

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: <u> May 2008 </u>	Substance: <u> Camu Camu Powdered Extract </u>																								
Committee: Crops <input type="checkbox"/> Livestock <input type="checkbox"/> Handling <input checked="" type="checkbox"/> Petition is for: <u> Inclusion of non-organically produced Camu Camu Extract on the National List § 205. 606 </u>																									
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 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: <u> 4 </u> Comments: <u> Petition does not address why organically produced Camu Camu produced in Brazil cannot be used </u>																									
C. Proposed Annotation (if any): _____ Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____																									
D. Recommended Committee Action & Vote (State Actual Motion): Include non-organically produced Camu Camu Extract on the National List §205.606 Motion by: <u> Gerry Davis </u> Seconded: <u> Katrina Heinze </u> Yes: <u> 0 </u> No: <u> 5 </u> Absent: _____ Abstain: <u> 1 </u>																									
1) Substance as "allowed" on 205._____ with	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td style="width: 15%;">Crops</td> <td style="width: 15%;"></td> <td style="width: 20%;">Agricultural</td> <td style="width: 10%;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Allowed¹</td> <td style="width: 10%;"></td> </tr> <tr> <td>Livestock</td> <td></td> <td>Non-Synthetic</td> <td></td> <td>Prohibited²</td> <td></td> </tr> <tr> <td>Handling</td> <td><input checked="" type="checkbox"/></td> <td>Synthetic</td> <td></td> <td>Rejected³</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>No restriction</td> <td></td> <td>Commercially Un-Available as Organic¹</td> <td><input checked="" type="checkbox"/></td> <td>Deferred⁴</td> <td></td> </tr> </table>	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	<input checked="" type="checkbox"/>	Deferred ⁴	
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	<input checked="" type="checkbox"/>	Deferred ⁴																					
voted to be added National List to § 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: <u> Petition does not address why organically produced Camu Camu produced in Brazil cannot be used. </u>																									
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 Weisman </u> <u> March 31, 2008 </u> Committee Chair Date																									

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance - Camu Camu 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]		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]				
13. Does the substance contain residues of heavy metals or 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 - Camu Camu 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		
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		Petition pgs. 1-2 states that the extract is produced from juicing and straining berries of the Camu Camu bush (<i>Myrciaria dubia</i>), which is then concentrated and spray dried along with organic cassava starch (30%).
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	Substance is natural.
5. Is there an organic substitute? [§205.600 b.1]	X			The Instituto Biodinamico (IBD) in Brazil does certify wild harvested Camu Camu as organic, but IBD reports that there is no domestic (US) organically certified product available at this time.
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		Nutritional benefits of Camu Camu are somewhat unique.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			Agricultural product being petitioned for inclusion on §205.606
9. Is there any alternative substances? [§6518 m.6]		X		Nutritional benefits of Camu Camu are somewhat unique.
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 - Camu Camu 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			Petition describes the Camu Camu berry cropping practice as potentially satisfying §205.207 (Wild crop harvesting practice standard). Extraction process is compatible.
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X			See above.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			Following wild crop standards would be compatible with a system of sustainable agriculture.
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:		X		
a. copper and sulfur compounds;				
b. toxins derived from bacteria;				
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?				
d. livestock parasiticides and medicines?				
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?				

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 - Camu Camu berry extract

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			Petition states that Camu-Camu berry has never been available as organic. The berry is harvested in remote wilderness areas of the Amazon flood plain over vast areas which have not been practical to manage under an Organic System Plan.
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		
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		
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			Petition states that difficulties exist of obtaining any quantities of certified organic Camu Camu powdered extract. Additional industry information suggests that certified organic material <u>may not</u> be obtainable at this time.
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:	X			See Question #1. HC contacted the Instituto Biodinamico (IBD) in Brazil, which does certify juice product made with the pulp of wild harvested Camu Camu as organic, but IBD reports that no certified Camu-Camu powdered extract is available at this time.
a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;		X		
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			