

Final 4-20-09
Materials Working Group Discussion Document
Clarification of Definition of Synthetic Substance

DATE: April 2009

TO: National Organic Standards Board

FROM: Materials Working Group *see last page for list of members

Discussion Document to Further Clarify the Definition of Synthetic Substance

The Materials Working Group (MWG) has been asked by the NOSB to assist it in forming a recommendation concerning further clarification of the meaning of “synthetic” in making materials determinations for the National List. We were asked by the NOSB Materials Committee to use as a starting point the March 9, 2006 memorandum from Valerie Frances, Executive Director of the NOSB, concerning a recommended framework to further clarify the definition of synthetic. The document was produced by the AMS Science Division in response to the NOSB Formal Recommendation of August 17, 2005, titled “NOSB guidance for the review of synthetic and non-synthetic substances.”

Our objective has been to examine the difference between what the NOSB recommended and how AMS responded, and to suggest further clarifications. Starting with this document, we have added and revised definitions and included additional discussion of our suggested revisions. For ease of comparison, the revised MWG definitions are bulleted and directly below the definitions proposed in the 2009 memorandum. In the discussion portion, deletions are indicated in strike out mode while additions are underlined. Discussion of additional related questions follows at the end of this document, along with a suggested revised decision tree.

We believe this document improves the likelihood of consistent determinations of synthetic or nonsynthetic status for substances being considered for inclusion on the National List. However, there remains an agreement with dissent among the MWG in enough instances to suggest that perfect consistency is not achievable. No policy can anticipate every particular manufacturing process, and this framework will require updating as more is learned.

1. Introduction

One of the primary determinants of whether a food can be considered “organic” is whether it contains or was produced with “synthetic” substances. The OFPA and the NOP rule define “synthetic,” and the NOP and NOSB apply this definition in various regulatory and policy contexts such as the consideration of substances for inclusion on the National List. In some cases, the NOSB and NOP have encountered uncertainties in applying the definition of “synthetic” to specific substances because some phrases in the definition have been found to be ambiguous in certain citations. The framework presented below ~~resolves~~ developed by the AMS Science Division and refined by the MWG helps to clarify these ambiguities.

2. Definitions

2.1 Relevant Existing Definitions

The terms below are defined in the OFPA and the NOP rule. The definition of “synthetic” is included below because the purpose of this document is to refine the intended meaning of “synthetic” as it is applied to substances petitioned for addition or prohibition to the National List. The existing definitions of “nonsynthetic” and “processing” are included below because these terms are relevant to the discussion of newly defined terms.

- **Synthetic** – “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.” (7 CFR 205.2)
- **Nonsynthetic (natural)** – “A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the [OFPA] (7 U.S.C. 6502(21)). Nonsynthetic is used as a synonym for natural as the term is used in the [OFPA].” (7 CFR 205.2)
- **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.” (7 CFR 205.2)

2.2 Proposed New Definitions

The terms below are the new definitions proposed in the March 9, 2006 Memorandum. The MWG revisions and one additional definition are bulleted:

Natural Source – Naturally occurring mineral, plant, or animal matter used to obtain nonsynthetic inputs for organic production or handling.

- **MWG: Natural Source** – Naturally occurring mineral or biological matter used to obtain nonsynthetic inputs for organic production or handling.

Extraction – The removal of a substance from a natural source by any chemical (e.g., solvent extraction, chemical precipitation) or physical (e.g., mechanical pressure, centrifugation, heating) manner and with any substance.

- **MWG: Extract** - To separate, withdraw or obtain one or more essential constituents of an organism, substance or mixture by use of solvents or mechanical or physical methods.

Formulation (manufacturing) – The manufacture of an agricultural or handling input that is

derived from a substance extracted from a natural source or produced by a naturally occurring biological process. Formulation is a synonym for manufacturing as the term is used in the OFPA definition of “synthetic.”

- **MWG: Manufacture** - To make a crop, livestock or handling input from raw materials.
- **MWG: Formulate** - To combine different materials according to a recipe or formula, to prepare the product being evaluated.
- **MWG: Generic** - The common and familiar non-proprietary name of a substance.

Substance – An element, molecular species, or chemical mixture that possesses a distinct identity (e.g., having a separate Chemical Abstract Service (CAS) number, Codex International Numbering System (INS) number, or FDA or other agency standard identity).

- **MWG: Substance** – An element, molecular species, or chemical compound that possesses a distinct identity (e.g., having a separate Chemical Abstract Service (CAS) number, Codex International Numbering System (INS) number, or FDA or other agency standard identity).

Naturally occurring biological process – Chemical changes that occur in living cells or due to the action of products of living organisms, such as enzymes.

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.”)

3. Discussion

This section provides the basis and rationale for the definitions proposed in Section 2.2. In addition, this section explains how the newly defined terms are intended to affect the meaning of “synthetic” (e.g., as it is applied to substances petitioned for addition or prohibition to the National List).

3.1 Natural Source

The term “natural source” is not used in the definition of “synthetic.” However, the proposed definition of “natural source” is derived from and consistent with the definitions of “synthetic” and “nonsynthetic” in the OFPA and NOP rule. The term “natural source” is used in other newly proposed definitions. Biological organisms are natural sources so long as they are not produced by excluded methods.

3.2 Extract (formerly “Extraction”)

The AMS document defined “Extraction” to clarify its meaning as used in the OFPA definition of “synthetic.” Our discussions suggest that the verb form “extract” is more helpful in clarifying

the distinction between extraction and chemical change. An extracted substance is nonsynthetic if:

- It is extracted from a natural source;
- It is present in the same form in the natural source;
- It is not chemically changed into a different substance during extraction;
- The process of extraction does not alter the substance into a chemical form (e.g., isomer) that does not occur in nature;
- Important functional properties (e.g., nutritional value) of the substance are not altered by extraction; and
- 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.

Chemicals used in extraction do not necessarily have to be nonsynthetic.

- The definition of “insignificant levels” is important in order to support consistent interpretation of the rule. The question of what constitutes an insignificant level may vary depending on the category of substance. We thus suggest that these levels be determined with reference to the applicable regulatory limits for the type of substance, in addition to technical and functional effects.

3.3 Formulate (formerly “Formulation” and used synonymously with “Manufacturing”)

The AMS document defined “Formulation” in order to clarify the meaning of the term “formulation or manufacturing” as used in the OFPA definition of “synthetic.” The MWG suggests using the verb form of “formulate” to further clarify its meaning, as well as the differences between extraction, formulation, manufacturing and processing. Although the NOP uses “Manufacturing” synonymously with “Formulating,” a product can be manufactured without necessarily being formulated. Formulation, in this context, is one form of manufacturing.

Generic substances such as enzymes and flavors are examples of formulated products that must be reviewed for inclusion on the National List. A formulated ~~substance-product~~ is nonsynthetic if:

- It contains only:
 - Nonsynthetic substances.
 - ~~= Synthetic substances on the National List~~
- The process of formulation does not transform a component into 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 active ingredients.

A formulated product that contains greater than insignificant levels of a synthetic substance may be approved for use in organic production or handling if the synthetic substance appears in the applicable section of the National List.

Formulation typically involves the use of diluents, additives, carriers and stabilizers. Formulations should be addressed when the NOSB considers a broader category of generic substance that is proposed for the National List, such as “natural flavors”, “enzymes”, “dairy cultures”, or “aquatic plant products”. In these cases, the NOSB should evaluate the general type of formulators commonly used to determine whether any restrictions on source of these substances is warranted and expressed as an annotation. Otherwise, all possible formulations of such products would be considered acceptable.

3.4 Substance Manufacture (formerly “manufacturing”)

Although the NOP proposed that “formulation” and “manufacturing” be considered synonyms as used in the definition of synthetic, the meaning is clearer if they are kept separate. Furthermore, the NOSB did not recommend that the two terms be used interchangeably. As for “extract” and “formulate,” the MWG suggests using the verb form of “manufacture” for improved clarity.

For the purposes of materials review by the NOSB, manufacturing refers to the initial creation of a substance used as an input in organic production or handling. Formulation is the combining of substances to produce a generic input, or a final product for the marketplace.

Manufacturing in this context is not intended to address the processing of an agricultural product by a handling operation for human or animal consumption. These definitions apply only to substances used as inputs in crop, handling and livestock operations.

August 16th 2005 NOSB Clarification on the Definition of Synthetic:

Formulation or manufacturing as defined in this section is not intended to address the processing of an agricultural product by a handling operation or food (see definition of processing below). This definition applies only to the individual inputs used in crop, handling and livestock operations. Additionally, if an extracted substance is formulated with other substances, those substances if synthetic would have to be petitioned for inclusion on the National List.

The definition of synthetic as defined in the regulation is clarified in this document as it applies to adding substances to the National List (205.601-606). Processing of an agricultural product by a handling operation or food may involve synthetic and nonsynthetic substances on the list and these substances along with the agricultural component(s) may undergo chemical changes as they are processed. These chemical changes are allowed under OFPA 2103(21) and the NOP rule (205.270).

3.5 Substance

Minerals and inorganic substances generally can be identified by an exact molecular weight and chemical formula. Large, complex biochemicals (e.g., proteins, polysaccharides, lipids) are generally identified according to their carbon-based structure units and attached functional groups. Large organic chemicals often cannot be described by exact atomic composition or molecular weight. For example, the functional groups or the number of monomers in a natural polymer can vary without changing identity of the whole molecule. The definition of “substance” recognizes that a substance does not necessarily have a uniform and static atomic or molecular composition. Therefore, substances are distinguished from one another based on identities assigned by independent naming or regulatory bodies, such as the Chemical Abstract Society (CAS). Such identities may be based on chemical, technical, or functional properties.

Any synthetic substance for use in crops and livestock, and any nonorganic substance for use in food processing, must be a separate entry on the National List.

3.6 Naturally Occurring Biological Process

Substances created by naturally occurring biological processes are not considered synthetic. For example, lactic acid is considered a nonsynthetic substance when it has been formulated via the fermentation of lactose (milk sugar) by the bacterium *Lactobacillus*.

3.7 Chemical Change

A chemical change is intended to mean an event in which one substance becomes one or more different substances. A chemical change may result from specific types of chemical reactions such as:

- (1) Addition or combination reactions;
- (2) Decomposition reactions;
- (3) Displacement reactions; ~~and~~
- (4) Protein configuration changes; and
- (5) Polymerization.

The occurrence of these types of reactions does not necessarily result in a chemical change, however, because it is possible for the atomic composition or configuration of a substance to change without a change in the identity of the substance. This is particularly true for large, complex biomolecules or for substances that are mixtures of various chemical species. Therefore, the occurrence of a chemical change is identified based on the identity and empirical properties of the starting and resulting substances.

In cases where the starting and/or resulting chemicals or chemical mixtures have not previously been assigned recognized identities (e.g., CAS numbers) or where the occurrence of a chemical change is uncertain for other reasons, NOSB and NOP may consider additional factors such as:

- Changes in the technical or functional properties (e.g., nutritional value, flavor, efficacy for an intended use) of the chemicals involved;
- Whether the chemicals involved are found in natural sources;

- Whether naturally occurring biological processes are involved;
- The role of synthetic substances, if any; and
- The extent to which chemical reactions of the types listed above are involved.

Using the Decision Tree

The Materials Working Group has also developed an improved Decision Tree for use by the NOSB in evaluating substances (attached). The tree proposed by AMS in 2006 places too much emphasis on extraction and formulation, when the primary issue should be a determination on whether a chemical change has occurred. The order of questions in the tree may need to be varied when dealing with specific manufacturing processes, and additional refinements will be needed. The NOSB should keep in mind the following core questions:

- 1) Does the initial substance undergo a chemical change (apart from those derived from a biological process)?
- 2) Were synthetic substances added during manufacturing, that remain in the generic product at greater than insignificant levels?

Additional Concerns:

Clarification of § 205.270(c)(2)

In the course of our discussions regarding the evaluation of handling inputs, a related inconsistency came to light concerning the interpretation of § 205.270(c)(2). Most members of the MWG interpret this prohibition on volatile synthetic solvents and processing aids as not allowed for substances listed at § 205.605 and § 205.606. This interpretation is supported by the second clause, which *permits* “made with organic” products to use non-organic ingredients that are produced with prohibited volatile synthetic solvents. However, some members pointed out that the section is ambiguous, since the handler of an organic processed product would not be using these substances directly. Furthermore, the NOP posted clarification via the Q & A section of their website explaining that synthetic solvents and synthetic processing aids are permitted unless specifically restricted by an annotation, such as is the case with Natural Flavors. The NOSB should clarify whether synthetic solvents and other synthetic processing aids are prohibited in formulation of all ingredients listed in § 205.605 and § 205.606, or if these are being considered during the National List review process.

We recommend that guidance be issued to clarify this section. For further elaboration on the topic, refer to a comment submitted by Oregon Tilth and PCO to the NOP on April 29th 22, 2008 concerning Docket AMS-TM-07-0062 (attached).

Chemical Change

There was disagreement within the MWG concerning the definition of “chemical change.” Two specific suggestions were proposed, but consensus was not reached. These proposals are:

1. “Chemical change is a reaction in which a gain, loss, or sharing of electrons occur.”

There was general agreement that this is an accurate description of the chemical change that must occur in order for a synthetic substance to be formed. However, there were objections that putting forward this definition may not fully align with the definition that was proposed in 2005 because it does not identify all kinds of chemical changes.

2. Remove displacement reactions from the list of chemical reactions that are considered to be chemical change.

This was proposed because dissolution and crystallization in natural brine solutions is not universally considered to be a chemical reaction; these are physical changes. Two examples of such displacement reactions are the drying of sea salt and the solution harvesting of natural mined minerals.

The MWG lacked the time to consider other historic exemptions for certain manufacturing processes that have generally been considered natural, such as combustion of biological materials. NOSB may want to develop a specific list of processes that are considered "natural" even though the result might be a changed chemical substance or form.

Synthetic definition:

Some members of the MWG have also suggested that the commonly understood meaning of “synthetic” has long been recognized as an inaccurate basis for determinations concerning the acceptability of a substance for use in organic production or handling. While this problem lies outside the scope of our current discussion, a separate document representing those viewpoints and proposing alternate solutions was developed by some members and submitted as individual comment. This document was not discussed by the MWG, and is not presented as part of this discussion document.

The Material Working Group is an unaffiliated collection of individuals with technical and regulatory background. Participation in the group was open and available to any interested party. The goal of the MWG is to offer working papers to the NOSB on materials issues.

MWG Members

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