

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

Date: December 2, 2011

Subject: Petition to amend annotation for sulfur dioxide on 205.605

Chair: Tracy Miedema

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

Statement of the Recommendation (Including Recount of Vote):

Motion to amend the annotation to § 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--Sulfur dioxide--for use only in wine, provided that total sulfite concentration does not exceed 100 ppm.

The motion failed with a vote of 9 yes and 5 no.

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

The Handling Committee recommendation is attached.

NOSB Vote:

Moved: Steve DeMuri		Second: John Foster		
Yes: 9	No: 5	Abstain: 0	Absent: 0	Recusal: 0

Form NOPLIST1. Committee Transmittal to NOSB

Substance: Sulfur dioxide

A. Evaluation Criteria (Applicability noted for each category; Documentation attached)		Criteria Satisfied? (see B below)		
1. Impact on Humans and Environment		Yes ☐	No ☒	N/A ☐
2. Essential & Availability Criteria		Yes ☒	No ☐	N/A ☐
3. Compatibility & Consistency		Yes ☒	No ☐	N/A ☐
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)		Yes ☐	No ☐	N/A ☒

Substance Fails Criteria Category: Comments: Annotation provides adequate mitigating conditions.

Basis for annotation: To meet criteria above: 1 Other regulatory criteria: _____ Citation: _____

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

Motion by: John Foster Seconded: Steve DeMuri Yes: 5 No: 0 Absent: 2 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	

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 _____

10-14-10
Date

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance: sulfur 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			Yes, but not at levels used TAP 9-26-11 Draft ln 422-424. TAP 9-26-11 Draft ln 84-89
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			Yes, but not at levels used TAP 9-26-11 Draft ln 422-424. TAP 1-14-11 ln 68-73, 270-275, 277-281; TAP 9-26-11 Draft ln 84-89, ln 406-414.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]			X	N/A-for handling purposes
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1) (B)(ii); 205.601(m)2]			X	N/A-for handling purposes
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	N/A-for handling purposes
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	N/A-for handling purposes
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			Yes, but not at levels used TAP 9-26-11 Draft ln 422-424. TAP 9-26-11 Draft ln 84-89
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]	X			Yes, but not at levels used TAP 9-26-11 Draft ln 422-424. TAP 9-26-11 Draft ln 84-89. TAP 1-14-11 422-434;
10. Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)I; §6518 m.4]	X			TAP 1-14-11 ln; TAP 9-26-11 Draft ln 434-459, 461-462;
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]	X			TAP 1-14-11 ln 440-445, 447-477; 21 CFR 182.3762; TAP 9-26-11 Draft ln 430-432. 1995 TAP Bob Durst.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			TAP 9-26-11 Draft ln 338-347; 21 CFR 182.3762
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		TAP 9-26-11 Draft ln 395-396;

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 sulfur 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			TAP 1-14-11 ln 258-265.
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			Possible: TAP 9-26-11 Draft ln 402-403; 1995 TAP R.C. Theuer.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X			TAP 1-14-11 ln 258; TAP 9-26-11 Draft ln
4. Is there a natural source of the substance? [§205.600 b.1]	X			TAP 1-14-11 ln 258-260. TAP 9-26-11 Draft 322-331; 1995 TAP R.C. Theuer.
5. Is there an organic substitute? [§205.600 b.1]			X	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	X			TAP 9-26-11 Draft 327-328. 1995 TAP Bob Durst. TAP 9-26-11 Draft ln 172-176.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		X		TAP 9-26-11 Draft ln 467-478. 1995 TAP R.C. Theuer.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	N/A- Synthetic
9. Is there any alternative substances? [§6518 m.6]		X		TAP 9-26-11 Draft ln 467-478. 1995 TAP Bob Durst
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		TAP 9-26-11 Draft ln 467-478

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; sulfur 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		
2. Is the substance consistent with organic farming and handling, and biodiversity? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]			X	N/A-for handling purposes
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	N/A-for handling purposes
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			TAP 9-26-11 Draft ln 387-389.
5. Is the primary use as a preservative? [§205.600 b.4]	X			TAP 9-26-11 Draft ln 377. 1995 TAP R.C. Theuer
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		TAP 9-26-11 Draft ln 377
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:		X		N/A-for handling purposes
a. Copper and sulfur compounds;			X	N/A-for handling purposes
b. Toxins derived from bacteria;			X	N/A-for handling purposes
c. Pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	N/A-for handling purposes
d. Livestock parasiticides and medicines?			X	N/A-for handling purposes
e. Production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	N/A-for handling purposes

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: sulfur dioxide

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 is to amend annotation of an all ready allowed synthetic.
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	N/A.
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	N/A.
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	N/A.
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			X	
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	