

ORGANIC MATERIALS REVIEW INSTITUTE

Comments on USDA National Organic Program
Proposed Amendments to the
National List of Allowed and Prohibited Substances
7 CFR Part 205, Docket No.TMD-04-01

November 15, 2005

Arthur Neal
Director of Program Administration
National Organic Program
USDA-AMS-TMP-NOP
1400 Independence Ave., SW, Room 4008 So.
Ag Stop 0268
Washington, D.C. 20250

RE: Docket No. TMD-04-01
Sent Via E-Mail to: National.List@usda.gov
Sent Via Fax to: 202.205.7808

Dear Mr. Neal:

OMRI appreciates the opportunity to comment on the proposed amendments to the USDA National List of Allowed and Prohibited Substances (National List), Docket Number TMD-04-01.

OMRI supports the intent of the National Organic Program to adhere to the public process as set out in the Organic Foods Production Act of 1990 (OFPA). With respect to this Docket, as we also did in our April 16, 2003 Docket (TMD-02-03) comments, we would like to comment on the advisory function of the NOSB for implementing and amending the National List as well as the need for adequate opportunities for public comment on NOSB recommendations and proposed amendments to the National List.

Crops

OMRI supports the addition of the following items to the National List as annotated:

205.601
Ferric phosphate
Glycerine oleate
Hydrogen chloride
Tetrahydrofurfuryl alcohol

Please note that the following forms of glycerine oleate have been reclassified as EPA List 4A on the August 2004 edition of the EPA's list of inert ingredients:

CAS#	Substance	EPA List#
111-03-5	9-Octadecenenoic acid (Z)-, 2,3-dihydroxypropyl ester	4A
25496-72-4	Octadecanoic acid (9Z)-, monoester with 1,2,3 9-propanetriol	4A
37220-82-9	Glycerine oleate	3

It appears that the references of CAS #111-03-5 and CAS #25496-72-4 are redundant to the allowance of EPA List 4 substances. However, CAS #37220-82-9 should be added to the National List with a deadline to be reclassified to EPA List 4 or removed from the National List by December 31, 2006.

Processing

OMRI supports the addition of the following substances to the National List as proposed:

205.605(a)

Egg white lysozyme

L-malic acid

Microorganisms

OMRI supports the addition to the National List of the following substances with revised annotations:

205.605(b)

Activated charcoal

Cyclohexylamine

Diethylaminoethanol

Octadecylamine

Peracetic acid / Peroxyacetic acid

No explanation was given in the *Federal Register* for the reason that the NOP did not accept the annotations provided by the NOSB for these five substances. The substances proposed to be added to 205.605(b) will to be addressed on a case-by-case basis.

Activated charcoal is a processing aid that is used for filtering. OMRI conducted the TAP review for activate charcoal and supports the annotation that in order to be used in organic processing, activated carbon must come from vegetative sources. While they may be present in incidental amounts, it is OMRI's opinion that filtering aids—whether synthetic or non-synthetic—are required to be on the National List in order to be used in *or on* organic ingredients. OMRI does not believe that this excludes products labeled “organic.” OMRI proposes that the activated charcoal be added to the National List with the following annotation:

205.605(b)

Activated charcoal (CAS #7440-44-0; 65365-11-3)—only from vegetative sources; for use only as a filtering aid. ~~in handling agricultural products labeled ‘made with organic (specified ingredients or food group(s));’ prohibited in handling agricultural products labeled “organic.”~~

OMRI supports the addition of peracetic acid to the National List with the annotation proposed by the NOSB. Because it is used as a disinfectant in direct contact with raw whole agricultural commodities, the ‘made with’ annotation is not appropriate. The substance is commonly used with hydrogen peroxide and should be annotated consistently with hydrogen peroxide:

205.605(b)

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. ~~Restricted to use in handling agricultural products labeled ‘made with organic (specified ingredients or food group(s));’ prohibited in handling agricultural products labeled “organic.”~~

Cyclohexylamine, diethylaminoethanol, and octadecylamine were intended only for use in steam used to sterilize food contact surfaces, such as bottles and caps, but should be prohibited for direct contact with food. Because they are miscible in water and form azeotropes, they become part of the food and cannot be considered ‘food contact substances.’ Labeling as ‘made with organic’ is not relevant because if they are used according to the annotation and Good Manufacturing Practices, the substances are restricted to uses that will not permit them to contact food or become ingredients at even incidental amounts.

205.605(b)

Cyclohexylamine (CAS #108-91-8)—for use only as a boiler water additive for packaging sterilization. ~~Restricted to use in handling agricultural products labeled ‘made with organic (specified ingredients or food group(s));’ prohibited in handling agricultural products labeled “organic.”~~

...

Diethylaminoethanol (CAS #100-37-8)—for use only as a boiler water additive for packaging sterilization. ~~Restricted to use in handling agricultural products labeled ‘made with organic (specified ingredients or food group(s));’ prohibited in handling agricultural products labeled “organic.”~~

Octadecylamine (CAS #124-30-1)—for use only as a boiler water additive for packaging sterilization. ~~Restricted to use in handling agricultural products labeled ‘made with organic (specified ingredients or food group(s));’ prohibited in handling agricultural products labeled “organic.”~~

Tetrasodium Pyrophosphate and Sodium Acid Pyrophosphate

OMRI does not support the addition of the substances tetrasodium pyrophosphate (TSPP) and sodium acid pyrophosphate (SAPP) to the National List. The NOSB should complete

the review and recommendation of TSPP and SAPP because they appear as ingredients in foods beyond an incidental amount. The annotation proposed may be appropriate, but OMRI cannot support it without an NOSB recommendation.

OMRI previously commented on TSPP, stating that the annotation for “use only in textured analog meat products” is vague. This expression is not a well-defined food term. The absence of an NOP definition leaves its applicability unclear. We also request clarification of the types of food products for which TSPP is approved. According to the proposed amendment listing, it appears that any non-meat-based product that makes an artificial meat claim may qualify under the NOP.

Due to this vagueness in definition and applicability, we believe the listing of TSPP will be inconsistently implemented by certification agencies. Also, the primary use of TSPP appears to be for creating a texture that is similar to a meat product. However, this use directly conflicts with the criterion established at §205.600(b)(4), which states:

“The substance’s primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive values lost during processing...”

The NOSB received information regarding the intended use, alternatives, and functionality of TSPP from the petitioner prior to its September 19, 2002 meeting and did not provide this information to the public. Without complete information available to the public, it is inappropriate to include a material on the National List.

Also relevant to these points on transparency and adequate public comment period for TSPP is the handling of sodium acid pyrophosphate, or SAPP. According to the NOP Website, accessed November 7, 2005, “NOP returned this recommendation to the NOSB for further documentation. No further action will be taken until the requested documentation is received. The reader is reminded that use of this material is prohibited.”

There is no TAP review for SAPP, the one provided is for potentially similar materials. OMRI requests a second time that the NOSB recommendations be tabled until further review when both TSPP and SAPP can be opened to a full public review. OMRI also requests that all information supporting the TSPP and SAPP decisions be made publicly available for comment prior to any listing in a final amendment to the National List.

To reiterate our previous comment with respect to the current amendment to add SAPP and TSPP to the National List, OMRI believes further clarification and an additional period of public review and comment is justified for the following reasons:

(1) concerns raised in the TAP review in the case of TSPP and the entire lack of a TAP review in the case of SAPP.

(2) lack of publicly available additional information, which was used in the decision making leading to the recommendation for listing TSPP and SAPP, apparently this was provided to the NOSB outside of a public meeting.

(3) questions regarding TSPP's and SAPP's acceptability under both the NOP and internationally recognized criteria.

In addition to the reasons raised in our June 2, 2003 comments on TMD-03-02, OMRI requests that the following substances be sent back to the NOSB for further consideration.

Ammonium Hydroxide

OMRI does not support the addition of ammonium hydroxide to the National List: The phase out period expired on October 21, 2005. The background paper on boiler chemicals and the ammonium hydroxide TAP review shows that there are many alternatives to ammonium hydroxide for boiler maintenance. Substances used in boiler water should not carry over into organic food.

Recommendations Not Accepted

OMRI reminds the USDA that the NOSB has recommended that additional substances be added to the National List. OMRI requests that, for each material not yet included in a Federal Register notice to amend the National List, the NOP state whether the recommendation was not accepted, thus resulting in the continued prohibition of the substance.

OMRI notes that two substances were recommended to be added to 205.601 and one was recommended to be added to 205.602. While the recommendations for chitosan and sucrose octonate ester were made after the period specified in the Federal Register notice, the other recommendations were made within the period specified. However, the NOSB affirmed its recommendation to put sodium chloride on the prohibited non-synthetic list in 2003, but that recommendation was not included in this docket. The NOSB also made a recommendation to clarify the status of compost and compost tea.

The NOSB recommended that 22 substances be added to 7 CFR 205.603 for use in organic livestock production: Activated carbon, Adrenaline, Atropine, Bismuth Subsalicylate, Butorphanol, Calcium borogluconate, Calcium propionate, Epinephrine, Excipients, Flunixin, Furosemide, Kaolin Pectin, Magnesium oxide, Magnesium hydroxide, Moxidectin, Peracetic acid, Pheromones, Poloxalene, Potassium sorbate, Propylene glycol, Tolazoline, and Xylazine. OMRI asks the NOP to address the status of these recommended substances.

The NOSB also recommended that two agricultural substances be included on 7 CFR 205.606: Gelatin and Shellac, Orange—unbleached. OMRI requests that the NOP either propose those substances to be added to the National List or issue a statement that the substances are required to be from an organic source if used in or on processed products labeled as 'organic.' OMRI has three products that are Unresolved in waiting for the determination of the NOP if shellac is available from an organic source.

Conclusion

The information on the NOP website regarding petitions, NOSB recommendations, and NOP status does not appear to be current. Comment on this *Federal Register* notice would be better if the site had up-to-date information.

Based on OMRI's interaction with the organic industry, we perceive a need for NOP to provide guidance concerning materials that the NOSB has reviewed and provided reasonable recommendations and annotations, but which have not yet been included in a Federal Register notice. Lacking NOP guidance, individual certifiers and producers are confused and thus at risk of inadvertently violating the organic regulations.

OMRI appreciates the opportunity to comment on these proposed amendments. We support the work of the NOP and NOSB in developing the National List. We also support a public process that maintains a strong organic program to ensure continued success for organic producers. We would appreciate a response from the NOP on those substances not proposed to be added to the National List and look forward to a more transparent process in the future amendments that will be proposed.

Respectfully submitted,

Dave DeCou
Executive Director
Organic Materials Review Institute