

November 23, 2011

**MEMORANDUM FOR THE NATIONAL ORGANIC STANDARDS BOARD (NOSB)**

**FROM:** Miles McEvoy  
Deputy Administrator  
National Organic Program (NOP)



**SUBJECT:** Request for Clarification of “Other Ingredients” in Processed Organic Products  
*November 23, 2011 Revision – Supersedes November 15, 2011 Version*

The Organic Foods Production Act (OFPA) authorizes USDA to establish the National List of Allowed and Prohibited Substances. OFPA also grants the National Organic Standards Board (NOSB) the authority to recommend adding materials to or removing materials from the National List. The National List identifies substances that may and may not be used in organic crop and livestock production. In general, synthetic substances are prohibited for use in organic production unless specifically allowed, and non-synthetic (natural) substances are allowed unless specifically prohibited. For handling, the National List includes the non-organic substances that may be used in or on processed organic products. OFPA requires that the National List contain an itemized list of each permitted synthetic substance, including its specific use and application. The NOP recognizes that additional clarity is needed regarding non-agricultural ingredients used in processed organic products and listed under § 205.605.

When used as a formulated product, some substances on the National List may contain additional ingredients in various categories, including, but not limited to, carriers, stabilizers, and preservatives. Such “other ingredients” are sometimes referred to as inert ingredients, excipients, or incidental additives. For organic crop and livestock production, these “other ingredients” are specifically outlined in the regulations. For example, each ingredient in a livestock input material (e.g. medication, pesticide, feed additive) must meet one of the following criteria:

- Nonsynthetic (natural) substance which is not prohibited on § 205.604.
- Allowed synthetic substances which is allowed on § 205.603.
- Synthetic inert ingredient which is allowed on § 205.603(e), if listed on the Environmental Protection Agency (EPA) List 4-Inerts of Minimal Concern, and used in combination with allowed pesticide active ingredients.
- Excipient, only for use in the manufacture of drugs used to treat organic livestock if the excipient meets one of the following criteria:
  - Identified by the FDA as Generally Regarded as Safe.
  - Approved by the FDA as a food additive.
  - Included in the FDA review and approval of a new animal drug application or new drug application.

Additionally, all agricultural ingredients listed in the ingredients list for feed additives and supplements must be organic.

For organic crop production, examples of products with multiple ingredients include blended fertilizers, pesticides with inert ingredients, and potting soil with wetting agents. However, each ingredient must meet one of the following criteria:

- Nonsynthetic (natural) substance which is not prohibited on § 205.602.
- Synthetic substance which is allowed on § 205.601.
- Synthetic inert ingredient which is allowed on § 205.601(m), if listed on the Environmental Protection Agency (EPA) List 4-Inerts of Minimal Concern , and used in combination with allowed pesticide active ingredients. For passive pheromone dispensers, substances on EPA List 3-Inerts of Unknown Toxicity are also allowed.

Currently, the allowance of “other ingredients” in substances on the National List for use in processed organic products is unclear. Several certifying agents and members of the organic trade have asked the NOP to clarify which “other ingredients” are allowed. Since OFPA requires that each non-agricultural ingredient be specifically allowed, and because the National List doesn’t specifically list “other ingredients” commonly found in formulated products, the NOP is requesting that the NOSB specify whether these “other ingredients” are allowed.

#### **NOP Request to NOSB**

The NOP is requesting that the NOSB develop a policy on “other ingredients” in § 205.605 substances that is comparable to the comprehensive policy for crop and livestock materials. From this point forward, the NOP is requesting that the NOSB consider the presence of any “other ingredients” as part of their review processes. As substances on the National List come up for sunset review, or as new petitions are considered, the NOP requests that NOSB clarify whether any restrictions are warranted for “other ingredients” in § 205.605 substances. Any third-party technical report that the NOP provides will include information on any “other ingredients” commonly found in the substance under review.

The NOP is requesting that the NOSB specify any allowed “other ingredients” in the background section of their recommendations for substances recommended for listing on § 205.605, so that these allowances are clear to the organic trade, certifying agents, and the NOP. Any “other ingredients” that are not listed on § 205.605, or that are not referenced in the background section of the recommendation, would not be allowed in formulations of substances on § 205.605 that are used in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))”.

The NOP recognizes that the NOSB may want to address the subject further in the future with a comprehensive policy for “other ingredients” that may be included in permitted handling materials. Some questions that could be addressed in a future recommendation could include the following:

1. Should all agricultural ingredients that are “other ingredients” be organically produced?
2. Are synthetic preservatives allowed as “other ingredients?”

These steps will allow the NOP to clearly identify which formulated products are allowed under the processing section of the National List. Clear regulations will in turn allow certifying agents and the organic trade to consistently interpret these requirements. The NOP looks forward to working with the NOSB to continue to enhance the integrity of USDA organic products.