

**National Organic Standards Board  
Materials Committee  
Extractants and Solvents Discussion Paper  
March 21, 2012**

## **Background**

Extractants or solvents are used to produce materials used in crops, livestock, and processing. There are limitations on the use of certain extractants, but they are not uniform or consistent. There are numerous places in the rule where solvents are prohibited generally and specifically by name of chemical, or “water process only.” The lack of consistency leads to problems in deciding on classification and listing issues. The Materials Committee seeks to clarify the issues around the use of extractants and solvents to ensure more informed and logical decision making across numerous NOSB committees and material reviews.

## **Extractants and Solvents in OFPA and Regulations**

The Organic Foods Production Act (OFPA) mentions extracting as a means of processing. The only other mention of solvents or extraction is in the definition of “synthetic”:

**§.2103 [7 U.S.C. 6502] Definitions**(21) The term "synthetic" means a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

Several definitions in the regulations mention extraction or solvents, including the definition of “synthetic” repeated from OFPA:

### **§ 205.2 Definitions.**

*Excipients.* Any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g., enhancing absorption or controlling release of the drug substance). Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.

*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, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

*Processing.* Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

“Extracting” is mentioned as an allowed processing method in § 205.270(a). § 205.270 (c) prohibits the use of “volatile synthetic solvents” in organic handling of agricultural products:

(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.

There are a few more specific prohibitions on solvents:

§205.601(j) As plant or soil amendments.

(1) Aquatic plant extracts (other than hydrolyzed)—Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction.

(3) Humic acids—naturally occurring deposits, water and alkali extracts only.

§205.606(k) Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).

§205.605(a) Nonsynthetics allowed:… Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

At its November 2011 meeting, the NOSB recommended the approval of a petition for Docosahexaenoic acid (DHA) algal oil petition with the following annotation: DHA from Algal Oil, not hexane extracted; other ingredients that are agricultural must be organic” to the National List at 7 CFR, §205.605(a)

## Issues and Discussion

### 1. What is a volatile synthetic solvent?

A volatile synthetic solvent is, first of all, synthetic. This is important to keep in mind, since many natural substances otherwise meet the definition –water, for example.

There are many definitions of volatile in the context of “volatile organic chemical,” which is a regulated class of chemicals. Some focus on specific regulatory aspects (such as

EPA's definition for air pollution purposes, any organic compound that participates in a photoreaction.) For our purposes, however, the crucial aspect is volatility. Volatility is most precisely defined in terms of vapor pressure, which is not very intuitive to most people. Equivalent definitions can be expressed in terms of boiling point, which is more intuitive and is a commonly reported property of chemicals. The most commonly used definition is a chemical with boiling point between 69 and 287 degrees Celsius, and very volatile is defined as having a boiling point below 69 degrees Celsius.<sup>1</sup> For our purposes, very volatile and volatile should be combined.

A solvent is a chemical capable of dissolving another substance.

Thus, a volatile synthetic solvent is a synthetic chemical with boiling point less than 287 degrees Celsius that can dissolve another substance.

Some examples of volatile synthetic solvents and their boiling points in degrees Celsius:

Ethanol (may be nonsynthetic)	15.8
Dichloromethane	40
Acetone	56
Chloroform	61
Hexane	69
Benzene	80
Isopropyl alcohol	82
Toluene	111
Super critical carbon dioxide	<sup>2</sup>

## 2. When does the use of a synthetic solvent change the classification of the material?

### Agricultural -> Nonagricultural

A nonagricultural substance is defined as:

A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction. (**§ 205.2**)

In November 2009, the Board approved a revised definition of nonagricultural, which has so far not been written into regulation: "A product, such as a mineral or atmospheric

<sup>1</sup> Eurofins Product Testing –What means VOC? <http://www.eurofins.com/voc.aspx>

<sup>2</sup> [Carbon dioxide](#) usually behaves as a [gas](#) in [air](#) at [standard temperature and pressure](#) (STP), or as a [solid](#) called [dry ice](#) when frozen. If the [temperature](#) and [pressure](#) are both increased from [STP](#) to be at or above the [critical point](#) for [carbon dioxide](#), it can adopt properties midway between a [gas](#) and a [liquid](#). More specifically, it behaves as a [supercritical fluid](#) above its critical temperature (31.1 °C) and critical pressure (72.9 atm/7.39 MPa), expanding to fill its container like a [gas](#) but with a [density](#) like that of a [liquid](#).

gas, that does not originate from agriculture. For the purposes of this part agricultural refers to the production or handling of crops or livestock.” The NOP stated,<sup>3</sup> “The NOP does not object to the above definition, but proposes that some ambiguity remains. For example, does the removal of the example of ‘bacterial culture’ mean that microorganisms, dairy cultures, and their products are considered agricultural? The NOSB has indicated they will be determining this on a case by case basis. If so, it would be useful to develop criteria for this review of microorganisms and their products. The NOP acknowledges that the current definition, which includes pectins and gums as nonagricultural conflicts with the present listings at 205.606.”

Thus, the use of a solvent –synthetic or nonsynthetic—may result in production of a nonagricultural product from an agricultural substance under the current definition, though if the revised definition were written into the regulations, it would not. It is not clear whether the definition in the regulations will be changed. The definition is pertinent because, as noted below, the prohibition against extraction with a volatile synthetic solvent in §205.270(c) applies only to agricultural substances.

### **Nonsynthetic -> Synthetic**

The issue of when the use of a synthetic solvent changes the classification from nonsynthetic to synthetic has been addressed in the Recommendation on Classification of Materials, adopted by the Board in November 2009:

It is our intent through this recommendation that a material would be classified as synthetic when:

- The source of the material is not “from mineral, plant, or animal matter” (from the definition of nonsynthetic) and is not a “substance created by naturally occurring biological processes” (from the definition of synthetic) or;
- The process used to manufacture the material is synthetic (per the definition of synthetic and clarifying definitions in our recommendation) or;
- The material contains, at a significant level, a synthetic substance not on the National List of allowed synthetics. (p5)

Thus, there are two cases in which the use of a synthetic solvent can change the classification of a material from nonsynthetic to synthetic:

- a. If the addition of the synthetic solvent results in chemical change, then the resulting substance is synthetic, and
- b. If the material contains a significant level of the synthetic solvent, then it is synthetic.

<sup>3</sup> Miles McEvoy, September 30, 2010. Memorandum for the chairman of the National Organic Standards Board, p. 15.

The definition of “chemical change” approved by the NOSB in November 2009 (and amended slightly in April 2011 in Update and Proposed Guidance Document, Classification of Materials) 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 definition of “substance” included in the November 2009 guidance is:

*Substance* An element, molecular species, or chemical compound that possesses a distinct identity (For example, a distinct identity may be demonstrated through the material having a separate Chemical Abstract Service (CAS) number (in some cases the same material may have multiple CAS numbers), Codex International Numbering System (INS) number, or FDA or other agency standard of identity).

The latest April 2011 recommendation to define a significant residue in the classification of materials policy was unsuccessful. At the April 2011 meeting, the motion was made 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. 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.

The other approach that was supported by a minority of the committee and considered, as documented in the proposed guidance document was that, “[A]ny 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.... 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 question as to what level of synthetic residue would result in the change in classification of a nonsynthetic material to synthetic therefore awaits clarification by the NOSB.

- 3. Does the use of a volatile synthetic solvent in an ingredient mean that the ingredient is not permitted in organic food? This has to do with the heritage of an input—does a prohibition against its use carry back to the origin of the ingredients?**

§205.270(c) of the regulations states, “(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.

It is not clear whether the use of a volatile synthetic solvent in an ingredient that is subsequently used in another product disqualifies the second product as being labeled organic. On one hand, one could argue that it makes the ingredient nonorganic, but the ingredient could be used as part of the 5% in an organic product, but not used in a 100% organic product. But that would make the exception unnecessary.

The alternative interpretation is 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, it may be proper to disallow ingredients made using volatile synthetic solvents anywhere in their history.

### **Other Issues Concerning Solvents**

Regardless of whether the material being extracted is synthetic or nonsynthetic, if the material is being considered for use in organic production –for example, as a crop input to be listed on §205.601– the impacts of the extractant need to be considered as part of the review of the material. These impacts are not limited to the impacts of the residues in the material, but also include the impacts of the manufacture, use, and disposal of the solvent material. Questions that need to be asked include:

1. Is the site where the solvent is manufactured at a site where there is contamination, such as a Superfund site?
2. Is solvent released into the air or water during or following the extraction process?
3. What happens to waste solvent?

### **Comments Requested**

The Committee requests public comments on the following 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?
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 synthetic or nonsynthetic? When this happens to an agricultural material that is currently organically grown, does this changed material then need to be petitioned?
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.
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?
6. Is guidance needed concerning whether or under what circumstances the use of an extractant/solvent causes chemical change in the extraction process?
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?
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?

**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: C. Reuben Walker

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