

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

February 5, 2013

Summary of Proposed Action:

Thirteen synthetic amino acids were petitioned for use in organic pet foods. The Subcommittee evaluated the petition and 2012 technical report (TR), and had discussions with State Feed Control Officials. Based on this information, the Subcommittee concluded that only Taurine for cats was deemed necessary as a synthetic additive to meet nutritional requirements and thus should be allowed in organic pet food. The Subcommittee determined that the manufacturers could meet the required levels of Arginine, DL-Methionine, Cysteine, L-Lysine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, and Valine to meet the criteria for "complete and balanced" as required by American Association of Feed Control Officials (AAFCO) with organic agricultural ingredients.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)

Criteria

Satisfied?

Impact on Humans and Environment	☒ Yes	☐ No	☐ N/A
1. Essential & Availability Criteria	☒ Yes	☐ No	☐ N/A
2. Compatibility & Consistency	☒ Yes	☐ No	☐ N/A
3. 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(d)(4) Taurine (CAS 107-35-7) for use in cat food only

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

Notes: The other 12 petitioned Amino Acids failed to meet the necessity criteria as manufacturers should be able to meet the required AAFCO levels through use of organic agricultural ingredients.

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 Stone Seconded by: Jean Richardson
Yes: # 9 No: # 0 Absent: # 0 Abstain: # 0 Recuse: # 0

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

Motion by: Mac Stone Seconded by: Colehour Bondera
Yes: # 0 No: # 9 Absent: # 0 Abstain: # 0 Recuse: # 0

Listing Motion: Motion to list taurine CAS (107-35-7) at 205.603(d), as a feed additive, for use in cat food only

Motion by: Mac Stone Seconded by: Jean Richardson
Yes: # 8 No: # 0 Absent: # 0 Abstain: # 1 Recuse: # 0

Crops	☐	Agricultural	☐	Allowed¹	☒
Livestock	☒	Non-synthetic	☐	Prohibited²	☐
Handling	☐	Synthetic	☒	Rejected³	☐
No restriction	☐	Commercial unavailable as organic	☐	Deferred⁴	☐

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(d)(4) for use in cat food only

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 § 205.603 .
Describe why material was rejected: NOTE: 12 petitioned amino acids were rejected for lack of necessity to formulate complete and balanced feeds for cats and dogs. The Subcommittee determined that manufacturers should be able to meet the AAFCO required levels through use of agricultural ingredients.

⁴Substance was recommended to be deferred because

Approved by Subcommittee Chair to Transmit to NOSB
Tracy Favre February 5, 2013

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment?
Substance: Amino Acids for Pet Food

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]		x		
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		
10. 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 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: Amino Acids for Pet Food

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		
4. Is there a natural source of the substance? [§205.600 b.1]	X			The petition states the plant and animal sources of each AA.
5. Is there an organic substitute? [§205.600 b.1]	x			From the listed sources of AA in the petition, some of these agricultural ingredients may be organic.
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 TR and petition and discussions with Feed Control Officials, only Taurine was determined absolutely necessary for cats, for diet formulators to meet AAFCO guidelines. The other twelve amino acids can be provided through use of agricultural ingredients.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X	Not for taurine		The TR indicates that natural forms of taurine are less available in agricultural products and degraded during commercial processing to the point the nutritional

				requirements of cats cannot be maintained.
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]	Yes for other amino acids	Not for taurine		The petition and TR indicate the non-synthetic forms of taurine from any source are degraded during processing moreso than the other AA.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	Yes for other amino acids	Not for taurine		The TR describes how raw food diets of organ meats, bone, fat, and meat are a substitute, with risk to nutritional imbalance and bacterial contamination

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: Amino Acids for Pet Food

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 - Taurine only			Synthetic vitamins and minerals are allowed in organic foods and livestock feeds to maintain the nutritional quality. 205.603(d)(2)(3)
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X - Taurine only			The petition describes which organic agricultural products and by-products are used in the production of pet foods. Taurine is not readily available in these products. Providing optimum nutrition to animals under our care is a tenant of organic farming.
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 – Taurine			Consultation with AAFCO officials confirm our ingredient panel surveys that to meet the nutritional requirements for cats can only be accomplished with synthetic form supplementation.
5. Is the primary use as a		x		

preservative? [§205.600 b.4]				
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 Taurine			Due to the degradation during heat processing and preservation required for pet food manufacture as stated in the petition and TR.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:		x		Numerous synthetic amino acids are added during processing of commercial pet foods is common in the manufacture of pet foods as stated in the petition and TR.
a. copper and sulfur compounds;				
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: Amino Acids in Pet Food**

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			X	

why the material /substance cannot be obtained organically in the appropriate <u>quality</u> to fulfill an essential function in a system of organic handling?				
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:			X	
a. Regions of production (including factors such as climate and number of regions);				
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	

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

National Organics Standard Board
Livestock Subcommittee
Proposal: Required Synthetic Amino Acids for Pet Foods
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Introduction

The growth of the organic food sector extends into the pet food market. Consumers are looking for organic alternatives for their pets because they understand the strict policies behind the organic seal and it corresponds with their values in terms of no Genetically Modified Organisms (GMOs), transparent sourcing of ingredients, and lessened environmental impact of production. Certifiers currently certify pet food products by following relevant sections of the USDA organic regulations as it pertains to livestock feed, processed products, and associated labeling requirements. Specific organic pet food standards are not currently part of these regulations; however, the National Organic Program (NOP) is currently drafting a Proposed Rule to regulate organic pet food based on the 2008 NOSB recommendation.

In some cases, synthetic amino acids, like vitamins and minerals, have been allowed for organic pet food, if required by the U.S. Food and Drug Administration. However, the NOP recently reviewed the allowance for nutrients, including amino acids, for use in organic processed products such as organic pet food, and determined that the NOSB should review these nutrients through the petition process. Therefore, the Pet Food Institute has petitioned the NOSB to place the 13 essential synthetic amino acids for dogs and cats on the National List. Sourcing organic ingredients to meet the amino acid needs of pets and achieve “organic” or “made with organic” status is challenging in terms of seasonal and geographic constraints on availability of feedstuffs. Dogs, cats, and specialty pets that live in tanks or cages, have dietary demands that must be met with a sole source feed formulation specific to their species and stage of life.

Background

Meeting the nutritional needs of pets with a single source of feed requires manufacturers to follow strict dietary guidelines. These guidelines are regulated by a series of regulators and scientific communities. The Food and Drug Administration (FDA) regulates pet food under the Federal Food, Drug, and Cosmetic Act that requires all animal feeds, like human foods, to be safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled. The FDA Center for Veterinary Medicine (CVM), that manages the non-human aspect of the regulation for the agency, accepts the determination of an *ad hoc* expert nutrition committee under the Committee on Animal Nutrition for the National Research Council (NRC) in the National Academy of Sciences to establish nutrient requirements for dogs, cats, and all other species of animals. For dogs and cats, the required essential nutrients are listed and described in the *NRC 2006 edition of Nutrient Requirements of Dogs and Cats*. The 2006 edition is the standard State Feed Control Officials use when evaluating diet formulations and to verify labels as sufficient for use in their state. These State Feed Officials have formed the Association of American Feed Control Officials (AAFCO) to act as a forum and clearinghouse for developing an overall regulatory structure that is consistent across the country for continuity of interstate commerce. FDA officials sit on the standing committees of this organization to ensure

compliance with the regulations. The State Feed Control Officials implement the regulatory process through their legislative system.

Through this system, for a pet food to make the label claim “complete and balanced,” it must meet the standards in the NRC 2006 edition of Nutrient Requirements for Dogs and Cats.

The current AAFCO standard classifies 13 amino acids (AA) as essential for dogs and cats (Appendix). This means they cannot be synthesized by the body and must be supplied by the feed. All of these AA are naturally occurring in nature. Prior to domestication, these animals sought out food sources to supply these AA in the correct balance to meet their needs. With domestication came the need to supply the animals a complete and balanced diet with the correct food sources. It can be difficult to achieve the required balance of AA given access to ingredients and the processing requirements for preserving and packaging them for market. These AA are also manufactured by chemical synthesis, fermentation, and enzymatic synthesis to supplement diets that may be deficient in one or more of them. The AA produced from each of these processes would be considered synthetic under the working definition of the NOSB. The fermentation process could use excluded methods.

Some pet foods on the market are certified organic without the use of synthetic AA and meet the complete and balanced claim, albeit a very small segment of the market. Some are certified with the understanding that synthetic nutrients, including synthetic AA are allowed, along with vitamins and minerals, without regard to source and “other ingredients” under the livestock feed standards. Certifiers, to date, are using the livestock feed standards at 7 CFR 205.237 for processing and handling; and label standards at section 205.301 to certify these products.

In 2012, the NOP notified the industry that these amino acids must be petitioned individually, as they do not fall under the current allowance for vitamins and minerals on the National List. In 2005, a Pet Food Task Force (PFTF) was formed by the NOSB and NOP to advise the NOSB on future recommendations to implement pet food standards. This led to the NOSB making recommendations to the NOP in fall 2008 on numerous changes to regulate pet foods in the USDA organic regulations. These recommendations included the use of mammalian and poultry products and by-products as allowed since pets are not part of the food chain. This point is the fundamental reason pet foods must be distinguished from livestock feeds. It also clarified labeling requirements, and the need for additions to the National List. Currently the NOP intends to announce proposed rulemaking on this topic in 2013. When the rulemaking process is complete, only approved synthetic AA will be allowed in organic pet foods.

Discussion

The Pet Food Institute has petitioned the NOSB to place Arginine, Methionine, Cystine, Lysine, Taurine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, and Valine, as synthetic AA, on the National List. These AA, must be supplied by the feed, in some form, at minimum levels, for the feed to meet the AAFCO standards of complete and balanced. However, the petition states that

Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, and Valine are available in agricultural products used as feedstuffs and will not need to be utilized in synthetic form. Therefore, the committee focused its work on Arginine, Methionine, Cystine, Lysine, Taurine, and Tryptophan, the AA listed on the 2008 NOSB pet food recommendation as potentially necessary in synthetic form. Carnitine was also on the 2008 recommendation however, it is not part of this petition.

Dog foods must be at least 22% protein, however, some go much higher to mimic natural diets. The higher protein (meat based) diets may require less AA supplementation, yet be more expensive to produce. Many commercial dog food formulations have synthetic Taurine, DL-Methionine, L-Lysine and Carnitine listed on the ingredient panel. In addition, there are many dog foods on the market with no added synthetic AA.

Virtually all cat foods have synthetic Taurine because of the relatively high requirement for cats, and degradation during processing no matter the protein percentage. Many cat foods also list synthetic Methionine and Lysine on their labels. The Technical Report states several pet food brands are on the market as complete and balanced without the use of synthetic AA.

There is no mention of “other ingredients” such as anti-oxidants, carriers, etc. associated with these AA. The committee would like to know more about other ingredients associated with these products. Those derived from fermentation would have to document no excluded methods are used in the process. It is reported that Taurine is particularly sensitive to heating and is severely degraded in the manufacturing process.

The use of synthetic AA in pet foods is based on the ability of the manufacturer to formulate a diet that supplies the correct balance of AA to meet AAFCO standards of “complete and balanced”. In the case of organic pet foods, manufacturers have limited access to organic ingredients, thus the petitioner’s stated need to utilize synthetic nutrients to balance the formulations. It is unclear from the information at hand that the allowance of synthetic AA will foster the expanded use of organic by-products and other organic inputs because manufacturers will be have these limiting AA at their disposal. It is also unclear that if these synthetic AA are available to manufacturers, if it will allow the use of lower quality ingredients, supplemented with these AA, to be more competitive in the market place.

Relevant Areas of the Rule

The [2008 NOSB recommendation](#) proposed a change to the organic regulations to support labeling of organic pet food and provide clarity where any conflicts may have existed between organic labeling claims and the existing state requirements for pet food labeling. The intent of the proposed regulation was to create a pet food label that is consistent with labeling for human food.

Appendix

	AAFCO Dog Food Nutrient Profiles			
		Growth	Adult	
	Units	Reproduct	Maintena	
	Basis	Minimu	Minimu	Maximum
Arginine	%	0.62	0.51	
Histidine	%	0.22	0.18	
Isoleucine	%	0.45	0.37	
Leucine	%	0.72	0.59	
Lysine	%	0.77	0.63	
Methionine-	%	0.53	0.43	
Phenylalanine-	%	0.89	0.73	
Threonine	%	0.58	0.48	
Tryptophan	%	0.20	0.16	
Valine	%	0.48	0.39	

	AAFCO Dog Food Nutrient Profiles			
	Units	Growth &	Adu	
	1000	Reproduct	Maintenan	
	M	Minimum	Minimum	Maximum
Arginine	g	1.77	1.46	
Histidine	g	0.63	0.51	
Isoleucine	g	1.29	1.06	
Leucine	g	2.06	1.69	
Lysine	g	2.20	1.80	
Methionine-	g	1.51	1.23	
Phenylalanine-	g	2.54	2.09	
Threonine	g	1.66	1.37	
Tryptophan	g	0.57	0.46	
Valine	g	1.37	1.11	

	AAFCO Cat Food Nutrient Profiles			
		Growth &	Adu	
	Units	Reproduct	Maintenan	
	Basis	Minimum	Minimum	Maximu
Arginine	%	1.25	1.04	
Histidine	%	0.31	0.31	
Isoleucine	%	0.52	0.52	
Leucine	%	1.25	1.25	
Lysine	%	1.20	0.83	
Methionine-	%	1.10	1.10	

Methionine	%	0.62	0.62	1.50
Phenylalanine-tryosine	%	0.88	0.88	
Phenylalanine	%	0.42	0.42	
Threonine	%	0.73	0.73	
Tryptophan	%	0.25	0.16	
Valine	%	0.62	0.62	
Taurine (Dry	%	0.10	0.10	
Taurine (Wet	%	0.20	0.20	

	AAFCO Cat Food Nutrient Profiles			
	Units	Growth &	Adu	
	1000	Reproduct	Maintenan	
	M	Minimum	Minimum	Maximum
Arginine	g	3.10	2.60	
Histidine	g	0.78	0.78	
Isoleucine	g	1.30	1.30	
Leucine	g	3.10	3.10	
Lysine	g	3.00	2.08	
Methionine-	g	2.75	2.75	
Methionine	g	1.55	1.55	3.75
Phenylalanine-	g	2.20	2.20	
Phenylalanine	g	1.05	1.05	
Threonine	g	1.83	1.83	
Tryptophan	g	0.63	0.40	
Valine	g	1.55	1.55	
Taurine (Dry	g	0.25	0.25	
Taurine (Wet Food)	g	0.50	0.50	

Common Name	Chemical Name	CAS Number	Trade Names	Other Codes
Arginine	(S)-2-Amino-5-guanidinopentanoic acid	74-79-3	Arginine (L-)	EINECS: 230-571-3
Methionine	2-amino-4-(methylthio)butanoic acid	63-68-3 (L-); 59-51-8 (DL-)	Mepron®; Alimet®	EINECS: 200-432-1
Cysteine	2-amino-3-sulfanylpropanoic acid	52-90-4; 3374-22-9 (DL-)	L-Cysteine; L-Cysteine Hydrochloride Monohydrate	EINECS: 222-160-2
Lysine	2,6-diaminohexanoic acid	56-87-1 (L-); 70-54-2 (DL-)	VitaLys®; L-Lysine Premium®	EINECS: 200-740-6
Taurine	2-aminoethane sulfonic acid	107-35-7	Taurine: AI3-18307; O-Due; Taurina; Taukard	EINECS: 203-483-8
Tryptophan	(2S)-2-amino-3-(1H-indol-3-yl)propanoic acid	73-22-3 (L-); 54-12-6 (DL-)	TryptoPure®; L-Tryptophan	EINECS: 200-194-9
Threonine	2-Amino-3-hydroxybutanoic acid	72-19-5 (L-); 80-68-2 (DL-)	L-Threonine; DL-Threonine;	EINECS: 201-300-6
Histidine	2-Amino-3-(1H-imidazol-4-yl)propanoic acid	71-00-1 (L-); 4998-57-6 (DL-)	L-Histidine	EINECS: 225-660-9
Isoleucine	2-Amino-3-methylpentanoic acid	73-32-5 (L-); 328-39-2 (DL-)	L-Isoleucine	EINECS: 207-139-8
Leucine	2-Amino-4-methylpentanoic acid	61-90-5 (L-); 328-39-2 (DL-)	L-Leucine	EINECS: 206-328-2
Valine	2-Amino-3-phenylpropanoic acid	72-18-4 (L-); 516-06-3 (DL-)	L-Valine	EINECS: 208-220-0
Phenylalanine	2-Amino-3-phenylpropanoic acid	63-91-2 (L-); 150-30-1 (DL-)	L- Phenylalanine	EINECS: 205-756-7
Tyrosine	L-2-Amino-3-(4-hydroxyphenyl)propanoic acid	60-18-4 (L-); 556-03-6 (DL-)	L-Tyrosine	EINECS: 209-113-1