



April 29, 2008

The National Organic Standards Board
c/o Valerie Frances, Executive Director, NOSB
1400 Independence Avenue, SW
Room 4008 – South Building, Ag Stop 0268
Washington D.C. 20250-0200

RE: Recommendations on 205.606 Petitioned Materials (Docket No. AMS-TM-08-0021)

Dear NOSB:

Oregon Tilth, Inc. and Pennsylvania Certified Organic (PCO) appreciate the opportunity to submit comments on § 205.606 petitioned materials. We have a number of specific questions related to the allowed manufacturing processes and potential formulation aids used to produce the non-organic agricultural ingredients listed on § 205.606. As you are aware, an Interim Rule allowing the use of 38 new substances was published on June 22nd, 2007. In the intervening year, we have had a challenging experience determining the compliance of § 205.606 materials. We ask you to carefully consider these questions as you discuss and recommend the addition of more materials to the National List. In summary the key issues are:

- What does the NOSB consider as “part” of the product that is listed as permitted on § 205.606? Do certifiers need to review formulation aids such as carriers, binders, or additives in the ingredients as supplied to certified processors?
- Can synthetic solvents not allowed under § 205.605 be used to extract materials listed on § 205.606?

NOP Rule:

§ 205.270 Organic Handling Requirement

(c) The handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” or in or on any ingredients labeled as organic:

(1) Practices prohibited under paragraphs (e) and (f) of § 205.105 [excluded methods, ionizing radiation]

(2) A volatile synthetic solvent or other synthetic processing aid not allowed under § 205.605: Except, That, nonorganic ingredients in products labeled “made with organic (specified ingredients or food group(s))” are not subject to this requirement.

Clarification 1

Given the lack of annotations in § 205.605 addressing the use of synthetic solvents, processing aids, carriers and/or additives and the ambiguity of section § 205.270(c)(2), Oregon Tilth and PCO request clarification on the allowed practices and materials used in or on non-organic agricultural ingredients used in organic products. For example, would an agricultural color extracted with synthetic solvents, such as hexane be allowed? Could an extract, such as the Peony Root Powdered Extract petitioned for this meeting, contain a non-organic carrier unlike the organic astragalus root carrier described in the petition?

Clarification 2

Oregon Tilth and PCO request clarification on whether the prohibition specified in § 205.270(c)(2) regarding synthetic solvents and “other synthetic processing aids” also extends to ingredient formulation aids such as carriers, binders and standardizing agents not included on the National List. Would the addition of a synthetic carrier or artificial preservative added to an agricultural color product be allowed? Would the use of an agricultural carrier such as maltodextrin or cornstarch need to be organic? While colors are the focus of our comments, we recognize that this clarification extends to any non-organic agricultural ingredient appearing on § 205.606 of the National List.

Analysis

§ 205.270(c)(2) prohibits the handler of a certified operation from using a volatile synthetic solvent or other synthetic processing aid not allowed under § 205.605 in products intended to be sold, labeled, or represented as “organic.”

Explicit specification of the organic handler in this paragraph suggests that volatile synthetic solvents and processing aids not allowed by § 205.605 may be used by a non-organic handler supplying non-organic ingredients to an organic handler. Alternatively, the organic handler’s use of the non-organic handler’s product in assembling a certified organic product may be viewed as (secondary) ‘use of the synthetic solvents and processing aids’ by the organic handler (which would be prohibited).

Additionally, while (c) of this section refers to the certified product and the organic ingredients contained in that product, the exception in (c)(2) implies the prohibition also applies to *non-organic ingredients* in *organic* products.

The Interim Rule lists 38 new substances, along with restrictive annotations, to § 205.606 of the National List. Nineteen of these substances are colors. The change in classification from non-agricultural to agricultural raises the question of how the new ‘**agricultural colors**’ should be evaluated differently from their former broad category listing as ‘**nonagricultural colors**’.

Formerly, certifiers verified that non-agricultural colors are derived from non-synthetic sources and that the color, including any incidental components making up that color, were produced and handled without the use of excluded methods, ionizing radiation and sewage sludge. The use of volatile synthetic solvents and synthetic processing aids were not, however, grounds for rejection; the premise is that they were evaluated during the material review and National List process and any restrictions would be stated in the annotation. This approach is supported by the following Q & A formerly posted on the NOP website:

Q: Do nonagricultural substances included on the National List of Allowed and Prohibited Substances have to be produced without the use of volatile synthetic solvents? My certifying

agent says yes because of the prohibition on the use of volatile synthetic solvents found in section 205.270(c)(2).

A: No. Section 205.270(c)(2) prohibits the use of a volatile synthetic solvent unless included on the National List as an allowed substance. However, synthetic solvents do not have to be on the National List to be allowed in the production of an allowed nonagricultural substance found on the National List. The use of volatile synthetic solvents in the production of allowed nonagricultural substances included on the National List is considered approved through the materials review process, unless otherwise stated through an annotation to the approved substance. (Example: § 205.605(a)(9), Flavors -- nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.)

This question addresses *non-agricultural* substances, and although not specifically mentioned here, the same logic might be applied to other substances on the National List, including non-organic *agricultural* ingredients listed on and proposed for § 205.606.

However, Oregon Tilth and PCO are concerned that alternate extraction methods or use of processing aids and carriers may not have been given full consideration by the NOSB. Colors reviewed by the NOSB were all extracted using aqueous or physical extraction if a liquid, or were dried if a powder, however no annotation requiring these methods or prohibiting others is included. Many of the petitions provided to NOSB had manufacturing information redacted as confidential, so it is not clear what exact manufacturing process was considered. For instance, some natural colors listed on § 205.606 may be spray dried, and formulated with standardizing agents not on the National List, such as dextrose or maltodextrin. Was this considered as part of the petition review? While TAP reviews were conducted for shellac and gelatin, and a technical report for fructooligosaccharides, the rest of the proposed substances did not receive a TAP review. Therefore adequate information needed to objectively evaluate petitions and alternate practices and materials was not available and appears to have been omitted from the review.

Comprehensive consideration of such practices and materials may have been seen as unnecessary given the agricultural status of the substance. The board may not have foreseen, however, that many “agricultural” substances petitioned for § 205.606 are not simple, single ingredient commodities but highly refined substances that can be formulated with a variety of other ingredients. However, the current rule does not provide clear guidance regarding source and formulation and nowhere is there guidance that a certifier should approve a National List material only if it is produced and handled like the petitioned material.

The preamble to the final rule supports the implication that non-organic ingredients in organic products must not be produced using synthetic solvents or other synthetic processing aids not allowed under § 205.605. However, the regulation is ambiguous on whether this prohibition applies only to the handler of the organic handling operation, or if the prohibition’s applicability extends to producer(s) of the non-organic ingredients prior to arrival at the NOP certified facility. This latent ambiguity regarding the scope and applicability of the prohibition of synthetic solvents invites a situation where the regulations may be interpreted and applied differently by certification agents. Without clarification, it is difficult to ensure the regulations are applied in a fair and equitable manner.

FR 80575, Dec. 21, 2000
Handling - Clarifications

Clarification is given on the following issues raised by commenters.

(1) Use of Nonorganic Ingredients in Processed Products.

We have corrected paragraph (c) of section 205.270 to clarify what must not be used in or on organically produced ingredients and nonorganically produced ingredients used in processed organic products. The prohibition on use of ionizing radiation, excluded methods, and volatile synthetic solvents applies to all organically produced ingredients. The 5 percent of nonorganic ingredients in products labeled "organic," also are subject to the three prohibited practices. The nonorganic ingredients in products labeled "made with organic ingredients" must not be produced using ionizing radiation or excluded methods but may be produced using volatile synthetic solvents. The nonorganic ingredients in products containing less than 70 percent organically produced ingredients may be produced and processed using ionizing radiation, excluded methods, and synthetic solvents.

Conclusion:

There appear to be two possible options for this situation:

- 1) The manufacturing process is considered during NOSB review and all extraction methods, other additives and processing aids are considered during the materials review process and deemed allowed unless specifically annotated as restricted; or
- 2) The prohibition on synthetic solvents, synthetic processing aids, and other carriers and additives not allowed under § 205.605 or § 205.606 applies to the production and handling of all non-organic agricultural ingredients used in products labeled "organic".

If Option 1 is correct, then the Q & A section of the NOP website included above should be changed to include both non-agricultural and agricultural substances, and be extended to include other synthetic processing aids to be consistent with the language in 205.270(c)(2). Accordingly, while organic handlers cannot use synthetic solvents or additives not on the National List, these substances may be used in the formulation of ingredients that appear on the List at 205.605 or 205.606. The Q & A should also be adjusted to include carriers, binders, fillers and other similar formulation aids if they are also considered approved through the material review process.

If Option 2 is correct, then the Q & A should be adjusted as follows (changes are underlined):

Q: Do nonagricultural and agricultural substances included on the National List of Allowed and Prohibited Substances have to be produced without the use of volatile synthetic solvents and synthetic processing aids not allowed under the National List? My certifying agent says yes because of the prohibition found in section 205.270(c)(2).

A: The answer depends on whether the substance is nonagricultural or agricultural.

Section 205.270(c)(2) prohibits the use of a volatile synthetic solvent or synthetic processing aid unless included on the National List as an allowed substance. However, synthetic solvents and synthetic processing aids do not have to be on the National List to be allowed in the production of an allowed nonagricultural substance found on the National List at § 205.605. The use of volatile synthetic solvents and synthetic processing aids in the production of allowed nonagricultural substances included on the National List is considered approved through the materials review process, unless otherwise stated through an annotation to the approved substance. (Example: § 205.605(a)(9), Flavors -- nonsynthetic

sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.)

For agricultural substances, the answer is yes. The prohibition in section 205.270(c)(2) does apply to non-organic agricultural substances listed at § 205.606. Thus, these non-organic agricultural substances must be produced and handled without the use of volatile synthetic solvents and synthetic processing aids unless included on the National List as an allowed substance. Carriers, binders, fillers and other similar formulation aids must also be compliant with the National List.

In addition to the above Q & A clarification, the following adjustment to the Rule should be made:

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as "organic," only when handled in accordance with § 205.270 and any restrictions specified in this section, and only when the product is not commercially available in organic form.

Neither option is perfect, but one must be chosen. Option 1 requires that the NOSB do more research, and be prepared to evaluate many possible methods for manufacturing and formulating agricultural ingredients. TAP reviews may be necessary in order to do this. Option 2 requires more work from certifiers and processors who must evaluate all sub-ingredients in formulated products for compliance, however this is similar to the approach currently taken for brand name review of other inputs. It may provide a higher degree of confidence in compatibility of non-organic ingredients for use in organic products and prevent unwitting incorporation of synthetic preservatives or other prohibited materials.

As presented, both options have significant ramifications for the material evaluation process you are now undertaking. In order to ensure that compliance decisions are made accurately and consistently by certifiers, clarification of this issue prior to adding more substances to § 205.606 is absolutely crucial.

Thank you again for this opportunity and for carefully considering Oregon Tilth’s and PCO’s comments.

Respectfully submitted,

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