

## Public Comments on Significant Residues in Classification of Materials Policy Discussion Paper

### Short public comments

- A number of individuals advocated clarifying the policy on significant residues and defining significant residues of a synthetic as any (detectable) residue (10).

- CCOF:

“any policy made must be achievable by certifiers and MROs.”

- Wolf, DiMatteo and Associates (WDA) supports OTA comments.
- Small Planet Foods (SPF) supports OTA comments and offers the following additional comments:
  - The topic of significant residues should be addressed within the whole of a materials review policy.
  - Discussion should occur within the context of specific materials whose classification has long been established.
  - Look to the OFPA preamble and Senate Report on OFPA for guidance.

- Midwest Organic and Sustainable Education Service (MOSES) supports the comments of the National Organic Coalition and says,

“By having a strict interpretation on residues and definitions that affect the classification of ingredients used in organic foods, we encourage research into formulations and processing strategies that avoid synthetics.”

### Longer comments that addressed questions in more depth were received from Beyond Pesticides, National Organic Coalition (NOC), Organic Materials Research Institute (OMRI), Organic Trade Association (OTA), Cornucopia Institute, and Marsha Kopral.

- Beyond Pesticides says:

“The need to define “significant residue” arises from the Classification of Materials Policy 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....

The Classification of Materials Policy is contrary to OFPA, which requires the examination of *all* synthetics used in organic production and handling, including their impacts from their manufacture, use, and disposal. *Somehow* that examination must be made. Since the NOSB does not have routine oversight of nonsynthetic substances, substances made using a synthetic extractant, reactant, or processing aid must be classified as synthetic either by virtue of the use of those synthetics in their manufacture or because there is a significant residue of the synthetic extractant, reactant, or processing aid in the substance. We prefer the former approach because the cradle-to-grave impacts of the synthetics used are relevant regardless of the level of residue.

- NOC says:
 

NOC proposes that, for the purpose of regulation of organic food, a “significant” residue be defined as any residue above the level of detection for a compound, element, or organism. As required in §205.670 of the NOP regulations, methods of analysis related to implementation of the regulations are provided in the most current edition of the *Official Methods of Analysis of the AOAC International*. This reference, which is maintained by the Association of Official Agricultural Chemists, a non-profit scientific organization whose primary purpose is to serve the needs of government, industry, and academic laboratories, provides not only detailed instructions on how to perform analyses, but also information on how to interpret the results of a wide range of chemical and microbiological tests. AOAC states that its *“Official Methods Program is designed to provide methods of analysis with known performance characteristics, such as accuracy, precision, sensitivity, range, specificity, limit of measurement [emphasis added], and similar attributes.”* Therefore, NOC asserts that the AOAC information on “limits of measurement” provides the most appropriate basis for defining the term “significant” as used in the discussion of “significant residues.”
- Cornucopia says:
 

Any residue of a synthetic is “significant” and should trigger review. Under OFPA, synthetics are prohibited unless reviewed and approved, and non---synthetics are approved unless reviewed and prohibited. This is why it is so important to ensure that any materials that are produced with the use of synthetics be classified as synthetics, since this is the only way to trigger the required review by the NOSB.

We support the following definition of “significant”:

*“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.”*
- OTA, SPF, OMRI, WDA, and White Wave Foods ask the board to postpone consideration of this issue until the NOP issues guidance on the classification of materials.
- Marsha Koprak says:
  - By setting a limit of none detectable, it significantly impacts a company’s ability to manufacture and promote products that are healthy, safe and desired by consumers.
  - I do not believe it is practical to state that any level of a synthetic substance that is known or detectable would render a food unacceptable for use in organic products. Under this scenario, the use of food grade grease on food processing equipment might not be allowed which would eliminate the use of many processing operations for organic foods.
- OMRI introduced its comments by explaining the flow chart the organization uses to evaluate materials.
- In response to 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?**

- Beyond Pesticides, NOC, and Cornucopia say that any detectable level of a synthetic impurity should trigger an examination of the impacts of the synthetic.
- OTA says,
 

This question depends on whether the review is being conducted by NOSB or by a certifier or MRO. For the certifier or MRO, review of a synthetic residue would be the final step of determining whether a material is non-synthetic. If the synthetic residue is significant, it would not trigger NOSB review but rather the input would be denied, or allowed if that synthetic were on the National List. At the NOSB level, an otherwise prohibited material under review for addition to the National List would be evaluated to OFPA criteria.
- Marsha Koprak says, “In a situation where any one of these criteria is met (above regulatory limit, having a technical effect or having a functional effect), the residue would be considered to be present at a significant level.”
- OMRI says,
 

Currently OMRI refers any product containing prohibited materials to the petition process with the NOSB for review at the manufacturer’s discretion. The product may contain a synthetic material left over from the processing of the product, or the manufacturing of the product itself renders it synthetic. Again, we would only refer a product manufacturer to the NOSB if a reasonable removal step of all synthetics not on the National List was not apparent in the manufacturing process.

**2. Do any of the three approaches described make sense? If so, why?**

- Beyond Pesticides, NOC, and Cornucopia support the second approach because (as stated by Beyond Pesticides):
 

there is no level of residue that can be considered non-significant or insignificant. Therefore, under OFPA, any residue of a synthetic that is a function of the production, handling, or processing process is by definition significant. The OFPA standard, as stated in 7 USC 2517(c)(1) states this clearly.

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...”
- OTA supports the first approach “because it is consistent with past NOSB practice and precedent,” citing a 2005 recommendation:
 

As long as a chemical reaction does not occur, the substances that are removed from a natural occurring plant, animal or mineral source are non-synthetic, provided any synthetic substance used in the extraction process do not remain in

the final product above insignificant levels and do not have any technical or functional effect.

- OTA expresses a hope that NOP will clarify the reference to applicable regulatory limits in its guidance. OTA cites concerns about disruptions to industry and expresses a concern about the “consistency of detecting “any known level” as this would depend on the detection method, which would be a moving target over time.” OTA also says “[T]here are aspects of the third approach that should be incorporated, namely providing certifiers and MROs with guidance on how to determine if a synthetic residue is significant.”
- Marsha Koprak supports the first approach because although low levels of incidental contaminants may enter the food supply, they have no health or environmental significance unless they exceed regulatory limits or have a technical or functional effect in the final material.
- OMRI says,

Although each approach has pros and cons, it is OMRI’s opinion that the first, originally recommended approach of evaluating the technical and functional effects of the synthetic substance in the final material is the most reasonable. In discussing how we would implement such a practice, OMRI technical staff agrees that this approach will be the most consistent and reasonable way to go forward. In our examples above with potassium sorbate, when evaluating the technical or functional effect, neither product would contain “significant residues” of potassium sorbate such that it would exert preservative effects on the final product.

We do not agree with the third approach comparing any residues to a list of “harmful chemicals.”

[Note: to fully appreciate OMRI’s comments, it is necessary to go through the flow chart with their examples.]

- 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?**

- Beyond Pesticides says,

The Classification of Materials Policy is contrary to OFPA, which requires the examination of *all* synthetics used in organic production and handling, including their impacts from their manufacture, use, and disposal. *Somehow* that examination must be made. Since the NOSB does not have routine oversight of nonsynthetic substances, substances made using a synthetic extractant, reactant, or processing aid must be classified as synthetic either by virtue of the use of those synthetics in

their manufacture or because there is a significant residue of the synthetic extractant, reactant, or processing aid in the substance.

- Cornucopia says, “The use of the term “significance” is confusing. The only way to ensure proper review is by requiring review of any substance with 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.”
- 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?**
- Beyond Pesticides and Cornucopia would prefer changing the classification of materials policy so that substances made using a synthetic extractant, reactant, or processing aid would be classified as synthetic by virtue of the use of those synthetics in their manufacture.
  - OTA says, “First, this question does not accurately convey the Classification of Materials Policy. The policy adopted states that the use of a synthetic processing aid does not affect the classification of a material **IF** it does not result in a chemical change or if it does not remain in the final product in a significant amount.”
  - OTA and OMRI say that the issue should be tabled until the NOP publishes draft guidance.
- 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?**
- Beyond Pesticides says,  
If residues of a synthetic in a material classified as a nonsynthetic are discovered to be significant by a Material Review Organization (MRO) prior to use, the MRO prohibits its use and notifies the NOP that the material appears to be a synthetic, requiring listing on the National List. If discovered while the material is in use, the MRO should similarly notify the NOP that the material appears to be a synthetic. If the NOSB discovers that synthetic residues are significant in a material classified as a nonsynthetic, then it should reclassify the material as synthetic and notify the manufacturer that it will need to be listed on the National List in order to continue its use in organic production or handling. If significant residues of a synthetic are discovered in a synthetic material on the National List, the NOP should be notified so that the new information can be addressed in the next sunset review.

- OTA says, “If the residue is synthetic, it needs to be on the National List. If it’s not on the National List, the material cannot be allowed.” It also says,  
In support of the Compliance, Accreditation and Certification Committee recommendation on Criteria for MROs, we also urge NOP to expedite its work as stated in the MRO recommendation:  
Establish that material review organizations may not make synthetic vs. non-synthetic or agricultural vs. non-agricultural determinations except when made in strict compliance with NOP guidance. **We urge NOP to expedite the publication of clear guidance for making such determinations, based on earlier recommendations of NOSB.** The classification of materials is of foundational importance to the integrity of organic products, and such **guidance is extremely critical, given the thousands of synthetic vs. non-synthetic and agricultural vs. non-agricultural determinations made by certifiers each year.**
- OMRI says,  
In this situation, OMRI currently prohibits the product and refers the manufacturer to petition the NOSB at their discretion; or the manufacturer can reformulate and reapply at a later date (b) in this situation, OMRI suggests that the ACA/MRO discontinue the approval of the product and refer the manufacturer to petition the NOSB at their discretion; (c) the NOSB should elicit public comment, make a recommendation, and allow the NOP to issue guidance, proposed rule, or policy.