

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date:

Subject:

Chair:

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement:

Other:

Statement of Recommendation: (Motion # 1)

Motion to classify sulfuric acid (CAS 7664-93-9) as petitioned as synthetic.

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

Based on the technical Report, line 262, Sulfuric acid, including food-grade sulfuric acid, is chemically synthesized.

Committee Vote:

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

Statement of Recommendation: (Motion # 2)

Failed

Motion to add sulfuric acid (CAS 7664-93-9) as petitioned to section 205.605(b) of the National List.

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

The petition and TR do not provide sufficient information to fully evaluate this material. However, based on limited information, it appears that this material fails several evaluation criteria, including 1. Impact on Humans and Environment, 2. Essentiality & Availability, and 3. Compatibility & Consistency. Additionally, there were few or no comments from potential users indicating a need for this substance, not were there comments from those supporting it's addition.

Committee Vote:

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

**National Organic Standards Board
Handling Sub Committee
Petitioned Material Proposal
Sulfuric Acid**

January 9, 2013

Summary of Proposed Action:

The petition is for the listing of sulfuric acid on 205.605(b) for use as a processing aid in the production of seaweed extract. Sulfuric acid is used as a pH adjuster in the extraction water for the production of seaweed extracts, particularly a class of seaweed extracts called fucoidans, which are largely used as ingredients in dietary supplements.

For a number of reasons, the Handling Subcommittee recommends that sulfuric acid not be added to the national list as petitioned:

- The redaction of substantial amounts of confidential business information (CBI) from the petition makes it impossible to evaluate the use of sulfuric acid in the manufacturing process, and impossible to establish whether the resulting seaweed extract undergoes sufficient chemical change as to render it a synthetic substance.
- The petition and TR fail to demonstrate the essentiality of this substance in the production of organic food, or the absence of viable alternatives. The petition provides little economic data or market narrative to demonstrate that this substance might play a compelling role in the production of organic products, and the redacted CBI makes it impossible to even understand how sulfuric acid is used in seaweed extract production.
- The TR clearly documents negative environmental impacts of the production of this substance, suggests negative health effects in its production and industrial use, and overwhelmingly demonstrates the substance's incompatibility with a system of organic agriculture.

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 § 205.606)

Criteria Satisfied?

<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A

Substance Fails Criteria Category: [1, 2 and 3] **Comments:**

Proposed Annotation (if any):

Basis for annotation: To meet criteria above Other regulatory criteria Citation

Notes:

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Motion to classify sulfuric acid (CAS 7664-93-9) as petitioned as synthetic:

Motion by: Joe Dickson

Seconded by: John Foster

No further discussion

Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Listing Motion: List sulfuric acid (CAS 7664-93-9) as petitioned on 205.605(b)

Motion by: Joe Dickson

Seconded by: Tracy Favre

No further discussion

Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

Crops	<input type="checkbox"/>	Agricultural	<input type="checkbox"/>	Allowed¹	<input type="checkbox"/>
Livestock	<input type="checkbox"/>	Non-synthetic	<input type="checkbox"/>	Prohibited²	<input type="checkbox"/>
Handling	X	Synthetic	X	Rejected³	X
No restriction	<input type="checkbox"/>	Commercial unavailable as organic	<input type="checkbox"/>	Deferred⁴	<input type="checkbox"/>

¹Substance voted to be added as "allowed" on National List to § 205. with Annotation (if any):

²Substance to be added as "prohibited" on National List to § 205. with Annotation (if any):

Describe why a prohibited substance:

³Substance was rejected by vote for amending National List to § 205.605(b). Describe why material was rejected:

⁴Substance was recommended to be deferred because

If follow-up needed, who will follow up:

Approved by Subcommittee Chair to Transmit to NOSB

John Foster, Subcommittee Chair

January 9, 2013

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment?

Substance: Sulfuric Acid

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			The TR notes that sulfuric acid is a substantial source of acid rain, and that the manufacture of this material presents adverse environmental impact (lines 327-353)
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	x			TR lines 327-353
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	x			TR lines 327-353
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			TR lines 327-353
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]	x			TR lines 327-353
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]	x			While there is no documented detrimental effect on human health from dietary sources of the material as petitioned, the manufacture and industrial use of the material present harmful effects on health. "Sulfuric acid is considered very toxic and may be fatal if inhaled or swallowed. It is corrosive to the eyes, skin, and respiratory tract, and exposure may cause blindness and permanent scarring." –TR Lines 41-42
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		x		Not from dietary sources.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	x			It is not clear from the TR that sulfuric acid is GRAS for the petitioned use; the TR does list a number of other GRAS uses (TR Lines 276-282)
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600		x		The petition and TR provide insufficient information to satisfy this criterion. "While residues and impurities (i.e., copper, iron,

b.5]			zinc, arsenic, mercury, lead, and selenium) have been reported in manufactured sulfuric acid product, no information was found to indicate the levels of these substances in sulfuric acid used for pH adjustment. Therefore it is unknown if these contaminants are in excess of FDA tolerances in sulfuric acid. “ – TR Lines 318-321
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¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production? Substance: Sulfuric Acid

Question	Yes	No	N/A¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	x			TR lines 262-263
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		
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		TR lines 268-269
5. Is there an organic substitute? [§205.600 b.1]		x		Because the manufacturing process is redacted from the petition, it is impossible to determine whether the use of other pH adjusters such as citric or lactic acid is viable or appropriate. TR lines 392-398
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		x		TR lines 392-398
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			x	Again, the petition and TR do not provide sufficient information to determine the necessity of the material, or if the resulting seaweed extract has undergone sufficient chemical change to be rendered synthetic.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		x		
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.

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices? Substance: Sulfuric Acid

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	CBI redacted from petition makes it impossible to establish how the substance impacts the food.
5. Is the primary use as a preservative? [§205.600 b.4]		x		It is not clear that the petitioned use is as a preservative per se, but the TR notes a number of preservative uses of the substance (lines 288-298)
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		TR line 305
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	

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

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 Name: Sulfuric Acid

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
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	
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	
5. Does the industry information provided 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);			x	
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	