

**Formal Recommendation by the
National Organic Standards Board (NOSB)
to the National Organic Program (NOP)**

Date: December 2, 2011

Subject: Petition to remove/amend silicon dioxide from the National List
§ 205.605

Chair: Tracy Miedema

The NOSB hereby recommends to the NOP the following: Rulemaking Action

Statement of the Recommendation

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 non-synthetic alternatives are not commercially available for a specific product/process is presented.

Correction made by NOP on 4/12/12: The motion as stated in the meeting transcript is: “Move to change the annotation of Silicon Dioxide on §205.605 non-agricultural substances be synthetics allowed for use as a defoamer. May be used in other applications when non-synthetic alternatives are not commercially available.”

The motion passed with a vote of 11 yes and 3 no.

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

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 committee agreed that silicon dioxide was previously listed because of its unique properties, historically safe use in food, relatively broad utility in food processing, and limited environmental concerns. 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. 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 above.

NOSB Vote:

Moved: John Foster		Second: Steve DeMuri.		
Yes: 11	No: 3	Abstain: 0	Absent: 0	Recusal: 0

**National Organic Standards Board
Handling Committee
Proposed Recommendation
Silicon Dioxide**

December 2, 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 an 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 functionality 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. SiO₂

	<u>2007-2008*</u>	<u>2009-Present*</u>
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: SiO₂

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. Committee Vote

Motion: John Foster Second: Steve DeMuri 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 non-synthetic alternatives are not commercially available for a specific product/process is presented.

Yes: 5 No: 1 Abstain: 0 Absent: 1