

## Classification of Materials

### Summary

Support the recommendation to change the definition of “chemical change” back to the language adopted in November 2009. The sentence added in April 2010 did not belong in the definition.

Reject the committee recommendation on “significant level of a synthetic substance” because it relies on standards that are not part of OFPA and does not allow the application of OFPA standards to low levels of synthetic substances. Instead, define “significant level of a synthetic substance” as *“any 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.”*

### More Details

OFPA creates a preference for nonsynthetic over synthetic inputs. Nonsynthetic inputs are presumed to be allowed unless petitioned and found to be unacceptable. Synthetic inputs are presumed to be prohibited unless petitioned and found to be acceptable. This preference sets the context for considering what constitutes a “significant” level of a synthetic residue in an otherwise nonsynthetic material.

The Addendum to November 6, 2009 Recommendation on Classification of Materials states that, “It is our intent through this recommendation that a material would be classified as synthetic when: . . . The material contains, at a significant level, a synthetic substance not on the National List of allowed synthetics.”

The question “What level of a synthetic residue is insignificant?” therefore really means “What level of a synthetic residue will we permit to override the duty to consider whether the contaminated input is acceptable?”

There are two key issues that must be addressed in the implementation of this statement of intent: (i) the process and elements associated with the review of the added synthetic substance, and (ii) the substantive criteria and standards utilized in the “significant level” determination.

### Process of Review

To fully implement the Classification of Materials definition and this addendum, the NOSB must have the ability to make the determination as to whether the use of a synthetic material results in a “significant level” in the finished material. Therefore, all materials that are manufactured or processed with synthetic agents, regardless of the function they perform, must be evaluated for significance. As the draft Classification of Materials document lays out, regardless of the finding as to whether the use of a synthetic material in manufacturing or processing results in chemical

change, a determination on “significant level” must be made for that synthetic material by the NOSB.

Therefore, a full review under the Classification of Materials definition must take place in two parts. First, a determination must be made as to whether the use of a synthetic agent has caused chemical change. Second, regardless of the determination on chemical change, a finding must be reached on the question of “significant level” of the synthetic agent in the end material.

### **Standard of Review**

The underlying statutory standard in the Organic Foods Production Act with regard to synthetic agents and their allowance is found in Sec. 2118 [7 U.S.C. 6517] NATIONAL LIST, c)(1) GUIDELINES FOR PROHIBITIONS ON EXEMPTIONS.-EXEMPTION FROM PROHIBITED SUBSTANCES IN ORGANIC PRODUCTION AND HANDLING OPERATIONS.- “The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this title only if- (A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances- (i) would not be harmful to human health or the environment...” While the law does not envision the use of purposefully added synthetic materials not on the National List, the list provides the mechanism for evaluating harm.

The overriding standard, unique to OFPA, which must be upheld is “would not be harmful.” This statutory intent is captured in the “Evaluation Criteria for Substances Added to the National List” with the questions, “Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)]; §6518 m.4]?” and, “Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]?”

The standard of review must be able to make a determination as to whether there is harm associated with the use of the synthetic substance, analogous to the standard of review used in the process of allowing synthetic substances on the National List. This is not solely a function of amount of substance since there is no general rule in toxicology as to the specific amount of all synthetic substances being insignificant. This issue takes on a special element of importance as scientists have discovered that classical toxicology, which assumed that the dose makes the poison, is overtaken by new understanding that endocrine disrupting chemicals effect an inverse dose response curve, where miniscule doses cause adverse effects that are more closely associated with timing of exposure than amount of chemical. We can delve into this issue further, but suffice it to say that incredibly small doses are causing serious adverse impacts at the beginning and throughout the life of an organism. Furthermore, as explained below, the NOSB cannot rely on standards developed to implement other laws.

So, if we focus just on the amount of synthetic residue that is “harmful” in the end product, we come to the conclusion that harm is a function of the quantity and toxicological properties of the synthetic residue, and of the use of the material to which it is added. Any residue must be examined at least to the extent of determining the health and environmental impacts of the quantity of residue *as a result of the material/s use in organic agriculture.*

Furthermore, however well-intentioned, the NOSB does not have the authority to waive its authority and responsibility to review and assess synthetic chemical effects that are utilized in organic manufacturing and processing. Certainly, regardless of whether a synthetic substance ends up in the end product, the NOSB must answer the question, “Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]?” That aside, while the board may deem a substance harmless after reviewing it, the substance must be reviewed. And, it would defy reality to find that a synthetic substance does not exist in a material if it is detectable.

The November 2009 recommendation said,

The MWG spent considerable time discussing the terms insignificant and significant level. We concur with their conclusion that a significant level should be determined with reference to the applicable regulatory limits for the type of substance, in addition to technical and functional effects produced by the residual level of the synthetic.

This strategy will fulfill the board’s duty only if the criteria are applied to the material *as used*, the impacts of manufacture, use, misuse, and disposal are considered, and the “applicable regulatory limits” are based on the “no harm” standard of OFPA. As always, the judgment of acceptability must take into account the particular use as well as nonsynthetic materials and other methods for accomplishing the same purpose.

Returning, then, to the question of insignificant residues, and understanding its equivalence to the question of when we may forego investigation of the harm associated with the presence of the synthetic contaminant, we find that ***no known level of a synthetic can be considered insignificant***. This is true whether or not the synthetic is on the National List because all synthetics are listed for particular uses. It also holds for cases in which we know the contaminant is present below detection limits. With the adoption of this approach, we are recognizing that the NOSB can fulfill its duty to evaluate for harm.

**Proposed Definition:** Significant is defined as “*any 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.*”

### **For More Information and To Submit Comments**

More information about the classification proposal can be found in the Materials Committee section of the [NOSB meeting packet](#).

You may submit comments at the [Regulations.gov website](#). Please identify your comments with “MC: classification.” You will have 20 minutes to type comments of 2000 *characters* or less, or you may upload a file. You may see a list of all comments that have been submitted on all proposals [here](#).