National Organic Standards Board Livestock Subcommittee Petitioned Material Proposal Required Synthetic Amino Acids for Pet Foods

August 20, 2012

Summary of Proposed Action:

Thirteen synthetic amino acids were petitioned for use in organic pet foods. The Subcommittee evaluated the petition, TR, had discussion with State Feed Control Officials and concluded that only Taurine for cats was deemed necessary as a synthetic addative and thus allowed. It was determined that the manufacturers could meet the required levels of Arginine, DL-Methionine, Cysteine, L-Lysine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, Valine to meet the criteria for "complete and balanced" as required by American Association of Feed Control Officials (AAFCO) with typical ingredients.

This petition checklist is only for Taurine for cats.

Evaluation Criteria

(Applicability noted for each category; Documentation attached) Satisfied? (see "B" below)	Criteria	
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		
Commercial Supply is Fragile or Potentially Unavailable	🛛 Yes 🛛	
No 🗆 N/A		
as Organic (only for § 205.606)		

Substance Fails Criteria Category: [] Comments:

Proposed Annotation (if any): 205.603(e)(4) Taurine (CAS 107-35-7) for cats

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

Notes: The other 12 petitioned Amino Acids failed to meet the necessity criteria

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

Classification Motion:Motion to classify amino acids (Arginine, Methionine,
Cystine, Lysine, Taurine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine,
Phenylalanine, Tyrosine, and Valine) as synthetic.Motion by:Mac StoneYes:# 7 No:# 0Absent:# 1Abstain:# 0Recuse:# 0

Listing Motion: Motion to list amino acids (Arginine, Methionine, Cystine, Lysine, Taurine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, and Valine) on section 205.603 on the National List for use in organic pet food.

Motion by: Mac StoneSeconded by: Colehour BonderaYes: #No: #7Absent: #1Abstain: #0Recuse: #0

Listing Motion: Motion to list Taurine (CAS 107-35-7) on 206.603(e)(4) for cats Motion by: Wendy Fulwider Seconded by: Calvin Walker Yes: # 7 No: # 0 Absent: # 1 Abstain: # 0 Recuse: # 0

Crops		Agricultural		Allowed ¹	\boxtimes
Livestock	Χ	Non-synthetic		Prohibited ²	
Handling		Synthetic	\boxtimes	Rejected ³	
No restriction		Commercial unavailable as		Deferred ⁴	
		organic			

¹Substance voted to be added as "allowed" on National List to § 205.603 with Annotation (if any): Taurine (CAS 107-35-7) on 206.603(e)(4) for cats

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. Describe why material was rejected: 12 petitioned items rejected for lack necessity to formulate complete and balanced feeds for cats and dogs

⁴Substance was recommended to be deferred because If follow-up needed, who will follow up:

Approved by Committee Chair to Transmit to NOSB

Wendy Fulwider, Committee Chair 8/16/12

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: Taurine

	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		
2.	Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		Х		
3.	Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		x		
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		
9.	Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		x		
	Are there any harmful effects 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			х	

applicable Federal regulations? [205.600 b.3]			
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		

NOSB Evaluation Criteria for Substances Added To the National List

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

	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			
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		
	Is there a natural source of the substance? [§205.600 b.1]	x			
5.	Is there an organic substitute? [§205.600	х			

	b.1]			
6.	Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	X Taurine	Arginine, DL- Methionine, Cysteine, L- Lysine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, Valine	From the TAP and petition and discussions with Feed Control Officials, only Taurine was determined absolutely necessary for cats, for diet formulators to meet AAFCO guidelines
7.	Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	Х		
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]		х	
10	Is there another practice that would make the substance unnecessary? [§6518 m.6]		x	

NOSB Evaluation Criteria for Substances Added To the National List

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

	Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1.	Is the substance compatible with organic handling? [§205.600 b.2]	х			
2.	Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	x			

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3.	Is the substance compatible with a			х	
	system of sustainable agriculture?				
	[§6518 m.7]				
4.	Is the nutritional quality of the food	Х			
	maintained with the substance?				
	[§205.600 b.3]				
5.	Is the primary use as a		х		
	preservative? [§205.600 b.4]				
6.	Is the primary use to recreate or	x			
0.	improve flavors, colors, textures,				
	or nutritive values lost in				
	processing (except when required				
	by law, e.g., vitamin D in milk)?				
	,				
7	[205.600 b.4] Is the substance used in		V		
1.			х		
	production, and does it contain an				
	active synthetic ingredient in the				
	following categories:				
	a. copper and sulfur compounds;				
	b. toxins derived from bacteria;		Х		
	c. pheromones, soaps,		Х		
	horticultural oils, fish				
	emulsions, treated seed,				
	vitamins and minerals?				
	d. livestock parasiticides and		Х		
	medicines?				
	e. production aids including			Х	
	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)] **Substance: Name: Taurine**

	Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1.	Is the comparative description provided as to why the non- organic form of the material /substance is necessary for use in organic handling?			Х	
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 <u>form</u> 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 <u>guality</u> 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 <u>quantity</u> 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	