



Response to Comments

Products in the “Made with Organic *” Labeling Category**

This document summarizes comments received on the Notice of Draft Guidance Concerning ““Made With Organic (Specified Ingredients or Food Groups)” Products: Product Composition and Use of Percentage Statements,” which was posted on the NOP Web site for public comment. The public was notified in a Federal Register notice ([76 FR 2328](#)) on January 13, 2011.

This guidance describes the requirements for products in the “made with organic (specified ingredients or food group(s))” labeling category. Specifically, this guidance clarifies the following aspects of products in this labeling category, referred to as “made with organic ***.”

1. Composition;
2. Compliant organic labeling claims;
3. Organic and nonorganic forms of the same ingredient;
4. Percentage of organic ingredients statements; and
5. Ingredients or food groups in the “made with organic ***” claim.

The NOP received a total of 26 individual comments on the Notice of Draft Guidance. Based on the comments received, the NOP revised the draft guidance and is publishing NOP 5032: Products in the “Made with Organic ***” Labeling Category. This action addresses a National Organic Standards Board (NOSB) recommendation from March 2005.

- ***CHANGES MADE IN RESPONSE TO COMMENTS***

1) Synthetic substances used to manufacture ingredients listed in 7 CFR § 205.605.

Commenters expressed concern that the following statement in the draft guidance differed from the industry’s current understanding of composition requirements regarding substances on § 205.605 of the National List of Allowed and Prohibited Substances (National List), particularly with respect to synthetic carriers and incidental additives:

“Any synthetic substance may be used to manufacture a substance on § 205.605; however, if the synthetic is present in the final § 205.605 substance, the synthetic must also be on the National List and allowed for the intended use.”

Furthermore, commenters indicated that the NOSB considers these “other ingredients” when reviewing substances petitioned for inclusion on § 205.605 of the National List. These commenters assert that the complexity of this issue merits a separate clarification. We agree the issues this statement has introduced are beyond the intended scope of this guidance and should be addressed separately. Accordingly, we removed the statement in the final guidance.



- 2) **List of food groups.** A commenter asked if the list of food groups identified in 7 CFR § 205.304(a)(1)(ii) is exhaustive. The Preamble to the NOP Final Rule indicates that this list is intended to be a complete account of food groups that may appear in the statement “made with organic (specified food groups)”:

“The following food groups can be specified in the “made with organic ****” labeling statement: fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables. In addition, organically produced and processed butter, cheeses, yogurt, milk, sour cream, etc., may be identified as a “milk products” food group” (65 FR 80579).

Therefore, operations cannot identify other food groups in their “made with organic****” label claims. We have clarified this in the final guidance.

- 3) **Example of acceptable and unacceptable label claims is confusing.** Commenters remarked that the example, “Made with X% organic ingredients,” as an acceptable percentage statement is confusing. These commenters referenced a statement in the draft guidance, which informed that “made with (insert number)% organic ingredients” would not be an acceptable variation of the “made with organic****” statement. The statement, “Made with X% Organic *Ingredients*” would be incorrect if used without a “made with organic...” statement that lists up to three organically-produced agricultural ingredients or food groups. We agree this distinction could easily be confused and instead provided specific examples in the final guidance.
- 4) **Using both ingredients and food groups in a “made with organic...” statement.** Commenters asked if it was acceptable to mix and match food groups and ingredients in the “made with organic ****” statement. In the final guidance we state this is allowed, provided that the statement does not contain more than a total of three ingredients and/or food groups.
- 5) **Prohibit the use of organic and nonorganic forms of the same ingredient.** Commenters stated that the use of organic and nonorganic forms or derivations of the same ingredient should not be allowed. We added a section to clarify that:

If an ingredient is identified in the “made with organic ****” statement, it must be a truthful claim. This means the product can only contain organic forms of that specific ingredient or any further processed form of it. For example, if the label states, “made with organic corn,” all raw and processed corn-based ingredients, such as blue corn, corn oil, and corn starch, must be certified organic. This policy is consistent with 7 CFR § 205.300(a) and the preamble to the NOP final rule (65 FR 80548).

If an ingredient is not identified in the “made with organic ****” statement, the product may contain both organic and nonorganic forms of the same ingredient. However, they must be listed separately in the ingredient statement on the information panel.



The final guidance contains examples to help certifiers and certified operations determine if a “made with organic***” statement is acceptable.

- 6) **Prohibition on excluded methods for 7 CFR § 205.605 substances.** A commenter observed that the draft guidance makes explicit that substances on § 205.606 of the National List must not be produced using excluded methods, but does not make clear that the prohibition also applies to substances on § 205.605 of the National List. 7 CFR § 205.301(c) prohibits the use of excluded methods to manufacture any ingredients in “made with organic***” products; this includes nonagricultural substances on § 205.605 of the National List and nonorganic agricultural products. In the final guidance, we clarify that “made with organic ***” products must not contain any ingredient that was produced using excluded methods, such as genetic engineering, sewage sludge, or ionizing radiation. (See [7 CFR § 205.105](#)).
- 7) **“Made with organic***” statements should be optional.** A number of commenters requested clarification on the statement in the draft guidance:

“The “made with organic (specified ingredients or food group(s))” statement is essential to clarify the product category....”

Since the USDA organic regulations state that eligible agricultural products “may” bear this claim, commenters expressed confusion about this statement being mandatory. Some commenters urged that the “made with organic***” statement not be required in order to be consistent with the Canadian Organic Products Regulations (COR), which do not have a “made with organic***” labeling category, but provide for percentage statements to designate products that contain less than 95% organic content. These commenters asserted that requiring a “made with organic...” statement to accompany a percentage statement would increase costs for companies to develop different labels for NOP- and COR-certified products. Other commenters supported that the “made with organic***” statement be mandatory to alleviate consumer confusion.

We accept that products that qualify for a “made with organic***” claim are not required to display that statement and have revised the final guidance to make the “made with organic***” statement optional. However, if these products display a percentage statement, a “made with organic***” statement is required.

- ***CHANGES REQUESTED BUT NOT MADE***

- 1) **Eliminate “made with organic” product category.** We received comments suggesting that there should be no “made with organic (specified organic ingredients)” category at all. Eliminating a product composition and labeling category would require regulatory action to amend the USDA organic regulations.
- 2) **Consumer confusion between organic products and 95% organic “made with organic (specified ingredients).”** Several commenters noted that it is confusing that two products



could have labeling claims, “contains 95 percent organic ingredients,” but the use of the USDA organic seal would be allowed in one and prohibited in the other. This distinction depends on the ingredients in the product’s remaining 5 percent:

Organic products: (1) nonagricultural ingredients specifically allowed on § 205.605 of the National List; and (2) nonorganic agricultural ingredients that are not commercially available in organic form and appear on § 205.606 of the National List.

*“Made with organic ***” products:* (1) nonagricultural ingredients specifically allowed on § 205.605 of the National List; and (2) nonorganic agricultural ingredients.

For example, a muffin mix contains 95 percent organic content. The remaining five percent is composed of nonorganic walnuts, baking soda, and salt. Since the mix contains nonorganic walnuts (not listed on § 205.606 of the National List), the muffin mix does not qualify for the “organic” labeling category. Unless the muffin mix was reformulated to contain organic walnuts, it is only eligible for the “made with organic ***” labeling category and its label cannot include the USDA organic seal.

The USDA organic regulations allow percentage organic ingredient statements on both “organic” (see 7 CFR § 205.303(a)(2)) and on “made with organic***” (see 7 CFR § 205.304(a)(2)) products. Therefore, we did not make any changes based on this comment.

- 3) **Use of the term “natural.”** One commenter noted the use of the term “natural” in the policy statement and suggested use of the term “nonsynthetic” to align with the wording in the titles of the subsections of 7 CFR § 205.605. Under the USDA organic regulations, the terms “nonsynthetic” and “natural” are synonymous. The term “natural” was used to improve the plain language and readability of the document. However, neither term is used in the final guidance.
- 4) **Use of the labeling statement “made with 100 percent organic (specified ingredients).”** Several commenters advocated for an exception to allow “made with organic***” product labels to make a 100 percent organic claim for specific ingredients. For example, commenters stated that wines that are made with only organically-grown grapes and contain added sulfites should be allowed to state, “made with 100 percent organic grapes.” The commenters asserted it is unfair for handlers to use only organic ingredients and then not be able to make a 100 percent organic claim. We believe that restricting 100 percent organic content claims on “made with organic***” products is warranted. “100 percent organic” is a labeling category established in the USDA organic regulations. The use of this phrase on “made with organic***” products, particularly if neither the optional “made with organic***” statement nor an ingredient statement (optional on alcohol beverages) are present, could lead consumers to believe that the *product* is “100 percent organic.” The final guidance clarifies that 100 percent claims for specified ingredients is not allowed.