

**Formal Recommendation by the
National Organic Standards Board (NOSB)
to the National Organic Program (NOP)**

Date: April 29, 2011

Subject: Classification of Materials

Chair: Tracy Miedema

The NOSB hereby recommends to the NOP the following:

Rulemaking Action
Guidance Statement
Other x

Statement of the Recommendation (Including Recount of Vote):

The Materials committee provided an update and proposed guidance to continue the work of the National Organic Standards Board on classification of materials. The document included an update on the committee's work on classification and two action items related to classification of materials.

The first action item was a motion to rescind the April 2010 NOSB recommendation adding a second sentence to the definition of chemical change. This second sentence was added to address public comment received at the November 2009 NOSB meeting saying that the definition of chemical change, as recommended by the NOSB at that meeting, was too broad. Since the April 2010 meeting it has become clear to the committee that the public comment could be addressed through the guidance document being developed and did not need the additional sentence added to the definition of chemical change. Therefore the committee recommended rescinding the second sentence. Public comment received at the April 2011 meeting uniformly supported rescinding the second sentence. The NOSB voted 14 yes and 0 no in favor of the motion to rescind the April 2010 NOSB recommendation adding a second sentence to the definition of chemical change.

The second action item in the Materials committee document was proposed guidance that a significant level of a synthetic substance in the final material means a level exceeding any applicable regulatory limits, where in effect for the material being classified, and a level without any technical and functional effects in the final material. Providing clarity to how to approach what is a significant level of a synthetic substance remaining in a final material being

classified has been a consistent request of public comment during the time NOSB has been working on classification. The guidance proposed by the Materials Committee received mixed public comment. Public comment was unified that the classification work needs to be completed since it is foundational to so many board decisions.

Key points of the NOSB discussion on the second action item were:

- What are technical and functional effects? How are they different?
- Is it 'a level exceeding applicable regulatory limits AND a level without technical/functional effects'? Should it be 'OR a level without technical/functional effects'?
- What are the implications to current classification of materials with this guidance?
- Examples of how the proposed guidance would be used in practice were needed to clarify for the board its application

The Materials Committee asked that the board vote on the proposed guidance, despite the questions, so that the committee could proceed with the guidance document on classification with an understanding of the perspective of the full board on this important topic. The motion was to accept the proposed guidance that a significant level of a synthetic substance in the final material means a level exceeding any applicable regulatory limits, where in effect for the material being classified, and a level without any technical and functional effects in the final material. This motion was made by Katrina Heinze and seconded by Steve DeMuri. The vote was 8 yes and 6 no. Since the vote was not decisive, the motion failed and the proposed guidance was sent back to the Materials Committee for further refinement.

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

See accompanying recommendation

Committee Vote:

Moved: Katrina Heinze		Second: Tina Ellor		
Yes: 8	No: 6	Abstain: 0	Absent: 0	Recusal: 0

**National Organic Standards Board
Materials Committee
Update and Proposed Guidance Document
Classification of Materials**

April 29, 2011

At the November 2009 National Organic Standards Board (NOSB) meeting, the NOSB passed a recommendation on Classification of Materials. The recommendation included several “Next Steps,” that the NOSB felt were required in order for the recommendation to be implemented. The primary further work required of the NOSB was development of a Guidance Document that the various stakeholders (e.g., Accredited Certifying Agents, committees of the NOSB, National Organic Program personnel) could use when classifying materials.

At the April 2010 NOSB meeting, the Joint Materials and Handling Committee presented a draft Guidance Document for public input. It was clear from that public input that the guidance document needed more work. Key points from public comment were:

- The draft guidance document accurately reflected the November 2009 NOSB recommendation
- Separate guidance documents for crops, livestock and handling inputs are needed
- Examples of crops and livestock material and how they would be evaluated need to be included
- Agreement with the committee that further clarification was needed in determining whether materials contain a “significant” amount of a synthetic input in the final material.

At the same April 2010 NOSB meeting, the NOSB passed an addendum to the definition of chemical change that the NOSB had recommended at the November 2009 NOSB meeting.

In September 2010, the National Organic Program (NOP) responded to the NOSB recommendations of November 2009 and April 2010. In general, the NOP’s comments aligned with those received in public comment at the April 2010 meeting. Additionally, the NOP did not support the addendum to the definition of chemical change.

The Materials Committee has been working in response to these comments to develop a final proposed guidance document. Unfortunately, we have not made as much progress as we would have liked and do not have a complete proposed guidance document available for public review and comment at this time. Key topics that we have discussed have been the format of a guidance document, clarification of significant level of synthetic input remaining in a material, definition of chemical change and scope of classification. The purpose of this document is to provide an update to the full NOSB, the NOP and the public.

Proposed Action -- Definition of Chemical Change

The definition of chemical change approved by the NOSB in November 2009 is:

Chemical Change An occurrence whereby the identity of a substance is modified, such that the resulting substance possesses a different distinct identity (see related definition of “substance”)

The April 2010 addendum approved by the NOSB is (shown as the underlined sentence):

Chemical Change An occurrence whereby the identity of a substance is modified, such that the resulting substance possesses a different distinct identity (see related definition of “substance”). Processing, as defined in §205.2, of agricultural products using materials allowed on the applicable section of the National List (i.e., §205.601 for crops, §205.603 for livestock and §205.605 / §205.606 for handling), does not result in chemical change as it applies to classification of materials.

We appreciate the NOP’s perspective on this second sentence. This recommended second sentence was the focus of much public comment at the April 2010 NOSB meeting and was edited several times by the committee during the meeting in response to public comment. After reviewing the topic and the original intent of the addendum, the Materials Committee is recommending that the NOSB rescind their April 2010 recommendation adding the second sentence to the definition of chemical change. We believe that we can address the concerns that prompted the addition of the second sentence, discussed below, through a guidance document.

The intent of the addendum was to address “whether chemical changes generated during processing methods specifically allowed in the Organic Foods Production Act (OFPA) and/or allowed National List materials, would render an otherwise agricultural product “synthetic.” Public comment received at the November 2009 meeting showed a consistent concern that the recommended definition of chemical change, and its associated definition for substance, went too far and would result in a number of agricultural materials being classified as synthetic. A simple example to illustrate this point is toasted wheat kernels. Wheat kernels are clearly agricultural. When exposed to heat, the kernels toast resulting in chemical change. Public comment clearly indicated that classifying something like a toasted wheat kernel as synthetic was not the intent of OFPA.

The Materials committee agrees and will work with the original November 2009 NOSB recommended definition of chemical change within our guidance document to show that chemical changes generated during processing methods allowed in OFPA or with National List materials, where appropriate, do not result in a material being classified as synthetic.

Proposed Guidance -- Significant Amount/Level of Synthetic Input Remaining in the Material to be Classified

A key topic left unresolved in the April 2010 Draft Guidance Document was the question, “What is a significant amount/level of a synthetic input to the process remaining in the final material?” The Materials Committee spent the majority of our time on this topic evaluating two different approaches.

One approach we considered would be evaluate any known level of a synthetic substance in the final material or in the environment, as a result of the substance’s manufacture, use and disposal would be a significant level. In March 2006, in a response to NOSB, the National Organic Program wrote, “One of the primary determinants of whether a food can be considered ‘organic’ is whether it contains or was produced with ‘synthetic’ substances.”

Proponents of this approach suggest that consumer trust is paramount for long-term organic viability, requiring an assurance that organically labeled products meet a consistent standard in compliance with the OFPA statutory standard on synthetic agents and their allowance. OFPA states, “The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this title only if (A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances (i) would not be harmful to human health or the environment...” (Sec. 2118 [7 U.S.C. 6517]). While the law does not envision the use of purposefully added synthetic materials not on the National List, the list provides the mechanism for evaluating harm. This statutory intent is captured in the “Evaluation Criteria for Substances Added to the National List” with the questions, “Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A); §6518 m.4]?” and, “Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]?” Proponents believe this standard of review requires a determination as to whether there is harm associated with the use of the synthetic substance, and therefore subject to the National List review process. Under this approach, all synthetic inputs or residues must be examined to determine their associated health and environmental impacts.

The second approach we considered, and which ultimately received the support of the majority of the committee, was that a significant level of a synthetic substance in the final material means a level exceeding any applicable regulatory limits, where in effect for the material being classified, and a level without any technical and functional effects in the final material. Proponents of this approach believe this approach is more consistent with past NOSB practice and precedent, is consistent with the recommendation of the Material Working Group and reflects the bulk of the public comment we’ve received on this topic. Additionally, the majority of the Materials Committee was concerned with using an approach of “any known level” knowing that technology allows the detection of ever decreasing amounts of material. So a material that today has no known level of synthetic input in it may very well tomorrow have a detectable level. The majority of the committee felt that using the “any known level” approach would be disruptive to the industry as it differs from past practice and precedent and would lead to an on-going reevaluation of materials on a perpetual basis as detection levels change. As we discussed this approach, we acknowledge that a given material may not have any applicable regulatory limits or may have several. In the case where no regulatory limit is available, technical and functional effects of any remaining synthetic would need to be evaluated. In the case where, multiple regulatory limits exist, the reviewer should evaluate which best applies for the classification. For example, for a synthetic solvent used to extract a natural sourced material there may exist an OSHA inhalation limit and EPA tolerance level for an inert. Since the synthetic is present in a material to be used in crops, the EPA limit is most appropriate.

As a result of our discussions, the Materials committee recommends that the NOSB adopt as guidance that a significant level of a synthetic substance in the final material means a level exceeding any applicable regulatory limits, where in effect for the material being classified, and a level without any technical and functional effects in the final material. This guidance is intended to apply only in cases where a synthetic input is removed from the

final material with the intention of fully removing the synthetic input but complete removal is not possible. For example, extraction of a natural with a synthetic solvent.

Update -- Scope of Classification

The Materials Committee spent a considerable amount of time discussing the scope of classification and whether it should include evaluation of whether a material is allowed or prohibited for use in organic production or handling. Consistent with all past NOSB thinking on this topic, we concur that classification of a material is a separate evaluation step for a material from the evaluation of whether use of the material is consistent with organic practices.

While our conclusion may seem self-evident, we affirm that this is a critical topic for all boards to discuss and understand. As an example of the criticality of this distinction, a material, manufactured with a synthetic, may be classified as non-synthetic. However, the NOSB has a further obligation to determine whether use of that material is consistent with organic practices. In their review for classification, a NOSB committee may determine that while non-synthetic the material should be prohibited for use in organic production. Similarly, an ACA or Material Evaluation Programs may when reviewing a material determine that it is non-synthetic but during review of the manufacturing process develop concerns about its compatibility with organic practices. We believe that all stakeholders in the organic industry have an obligation to bring that information to the attention of the NOSB so that the NOSB can meet our statutory responsibility to review materials to determine if their use in organic production and handling is compatible with organic practices.

References

National Organic Standards Board Recommendations & other documents:

- Materials and Handling Committee, "Classification of Materials," May 24, 2010
- Materials and Handling Committee, "Classification of Materials," November 6, 2009
- Materials and Handling Committees, "Discussion Document on the Definition of Materials," October 19, 2007
- Handling Committee and Materials Committee, "Recommendations Relative to "Agricultural" and "Nonagricultural" Substances for National List Consideration," September 15, 2006
- Handling Committee, "Recommendations Relative to "Agricultural" and "Nonagricultural" Substances," July 14, 2005
- Materials and Handling Committee, "Clarification of the definition of Synthetic as it is applied to Substances Petitioned for Addition or Prohibition to the National List(s)," June 23, 2005

Material Working Group

- May 2008 presentation at National Organic Standards Board meeting titled "Clarification of Definitions -- Agricultural vs. Non-agricultural"

- November 2008 presentation at National Organic Standards Board meeting titled “Clarification of Definitions -- Agricultural vs. Non-agricultural”
- May 2009 presentation at National Organic Standards Board meeting titled “Clarification of Definition of Synthetic Substance”

National Organic Program

- Memorandum for the Chairman of the National Organic Standards Board, “National Organic Standards Board Recommendations (April 2010 & November 2009),” September 30, 2010
- “Evaluation of the NOSB Recommendation on the Definition of Synthetic,” March 9, 2006

Committee Vote

Motion: To rescind our April 2010 recommendation adding a second sentence to the definition of chemical change

Motion: Katrina Heinze Second: Tina Ellor
Yes: 6 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Motion: move to accept this update to the public and the proposed guidance that a significant level of a synthetic substance in the final material means a level exceeding any applicable regulatory limits, where in effect for the material being classified, and a level without any technical and functional effects in the final material.

Motion: Katrina Heinze Second: Tina Ellor
Yes: 4 No: 2 Absent: 0 Abstain: 0 Recuse: 0