

**Formal Recommendation by the
National Organic Standards Board (NOSB)
to the National Organic Program (NOP)**

Date: **October 28, 2010**

Subject: **Annatto Extract Color, Oil and Water Soluble -- Sunset Review**

Chair: **Daniel G. Giacomini**

The NOSB hereby recommends to the NOP the following:

Rulemaking Action X
Guidance Statement
Other

Statement of the Recommendation (Including Recount of Vote):

Annatto Extract Color, Oil and Water Soluble was reviewed for sunset by the NOSB at the October 2010 meeting. A summary of the Handling committee's recommendation is attached. The Handling committee had originally recommended that the liquid form of annatto extract color not be relisted and the powdered form be relisted. At the October 2010 meeting there was discussion that the annotation should not be changed during the sunset process so the committee revised their recommendation adding a paragraph at the end of the discussion indicating that the Handling committee was recommending relisting at this time but intended to address which forms were available in response to a petition to remove annatto extract color from the National List. No comments were received during the meeting that disagreed with the committee's recommendation.

The NOSB voted to recommend relisting of Annatto Extract Color, Oil and Water Soluble on §205.606 with 14 voting yes and 0 no votes.

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

NOSB Vote:

Moved: Katrina Heinze		Second: Jennifer Hall		
Yes: 14	No: 0	Abstain: 0	Absent: 0	Recusal: 0

**National Organic Standards Board
Handling Committee
Recommendation for § 205.606
Sunset Review of Annatto Extract Color – Oil and Water Soluble**

October 28, 2010

List: 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.

(d) Colors derived from agricultural products

Committee Summary:

Annatto extract color (pigment CAS # 1393–63–1)—water and oil soluble was added to the National List (Federal Register Vol. 72, #123, June 27, 2007). This is the first time that annatto extract color is being reviewed for sunset. Annatto extract color is used as an ingredient in foods to meet the aesthetic requirements of consumers.

A Technical Review, dated October 14, 2005, on the category of colors was prepared for the National Organic Program (NOP) and NOSB. It is titled “Overview of Food Color Additives.”

Annatto extract color, as well as eighteen other colors, was added to section §205.606 of the National List after the §205.605(a) listing of Colors -- nonsynthetic only was allowed to sunset off the National List. The NOSB in their October 19, 2006 recommendation stated that:

“There was a comment addressing the concern that colors . . . were added to the National List without a technical review by the NOSB. The Handling Committee requested and received a technical overview of food color additives on October 14, 2005. This technical review offered no information that would suggest that non-synthetic colors are inconsistent with organic practices. There were numerous comments opposing renewing the listing of non-synthetic colors. A few commenters requested that they be moved to 205.606, an action which cannot be taken as part of Sunset. Several commenters cited that non-synthetic colors had been placed on the National List without being petitioned and without the recommendation of the NOSB. The Board finds merit in this observation. Colors, non-synthetic cannot be renewed through the Sunset process because there was never an NOSB recommendation for its placement on the National List.

As a result petitions were received for listing a number of colors on §205.606. Of those petitions, annatto extract color, as well as eighteen other colors, was recommended for listing by the NOSB. There was general agreement that annatto extract color should be listed on the National List but some debate as to the proper annotation. The Handling Committee originally recommended that the annotation include a restriction that only organic oil be used for extraction of the annatto. That annotation was viewed as being too restrictive and was not included in the final recommendation. Additionally, there was some discussion as to the two forms, liquid and powder of annatto extract color, and how to include both in the annotation. The final result was that the annotation reads “oil and water extracted.”

The NOSB has received ten public comments related to the relisting of annatto extract color in response to the Federal Register notice of the sunset of annatto (AMS-TM-09-0074). In summary:

- Five supported the relisting
- One handler specifically identified that they have been unable to source, as organic, a powdered version of annatto extract color which is necessary for their product. They have found a liquid form, as organic, but it is not suitable for use in their product. They have also tested a 100% ground annatto seed powder, which is highly variable in color and thus does not meet the consumer desire for consistency. Additionally, use of this seed powder resulted in off flavors not desired by the consumer.
- Three public comments asked that annatto extract color be removed from the National List because a sufficient organic supply was now available.
- One public comment was from a supplier of organic liquid annatto extract color saying that they were able to supply the market needs of industry.

In addition, six public comments were received in response to the Federal Register notice on the spring 2010 NOSB meeting (AMS-TM-10-0021) asking that all §205.606 items be relisted.

In response to these public comments, the NOSB Handling Committee conducted an informal market survey. It appears that products which would be expected to use a liquid annatto extract color (e.g., cheese, yogurt) are in fact using organic annatto. Conversely, products which would be expected to use a powdered annatto extract color (e.g., dry cheese powder products like macaroni and cheese) are not using organic annatto. This supports the public comments received. Additionally, the public commenter who is a supplier of organic liquid annatto extract color was contacted and confirmed that they do not have a powdered version available in organic form. A search of the internet did not find a powdered version beyond the 100% ground annatto seed referred to above.

A review of the original petitions and recommendations, historical documents, and public comments does not reveal unacceptable risks to the environment, human or animal health as a result of the use or manufacture of annatto extract color. As a §205.606 listed material, annatto extract color is subject to commercial availability scrutiny for use in organic products.

As a result of our review, the Handling Committee believes that liquid annatto extract color is now available in sufficient, form, quantity and quality and should no longer be listed on §205.606 but that the powdered form is not available in sufficient form, quantity or quality and should still be listed on §205.606.

Unfortunately, the listing for annatto extract color on §205.606 does not list the liquid and powdered forms in the annotation so current NOSB policy does not allow only one form to be removed. The NOSB has received a petition for the removal of annatto extract color from §205.606 which the Handling Committee intends to review immediately. At this time we are recommending that annatto extract color be relisted but expect to address the forms available in response to the petition we have received.

Committee Summary

The Handling Committee recommends that Annatto extract color (pigment CAS # 1393-63-1)—water and oil soluble be relisted on §205.606

Committee Vote

Motion: Katrina Heinze Second: Steve DeMuri
Yes: 0 No: 5 Abstain: 0 Absent: 2