of CACS.
2. Experience of the PRP members: NOP suggested 2 members have organic experience; the NOSB recommends 3.
3. The NOSB also recommends that the NOP pursue a rule change to §205.509 by removing the FACA reference, and allow the hiring of contractors as an independent assessment body in a manner consistent with the OIG findings.

NOP Response:

The NOP appreciates the great amount of work and thought that went into this recommendation. The NOP will consider increasing the number of peer review members to the Peer Review Panel, including an ex officio NOSB member. The NOP also intends to propose removing the FACA reference to 7 CFR 205.509.

4. Summary

The NOP acknowledges and sincerely appreciates the hundreds of hours NOSB members provided in developing the NOSB April 2015 recommendations. In addition, the NOP supports the NOSB's vital role in representing the diversity of the organic community to enhance organic regulatory implementation and ensure organic product integrity.