Public Comments on Extractants and Solvents Discussion Paper

Short public comments

- A number of individuals advocated clarifying the policy on extractants (10) and maintaining a prohibition on use of volatile synthetic solvents (12).

- CCOF:

"any policy made must be achievable by certifiers and MROs."

"The NOP has previously issued guidance through the question and answer format on their website that addressed the volatile synthetic solvent clause of the rule in §205.270. Since these questions have been taken down and are no longer publicly available, we urge you to provide current guidance on this issue. Once the NOP Classification of Materials policy comes out, this issue and the Significant Residues discussion can come back to the NOSB if necessary."

- Wolf, DiMatteo and Associates (WDA) supports OTA comments.
- Small Planet Foods (SPF) supports OTA comments and offers the following additional comments:
  - The topic of extractants 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), and Cornucopia Institute.

- Beyond Pesticides, NOC, and the Cornucopia Institute urge the board to make the prohibition on volatile synthetic solvents in processed food clear and consistent, to clearly define "volatile synthetic solvent," and suggested rewriting §205.270(c).
- 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.

- In response to questions:

1. **How should "volatile synthetic solvent" be defined, especially in relationship to the rule 205.270(c)2? Should we make a distinction between different types of solvents? If possible, reference to a standard scientific or regulatory definition is preferred. Should**

the toxicity of a volatile synthetic solvent affect how it is treated in classification and materials evaluation? Does supercritical carbon dioxide meet the definition?

- Beyond Pesticides, NOC, and the Cornucopia Institute supported the definition given in the discussion document. Beyond Pesticides suggested a change to clarify that supercritical carbon dioxide is not a volatile synthetic solvent: "A volatile synthetic solvent is a synthetic chemical with boiling point less than 287 degrees Celsius *at standard atmospheric pressure* that can dissolve another substance." All three organizations and Equal Exchange agreed that supercritical carbon dioxide is not a volatile synthetic solvent.

- OMRI says,
  Since handlers of "organic" and "made with organic" products can only use synthetic ingredients and processing aids on 205.605(b), and 205.270(c)(2) establishes that an organic handler may not use synthetic volatile solvents in producing a final certified organic product, a definition for "volatile synthetic solvent" would only be needed if such a substance was petitioned for addition to the National List at 205.605(b). While OMRI is not opposed to establishing a definition for "volatile synthetic solvent," we question whether it is necessary given the unlikely chance that a material would be petitioned for inclusion on 205.605(b), or that such a substance would pass the other criteria contained in OFPA for NOSB review of petitioned substances.

- OTA reminds us that §205.270(c)(2) applies to synthetic processing aids as well as volatile synthetic solvents and referred to a clarification formerly posted on the NOP website. OTA urges the NOP to formally clarify §205.270(c)(2).

2. **Is there a distinction between volatile solvents used for extraction vs. volatile solvents used for other purposes? Solvents are also used for purposes other than extraction, such as purification of a substance via crystallization. Solvents are also common inert ingredients in formulated pesticide products.**

- Beyond Pesticides and Cornucopia answered that the prohibition is against volatile synthetic solvents, however they are used. OTA points out that, "Historically, in the context of making synthetic and non-synthetic determinations, the focus is on extraction and manufacturing, and whether or not a synthetic substance (solvent, extractant or other processing aid) chemically changes the non-synthetic substance."

3. **Should the process of extraction change the classification of an agricultural product to a nonagricultural material? Does it matter whether the extractant is synthetic or nonsynthetic? When this happens to an agricultural material that is currently organically grown, does this changed material then need to be petitioned?**

- None of the commenters gave reasons supporting the change of classification from agricultural to nonagricultural because of the extraction process.

4. **Since §205.270 Organic Handling Requirements explicitly prohibits volatile organic solvents, ["(c) The handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented as "100 percent**

organic," "organic," or "made with organic (specified ingredients or food group(s))," or in or on any ingredients labeled as organic: **(2) A volatile synthetic solvent or other synthetic processing aid not allowed under §205.605: *Except,* That, nonorganic ingredients in products labeled "made with organic (specified ingredients or food group(s))" are not subject to this requirement"], should consumers expect that non-agricultural ingredients identified as "organic" be produced or extracted with the same restriction? Please explain the rationale for a different standard for agricultural and non-agricultural if that is the position.**

- Beyond Pesticides, NOC, and Cornucopia say that the prohibition on use of volatile synthetic solvents *only* by *certified* handlers and only in *agricultural* products is not logical. (See the flow charts from Beyond Pesticides comments.) They suggested rewriting §205.270(c):

  > (c) *Products sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s)),"* or in or on any *ingredients labeled as organic must not be made using*:
  > (1) Practices prohibited under paragraphs (e) and (f) of §205.105.
  > (2) A volatile synthetic solvent or other synthetic processing aid not allowed under §205.605: *Except,* That, nonorganic ingredients in products labeled "made with organic (specified ingredients or food group(s))" are not subject to this requirement *if the use of the volatile solvent is revealed in the ingredient statement*.

- OTA says the question doesn't make sense because non-agricultural ingredients are not identified as "organic." OTA also says,

  > It's important to note that the heading of § 205.605 refers to "ingredients" only. Under this section, a certified handler is allowed to use the listed substances referred to as "ingredients" in the 5% or 30% of a certified product. The reference to § 205.270(c)(2) is significant to the **handler** of a certified operation because it clarifies that **synthetic solvents and synthetic processing aids** used in or on products labeled "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s)),"** must also be on § 205.605 of the National List.

5. **Similarly, should synthetic substances allowed for use in organic crop production under §205.601 be allowed or prohibited from using volatile synthetic solvents in their production or extraction? Should nonsynthetic substances used in organic crop production be allowed or prohibited from using volatile synthetic solvents in their production or extraction, regardless of chemical change or significant residues?**

- Beyond Pesticides, NOC, and Cornucopia say that for materials used in crop production, the use of synthetic solvents in production is something that must be examined, so the extracted material should be classified as a synthetic.

- OTA says that if the use of the synthetic solvent or processing aid causes a chemical change or results in a significant residue, then the final material would be synthetic.

- OMRI warns that applying the prohibition on use of synthetic solvents to materials on §205.601 may affect many allowed substances.

6. **Is guidance needed concerning whether or under what circumstances the use of an extractant/solvent causes chemical change in the extraction process?**

- Beyond Pesticides and OTA point to the classification of materials policy, which gives guidance concerning chemical change.

- NOC says, "The use of a volatile synthetic solvent will always cause chemical change and would characterize the resulting material as a synthetic."

- Cornucopia says, "Chemical change as a result of extraction would classify a material as synthetic, but a material should be classified as a synthetic when a volatile synthetic solvent is used at all."

7. **What is a significant residue of a synthetic solvent? Should the prohibition on the use of volatile synthetic solvents include the use in any ingredient in the history of the product?**

- Beyond Pesticides, NOC, and Cornucopia said that any residue of a synthetic material is significant in the sense that it should trigger an examination of the possible impacts of that synthetic. NOC pointed out that the reference to detection level is precisely defined as required by §205.670, with reference to methods of analysis related to implementation of the regulations provided in the most current edition of the *Official Methods of Analysis of the AOAC International.*

- Beyond Pesticides and Cornucopia say the prohibition should apply to use in any ingredient in the history of the product. Beyond Pesticides says, "Similarly, for crop materials, if a synthetic solvent is used in the production of a material and it is, as a result, classified as synthetic, then any material in which *it* is used as an ingredient would need to be classified as a synthetic."

- OTA refers to their comments on the significant residues discussion document, which support the first approach proposed by the Materials Committee in the April 2011. OTA said that the prohibition should not include the use in any ingredient in the history of the product:

> The language in § 205.270(c)(2) is specific to the certified handler. The review of a volatile synthetic solvent would be conducted by NOSB on a case-by-case basis or by a certifier or MRO making a synthetic/non-synthetic determination. If NOP's recent clarification stands, a volatile synthetic solvent or synthetic processing aid is not outright prohibited in the production of any nonorganic ingredient.

8. **For substances already on the National List, should it be assumed that any extractant is allowed, or should the NOSB attempt to specify allowed extractants moving forward or for previously listed substances?**

- Beyond Pesticides and NOC say that in listing a substance, the NOSB should specify allowed extractants, and in performing sunset reviews, the NOSB should ensure that the listing adequately specifies allowed extractants. Cornucopia says volatile synthetic solvents should not be allowed in any ingredients in certified organic foods, including ingredients on §205.605 and §205.606.

- OTA says, "Based on clarification from the program, any extractant used during the manufacturing of an allowed non-organic ingredient should be allowed unless it is specifically prohibited by an annotation or specifically prohibited elsewhere in the regulation."

- OMRI says, "For substances already on the National List, OMRI assumes that any extractant is allowed unless otherwise annotated. If the NOSB deems it necessary or prudent to specify allowed extractants going forward, OMRI can provide meaningful comment to the applicability and enforcement of such annotations."