

**FORMAL RECOMMENDATION BY THE  
NATIONAL ORGANIC STANDARDS BOARD (NOSB)  
TO THE NATIONAL ORGANIC PROGRAM (NOP)**

**Date:** 4/21/2007

**Subject:** Annatto Extract, water and oil soluble, color for addition to National List under Colors, §205.606

**Chair:** Andrea Caroe

**Recommendation**

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: XXX

Guidance Statement: \_\_\_\_\_

Other: \_\_\_\_\_

**Statement of the Recommendation (including Recount of Vote):**

The Board recommends adding Annatto Extract, water and oil soluble, color to the National List under §205.606-nonorganically produced agricultural products

**NOSB Vote:**     **Motion:** Julie Weisman     **Second:** Joe Smilie

**Board vote:** Yes -13    No-0    Abstain- 0    Absent -2

**Rationale Supporting Recommendation (including consistency with OFPA and NOP):**

The National List of Allowed and Prohibited Substances §205.606

**Response by the NOP:**

# National Organic Standards Board

## Final Recommendation for

**Date: April 21, 2007**

**I. List:** *(where in FR rule example 205.606)*

**National Organic Program Subpart G: The National List of Allowed and Prohibited Substances. §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food groups(s)).”**

**II. Committee Summary:**

On October 19, 2006, as part of the Sunset Review process the NOSB voted not to re-list “Colors, non-synthetic sources only” as a broad category on § 205.605a of the National List. This category appeared on the National List as part of the original Rule which became effective on October 21, 2002. It had come to the attention of the Board during the Sunset review that this listing occurred without “Colors” being petitioned and without any recommendation from the NOSB. Therefore it was determined that “Colors” was not eligible for re-listing at the conclusion of the Sunset period. (Please see the “NOSB Final Sunset Recommendation for Colors, Non-Synthetic of October 19, 2006” for additional details)

Organic processors using Colors were strongly urged by the Board to petition agricultural ingredients used for color onto 205.606 as quickly as possible to avert a complete loss of access to color ingredients after October 22, 2007 when the category “colors” sunsets from §205.605a. As a result, numerous petitions were received for agricultural color materials. Annatto Extract, water and oil soluble, color, was one such material.

Simultaneous with the Sunset process was the development of criteria for determining commercial availability, an essential tool in evaluating whether or not petitioned materials could be listed on § 205.606. These criteria were finalized in the NOSB “Recommendation for the Establishment of Commercial Availability Criteria National List § 205.606” of October 19, 2006. That recommendation allows for pro-active listing on 205.606 of materials which may currently be available in an organic form, but the supply of which has a history of fragility due to factors such as limited growing regions, weather or trade-related issues. Furthermore, the recommendation reiterates the role of the Accredited Certifying Agent (ACA) in making the ultimate decision as to whether a 606-listed material may be used, on a case by case basis.

Petitions received for color materials contained widely varying amounts information with which to assess the current availability or fragility of current supply of organic forms of the petitioned color material.

The petitioners for Annatto Extract, water and oil soluble, color, made the case that while conventional Annatto is available, there currently is not an adequate source of raw organic Annatto seeds from which to extract an organic form of this color. Public comments were received that supported the petition.

The Handling Committee noted that agricultural substances are only required to be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

6517(c)(1)(a)

i) would not be harmful to human health or the environment;

(ii) is necessary to the production or handling of the agricultural product because of unavailability of wholly natural substitute products; and

(iii) is consistent with organic farming and handling;

Agricultural substances do not need to be evaluated against section 205.600 (b). (i.e. essentialness) . This additional criteria is only required for any synthetic substance used as a processing aid or adjuvant.

However, the Handling Committee discussed what constitutes “essential” for organic handling of a finished retail product and how that may be different from that of a material used in crop or livestock production. It was agreed that color materials might be essential for creating a product that meets consumer expectations of a product’s visual appearance. A number of commenters cited Annatto Extract, water and oil soluble, color, as an essential ingredient in the organic consumer products they make for this reason.

No Public Comment apposing Annatto Extract

**III. Board Recommendation**

Annatto Extract, water and oil soluble, color is passed for inclusion on §205.606 of the National List

*Moved: Julie Weisman Second: Joe Smillie*

*Board vote: Yes- 13 No- 0 Absent- 2 Abstain-0 Recuse-0*