

**NATIONAL CAMPAIGN FOR  
SUSTAINABLE AGRICULTURE**

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June 2, 2003

Richard Matthews, Program Manager  
National Organic Program,  
USDA-AMS-TMP-NOP  
1400 Independence Ave, S.W.  
Room 4008 – So., Ag. Stop 0268  
Washington, D.C., 20250

RE: Docket Number TMD-03-02  
FR 27941, V.68, No. 99, Thursday, May 22, 2003  
**National Organic Program; Proposed Amendments to the  
National List of Allowed and Prohibited Substances**

Dear Mr. Matthews:

The following constitute comments on the above-referenced Docket.

**Inadequate Comment period**

On May 23, 2003, The National Campaign for Sustainable Agriculture Organic Committee requested an extension to the deadline for comments to this Proposed Rule amending Section 205.605 of the National List.

This request was for an extension to June 23, 2003 – a reasonable 30-day comment period. A 10-day comment period, especially over a holiday weekend, provides too short a time for the preparation of substantive comments: in fact it was really only 6 working days.

In addition, it was not until Friday, May 29, 2003, that the Federal Register Notice was finally added to the NOP website, making it nearly impossible for any but the most savvy Federal Register watchers to have known there was a comment period.

In general, the 10-day public comment period allows little opportunity for those without computers and internet access to become aware of the Docket, much less compile detailed comments. It must not be forgotten that there is a large segment of the population that does not have daily access to the internet. A recent Organic Farming Research Foundation survey with 1000 organic farmer respondents, found that 22% of those responding had no internet access whatsoever.

By using the internet as the *sole* method of informing the public, rural and under-resourced populations have been left out of the process altogether. Where groups such as the National Campaign for Sustainable Agriculture attempt to mitigate that with public outreach to some of the organizations serving these populations, the 10-day comment period prevents any such attempt – there is simply not enough time.

Finally, The National Campaign for Sustainable Agriculture Organic Committee requests that

the National Organic Program institute a policy of 30-day absolute minimum for all public comment periods (including Federal Register notices as well as other policy proposals).

The following comments were compiled by the Organic Materials Review Institute (OMRI), and are used with their permission as our substantive comments on the materials:

### **NOSB Recommendations Not Included**

In the proposed rule notice, the NOP states, “This proposed rule would amend the National List to reflect recommendations submitted to the Secretary by the NOSB from November 15, 2000 through September 17, 2002. Between the specified time period, the NOSB has recommended that the Secretary add five substances to §205.605 of the National List based on petitions received from industry participants.”

Between November 15, 2000 and September 17, 2002, the NOSB recommended three substances be added to §205.605(a), 8 substances be added to §205.605(b), and 2 substances be added to §205.606. Furthermore, the NOSB recommended that annotations be changed for 2 substances currently on §205.605(b) (ethylene for degreening of citrus, and potassium hydroxide for peeling of peaches.) See the chart below for a complete list of processing substances NOSB has recommended that have not been addressed by either the April 22, 3003 Federal Register notice, or this current docket.

Please provide a regulatory justification for not including substances such as **activated carbon**. This is a filtering aid, widely used, similar in function to powdered cellulose, which was added. Activated carbon is considered a secondary direct additive when used as a boiler chemical, and is also considered a processing aid that is not listed as a food contact substance for filtering uses under FDA regulations. It is similar in function to other materials on the National List, such as perlite and diatomaceous earth used as filter aids. Since it does not appear in the docket, this material remains prohibited.

Similarly, the NOSB approved limited use of certain volatile **boiler chemicals**, which are considered secondary direct food additives under FDA regulations. These were subject of lengthy review and public comment, and also remain prohibited at this time.

**Peracetic acid** is a sanitizing agent used in rinse and wash water. This was approved by the NOSB in November of 2000, and is a valuable tool for managing food safety. It has advantages over chlorine use, and is used in commercial applications. The absence of this listing deprives the organic industry of a needed “green” post harvest handling technique.

As noted in comments filed April 28, 2002 by OMRI, this amendment also fails to list **orange shellac** and **gelatin** as permitted additives, despite the fact that they were recommended by the NOSB in May of 2002. OMRI is unable to review at least three separate products designed for use in organic fruit coatings due to this delay. These products, used to facilitate shipment of organic citrus will not be available in time for the 2003 citrus crop if shellac is not added to the list soon.

NOSB voted that shellac and gelatin are deemed to be “agricultural” ingredients subject to the

requirements of 205.606 regarding commercial availability. We note that there has been no clarification of the standard for commercial availability, which was subject to a public comment period at the time of final rule publication in December 2000. We would appreciate clarification of this standard and whether in fact agricultural substances deemed not commercially available need to be listed in section 205.606. We recommend that the approved status of these materials be clearly identified in context of the National List.

The NOP regulations and the National List should be updated to reflect NOSB recommendations. Absence of many of the NOSB recommended materials from the National List and the proposed amendment dockets creates undue hardships for the organic industry.

We also remain concerned that the 13 high-priority livestock medications approved by the NOSB have not been included in the proposed amendments, particularly given the urgency with which they were addressed by the NOSB. (see OMRI comments on docket TM-02-03). In October 2002, NOSB also recommended a specific allowance for excipients used in animal drugs to permit formulations of medical products containing approved active ingredients. We hope these missing items will be subject of a forthcoming docket, out of concern for prudent farm management and animal welfare.

### **Suggested Changes**

1. The listing for **cellulose** should be adjusted to accurately reflect the technical form of the substance. We suggest the following changed (underlined and strikeout)

205.605(b) cellulose, powdered ~~--for use in regenerative casings~~, as anti-caking agent (non-chlorine bleached) and filtering aid

205.605(b) cellulose, as regenerative casings.

These are two distinct forms of cellulose that should be listed as separate items. There are many cellulose derivatives that are used as food additives, including Hydroxypropyl methylcellulose and Methyl Carboxyl Cellulose (MCC)- both of which were rejected by the NOSB. The term “powdered cellulose” is recognized as a specific, less highly refined food additive and should be included in this name. In future, for clarity NOP should include all the FAO Individual Numbering System (INS) numbers to identify food additives, which may go under different names. OMRI can assist in providing this identification, on request.

2. **Tetrasodium pyrophosphate – (TSPP)**- We find the annotation for “use only in textured analog meat products” to be vague. There is no definition provided for “textured analog meat product,” which is not a common food term. We request clarification of the types of food products for which this substance is approved. It appears that any non-meat based product that makes an artificial meat claim might qualify, and we believe this requirement would be inconsistently implemented by certification agencies without further clarification. The primary use of this material appears to be to create a texture that is similar to a meat product, however this 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 and functionality of TSPP from the petitioner prior to its September 19, 2002 meeting and did not provide this to the public. As a processing aid that is exempt from labeling in the final product under FDA regulations, the inclusion of this material in organic products without clear consumer identification presents additional concerns. The lack of transparent review in this case undermines the process for collaborative public –NOSB review of materials and the integrity of the organic standard.

This material is not approved internationally and the basic forms of phosphate food additives (mono, di, and tri-phosphate forms) for use only in meat and dairy products are subject of debate at the CODEX level at present, with objections raised by the EU delegates and IFOAM. We believe an extended review and comment period is needed for this substance in view on the desirability of international harmonization of organic standards. This comment period is not sufficient for affected international parties to comment.

In addition, the NOSB has recommended an additional polyphosphate food additive be listed, (sodium acid pyrophosphate or SAPP –May 14, 2003) without any public availability of the TAP review documents or petitions for these substances. Both recommendations should be tabled, in order that public review can be adequate. All information supporting the TSPP and SAPP decisions should be made publicly available for comment prior to any listing in a final amendment to the National List.

We request that **TSPP be withdrawn** pending further clarification and more opportunity for public comment.

**3. Remove Natural Colors** – This amendment to the processing section of the National List once again fails to remove Natural Colors from the regulation. This substance was never reviewed by NOSB, and cannot be listed without violating the OFPA at 6517(d)(2) which states– “*No additions*” unless recommended by the NOSB. OMRI believes that “natural colors” may be primarily synthetic, do not have a FDA or NOSB definition and should not be included. Please explain the justification for their continued inclusion.

### **Conclusion**

We would like to stress the importance of following good administrative procedure in opening the proposed amendment dockets to public comment for a period that provides adequate time for review and preparation of comments. Transparency is a critical component of the collaborative process set out in OFPA, which envisioned a collaborative relationship between the NOSB and NOP to provide the public and industry with standards of high integrity.

**Processing Substances recommended by the NOSB from Nov. 2000 – May 2003**

<b>Material</b>	<b>NOSB Recommended category</b>	<b>NOSB Date of vote</b>	<b>NOSB recommendation and annotation</b>	<b>NOP Docket language</b> 68 Fed Reg 27941, May 22, 2003 7CFR 205 ( <u>additions and changes to December 21, 2000 Rule</u> )
<b>Processing</b>				
activated carbon	205.605(b)	9-19-02	Allowed with the annotation: <u>from vegetative sources only for use as filtering aid</u>	Not added.
ammonium hydroxide	205.605(b)	10-01	Synthetic, allowed. <u>For use as a boiler additive only until Oct. 21, 2005</u>	Not added.
calcium sulfate	205.605(a)	05-01	Nonsynthetic. <u>Allowed from nonsynthetic sources only.</u>	<u>205.605(a) Calcium sulfate - mined</u>
cellulose	205.605(b)	10-01	Synthetic, allowed. <u>For use in regenerative casings, as anti-caking agent (non-chlorine bleached) and filtering aid.</u>	<u>205.605(b) cellulose --for use in regenerative casings, as anti-caking agent (non-chlorine bleached) and filtering aid</u>
cyclohexylamine	205.605(b)	10-01	Synthetic, allowed. <u>For use only as boiler water additive for packaging sterilization only.</u>	Not added.
diethylamino-ethanol	205.605(b)	05-07-02	Synthetic, allowed. <u>For use only as boiler water additive for packaging sterilization only.</u>	Not added.
enzymes, animal derived	205.605(a)	11-00	Nonsynthetic, allowed. <u>Rennet (animal derived); catalase (bovine liver); animal lipase; pancreatin; pepsin; trypsin.</u>	Added as synthetic – <u>205.605(b) Animal enzymes Rennet animals derived; Catalase -bovine liver; Animal lipase; Pancreatin; Pepsin; Trypsin.</u>
Egg white lysozyme	205.605(a)	5-14-03	Allowed, as an animal derived enzyme	Not added
gelatin	205.606	05-07-02	Approved as agricultural, must be from organic source when commercially available	Not added.
glucono delta-lactone	205.605(a)	9-19-02	Nonsynthetic, Allowed with the annotation: <u>produced through microbial fermentation of carbohydrates only.</u>	<u>205.605(a) Glucono delta-lactone</u>
hydroxypropyl methylcellulose (HPMC)		9-19-02	Prohibited, for use in Made with Organic category and Organic	Not added.
octadecylamine	205.605 (b)	10-01	Synthetic, allowed. <u>For use only as boiler water additive for packaging sterilization only.</u>	Not added.
L-malic acid	205.605(a)	5-14-03	Nonsynthetic, allowed, <u>from microbial fermentation of carbohydrate substances</u>	Not added
Microorganisms	205.605(a)	5-14-03	Nonsynthetic, allowed, any food grade fungi, bacteria, and other microorganisms	Not added

<b>Material</b>	<b>NOSB Recommended category</b>	<b>NOSB Date of vote</b>	<b>NOSB recommendation and annotation</b>	<b>NOP Docket language</b> 68 Fed Reg 27941, May 22, 2003 7CFR 205 ( <u>additions and changes to December 21, 2000 Rule</u> )
peracetic acid	205.605(b)	11-00	Synthetic, allowed. <u>For direct food contact only in wash and/or rinse water. Allowed as sanitizer on surfaces in contact with organic food.</u>	Not added.
potassium hydroxide	205.605(b)(27)	10-01	Synthetic, allowed. Amend annotation to read: <u>Prohibited for lye peeling of fruits and vegetables except when used for peeling peaches during the individually quick frozen production process.</u>	<u>205.605(b) Potassium hydroxide - Prohibited for lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process..</u>
Sodium Acid Pyrophosphate	205.605(b)	5-14-03	Allowed, <u>for use only as a leavening agent</u>	Not added
shellac, orange deflaked (unbleached)	205.606	05-07-02	Approved as agricultural, must be organic when available	Not added.
tetrasodium pyrophosphate	205.603(b)	9-19-02	Allowed with the annotation: <u>for use only in textured meat analog products</u>	<u>205.605(b) Tetrasodium pyrophosphate- for use only in textured meat analog products</u>

Thank you for the opportunity to comment. We reiterate our hope that NOP will move to a more transparent mode of operation, and provide the public with reasonable comment periods.

Sincerely,

Liana Hoodes for the *National Campaign for Sustainable Agriculture Organic Committee*  
Co-Chairs:

Michael Sligh, *Rural Advancement Foundation International*

Elizabeth Henderson, *Peacework Organic Farm, Northeast Organic Farming Assoc.NY*

cc: Senator Tom Harkin  
Senator Patrick Leahy  
Congressman Jim Walsh  
Congressman Peter DeFazio  
Congressman Sam Farr