NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: __Fall 2011-Savannah, GA_____	Substance: __Silicon Dioxide_____

Committee: Crops ☐ Livestock ☐ Handling X Petition is for: Removal of Silicon Dioxide from the National List § 205.605(b)

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

1. Impact on Humans and Environment — Yes **X** No ☐ N/A ☐
2. Essential & Availability Criteria — Yes ☐ No **X** N/A ☐
3. Compatibility & Consistency — Yes ☐ No **X** N/A ☐
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) — Yes ☐ No ☐ N/A **X**

B. Substance Fails Criteria Category: _2, 3__ Comments: Silicon Dioxide (synthetic) no longer meets criteria 2, 3 because a natural, certified organic alternative is available for organic processors for certain applications._____

C. Proposed Annotation (if any): _
205.605(b) Synthetics allowed—Silicon Dioxide—providing sufficient evidence showing natural alternatives are not commercially available for a specific produce/process is presented.__

Basis for annotation: To meet criteria above: __2___ Other regulatory criteria: _____ Citation:_205.600(b)(1)_____

D. Recommended Committee Action & Vote, including classification recommendation (State Actual Motion):

_____

Classification of the material: Synthetic ___ Non- synthetic_____ Absent:_____ Abstain _____

Motion by: _____ *Seconded:*_____ *Yes:* _____ *No:* _____ *Absent:* _____ *Abstain:* _____

Recommended Committee Action & Vote ____Change annotation—see Committee Recommendation_____

_____

*Motion by: __John Foster Seconded:_Steve DeMuri_ Yes: _5 No: _1_ Absent: __1__ Abstain: _0_*

Crops		Agricultural		Allowed[1]	x
Livestock		Non-Synthetic		Prohibited[2]	
Handling	**X**	Synthetic	**X**	Rejected[3]	
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) (b) Synthetics allowed—Silicon Dioxide—**providing sufficient evidence showing natural alternatives are not commercially available for a specific product/process is presented.**

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 — **Committee Chair**

October 4, 2011 — **Date**

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance __ Silicon Dioxide _____

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			7/29/10 Petition pg. 3 1996 TAP questions. 1, 3
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		1996 TAP (Montecalvo, Jefferey) reviews questions. 2, 3
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		CP Kelco 2005 Petition to keep SiO2 on list, pg 1 1996 TAP questions 1, 2,3, 5 (Montecalvo, Jefferey, Zimmer)
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1) (B)(ii); 205.601(m)2]		X		The petition and TAP do not note any
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		1996 TAP (Jefferey, Montecalvo) 7/29/10 Petition to remove, pg. 3
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		1996 TAP (TR (Jefferey, Montecalvo) questions 2, 5
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	This is a handling material
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		1996 TAP 7/29/10 Petition to remove, pg. 3
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		1996 TAP questions: 2, 3, 5, 7 7/29/10 Petition to remove, pg. 3 CP Kelco 2005 Petition to keep SiO2 on list, pg 1
10. Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)I; §6518 m.4]	X			Only with improper use/handling. MSDS 1996 TAP, question 4 7/29/10 Petition to remove, pg 3
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]	X			NOSB materials database information 7/29/10 Petition to remove, pg 3
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			NOSB materials database information
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		Petition and TAP do not mention any.

[1] 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 2. Is the Substance Essential for Organic Production? Substance __ Silicon Dioxide _

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			7/29/10 petition to remove, pg 2 1996 TAP 1/20/10 pg 1 Ribus Letter to Miles McEvoy
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		7/29/10 petition to remove, pg 2 1996 TAP NOSB Materials Database
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		7/29/10 petition to remove, pg 2 1996 TAP NOSB Materials Database
4. Is there a natural source of the substance? [§205.600 b.1]	X			Yes, but not in functional amounts 1996 TAP
5. Is there an organic substitute? [§205.600 b.1]	X			7/29/10 Ribus petition to remove, pg 11
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		The function it performs is essential; not the substance 7/29/10 petition to remove, pg 11
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			7/29/10 petition to remove, pg 11
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		1996 TAP NOSB materials database 7/29/10 petition to remove, pg 1-11
9. Is there any alternative substances? [§6518 m.6]	X			1996 TAP 7/29/10 petition to remove, pg 1-11 1/20/10 pg 1 Ribus Letter to Miles McEvoy
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Using an alternate compound only. 7/29/10 petition to remove, pg 1-11 1996 TAP 1/20/10 pg 1 Ribus Letter to Miles McEvoy

[1] 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 ___ Silicon Dioxide

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		Synthetic substance and only needed if no alt. substances are avail. 1996 TAP review (Montecalvo)
2. Is the substance consistent with organic farming and handling, and biodiversity? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X		Synthetic substance and only needed if no alt. substances are avail. 1996 TAP review (Montecalvo)
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			x	This is a handling input. No negative impact on environment following use. 7/29/10 Petition pg. 3 1996 TAP questions. 1, 3
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]		X		TAP and petition do not note any.
5. Is the primary use as a preservative? [§205.600 b.4]		X		7/29/10 petition to remove, pg 1 NOSB materials database 1996 TAP review
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		7/29/10 petition to remove, pg 1 NOSB materials database 1996 TAP review
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	

[1] 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 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:_ Silicon Dioxide_

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	The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
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	The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
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	The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
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 petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			X	The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
a. Regions of production (including factors such as climate and number of regions);			X	The petition is for removal of SiO2 from 205.605 The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
b. Number of suppliers and amount produced;			X	The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
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	The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
e. Are there other issues which may present a challenge to a consistent supply?			X	The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2

National Organic Standards Board
Handling Committee
Proposed Recommendation
Silicon Dioxide

October 14, 2011

List: § 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(b) Synthetics allowed--Silicon dioxide.

Committee Summary

Silicon dioxide is a naturally occurring substance that is generated following oxidation reactions involving silicon in the Earth's crust. Silicon dioxide is a major component in sand, quartz, diatomaceous materials, and is found as biogenic silica in organisms. Silicon dioxide's (chemical formula is SiO_2) exists both as a amorphous and crystalline structures and is frequently found in a three-dimensional polytetrahydral structure where the two oxygen atoms of one SiO_2 molecule are associated with a silicon atom of another SiO_2 molecule. This molecular association generates structures exhibiting unique properties such as immiscibility in both water and oil and an extremely large surface area. These characteristics have been capitalized upon for their functionally in a diverse set of applications and industries including (but not limited to): glass production, ceramics, optical cable fiber production, food processing, food packaging, pharmaceutical production/packaging, soil amendments, and as inert compounds/carrier systems within pesticides. While silicon dioxide is found in natural sources, most industrial applications use silicon dioxide generated from synthetic sources/processes.

The food industry frequently uses a silicon dioxide as its properties allow for enhanced process-ability and functionality in food products and manufacturing practices. Some common applications of silicon dioxide in the food industry are: as an anti-caking agent (most common application), an anti-foam agent, a stabilizer in beer production, an adsorbent in foods prepared as tablets for special dietary use, as carriers (such as a component of microcapsules for flavoring oils), and for various other uses allowed under jurisdiction of the FDA. Silicon dioxide is also allowed internationally for various uses in food products (in both conventional and organic foods) by the European Union, Codex, Canada, Japan, and by IFOAM for organic processing.

In 2010 the NOSB voted to relist silicon dioxide despite knowing that an application to remove silicon dioxide was at the NOP. During the relisting process, the Handling Committee produced the following concerns based upon debate and information presented during the sunset review process:

1. The Handling Committee has discussed and collectively agrees that there is the need to encourage the growth of agricultural--and preferably organic--alternatives to nonagricultural substances presently allowed on the National List for use in organic handling operations, and considers this to be just such an opportunity.

2. Public comment indicates that while organic alternatives exist that may replace silicon dioxide as currently listed, the Handling Committee is concerned that *applicable* alternatives do not exist for sufficient uses and applications of silicon dioxide in organic handling.

Given the above concerns, the NOSB voted to relist silicon dioxide and publically note that additional information, data, and clarification of processors' needs regarding silicon dioxide would be needed for future deliberation during the upcoming discussion on silicon dioxide's removal from § 205.605(b).

As such, § 205.605(b) today allows silicon dioxide to be utilized in organic foods labeled in the "organic" and "made with organic" categories. The petition currently under consideration is to remove its listing on § 205. 605(b), stating there now exists a viable, non-synthetic, certified organic substitute to silicon dioxide available from a rice-hull based material. This alternative substance exhibits similar functional properties as silicon dioxide since it is produced from rice hulls which naturally contain a high concentration of silica. In addition, the current petition claims that the rice-hull product's applicability should not be in question as:

"The proposed rice concentrate has been produced and sold in commercial quantities (domestically and internationally) to organic and natural food / feed producers for many of the exact same uses as SiO2."

While an extensive review has been completed by the Handling Committee concerning the environmental, health, and applicability concerns of synthetic dioxide from the TAP reviews, previous petitions, prior NOSB discussions; the primary consideration/debate for whether or not synthetic silicon dioxide should remain on § 205.605(b) is rooted in consideration of § 205.600(b)(1) which states:

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

(1) The substance cannot be produced from a natural source and there are no organic substitutes

Given this section of the regulation, and the charge of the NOSB to make decisions consistent with the overall intent of the regulation, the NOSB has considered the current petition to remove silicon dioxide by analyzing the previous information as to why synthetic silicon dioxide was originally listed on § 205.605(b). Resultant of this analysis, it has been concluded that silicon dioxide was previously listed due its unique properties and its overall safety and limited environmental concerns. However, since the initial listing, the following new information regarding a new agricultural substitute has been presented:

Table 1. Use Rates of Organic Rice Concentrate vs. SiO_2

	2007-2008*	2009-Present*
Spice Blends	1:1 or 1.2:1	1:1
Dry Beverages	Did not work	1:1
Dried Fruit	Did not work	1:1
Tablets	1.1 or 1.2:1	1:1
Sauce Mixes	1.1 or 1.2:1	1:1
Flavor Carrier (oil & water)	1.2:1	0.8:1 or 1:1

*Ratios are expresses as rice concentrate: SiO_2

The above table from the petition attempts to demonstrate that the rice-hull based alternative described in the 2010 petition to remove silicon dioxide has been available since 2007 and has undergone reformulation in 2009 such that it now can be substituted for silicon dioxide nearly 1:1 ratios. Given this new information, the NOSB must determine whether sufficient evidence has been presented by the petitioner as to whether this natural organic alternative is sufficient in all applications to remove silicon dioxide from § 205.605(b).

While the new data does address concerns noted by the Handling Committee during the Sunset review process; the Handling Committee feels that it is still limited, not published from a third party source, and does not conclusively demonstrate its applicability in all products and processes. However, while the data presented in this petition is not sufficient to completely remove silicon dioxide, the Handling Committee feels that the availability of a natural alternative must be acknowledged.

Therefore, with respect to the change in NOSB Policy and Procedures Manual, the Handling Committee did not vote to remove silicon dioxide in its entirety but recommends a change to the annotation to silicon dioxide as noted below to be consistent with the intent of § 205.600(b)(1).

Committee Recommendations
1. Motion to remove the following substance:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”
(b) Synthetics allowed—Silicon dioxide

Committee Vote
Motion: John Foster Second: Steve DeMuri
Yes: 0 No: 5 Abstain: 0 Absent: 2

2. Motion to amend the annotation of the following substance:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”
(b) Synthetics allowed—Silicon dioxide—providing sufficient evidence showing natural alternatives are not commercially available for a specific product/process is presented.

Committee Vote
Motion: John Foster Second: Steve DeMuri
Yes: 5 No: 1 Abstain: 0 Absent: 1