

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 nucleotides as petitioned as synthetic.

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

The petition identified five nucleotides derived from yeast hydrolysate, plus their sodium salts

Committee Vote:

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

Statement of Recommendation: (Motion # 2)

Failed

Motion to list nucleotides for inclusion on 205.605(b) allowed for infant formulas only in the “organic” and “made with organic categories”.

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

Nucleotides are not mandated to be added to infant formulas under the FDA in 21 CFR 104.20, at 21 CFR 107.100 or 107.10, and are not listed at 21 CFR 104.20 for use in food fortification. The NOSB did not find them to be essential for use in organic infant formula, as clarified in the NOP proposed rule on Nutrient Vitamins and Minerals. It may also be possible to make or extract them from non-synthetic sources, although this is not commercially done at this time. The Handling Subcommittee recommends adding synthetic nucleotides to the National List.

Committee Vote:

Moved: Zea Sonnabend

Seconded: John Foster

Yes: 7

No: 8

Abstain: 0

Absent: 0

Recuse: 0

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Nucleotides**

August 21, 2012

Summary of Proposed Action:

Nucleotides are compounds that are made in the body from amino acids. These amino acids are abundant in whole foods with protein. The synthetic form has been petitioned for use in infant formula to increase levels of nucleotides to those in human breast milk.

Nucleotides are not mandated to be added to infant formulas under the FDA in 21 CFR 104.20, 107.100 or 107.10, as clarified in the NOP proposed rule on Nutrient Vitamins and Minerals. It may also be possible to make or extract them from non-synthetic sources, although that is not commercially done at this time. The Handling Sub-committee is recommending to add synthetic nucleotides to the National List.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)
(see “B” below)

Criteria Satisfied?

- | | | | |
|--|------------------------------|-----------------------------|--------------------------|
| 1. Impact on Humans and Environment
N/A | x Yes | <input type="checkbox"/> No | <input type="checkbox"/> |
| 2. Essential & Availability Criteria
N/A | x Yes | <input type="checkbox"/> No | <input type="checkbox"/> |
| 3. Compatibility & Consistency
N/A | x Yes | <input type="checkbox"/> No | <input type="checkbox"/> |
| 4. Commercial Supply is Fragile or Potentially Unavailable
N/A
as Organic (only for § 205.606) | <input type="checkbox"/> Yes | <input type="checkbox"/> No | x |

Substance Fails Criteria Category: [] **Comments:**

Proposed Annotation (if any):

Nucleotides—allowed for infant formulas only in the “organic” and “made with organic categories”. Nucleotides are allowed for the “made with organic claim” on all other food products.

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 nucleotides as synthetic.

Motion by: Tracy Favre

Seconded by: Harold Austin

Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

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or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]				
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]	X			
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		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 2. Is the Substance Essential for Organic Production?

Substance: Nucleotides

Question	Yes	No	N/A ¹	Documentation or Justification
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			Substances are natural, but they are synthetic when produced for commercial use
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X			They are created via natural processes, but synthetic systems are created to generate large volumes of these
4. Is there a natural source of the substance? [§205.600 b.1]	X			Yes, but not available in the quantity needed for commercial production
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		
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X	X		Yeast may be a suitable alternative. Breast milk.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			
9. Are there any alternative substances? [§6518 m.6]	X	X		See 7 above.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X	X		See 7 above.

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NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices?

Substance: Nucleotides

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			Not an essential nutrient, vitamin, or mineral.
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			
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?				

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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: Nucleotides**

Question	Yes	No	N/A ¹	Documentation or Justification
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:Regions of production (including factors such as climate and number of regions);			x	
a. Number of suppliers and amount produced;				
b. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt				

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production or destroy crops or supplies;				
c. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or				
d. Are there other issues which may present a challenge to a consistent supply?				

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