

May 1, 2012

National Organic Standards Board Spring 2012 Meeting Albuquerque, NM

## **Re. Extractants Discussion Paper**

**Dear Board Members:** 

These comments are submitted on behalf of Beyond Pesticides. Beyond Pesticides, founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and groups around the world.

Clarity and consistent policy would be welcome in the treatment of volatile synthetic extractants and solvents. The prohibition on volatile synthetic solvents in §205.270 dates back to the December 20, 2000 Final Rule. Volatile synthetic solvents have always been regarded as materials to avoid, but the term needs definition in order to apply the rule. We support the definition of "volatile synthetic solvent" included in the committee discussion document. We believe that use of a synthetic solvent in the production of a material becomes important in distinguishing a synthetic from a nonsynthetic substance, but not to differentiate between agricultural and nonagricultural substances. Regardless of whether the origin of the material is agricultural or nonagricultural, the underlying statutory prohibition of volatile synthetic solvents in organic products should be made consistent by including all users, precursors, and processes that touch the ingredients. The use of or presence of a synthetic solvent in a material used in organic production and handling must trigger full examination of the material. In order to subject the material containing the solvent to NOSB review, it must be classified as synthetic.

Below we address questions asked in the discussion document.

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?

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We agree that there needs to be a definition of "volatile synthetic solvent" in order to make §205.270(c)(2) workable. Although the December 2000 Final Rule did not include a definition of "volatile synthetic solvent," the 1997 proposed rule included a definition of "synthetic volatile solvent":

Synthetic volatile solvent. A synthetic substance used as a solvent, which evaporates readily, such as hexane or isopropyl alcohol.

The definition given in the discussion document is equivalent to the 1997 proposal, but better because it is more precise and more easily applied, since the boiling point of a substance is something that the committee evaluating a substance will be able to find easily.

**Exceptional cases should not drive the extractants policy.** If supercritical carbon dioxide is deemed to be a substance distinct from gaseous carbon dioxide and is proposed for use in extracting materials for use in organic products, then it should be evaluated by the NOSB. However, supercritical carbon dioxide is so far outside the norm of volatile synthetic solvents that, in any case, it should not drive the formation of this policy.

Nevertheless, under NOSB materials policy, supercritical  $CO_2$  is not a volatile synthetic solvent. First of all, according to the materials policy, supercritical  $CO_2$  is the same substance as carbon dioxide because the phase change between gaseous  $CO_2$  and supercritical  $CO_2$  is not a chemical change. Second, it is not "volatile" because it is naturally a gas and does not exist as a supercritical fluid at normal pressures and temperatures. Boiling points are generally evaluated at atmospheric pressure at sea level (standard atmospheric pressure), and carbon dioxide is a gas at that pressure. However, supercritical  $CO_2$  is not used and does not exist at that pressure.

To make this clear, the suggested definition of "volatile synthetic solvent" should specify that the boiling point is measured at standard pressure (sea level):

A volatile synthetic solvent is a synthetic chemical with boiling point less than 287 degrees Celsius at standard atmospheric pressure<sup>1</sup> that can dissolve another substance.

- 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.
- 3. Should the process of extraction change the classification of an agricultural product to a nonagricultural material? Does it matter whether the extractant is

<sup>&</sup>lt;sup>1</sup> Expressed as 101.325 kPa (1013.25 mbar, or hPa) or 29.92 inches of mercury (inHg) or 760 millimeters (mmHg)

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synthetic or nonsynthetic? When this happens to an agricultural material that is currently organically grown, does this changed material then need to be petitioned?

[Questions 2 and 3 are addressed together.] The prohibition on volatile synthetic solvents in §205.270(c)(2) does not depend on their use as extractants. However, there are extractant issues raised by the committee that involve volatile synthetic solvents, and some that do not depend on this type of extractant.

As the discussion document points out, there has been some inconsistency concerning materials resulting from extraction from an agricultural product. We suggest that "agricultural" be used to refer back to the source, and that the terminology not be confused by vague terms like "recognizable." Therefore, the definition of "nonagricultural substance" adopted by the board in 2009 is more workable:

Nonagricultural substance. A substance that is not a product of agriculture, such as a mineral or a bacterial culture, which is used as an ingredient in an agricultural product. For the purposes of this part agricultural refers to the production or handling of crops or livestock.

Thus, the use of extractants may result in a change of classification from nonsynthetic to synthetic, but would not change the classification from agricultural to nonagricultural. We also suggest that fermentation processes be treated as agricultural and standards be developed for certifying as organic products of fermentation.

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.

The prohibition on use of volatile synthetic solvents *only* by *certified* handlers and only in *agricultural* products is not logical. (See the flow charts appended to these comments for a graphical analysis.) Indeed, in the preamble explaining this change in the regulations, USDA said,

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We have corrected paragraph (c) of section 205.270 to clarify what must not be used in or on organically produced ingredients and nonorganically produced ingredients used in processed organic products. The prohibition on use of ionizing radiation, excluded methods, and volatile synthetic solvents applies to all organically produced ingredients. The 5 percent of nonorganic ingredients in products labeled "organic," also are subject to the three prohibited practices.

We suggest that §205.270(c) be rewritten as follows,

- (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*.

Since excluded methods and ionizing radiation are also included in the prohibitions of 207.205(c), the change we propose would also make those prohibitions consistent with prohibitions elsewhere in the rule.

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?

For materials used in crop production, the use of synthetic solvents in production is something that must be examined. In order to facilitate this review by the board, the use of synthetic solvents in the production of an input must result in its classification as a synthetic. Classification as a synthetic will guarantee that the board has the opportunity to examine possible residues and other impacts of the solvent, including the impacts of manufacturing, transporting, and disposing of the solvent.

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

The issue of chemical change occurring in extraction processes is certainly important. It is not always clear in such cases whether the process is "extraction" or "manufacture." Certainly, the classification of materials policy would require that chemical change occurring during extraction

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would result in the material being classified as a synthetic if the chemical change occurred as a result of the use of a synthetic material.

## 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?

Any residue of a synthetic material is significant in the sense that it should trigger an examination of the possible impacts of that synthetic.

We agree with the interpretation that by using an ingredient that has been produced using a volatile synthetic solvent, one is adding the solvent to the final product as well. Since the prohibition is absolute, ingredients made using volatile synthetic solvents anywhere in their history should not be allowed. Organic consumers do not expect synthetic ingredients, particularly volatile synthetic solvents, to be used in their food. Like the distinctions between certified handlers vs. noncertified handlers and agricultural vs. nonagricultural ingredients in the source of the volatile synthetic solvents, the distinction between whether the solvent is used in the ingredient or in an ingredient of an ingredient is irrelevant to consumer expectations and the underlying standard in the law. Please see the attached flow charts for a clarification of the current regulations, current interpretations (as we understand them), and our recommendations.

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.

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?

In listing a substance, the NOSB should specify allowed extractants. In performing sunset reviews, the NOSB should ensure that the listing adequately specifies allowed extractants.

Thank you for this opportunity to comment on the use of extractants and solvents in organic production and handling.

Sincerely,

Terry Shistar, Ph.D.

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**Board of Directors** 

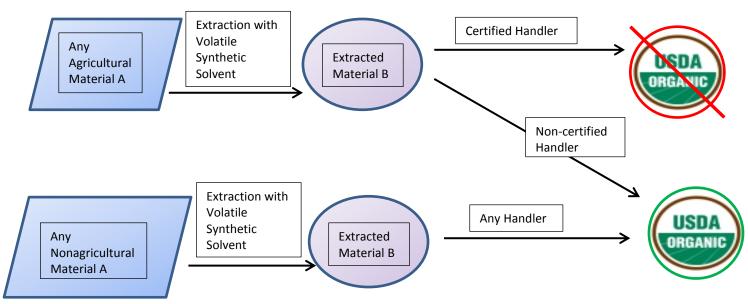
Attachment: Extraction Flow Charts

Beyond Pesticides, Extraction Flow Charts

## **Extraction Flow Charts**

Current regulations base the status of a formulated product on the status and classification (agricultural/non-agricultural) of the material being extracted, as well as who does the formulation. The regulations are silent about what happens when the formulated product (C) is incorporated into another product.

## **Current regulations (§205.270(c)) say:**



We propose that any material extracted using a VSS and incorporated into any product should be treated the same and that the prohibition should continue if the product is incorporated into another:

