

petitioned for addition to the National List at 205.605(b). While OMRI is not opposed to establishing a definition for “volatile synthetic solvent,” we question whether it is necessary given the unlikely chance that a material would be petitioned for inclusion on 205.605(b), or that such a substance would pass the other criteria contained in OFPA for NOSB review of petitioned substances.

MC QUESTION 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?

Response: Since it is not OMRI’s role to support or oppose any specific practice or material on the National List, we cannot comment whether synthetic solvents should or should not be allowed to extract nonsynthetic materials for use in organic crop and livestock production. However, based on our experience reviewing thousands of synthetic and nonsynthetic materials used in organic crop and livestock production, we would strongly caution the NOSB to consider the implications of a blanket prohibition on the use of synthetic solvents to extract nonsynthetic materials. In our experience, this would affect a great number of otherwise innocuous materials such as vegetable oils, botanical extracts, pyrethrums, lecithin, and neem oils.

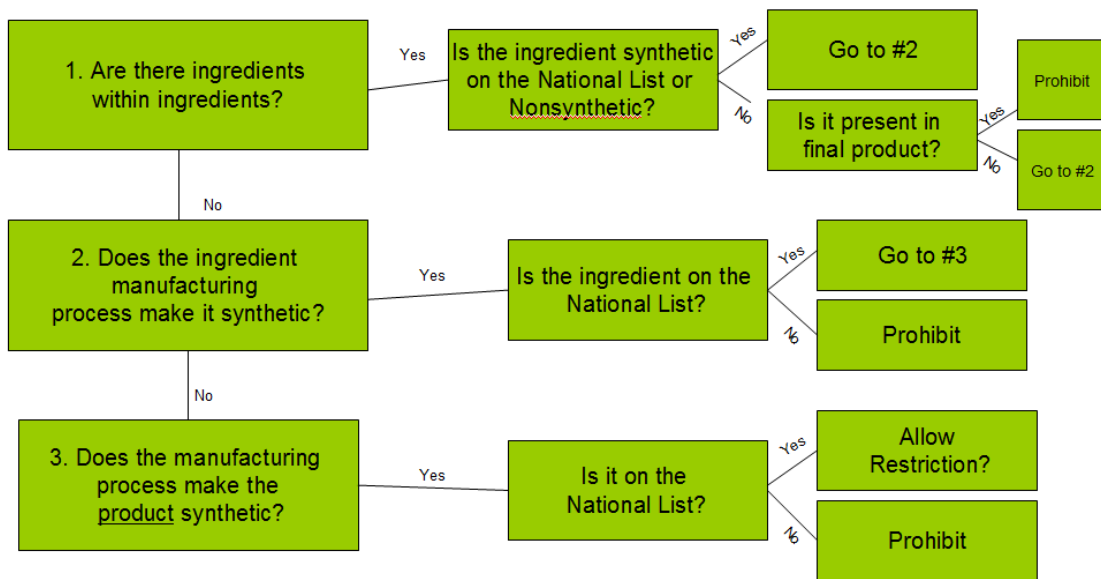
MC QUESTION 8: For substances already on the National List, should it be assumed that any extractant is allowed, or should the NOSB attempt to specify allowed extractants moving forward or for previously listed substances?

Response: For substances already on the National List, OMRI assumes that any extractant is allowed unless otherwise annotated. If the NOSB deems it necessary or prudent to specify allowed extractants going forward, OMRI can provide meaningful comment to the applicability and enforcement of such annotations.

We look forward to seeing many of these issues resolved through guidance published by the NOP and NOSB.

Significant Residues Discussion Document

For the purpose of understanding the concept of “significant residues” from OMRI’s experience, we would like start our comments on this subject by introducing our basic decision tree that covers most situations encountered during material review for crops inputs. Since OMRI finds it difficult to discuss such technical issues without real life examples, we are using a very common situation (feather meal with potassium sorbate preservative) to exemplify the concept of “significant residues” and how OMRI currently reviews them. In this case, we need only to focus on question #1 in our decision tree to determine whether “significant residues” influences the end compliance of the product.



Common situation #1: Feather meal containing potassium sorbate as a compost feedstock

1. Are there ingredients within ingredients? – Yes, there is potassium sorbate in the feather meal ingredient.
 - o Is the ingredient [within ingredient] synthetic on the National List or nonsynthetic? No – potassium sorbate is not on the National List and is not non-synthetic.
 - o Is it [potassium sorbate] present in the final product? OMRI considers a reasonable removal step based on the substance’s chemical properties in the final manufacturing process sufficient to determine that there are no “significant residues” in the final product. After a reasonable removal step in the manufacturing process, OMRI does not require lab analysis to show that the substance is no longer detectable. In fact, sometimes we cannot locate a lab that could test for certain materials. Since the feather meal with the potassium sorbate will be further composted, the microbes in the compost will effectively metabolize the potassium sorbate, thereby removing it from the final product. Thus, NO, the ingredient [potassium sorbate] is not present in the final product.

Common situation #2: A blended fertilizer with feather meal containing potassium sorbate as an ingredient

1. Are there ingredients within ingredients? – Yes, there is potassium sorbate in the feather meal ingredient.
 - o Is the ingredient [within ingredient] synthetic on the National List or nonsynthetic? No – potassium sorbate is not on the National List and is not nonsynthetic.

- Is it [potassium sorbate] present in the final product? Since the feather meal with potassium sorbate is simply blended with other ingredients and no reasonable removal step such as microbial metabolism occurs, YES, the potassium sorbate is present in the final product. Here is a typical formula of such a product:

Ingredient	Percent	Final concentration Potassium sorbate
Feather meal (w/ 0.1% potassium sorbate)	45	.00045% or 4-5ppm
Blood meal	25	
Bark dust	30	

Currently, OMRI would prohibit this formula because the potassium sorbate was not removed.

When looking at these two situations and hundreds more we see every day, the question for OMRI is not whether there are significant residues after a reasonable removal step for such substances; rather, we need to understand whether remaining synthetics such as potassium sorbate at 4-5 ppm is a significant residue?

Now that OMRI has established our current thinking on significant residues and how they affect material review, we would like to provide specific comments on the MC’s questions:

MC QUESTION 1: Under what circumstances, should the presence of a synthetic impurity trigger an examination of the impacts of the synthetic in relation to OFPA criteria?

Response: Currently OMRI refers any product containing prohibited materials to the petition process with the NOSB for review at the manufacturer’s discretion. The product may contain a synthetic material left over from the processing of the product, or the manufacturing of the product itself renders it synthetic. Again, we would only refer a product manufacturer to the NOSB if a reasonable removal step of all synthetics not on the National List was not apparent in the manufacturing process.

MC QUESTION 2: Do any of the three approaches described make sense? If so, why?

Response: Although each approach has pros and cons, it is OMRI’s opinion that the first, originally recommended approach of evaluating the technical and functional effects of the synthetic substance in the final material is the most reasonable. In discussing how we would implement such a practice, OMRI technical staff agrees that this approach will be the most consistent and reasonable way to go forward. In our examples above with potassium sorbate, when evaluating the technical or functional effect, neither product would contain “significant residues” of potassium sorbate such that it would exert preservative effects on the final product.

We do not agree with the third approach comparing any residues to a list of “harmful chemicals.” Based on our experience, this screening step is not necessary to trigger NOSB review of synthetic materials, because most synthetic residues are otherwise considered “safe” and not harmful. In order to demonstrate that this extra step is not necessary, we compiled a sampling (below) of some ingredients that were at “significant” levels in final products, and the status of each ingredient:

Table 1: Ingredients that were at “significant” levels in a final product, and the status of such ingredients:

Synthetic Ingredient	Purpose	Regulatory Status
Potassium bicarbonate	Ingredient in wine processing adjuvant	GRAS
Sodium lauryl sulfate	Active ingredient in pesticide	EPA 25(b) exempt active ingredient
1,2- Benzisothiazolin-3-one	Preservative in active pesticide ingredient	List 3 Inert
2-Heptanone	Inert ingredient in technical grade active ingredient	List 3 Inert
Potassium sulfate	Potassium source in fertilizer	GRAS
Sodium carbonate (by Solvay Process - synthetic)	Ingredient in processing adjuvant; is not same as nonsynthetic at 205.605(a)	GRAS; nonsynthetic equivalent on 205.605(a)
Calcium carbonate	Ingredient in foliar spray	GRAS
Magnesium carbonate	Magnesium fertilizer	GRAS
Potassium citrate	None; processing by-product	GRAS

MC QUESTION 4: The need for defining a significant residue arises from the Classification of Materials Policy adopted earlier that says that the use of a synthetic extractant or reactant does not affect the classification of a material, thereby allowing the use of synthetic extractants, reactants, or processing aids that may end up as impurities in the material. Should that policy be changed instead?

Response: OMRI recommends that you table this question until the NOP can issue guidance regarding classification of materials.

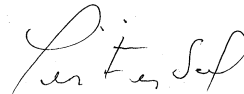
MC QUESTION 5: When residues of a certain synthetic impurity are identified as significant, how should the review proceed (a) if the material containing the impurity is under review by a MRO prior to use, (b) if the significant residues are discovered by a MRO/ACA when the material is in use, (c) if the material is under review by the NOSB?

Response: (a) In this situation, OMRI currently prohibits the product and refers the manufacturer to petition the NOSB at their discretion; or the manufacturer can reformulate and reapply at a later date (b) in this situation, OMRI suggests that the ACA/MRO discontinue the approval of the product and refer the manufacturer to petition the NOSB at their discretion; (c) the NOSB should elicit public comment, make a recommendation, and allow the NOP to issue guidance, proposed rule, or policy.

OMRI looks forward to a resolution to the issue of significant residues and how to evaluate them. Please do not hesitate to request more real-life examples to help facilitate this discussion to its fullest.



Peggy Miars
Executive Director/CEO



Lindsay Fernandez-Salvador
Program Director