

NOSB RECOMMENDED DECISION FORM

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: May 2009	Substance: Red Corn Color																								
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 type="checkbox"/> No <input checked="" 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?	C. Proposed Annotation: NONE																								
Criteria category: 2 and 4.	Basis for annotation: _____																								
Comments: see summary narrative below.	To meet criteria above: ____ Criteria: _____																								
	Other regulatory criteria: ____ Citation: _____																								
D. Final Board Action & Vote (State Actual Motion): To add Red Corn Color to the National List in section 205.606																									
Motion: Steve DeMuri Second: Katrina Heinze Yes: 0 No: 14 Abstain: 0 Absent: 1																									
<table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td style="width: 25%;">Agricultural</td> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 25%;">Nonagricultural</td> <td style="width: 10%;"></td> <td style="width: 20%;">Crops</td> <td style="width: 10%;"></td> </tr> <tr> <td>Synthetic</td> <td></td> <td>Not synthetic</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Livestock</td> <td></td> </tr> <tr> <td>Allowed¹</td> <td></td> <td>Prohibited²</td> <td></td> <td>Handling</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> </tr> <tr> <td>No restriction</td> <td></td> <td>Deferred⁴</td> <td></td> <td>Rejected³</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> </tr> </table>		Agricultural	<input checked="" type="checkbox"/>	Nonagricultural		Crops		Synthetic		Not synthetic	<input checked="" type="checkbox"/>	Livestock		Allowed ¹		Prohibited ²		Handling	<input checked="" type="checkbox"/>	No restriction		Deferred ⁴		Rejected ³	<input checked="" type="checkbox"/>
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Provide a summary narrative here or attach a more complete narrative, and attach the original committee recommendation that includes the evaluation criteria checklist:																									
<p>Categories 2 and 4, essence and availability criteria, were not met. The fragility or unavailability of a commercial supply of red corn as organic is not adequately addressed or explained in the petition, and there was no substantive written or oral comment provided as explanation after the committee recommendation was posted on the NOP website. A review of common, public accessible websites and phone calls to several organic ingredient suppliers revealed that a significant quantity of organic red corn exists in the marketplace currently, and there was no explanation provided as to why this organic agricultural material could not be converted into organic color. Additionally, although there are other conventional red color compounds listed in 205.606, there was no explanation as to why the currently listed red colors could not be used as an alternative to conventional red color made from red corn.</p> <p>1—substance voted to be added as “allowed” on National List on National List to § 205._____ with Annotation (if any): _____</p> <p>2—substance to be added to “prohibited” paragraph of National List to § 205._____ Describe why a prohibited substance: _____</p> <p>3—substance was rejected by vote for amending National List to § 205. 606. Describe why material was rejected: See summary narrative in Section D above and attached Committee Recommendation documentation.</p> <p>4-substance was recommended to be deferred § 205. _____ Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up _____</p>																									
E. Approved by NOSB Chair to transmit to NOP																									
Jeff Moyer _____ Chair	May 6, 2009 _____ Date																								
F. NOP Action: Include in FR to amend National List:																									
Return to NOSB Reason: _____																									
_____ Date																									

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: May 2009

Substance: Red Corn Color

Committee: Crops Livestock Handling Petition is for inclusion of Red Corn Color on the National List § 205.606.

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

- | | |
|---|--|
| 4. Impact on Humans and Environment | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> |
| 5. Essential & Availability Criteria | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/> |
| 6. Compatibility & Consistency | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> |
| 7. Not or Inconsistently Available as Organic | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/> |

B. Substance Fails Criteria Category: 2 and 4 Comments: The fragility or unavailability of a commercial supply of red corn as organic is not adequately addressed or explained.

C. Proposed Annotation (if any): _____

Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____

D. Recommended Committee Action & Vote (State Motion): Move to add Red Corn Color to the National List section 205.606.

Motion by: Steve DeMuri Seconded: Katrina Heinze Yes: 0 No: 4 Absent: 1 Abstain: 1

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

1) Substance voted to be added as "allowed" on National List to § 205. _____ with Annotation (if any) _____

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. 606. Categories 2 and 4, essence and availability criteria, were not met.

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
Committee Chair

Date: March 14, 2009

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance – Red Corn Color

Question	Yes	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		The manufacturing process is identified as CBI in the petition, but a review with NOP staff indicates that this criteria is satisfied. No adverse affects from use or disposal.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		Same as above.
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		This is an agricultural product
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		This is an agricultural product
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		This is an agricultural product
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		This is an agricultural product
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		This is an agricultural product
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		This is an agricultural product
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		This is an agricultural product
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		This is an agricultural product
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			X	This is an agricultural product
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			X	This is an agricultural product
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			X	This is an agricultural product

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 – Red Corn Color

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		The petition states that red corn colorant is a vegetable juice extract of red corn kernels from <i>Gramineae Zea Mays</i> . The manufacturing process is identified as CBI in the petition, but a review with NOP staff indicates that this criteria is satisfied. No synthetic solvents are used in the extraction process. No adverse affects from use or disposal.
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		A simple extraction process is employed. No chemical change.
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 an agricultural product.
5. Is there an organic substitute? [§205.600 b.1]			X	This is an agricultural product.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			X	This is an agricultural product.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			
9. Is there any alternative substances? [§6518 m.6]	X			There are some red color extracts (red cabbage, cherry juice, beet, red radish) currently listed in 205.606, but this petition does not explain why these currently listed non-organic red colors cannot be used as an alternative to the petitioned substance.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Potentially, the use of already listed non-organic red colors could be substituted for this petitioned substance.

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?
Corn Color

Substance – Red

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			This is an agricultural product
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			This is an agricultural product, and could be grown sustainably.
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		The substance is used to color food products, but not necessarily to recreate or improve colors lost in processing.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:		X		
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 agricultural substance inconsistently or not commercially available as organic?
Substance – Red Corn Color**

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in organic handling?		X		The petitioner describes the use of the red corn color as a natural color additive in beverages, yogurts, confectionary, soups, sauces, desserts, etc., but it does not satisfactorily address the reasons why a non-organic form must be used.
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		Although red corn color does not appear to be available in an organic form, the raw source of the color, red corn, is available currently in an organic form. It is quite common in organic red tortilla chips and similar products. There is no compelling explanation as to the reasons for not being able to use organic red corn as opposed to conventional red corn to produce the color.
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		There is some explanation regarding the breeding program currently underway to develop organic red corn for organic color manufacture, but there is no compelling evidence as to why currently available organic red corn is not suitable for this purpose.
4. 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 quantity to fulfill an essential function in a system of organic handling?		X		The petitioner describes development of a hybrid that is suitable for the red color they desire, but there is also no compelling explanation as to the reasons why the hybrid can't be grown organically, especially considering the relatively wide ranging growing area of red corn throughout the US and the world, and the availability of organic land. A narrative is given as to difficulty in obtaining organic growers, but it is not backed up by evidence.
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			There is some brief description of local (to the petitioner) red corn growing areas, but it does not appear to be comprehensive.
b. Number of suppliers and amount produced;		X		No data provided.
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		No data provided.
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		X		No explanation of any of these trade related factors was given, but they may not be relevant to red corn production.

e. Are there other issues which may present a challenge to a consistent supply?		X		None that were explained.
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