



Date: April 7, 2006

To: Valerie Frances, Executive Director, National Organic Standards Board
National Organic Standards Board members

From: Dave DeCou, Executive Director
Brian Baker, Research Director

Re: OMRI Comments on the Recommended Framework to
Further Clarify the Definition of Synthetic

The Organic Materials Review Institute (OMRI) is pleased to offer comments on the March 9, 2006 Memorandum from Valerie Frances, Executive Director of the National Organic Standards Board and the National Organic Program on the Recommended Framework to Further Clarify the Definition of Synthetic.

OMRI has participated in the discussion of developing guidance on matters pertaining to the National List prior to final rulemaking and implementation. The proposed framework is needed to help explain to producers, handlers, certifying agents, NOP staff, and input suppliers the basis for determining if a substance is synthetic. In general, OMRI finds the framework to be an improvement over the NOSB's recommendation. Reasonable people may disagree over whether a given substance is synthetic. The framework and accompanying flowchart offer a rigorous, well-defined, transparent procedure to evaluate specific substances. OMRI believes that this Framework can help build a consensus to avoid confusion over the status of substances used in organic production and handling.

2.2 Natural Source

This definition should include reference to microbiological organisms—including bacteria, protozoa, actinomycetes, and fungi—as natural. Such organisms are indirectly mentioned as “substances created by naturally occurring biological processes” in the OFPA synthetic definition. Many substances derived from microorganisms have been reviewed and determined to be natural by the NOSB - including dairy cultures, yeast, bacteria, actinomycetes (spinosad), and the class of microorganisms itself (NOSB, 2003).

Suggested change:

Natural source - Naturally occurring mineral, plant, microbiological, or animal matter used to obtain nonsynthetic inputs for organic production and handling.

2.2 and 3.3 Formulation or Blending?

One of the most difficult parts to understand in both the OFPA and the NOP rule is that substances are never used in a pure, isolated manner in organic production or handling. Both the

statute and the regulation need further clarification to avoid confusion of generic substances with brand name products and single ingredients with formulations. The accompanying independent evaluation of the NOSB's recommendations indicates that the NOP is aware of this dichotomy. For the most part, the Framework avoids these pitfalls, but in a few places falls into them, particularly in the definition and discussion on 'formulation (manufacturing).' The two are used interchangeably and synonymously when they are actually two different—but closely related—steps. OMRI suggests making a clear distinction between 'manufacturing' and 'formulation' and between 'substance' and 'input' by revising the definitions as follows. (suggested revisions included).

- **Formulate ion (manufacturing)** – To combine substances to prepare an input.
- **Input** – A substance or combination of substances that is used to produce or handle agricultural products, including fertilizers, pesticides, production aids, feed, feed additives, feed supplements, food additives, and processing aids.
- **Manufacture ing** - ~~The manufacture of an agricultural or handling~~ To make a substance that is derived from a synthetic substance, a substance extracted from a natural source or produced by a naturally occurring biological process.

Comment: The use of the term formulation in the OFPA definition of synthetic is not limited to formulation from strictly natural substances. A substance may be synthetic if is manufactured from a totally chemical process **or** if manufactured via a chemical change from a natural source.

“Synthetic- A substance that is formulated or manufactured by a chemical process **or** by a process that chemically changes a substance extracted from a naturally occurring plant, animal or mineral sources...” (OFPA 6502, emphasis added)

The synthetic definition further does not talk about formulation of inputs, which may be confused with final products used in organic production, hence it would be better not to include inputs in this definition, but describe allowed inputs in the discussion section.

Section 3.3 Manufacturing

1) A manufactured substance is nonsynthetic if

- It contains only ~~Nonsynthetic~~ substances that are from natural sources, and
- ~~and/or;~~
- ~~Synthetic substances on the National List~~
- The manufacturing process does not transform an ingredient into a different substance a different substance via a chemical change with the exception of substances formed via a naturally occurring biological process.
- ~~The process of formulation results in the retention of important functional properties (e.g. nutritional value) of the active ingredients.~~

2) Clarification of permitted inputs in production and handling,

a) 'a formulated substance input is nonsynthetic permitted for use in organic production if

- It contains only:
 - Nonsynthetic substances not on the National List of prohibited nonsynthetic substances and/or;
 - Synthetic substances on the National List of allowed synthetic substances.

- The process of formulation does not transform ~~an ingredient into a different substance~~ produce a different substance via a chemical change with the exception of substances formed via a naturally occurring biological process.
- The process of formulation ~~results in the retention of important functional properties (e.g. nutritional value) of the active ingredients.~~ maintains the identity of the substances used as ingredients.

b) A formulated substance input is nonsynthetic permitted for use in organic handling if

- It contains only:
 - Nonsynthetic non-agricultural substances on the National List, and/or
 - Synthetic substances on the National List,
 - Agricultural products that are organically produced, and/or
 - Agricultural products that are not organically produced, but appear on the National List and are not commercially available from organic sources.
- The process of formulation does not transform ~~an ingredient into a different substance~~ a different substance via a chemical change with the exception of substances formed via a naturally occurring biological process or processed with organic agricultural ingredients to make an organic food.
- The process of formulation ~~results in the retention of important functional properties (e.g. nutritional value) of the active ingredients.~~ maintains the identity of the substances used as ingredients.

The original first point has an inherent contradiction. A synthetic substance cannot become nonsynthetic by virtue of it being on the National List and blended with a nonsynthetic. However, formulating a product should be an accepted practice as long as further reactions do not occur.

Farmers use formulated products comprised of natural and allowed synthetic ingredients. To be practically implemented, the OFPA and the NOP must strike a balance between the clarity and simplicity of single substances and permitting formulated and manufactured products, and the reality of custom blends, formulated products, and tank mixes.

Custom blends, formulated feeds, and other inputs that are prepared specifically for the farm need to be subject to the same scrutiny whether they are produced on or off the farm. The difficulty is that the law and rule should not discriminate against either producers or manufacturers. Farmers and the pest control operators should be able to formulate a pesticide product on the farm no differently from an EPA registered manufacturing facility. It is OMRI's opinion that the producer is responsible for the verification that a formulated product complies with the standards whether the producer blends it on farm or purchases it from a supplier. The supplier and everyone back in the supply chain needs to be held accountable. Here are some examples of the situations that OMRI has encountered since implementation:

Producers and pest control operators who can legally prepare or mix pesticide products on the farm should be able to formulate tank mixes and custom blends that use synthetic substances on the National List, subject to the same restrictions as if they were the manufacturer of those pesticides. In particular, it is OMRI's opinion that the NOP rule permits the use of synthetic

adjuvants that appear on EPA List 4 with EPA registered pesticides when the application is for crop protection in a manner consistent with the organic system plan

Dry fertilizers as a rule will not create a chemical reaction when blended. Tank mixes of liquid products of allowed substances that are applied immediately after mixing may result in incidental reactions, but will not have the time for those reactions to reach equilibrium or concentrate the levels of nutrients. In OMRI's opinion, both kinds of blends should be permitted, whether formulated in a factory or combined on the farm. Not all combinations of allowed fertilizers will result in the production of synthetic chemical fertilizers. However, there are a few liquid products with synthetic ingredients in solution, such as fish treated with phosphoric acid or aquatic plant extracts, and humic acid derivatives that contain potassium hydroxide. After formulation, these synthetic substances can be reacted with each other or with non-synthetic substances to produce other synthetic fertilizers not on the National List. When the resulting product is distilled or crystallized, the chemical mixture will have an identity distinct from its components. For example, the reaction of potassium hydroxide and phosphoric acid will result in the production of potassium phosphate. It is OMRI's opinion that these fertilizers are prohibited in organic production, whether produced on the farm or by a chemical factory.

Finally, note that processing needs to be addressed separately from manufacturing or formulation.

3.3 Processing or Manufacturing?

The distinction between 'processing' and 'manufacturing' is important, and requires further development, particularly in light of the outcome of *Harvey v. Johans* and subsequent legislation. OMRI supports the intent to work with the NOSB to ensure that the rule is maintained and not weakened by the legislation.

OMRI supports the definition of substance. We agree that 'any nonorganic substance for use in processing' must be a separate entry on the National List' (section 3.4). In particular, any ingredient that appears on the label of an organic processed product should either be (a) organically produced and handled or (b) on the National List. OMRI requests that the Framework address the situation where manufacturers may take two substances on the National List and create a third substance not on the National List by adding the following bullet point under 3.3.

- All substances that appear on the label of a food or are used as processing aids in food manufacture must either be organically produced and handled agricultural products or appear on the National List as allowed non-organic ingredients.

Processes not included in the definition of processing that involve chemical agents and synthetic reactions—such as hydrogenation, ion exchange, and solvent extraction—are not permitted unless the chemical agents required to carry out those processes appear on the National List.

Food processors take food ingredients and make a finished food. The nature of processing is such that reactions take place that can be characterized as chemical in nature, but the products are identifiable as food. By contrast, manufacturers of nonagricultural ingredients take food

additives and combine them to make other food additives. The manufacturer of a food additive should be able to process ingredients acceptable for organic processing the same as a certified organic processor. Synthetic ingredients that do not appear on the National List are prohibited, even if the manufacturer of the prohibited ingredients operates in a certified organic handling facility.

If a synthetic food additive is not on the National List, that ingredient is prohibited whether made by a certified organic food processor or a manufacturer. In particular, sodium lactate and calcium lactate do not appear on the National List. For example, a similar reaction of benzoin gum—classified by FDA as a ‘natural flavor’ [21 CFR 173.510] — and sodium hydroxide could be used to make sodium benzoate. Certification of an organic handling operation should not give that operation a license to manufacture or use synthetic chemical food additives—as distinguished from organic food ingredients—that do not appear on the National List. In order to appear on the label of a product that is certified organic, those ingredients need to appear on the National List or at least be identified by the reacted substances if the reaction takes place as part of the processing of organic food.

3.2 Extraction or Reaction?

The clarification of when extraction results in a nonsynthetic substance is well-presented. In general, extraction steps do present certain concerns.

- 1) Reactions that are not truly extraction, but instead are the reaction products of a hydrolysis / precipitation reaction (e.g. aquatic plant extracts, humic acid derivatives).
- 2) Extraction products in a synthetic solvent base (e.g. botanical insecticides) because the solvent remains in the final product, often at a greater concentration than the extracted substance.
- 3) Synthetic solvents that are partially removed but remain as contaminants in the final product (e.g. flavor and color extracts).

The framework provides guidance for evaluation when substances that are identified as ‘extracts’ or ‘derivatives’ are in fact synthetic products.

3. 2 Extractions – not contaminated with “significant level of a synthetic substance..”

The evaluation of the NOSB’s recommendation correctly identifies that contamination is inevitable and that establishing acceptable limits on unacceptable substances is inherently difficult. OMRI concurs with the NOP that this is a flaw in the NOSB’s recommendation that should be corrected. While an improvement, the proposed solution still is vague and difficult to monitor or enforce.

‘Significant level’ varies not only according to technical or functional effect, but also according to the classification of the product. A substance used to make a fertilizer might have a higher level of contamination than a substance used as a feed additive.

The greatest concern in production is with botanical extracts that are in aromatic petroleum solvents. Many of these solvents will be inert ingredients of probable toxicological concern (List 2) and in some formulations will have higher levels of the solvents than the active ingredients. The EPA maintains a reporting requirement of 0.1% for inert ingredients that are impurities, with

lower limits for inerts of toxicological concern. While organic standards may want to establish stricter limits, at present the EPA reporting requirements are an established regulatory limit that currently is being used. Similarly, with food additives, *Food Chemicals Codex* gives tolerances established for food grade ingredients. OMRI is interested in working on the development of thresholds to establish what is avoidable or truly beyond the operator's control. OMRI suggests the following:

'An extracted substance is nonsynthetic if:

- It is not contaminated with a significant level of a synthetic substance that is not on the National List. "Significant level" in this context is an amount capable of producing a functional or technical effect. ~~It is not contaminated with a significant level of a synthetic substance that is not on the National List with a synthetic substance that is not on the National List. "Significant level" in this context is an amount capable of producing a functional or technical effect.~~ For pesticides, the solvent used is removed to an unavoidable minimum amount not to exceed the US EPA's reporting requirements for product formulations.

Organic Extracts

Separation done in processing may be mechanical or chemical. If chemical, the agents should be on the National List. Diatomaceous earth and perlite appear as filtering agents for this reason. Activated carbon should also be added to the National List, as recommended by the NOSB. While synthetic solvents are generally prohibited, the National List permits carbon dioxide and thus the use of supercritical techniques for extraction.

A substance extracted from an organically produced agricultural ingredient may be labeled 'organic' if:

- It is extracted by mechanical or physical means defined as processing;
- It is extracted using chemical means by the use of other organic ingredients or by the use of substances that appear on the National List of Allowed Nonorganic Ingredients allowed as ingredients in or on processed products labeled as 'organic' or 'made with organic (specified ingredients or food groups(s)).
- The important functional properties (e.g. nutritional value) of the agricultural ingredient are retained.

3.4 Substance

OMRI supports the requirement that substances have a distinct identity as described by CAS, numbers, INS numbers, or FDA standard of identity. The National List may need to be restructured and revised to take into account the few exceptions that do not meet up to this guidance. In particular, additional guidance on electrolytes, milk replacers, and natural colors may be needed if these substances remain on the National List after Sunset.

OMRI suggests that the statement that identifies what substances must appear on the National List be revised as follows:

‘Any synthetic substance allowed and any non-synthetic substance prohibited for use in crops and livestock, and any nonorganic substance for use in processing, must be a separate entry on the National List. Categories of substances must be distinguished by a recognizable standard of identity.’

Flowchart

OMRI appreciates the visual representation as a flow chart and would like to see changes made in the flow chart that correspond to the suggestions made above. Specifically:

- Begin by separating substances used in production from substances used in handling.
- Revise the definition of formulation
- Revise the definition of natural substance
- Adjust the diamond shaped box to say “Is formulation needed to produce a substance used in agricultural production or handling input?”
- Adjust the box under “formulation” at point (1) to say “Does the substance input (or ingredient in the case of processing) contain any synthetic substance ~~not on the National List?~~”
- Separate the steps of determining whether a given substance is synthetic from the issue of whether a formulated input is allowed.

It is important to emphasize that this flow chart is for use in identifying generic **non-organic** substances as non-synthetic or synthetic. It is not designed to evaluate formulated brand name type of products as inputs, so the term “agricultural or handling input” in the formulation question is misleading. It is not designed to determine whether an organic processed food product is certifiable. An additional series of questions could be added for the purpose of determining when manufactured products are permitted in organic systems for either production or handling inputs.

Once again, OMRI appreciates the progress that the NOP has made on this guidance and applauds their good faith effort to deal with the NOSB’s recommendations. We look forward to helping with implementation of this framework.

Sincerely,



David DeCou
Executive Director



Brian Baker, Ph.D.
Research Director