

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: May 2008

Substance: Polygala Root Powdered Extract

Committee: Crops Livestock Handling Petition is for: Inclusion of Polygala Root Powdered Extract 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 type="checkbox"/> | No <input type="checkbox"/> | N/A |
| 3. Compatibility & Consistency | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" 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: The petition does not provide sufficient information to demonstrate that this material cannot be obtained organically in the appropriate form, quantity or quality (see specifics under category 4)

C. Proposed Annotation (if any): _____
 Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____

D. Recommended Committee Action & Vote (State Actual Motion): _____

Motion by: Julie Wiseman Seconded: Steve DeMuri Yes: 0 No: 5 Absent: 1 Abstain: 0

Crops		Agricultural	<input checked="" type="checkbox"/>	Allowed ¹	
Livestock		Non-Synthetic		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 Describe why material was rejected: Material was rejected because petition did not demonstrate that this material may not be available in organic form. An internet search by evaluator found polygala root sold as certified organic herbal extracts. The petitioner did not explain why this form could not be further processed into this material.

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:

Julie Wiseman
Committee Chair

3/8/2008
Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance - Polygala Root Powdered Extract

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]				Page 2 of petition – The root is harvested, dried, milled and placed into an extraction kettle. Water and ethanol are added and heat applied. The extracted liquid is concentrated into essential oils and standardized to the desired concentration. The essential oils are mixed with organic astragalus root carrier then spray dried and ground into a powder.”
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]				See 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 used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
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 used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]			X	This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		See comments for question 12
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		See comments for question 12
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]		X		Page 3 of petition – Polygala root extract powder was marketed in the U.S. prior to October 15, 1994. The Dietary Supplement Health and Education Act (DSHEA) provides that supplement ingredients that were marketed in the U.S. prior to the enactment of DSHEA on October 15, 1994 are considered safe and are “grandfathered in” as safe for use. This herb is also listed in The American Herbal Products Association’s Herbs of Commerce, 2nd Edition.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		Per MSDS sheet from petition

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 - Polygala Root Powdered Extract

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		Page 2 of petition – The root is harvested, dried, milled and placed into an extraction kettle. Water and ethanol are added and heat applied. The extracted liquid is concentrated into essential oils and standardized to the desired concentration. The essential oils are mixed with organic astragalus root carrier then spray dried and ground into a powder.”
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		See above
3. Is the substance created by naturally occurring biological processes? [6502 (21)]			x	This is an agricultural product
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	Material is being petitioned for inclusion on §205.606; see category 4 below.
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			Material is being petitioned for inclusion on §205.606; see category 4 below.
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? Substance - Polygala Root Powdered Extract

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		
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 - Polygala Root Powdered Extract

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. <u>Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?</u>		x		Petition did not provide information demonstrating why the non-organic form of the material is necessary for use in organic handling
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>Petition page 3 – Petitioner’s “procurement department is continuously searching for organic forms of the non-organic ingredients used in the company’s formulations. Regular searches include monthly review of trade journals, ingredient source contacts, internet searches and websites of both the Organic Trade Association and the Quality Assurance International organic ingredients. We continue with R&D efforts to find substitute organic ingredients to replace non-organic ingredients in our formulations where possible. None of these recurring efforts has yielded a positive result for a functionally equivalent organic ingredient that is commercially available for polygala root powdered extract.”</p> <p>An internet search by evaluator found polygala root sold as certified organic herbal extracts. The petition does not provide sufficient information to demonstrate that this material cannot be obtained organically in the appropriate form, quantity or quality.</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		See above
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		See above
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:		X		See above
a. Regions of production (including factors such as climate and number of regions);		X		See above
b. Number of suppliers and amount produced;		X		See above
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		See above
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		X		See above
e. Are there other issues which may present a challenge to a consistent supply?		X		See above