NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting:	or NOSB Meeting: <u>May 2008</u>					Substance: Polygonum Root Powdered Extract				
Committee: Crops ☐ Livestock X Handling ☐ Petition is for: <u>Inclusion of Polygonum Root Powdered Extract on the National List § 205.606</u>										
A. Evaluation Criteria (Applicability noted for each category; Documentation attached) 1. Impact on Humans and Environment 2. Essential & Availability Criteria 3. Compatibility & Consistency 4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) 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 W	/iseman Seconde	ed: Stev	ve DeMuri	Yes: <u>1</u>	No:	4 Absent: 1 Abs	stain:	0		
	0				_	A1111	T	1		
	Crops		gricultural	,	K	Allowed ¹ Prohibited ²				
	Livestock		Ion-Synthetic Synthetic			Rejected ³	1			
	Handling No restriction	С	commercially U			Deferred ⁴	X			
	140 Testriction	A	vailable as Or	ganic¹		Deletted				
Substance voted to be added as "allowed" on National List to § 205with Annotation (if any) Substance to be added as "prohibited" on National List to § 205with 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. 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:										
<u>Julie Weismar</u> Committee Chair	1		Da	ate		3/8/2008				

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance - Polygonum Root Powdered Extract

Category 1. Adverse impacts on numan	s or the	e envir	onment	? Substance – Polygonum Root Powdered Extract
Question	Yes	No	N/A¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]			X	Page 2 of petition – The rhizome is harvested, dried, clean 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]			X	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 agroecosystem.
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 agroecosystem.
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 agroecosystem.
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 agroecosystem.
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 – Polygonum root powdered extract 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 – Polygonum Root Powdered Extract

Substance – Folygonum Root Fowd	l LXI	1		
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)]		х		Page 1 of petition – The rhizome is harvested, dried, clean 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)]			Х	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]			х	
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]			Х	

If 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 – Polygonum 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]			Х	
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]			Х	
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			Х	
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?		Х		
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 - Substance - Polygonum Root Powdered Extract

1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling? 2. Does the current and historical industry	x X	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown) Petition did not provide information demonstrating why the non-organic form of the material is necessary for use in organic handling
as to why the non-organic form of the material /substance is necessary for use in organic handling?			Petition did not provide information demonstrating why the non-organic form of the material is necessary for use
as to why the non-organic form of the material /substance is necessary for use in organic handling?			the non-organic form of the material is necessary for use
material /substance is necessary for use in organic handling?	X		
organic handling?	X		in organic handling
	X		
2. Does the current and historical industry	X		
			Petition page 3 – Petitioner's "procurement department is
information, research, or evidence provided			continuously searching for organic forms of the non-
explain how or why the material /substance			organic ingredients used in the company's formulations.
cannot be obtained organically in the			Regular searches include monthly review of trade
appropriate form to fulfill an essential			journals, ingredient source contacts, internet searches and
function in a system of organic handling?			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 atractylodes extract powdered extract." An internet search did not find any organic polygonum
			root. The petition does not provide sufficient information
			to demonstrate that this material cannot be obtained
			organically in the appropriate form, quantity or quality.
3. Does the current and historical industry	X		See above
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?			
4. Does the current and historical industry	X		See above
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		Carabana
5. Does the industry information provided	A		See above
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);			
b. Number of suppliers and amount	-X		See above
produced;	ΙΛ		SCC aUUVC
c. Current and historical supplies related to	X		See above
weather events such as hurricanes, floods,	Λ		See above
and droughts that may temporarily halt			
production or destroy crops or supplies;			
d. Trade-related issues such as evidence of	X		See above
	Λ		See above
hoarding, war, trade barriers, or civil unrest			
that may temporarily restrict supplies; or	X		Coo above
e. Are there other issues which may present	A		See above
a challenge to a consistent supply?			