

**National Organic Standards Board
Materials Committee
Discussion Document
Significant Residues Definition in Classification of Materials Policy
March 27, 2012**

This discussion paper addresses a key issue left unresolved in the Materials Classification Policy adopted by the Board. The Addendum to November 6, 2009 Recommendation on Classification of Materials states that, “It is our intent through this recommendation that a material would be classified as synthetic when: . . . The material contains, at a significant level, a synthetic substance not on the National List of allowed synthetics.” However, the Board did not clarify this guidance by defining “significant” in this context.

The dictionary defines “significant” as “important” or “of consequence.” However, the question that remains is what level of a synthetic impurity found in a material under review is determined to be “of consequence” under the Organic Foods Production Act (OFPA). This discussion paper asks how the NOSB should apply the framework of OFPA to the definition of “significant.” Three different approaches are presented, and input is sought on the broad approach as well as details.

Materials Classification Policy

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 are required in order to implement the recommendation. In passing the recommendation, the NOSB indicated that further work is required of the Board to develop 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At the April 2010 NOSB meeting, the Joint Materials and Handling Committee presented a draft Guidance Document for public input.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. A key topic left unresolved was the question, “What is a significant amount/level of a synthetic input to the process remaining in the final material?” Prior to the April 2011 meeting, the Materials Committee evaluated two different approaches in the context of work on a classification of materials worksheet. They are discussed, along with a third approach, in “Issues and Discussion” section below.

OFPA and the Rule

The underlying statutory standard in the Organic Foods Production Act with regard to synthetic agents and their allowance is found in Sec. 2118 [7 U.S.C. 6517] National List, (c) Guidelines for Prohibitions on Exemptions.– (1) Exemption from Prohibited

Substances in Organic Production and Handling Operations.– 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...” The list criteria provide the mechanism for evaluating harm for all substances by weighing information from the other agencies along with the unique organic considerations.

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)(i); §6518(m)(4)]” and, “Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]” The scope of the possible harm that OFPA requires the NOSB to examine is identified in the question, “Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518(m)(3)]”

Issues and Discussion

In the context of OFPA and materials classification, a level of a synthetic impurity is “significant” when it is “of consequence” to materials classification and review. A major issue in defining “significant” is the degree to which harm must be identified before deciding the residue is significant. We also understand that decisions about significant residues are made not only by the Board, but also by materials review organizations (MROs) and certifiers, and that a definition of “significant synthetic residue” must allow MROs and certifiers to act on the information available to them. Two of the three approaches outlined below were discussed in the April 2011 Materials Committee Recommendation.

The first approach is the one proposed by the Materials Committee in the April 2011 recommendation, which failed to pass the Board by the required 2/3 margin. This approach says that an insignificant level of a synthetic substance in the final material means a level below any applicable regulatory limits for the type of substance and without any technical and functional effects in the final material. Proponents of this approach believe this approach is more consistent with past NOSB practices, is consistent with the recommendation of the Materials Working Group and reflects the bulk of the public comment 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 would lead to an on-going reevaluation of materials on a perpetual basis as detection levels change. As this approach was discussed, it was acknowledged 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 would evaluate which best applies for the classification. For example, for a synthetic solvent used to extract a natural sourced material there may be an OSHA inhalation limit and EPA residue limit. Since the synthetic is present in a material to be used in crops, the EPA limit is most appropriate.

The second approach was supported by a minority of the Materials Committee in April 2011. It would characterize any known or detectable level of a synthetic substance in the final material or in the environment, as a result of the substance's manufacture, use, and disposal as a significant level triggering NOSB review. Proponents of this approach point to the statutory standard in OFPA §6517(c)(1) with regard to synthetic agents and their allowance. Proponents believe this standard of review requires a determination as to whether there is harm associated with the use of the synthetic substance, analogous to the standard of review used in the process of allowing synthetic substances on the National List. The minority felt that citing regulatory standards set under different statutory criteria does not meet the OFPA intent or standards, but, like all other regulatory standards, we must be prepared to adjust regulatory action to advances in good laboratory practices as they improve. Finally, proponents believe that the quantity of synthetic residue is not the sole determinant of "harm" in the end product. The minimal residue that causes harm may not be known, and harm may be more dependent on other factors, like timing of exposure, than dose. Furthermore, OFPA requires consideration of the material's residual harm from manufacture to disposal, including its use in organic agriculture or processing.

A third approach acknowledges that MROs and certifiers have to make frequent evaluations of a variety of residues that occur in both food processing and crop inputs that do not always come to the attention of the NOSB because they are not petitioned or may change frequently. Therefore, the NOSB would need to offer guidelines to screen these potential synthetic residues rather than review each one. What would emerge would be a screen for all synthetic residues by evaluating them against a list of known harmful chemicals created by governmental and international organizations to determine whether they are significant. This process might be applied in field situations by Material Review Organization (MROs) and certifiers when a full NOSB review is not practical. Slightly different screens for crop inputs and food ingredients may be used because there are different sources of information on them and they are handled differently in the regulation. The first two steps in the screening process would be, "What chemical is it?" "Is it measurable?" Then, it would be compared to lists of known harmful materials. If the chemical is found on one of the lists of known harmful materials, then the residues would be considered significant and this would trigger a full NOSB review. In this scenario the guidelines would appear in the NOP Program Handbook or in guidelines for MROs and the individual impurity chemicals would not have to appear on the National List.

Comments Requested

The Committee requests comments on the following questions:

1. Under what circumstances, should the presence of a synthetic impurity trigger an examination of the impacts of the synthetic in relation to OFPA criteria?

2. Do any of the three approaches described make sense? If so, why?
3. Is it reasonable to tie the definition of “significance” in materials classification to the need for review under OFPA? If not, is there another way to ensure that the presence of a synthetic impurity in levels of consequence under OFPA trigger a review? And how would “significance” be defined in the context of materials classification if not in relation to the need for review under OFPA?
4. The need for defining a significant residue arises from the Classification of Materials Policy adopted earlier that says that the use of a synthetic extractant or reactant does not affect the classification of a material, thereby allowing the use of synthetic extractants, reactants, or processing aids that may end up as impurities in the material. Should that policy be changed instead?
5. When residues of a certain synthetic impurity are identified as significant, how should the review proceed (a) if the material containing the impurity is under review by a MRO prior to use, (b) if the significant residues are discovered by a MRO/ACA when the material is in use, (c) if the material is under review by the NOSB?

Committee Vote:

The Materials Committee moves to accept this document and present it for full Board discussion at the spring 2012 NOSB meeting:

Moved: Jay Feldman Second: Jennifer Taylor

Yes: 5 No: 0 Abstain: 0 Absent: 1