

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

Date: December 2, 2011

Subject: Petition to Remove Annatto extract color (pigment CAS # 1393-63-1): water and oil soluble -- from the National List §205.606

Chair: Tracy Miedema

The NOSB hereby recommends to the NOP the following:

Rulemaking Action

Statement of the Recommendation (Including Recount of Vote):

The NOSB recommended by a vote of 14 yes, zero no and zero absent to remove Annatto color, with all annotations, from the National List §205.606.

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

A petition to remove Annatto Extract Color: water and oil soluble was reviewed by the NOSB at the November 2011 meeting. A summary of the Handling committee's recommendation is attached.

The Handling committee had originally recommended that the annotation for Annatto extract color be changed from "water and oil soluble" to "liquid and powdered forms." Rationale for this annotation change is included in the committee's recommendation. Since no public comment was received indicating that either form of annatto extract color was not commercially available in sufficient quantity, quality or form, the NOSB decided that a vote on the annotation change was not necessary. However, it was noted that the original annotation did not properly represent the forms available in the market.

At the time of the Handling committee's recommendation they had received public comment confirmed through an informal market survey that the liquid form of annatto extract color was commercially available and widely used. They also had public comment that the dry form was available but the informal market survey showed that it was not as widely used. The committee recommended that both forms be removed from the National List section §205.606 but asked for public comment with examples of where the dry form that is available could not be used. No such public comment was received.

Two public comments were received in response to the committee's recommendation and posting for the November 2011 meeting. One supported the annotation change and supported the recommendation to remove both forms only if no public comment to the contrary was received. The other public comment asked that an appropriate transition time for handlers to reformulate and change packaging be considered.

Given that there was no public comment supporting the continued listing of annatto extract color, the NOSB voted unanimously for its removal.

NOSB Vote:

| | | | | |
|----------------------------|--------------|----------------------------|------------------|-------------------|
| Moved: Steve DeMuri | | Second: Jay Feldman | | |
| Yes: 14 | No: 0 | Abstain: 0 | Absent: 0 | Recusal: 0 |

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

| | |
|--|---|
| For NOSB Meeting: <u>November 2011</u> | Substance: <u>Annatto extract color (pigment CAS # 1393-63-1)—water and oil soluble</u> |
|--|---|

Committee: Crops Livestock Handling Petition is for removal of Annatto extract color (pigment CAS # 1393-63-1)—water and oil soluble on the National List § 205.606

| A. Evaluation Criteria (Applicability noted for each category; Documentation attached) | Criteria Satisfied? (see B below) |
|--|--|
| 1. Impact on Humans and Environment | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> |
| 2. Essential & Availability Criteria | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> |
| 3. Compatibility & Consistency | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> |
| 4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/> |

B. Substance Fails Criteria Category: 4 Comments: At this time, the Handling Committee believes that sufficient evidence exists that both forms, liquid and powdered, of organic annatto extract color are available. We understand that there may be applications where the forms available do not perform. We ask that handlers or certifiers who are aware of these applications provide written public comment for the fall 2011 NOSB meeting so they can be considered.

C. Proposed Annotation (if any): Current annotation is "Oil and Water Extracted." Proposed annotation is "Liquid and powdered forms." See committee comments at end of document for details_____

Basis for annotation: To meet criteria above: X Other regulatory criteria: _____ Citation: The Handling Committee is recommending an annotation change to include both forms of annatto extract color so that the NOSB has the flexibility to list one or the other should public comment be received that the forms of organic extract color that are available do not perform in all applications__

D. Recommended Committee Action & Vote (State Actual Motion): Recommend changing the annotation of Annatto Extract Color from "Water and Oil Soluble" to "Liquid and Powdered Forms."

Motion by: *Heinze* Seconded: *Dickson* Yes: 6 No: 0 Absent: 1 Abstain: 0

Recommend removing Annatto color, with all annotations, from the National List §205.606

Motion by: *Heinze* Seconded: *Dickson* Yes: 6 No: 0 Absent: 1 Abstain: 0

| | | | | | |
|----------------|-------------------------------------|---|-------------------------------------|--------------------------------|-------------------------------------|
| Crops | | Agricultural | <input checked="" type="checkbox"/> | Allowed ¹ / REMOVED | <input checked="" type="checkbox"/> |
| Livestock | | Non-Synthetic | | Prohibited ² | |
| Handling | <input checked="" type="checkbox"/> | Synthetic | | Rejected ³ | |
| No restriction | | Commercially Un-Available as Organic ¹ | | Deferred ⁴ | |

- 1) Substance voted to be REMOVED as "allowed" on National List to § 205. 606 with Annotation (if any) Liquid and Powdered Forms_____
- 2) Substance to be added as "prohibited" on National List to § 205. _____ with Annotation (if any) _____
Describe why a prohibited substance: _____
- 3) Substance was rejected by vote for amending National List to § 205. _____. Describe why material was rejected: _____
- 4) Substance was recommended to be deferred because _____ If follow-up needed, who will follow up _____

E. Approved by Committee Chair to transmit to NOSB:

Steve Demuri September 29, 2011
Committee Chair Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance – Annatto extract color (pigment CAS # 1393–63–1)—water and oil soluble

| Question | Ye s | No | N/A ¹ | Documentation (TAP; petition; regulatory agency; other) |
|---|---------|----|------------------|--|
| 1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2] | | X | | |
| 2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3] | | X | | |
| 3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i] | | X | | |
| 4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2] | | X | | |
| 5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1] | | X | | |
| 6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5] | | X | | |
| 7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5] | | X | | |
| 8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2] | | X | | |
| 9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2] | | X | | |
| 10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4] | | X | | |
| 11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3] | | X | | |
| 12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5] | | X | | |
| 13. Does the substance contain residues of heavy metals or | | X | | |

| | | | | |
|---|--|--|--|--|
| other contaminants in excess of FDA tolerances? [§205.600 b.5] | | | | |
|---|--|--|--|--|

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

**Category 2. Is the Substance Essential for Organic Production? Substance – Annatto extract color
(pigment CAS # 1393–63–1)—water and oil soluble**

| Question | Yes | No | N/A ¹ | Documentation (TAP; petition; regulatory agency; other) |
|--|-----|----|------------------|---|
| 1. Is the substance formulated or manufactured by a chemical process? [6502 (21)] | | X | | Material is manufactured by extraction from the annatto seed with either oil or water combined with physical agitation. |
| 2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)] | | X | | |
| 3. Is the substance created by naturally occurring biological processes? [6502 (21)] | | X | | |
| 4. Is there a natural source of the substance? [§205.600 b.1] | X | | | This is the natural source |
| 5. Is there an organic substitute? [§205.600 b.1] | X | | | Organic forms of this material are available in the marketplace |
| 6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6] | | X | | Not used for production |
| 7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)] | X | | | This is the natural source |
| 8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)] | X | | | This petition is for evaluation of commercial availability. See category 4. |
| 9. Is there any alternative substances? [§6518 m.6] | | X | | |
| 10. Is there another practice that would make the substance unnecessary? [§6518 m.6] | | X | | |

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 3. Is the substance compatible with organic production practices?
Annatto extract color (pigment CAS # 1393-63-1)—water and oil soluble

Substance –

| Question | Yes | No | N/A ¹ | Documentation (TAP; petition; regulatory agency; other) |
|--|-----|----|------------------|--|
| 1. Is the substance compatible with organic handling? [§205.600 b.2] | X | | | |
| 2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)] | X | | | |
| 3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7] | X | | | |
| 4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3] | | | X | |
| 5. Is the primary use as a preservative? [§205.600 b.4] | | X | | |
| 6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4] | | X | | Primary use is as a color. However use is not to recreate or improve color lost in processing but to provide consumers with a color with which they are familiar. For example, cheddar cheese is orange due to use of annatto. |
| 7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds; | | X | | |
| b. toxins derived from bacteria; | | X | | |
| c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals? | | X | | |
| d. livestock parasiticides and medicines? | | X | | |
| e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners? | | X | | |

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]
Substance - Annatto extract color (pigment CAS # 1393–63–1)—water and oil soluble

| Question | Yes | No | N/A | Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown) |
|---|-----|----|-----|--|
| 1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling? | X | | | 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). The NOSB recommended relisting at the October 2010 NOSB meeting: http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5088016&acct=nosb |
| 2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling? | | X | | <p>When annatto was originally listed public comment was received saying that organic annatto seeds were not available. Today organic seeds are available. However, annatto is used in both a liquid and powdered form. During the Sunset 2012 review of this material public comment was received, and supported by an informal market review by the NOSB Handling Committee, that the liquid form was available. Mixed public comment was received about the availability of the powdered form. At the time, removing one form but not the other could not be done during the sunset review process.</p> <p>This petition is for the removal of all forms from §205.606. The petitioner states that they have provided an organic liquid form for some time and have just recently, spring 2010, introduced a powdered form. The Handling Committee has conducted a second informal market survey and found that some, but not most, products (e.g., some brands of organic mac & cheese) that would be expected to be using the powdered form have switched to using organic annatto.</p> <p>At this time, the HC believes that sufficient evidence exists that both forms, liquid and powdered, of organic annatto extract color are available. We understand that there may be applications where the forms available do not perform. We ask that handlers or certifiers who are aware of these applications provide written public comment for the fall 2011 NOSB meeting so they can be considered.</p> |
| 3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling? | | X | | Quality of the organic annatto extract color has not been a question. The committee has no information indicating that organic forms of the material are not commercially available. |
| 4. Does the current and historical | | X | | The petitioner states that there is sufficient supply of |

| | | | | |
|---|---|---|--|---|
| industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling? | | | | organic annatto seeds and both liquid and powdered organic annatto extract color to meet demand. The committee has no information to contradict this statement. |
| 5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following: a. Regions of production (including factors such as climate and number of regions); | | X | | |
| b. Number of suppliers and amount produced; | X | | | The petition is from the supplier of organic annatto extract color. |
| c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies; | | X | | |
| d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or | | X | | |
| e. Are there other issues which may present a challenge to a consistent supply? | | X | | |