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) **(see "B" below)**	**Criteria Satisfied?**		
1. Impact on Humans and Environment N/A	☒ Yes	☐ No	☐
2. Essential & Availability Criteria N/A	☒ Yes	☐ No	☐
3. Compatibility & Consistency N/A	☒ Yes	☐ No	☐
4. Commercial Supply is Fragile or Potentially Unavailable N/A as Organic (only for § 205.606)	☒ Yes	☐ No	☐

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 Stone Seconded by: Colehour Bondera
Yes: # 7 No: # 0 Absent: # 1 Abstain: # 0 Recuse: # 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 Stone Seconded by: Colehour Bondera
Yes: # No: # 7 Absent: # 1 Abstain: # 0 Recuse: #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]**	☒
Livestock	☒	**Non-synthetic**	☐	**Prohibited[2]**	☐
Handling	☐	**Synthetic**	☒	**Rejected[3]**	☐
No restriction	☐	**Commercial unavailable as organic**	☐	**Deferred[4]**	☐

[1]Substance 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

[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: 12 petitioned items rejected for lack necessity to formulate complete and balanced feeds for cats and dogs

[4]Substance 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,		x		

use, or disposal? [§205.600 b.2]				
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		

[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.

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		
4. Is there a natural source of the substance? [§205.600 b.1]	x			
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 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)]	X			
8. Is the substance used in handling, not synthetic, but not organically		x		

produced? [§6517 c (1)(B)(iii)]				
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		

[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.

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]	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			
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: a. copper and sulfur compounds;		x		
b. toxins derived from bacteria;		x		
c. pheromones, soaps, horticultural oils, fish		x		

emulsions, treated seed, vitamins and minerals?				
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	

[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.

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: 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?			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			X	

as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;				
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	

[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.

National Organics Standard Board
Livestock Subcommittee
Proposal: Pet Food Amino Acids
August 10, 2012

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 logo and it corresponds with their values in terms of no GMOs, transparent sourcing of ingredients, and lessened environmental impact of production. Certifiers currently certify pet food products by following the livestock standards for production purposes, and the processed foods labeling regulations in the marketplace. To date, the National Organic Program (NOP) allows synthetic AA, like vitamins and minerals, to be allowed for organic livestock feed, if required by FDA. Based on a report from the Office of the Inspector General, this interpretation of the Rule has been overturned and the NOP is crafting Rulemaking language that will require any "accessory nutrient", other than vitamins and minerals, to be petitioned to the NOSB. The Pet Food Institute has petitioned the NOSB to place the 13 essential synthetic amino acids for dogs and cats on the National List. Pet food standards are not currently part of the Rule; however, the NOP is working towards a Proposed Rule based on the 2008 NOSB recommendation to regulate organic pet food. (See Appendix 1). Sourcing organic ingredients to achieve "organic" or "made with" status is challenging in terms of seasonal and geographic constraints on availability of feedstuffs. Dogs, cats, and animals 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 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 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 *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. (See Appendix 2). 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. The 13 essential AA petitioned for use in organic pet foods are listed in Appendix 3.

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 using the previous NOP ruling that synthetic nutrients 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 205.237 for processing and handling; and label standards 205.301 to certify these products. The synthetic AA have been considered accessory nutrients to vitamins and minerals as permitted by the 1995 NOP ruling allowing such. In 2010, the NOP determined this interpretation incorrect and all accessory nutrients must be petitioned individually, as they are not vitamins or minerals. In 2005 a Pet Food Task Force (PFTF) was formed by the NOSB and NOP to advise the NOSB on future recommendation to implement pet food standards. This led to the NOSB making recommendations to the NOP in fall 2008 on numerous Rule changes to regulate pet foods in the Rule. 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 is set to announce proposed rulemaking on this topic late in 2012 or early 2013. When the rulemaking process is completed, 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 goes on to say, Threonine, Histidine, Isoleucine, Leucine, Phenylalinine, 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.

Relative Areas of the Rule

Based on the NOSB recommendation in 2008:

§205.603 Synthetic substances allowed for use in organic livestock and pet food production.

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic livestock production, and for organic pet food production, as applicable.

(b) As livestock feed supplements—Milk replacers—without antibiotics, as emergency use only, no nonmilk products or products from BST treated animals.

(d) As feed supplements for pet food (reserved)

(d e) As feed additives.

(1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium—for use only in organic poultry production until October 21, 2008.

(2) Trace minerals, used for enrichment or fortification when FDA approved.

(3) Vitamins, used for enrichment or fortification when FDA approved.

(4) Other nutrients for use in pet foods: (reserved)

Individual AA would be listed under 205.603(e)(4)

Recommendation

Given the numerous pet food formulations on the market without synthetic AA, the committee feels that manufacturers have access to ingredients for organic pet foods to supply the balance of AA to meet the AAFCO standards for complete and balanced diet, except for Taurine for cats. The Livestock Sub-committee recommends Taurine (CAS 107-35-7) for cats, produced using chemical synthesis methodology, be added to 205.603(e)(4) when the pet food standards are implemented as part of the Rule.

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: Colehour Bondera

Yes: # 7 No: # 0 Absent: # 1 Abstain: # 0 Recuse: # 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 Stone Seconded by: Colehour Bondera

Yes: # No: # 7 Absent: # 1 Abstain: # 0 Recuse: #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

Appendix 1

Recommendations for Regulatory Change to 7 CFR Part 205 to include Organic Pet Food

Suggested additions to 7 CFR Part 205 are included in underline format. Deletions are marked in ~~strikethrough~~ format.

Subpart A Definitions:
205.2 Terms defined

Agricultural product. Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human, pet, specialty pet or livestock consumption.[2]

Livestock. Any cattle, sheep, goat, swine, poultry, or equine animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products; wild or domesticated game; or other nonplant life, except such term shall not include pets or specialty pets. ~~aquatic animals or bees for the production of food, fiber, feed, or other agricultural-based consumer products."~~[3]

Meat (feed ingredient) is clean flesh derived from slaughtered mammals and limited to that part of the striate muscle which is skeletal or that which is found in the tongue, in the diaphragm, in the heart, or in the esophagus; with or without the accompanying overlying fat and the portions of the skin, sinew, nerve, and blood vessels which normally accompany the flesh.[4]

Pet - dog or cat

Pet food - any commercial feed prepared and distributed for consumption by dogs or cats.
For the purposes of this regulation unless specifically noted the term "pet food" will include both pet and specialty pet food. Rabbits, horses and camelids are specifically excluded from this definition as they are classified as "livestock."

Poultry (feed ingredient) – is the clean combination of flesh and skin with or without accompanying
bone, derived from the parts or whole carcasses of poultry or a combination thereof, exclusive of feathers, heads, feet and entrails.[5] May not be listed as "poultry meat", may only be identified as "poultry"; or if species specific, can denote a species, as "chicken meat", "duck meat", "turkey meat", etc.

Slaughter by-products are all parts of the animal or poultry produced at slaughter, such as, but not limited to organs, blood, plasma, etc. but does not include meat from animals, poultry, or fish, or harvest products like eggs, milk, milk products, or wool.[6]

Specialty pet- any domesticated animal normally maintained in a cage or tank, such as, but not limited to, gerbils, hamsters, canaries, psittacine birds, mynahs, finches, tropical fish, goldfish, snakes, reptiles and turtles. For the purposes of this regulation unless specifically noted the term "pet" will include both pet and specialty pet.

Specialty Pet food: any commercial feed prepared and distributed for consumption by specialty pets:
which includes any domesticated animal normally maintained in a cage or tank, such as, but not limited
to, gerbils, hamsters, canaries, psittacine birds, mynahs, finches, tropical fish, goldfish, snakes and turtles. For the purposes of this regulation unless specifically noted the term "pet food" will include both pet and specialty pet food.

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2 This addition was necessary due to many other references in the rule to "agricultural product."
3 We have proposed removing the reference to aquatic animals to be consistent with the recommendation of the Aquaculture
Task Force.
4 AAFCO 2005 Official Publication, Feed ingredient definition 9.2
5 AAFCO 2005 Official Publication, Feed ingredient definition 9.57
6 AAFCO, 2005, sections 9 and 54 of Feed ingredient definitions

Subpart B Applicability:

§ 205.100 What has to be certified.

(a) Except for operations exempt or excluded in § 205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, pet food or other agricultural products that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.

§205.105 Allowed and prohibited substance, method, and ingredients in organic production and handling.

To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of:

(a) Synthetic substances and ingredients, except as provided in §

205.601 or § 205.603; (b) Nonsynthetic substances prohibited in §

205.602 or § 205.604;

(c) Nonagricultural substances used in or on processed products, except as otherwise provided in §
205.605;

~~(d)~~ Nonorganic agricultural substances used in or on processed products, except as otherwise provided in
§ 205.606;

(e) Synthetic substances and ingredients used in or on pet food, except as provided in §205.603, or §205.605 [7]

(~~e~~ f) Excluded methods, except for vaccines, *Provided,* That, the vaccines are approved in accordance with § 205.600(a);

(~~f~~ g) Ionizing radiation, as described in Food and Drug Administration regulation, 21 CFR 179.26 and 21 CFR 579; [8]

(~~g~~ h) Sewage sludge.

Subpart C Organic Production and Handling Requirements:

§ 205.237 Livestock feed and pet food.

(a) The producer of an organic livestock operation must provide livestock with a total feed ration composed of agricultural products, including pasture and forage, that are organically produced and, if

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[7] This means that synthetic substances approved for use either in human food processing or for livestock use may be used in pet food formulations as feed additives or supplements, must also be FDA approved for this use, see new 205.237(c). NOSB recommended in Nov. 2000 and again in Sept. 2002 that synthetics allowed at 205.605 for food should be allowed in livestock production, subject to FDA or AAFCO regulations. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5058542

[8] 21 CFR 179.26 applies specifically to production, processing and handling of food. 21 CFR 579 is the appropriate reference for irradiation applied to livestock feed and pet food.

applicable, organically handled: Except, that, nonsynthetic substances and synthetic substances allowed under § 205.603 may be used as feed additives and supplements.

(b) The producer of an organic livestock operation must not:
(1) Use animal drugs, including hormones, to promote growth;
(2) Provide feed supplements or additives in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage of life;
(3) Feed plastic pellets for roughage;
(4) Feed formulas containing urea or manure;
(5) Feed mammalian or poultry slaughter by-products, meat, or poultry to mammals or poultry[9]; or (6) Use feed, feed additives, and feed supplements in violation of the Federal Food, Drug, and Cosmetic Act.
(7) Feed organic pet food to livestock.

(c) Pet food must be composed of agricultural products that are organically produced and, if applicable, organically handled: Except that, nonagricultural nonsynthetic substances, and synthetic substances allowed under §205.603, and 205.605 may be used as feed additives and supplements provided they are allowed by the FDA in animal feed, Nonorganic agricultural ingredients allowed under § 205.606 may be used in products labeled organic provided they are commercially unavailable in organic form and allowed by the FDA in animal feed.

Subpart D Labels, Labeling and Market information:

§ 205.300 Use of the term, "organic."

(a) The term, "organic," may only be used on labels and in labeling of raw or processed agricultural products, including ingredients that have been produced and handled in accordance with the regulations in this part. The term, "organic," may not be used in a product name to modify a nonorganic ingredient in the product.

(b) Products for export, produced and certified to foreign national organic standards or foreign contract buyer requirements, may be labeled in accordance with the organic labeling requirements of the receiving country or contract buyer: Provided, That, the shipping containers and shipping documents meet the labeling requirements specified in § 205.307(c).

(c) Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part and labeled pursuant to this subpart D.

(d) Livestock feeds produced in accordance with the requirements of this part must be labeled in accordance with the requirements of § 205.306.

(e) Pet foods produced in accordance with the requirements in this part must be labeled in accordance with the requirements of subpart D, except for section 205.306. Pet food must be composed in accordance with the requirements of 205.301(g) and must be labeled in accordance with state and federal regulations.[10]

§ 205.301 Product Composition

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9 With this addition and the new definition of slaughter by-products, the rules clarify that neither slaughter by-products or mammalian or poultry products (meat) are permitted to be fed to organic livestock. Milk and eggs, are not prohibited as feed ingredients. Wool is a source of lanolin, used in production of some forms of Vitamin D.

10 This change means that almost all of subpart D, except for the section specific to livestock feed labeling will apply to pet food. Pet food will be composed according to the new section 205.301(g), rather than the current 205.301 (a-f).

(f) All products labeled as "100 percent organic" or "organic" and all ingredients identified as "organic" in the ingredient statement of any product must not:

(1) Be produced using excluded methods, pursuant to § 201.105(e); (2) Be produced using sewage sludge, pursuant to § 201.105(f);

(3) Be processed using ionizing radiation, pursuant to § 201.105(g);

(4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part: Except, That, products labeled as "100 percent organic," if processed, must be processed using organically produced processing aids.

(5) Contain sulfites, nitrates, or nitrites added during the production or handling process, Except, That, wine containing added sulfites may be labeled "made with organic grapes";

(6) Be produced using nonorganic ingredients when organic ingredients are available; or

(7) Include organic and nonorganic forms of the same ingredient.

(g) Pet Food

1. *Products sold, labeled, or represented as "100 percent organic."* A raw or processed agricultural product sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) 100 percent organically produced ingredients. If labeled as organically produced, such product must be labeled pursuant to § 205.303. No products may be produced using prohibited practices or substances specified in §205.301(f).

2. *Products sold, labeled, or represented as "organic."* A raw or processed agricultural product sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural ingredients ~~products.~~[11] Any remaining agricultural ingredients or processing aids must be organically produced, unless not commercially available in organic form and included on 205.606. Nonagricultural substances must be used in accordance with 205.237(c). No products may be produced using prohibited practices or substances specified in §205.301(f), except that nonsynthetic processing aids may be used. If labeled as organically produced, such product must be labeled pursuant to § 205.303.

3. *Products sold, labeled, or represented as "made with organic (specified ingredients or food group(s))."* Multi-ingredient agricultural product sold, labeled, or represented as "made with organic (specified ingredients or food group(s))" must contain (by weight or fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements in subpart C of this part. Nonorganic nonagricultural ingredients must be in accordance with 205.237(c). No products may be produced using prohibited practices specified in paragraphs (1), (2), (3), (5), and (7) of § 205.301(f). If labeled as containing organically produced ingredients or food groups, such product must be labeled pursuant to § 205.304.[12]

[11] Product labeled “organic” may contain multiple organic agricultural ingredients.
[12] We have included the requirement from 205.301(f) that organic and non-organic forms of the same ingredient are not permitted in a “Made with Organic” claim. This is an effort to prevent a misleading label claim; such as a product that claims it is “made with organic chicken” that might have 5% organic chicken and 25% non-organic chicken, as well as 65% other organic ingredients. A “made with organic” product could have organic chicken, as well as non-organic chicken meal however, as these are two distinct ingredients according to AAFCO definition. Although there is some uncertainty in the industry if organic and non-organic forms of the same ingredient are prohibited in a “Made with Organic” claim for human food, NOP has stated it concurs that this is the correct interpretation. NOSB has recommended this clarification; see “Final Recommendation for Rule Change Concerning Made with Organic Ingredients”, March 18, 2005. This pet food requirement should be made in concert with change to the requirements for human food.

4. *Products with less than 70 percent organically produced ingredients.* The organic ingredients in multi-ingredient agricultural product containing less than 70 percent organically produced ingredients (by weight or fluid volume, excluding water and salt) must be produced and handled pursuant to requirements in subpart C of this part. The nonorganic ingredients may be produced and handled without regard to the requirements of this part. Multi-ingredient agricultural products containing less than 70 percent organically produced ingredients may represent the organic nature of the product only as provided in § 205.305.

Subpart G Administrative:

§205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

(a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National
List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7
U.S.C. 6517 and 6518).

(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:……

(c) In addition to criteria set forth in the Act, any synthetic nutrient used in pet food should be considered in accordance with need established as requirements under FDA or in AAFCO Nutrient Profiles. [13]

§205.603 Synthetic substances allowed for use in organic livestock and pet food production.

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic livestock production, and for organic pet food production, as applicable.

(b) As livestock feed supplements—Milk replacers—without antibiotics, as emergency use only, no nonmilk products or products from BST treated animals.

(d) As feed supplements for pet food (reserved)

(d e) As feed additives.

(1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium—
for use only in organic poultry production until October 21, 2008.
(2) Trace minerals, used for enrichment or fortification when
FDA approved. (3) Vitamins, used for enrichment or fortification
when FDA approved.
(4) Other nutrients for use in pet foods: (reserved)

§ 205.604 Nonsynthetic substances prohibited for use in organic livestock and pet food production.

The following nonsynthetic substances may not be used in organic livestock production: (a) Strychnine

(b)-(z) [Reserved]

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[13] Determinations of necessity of a nutrient in a specific pet food diet can be justified by the requirements as established under FDA regulations or by the Dog and Cat Food Nutrient Profiles, as referenced in the most current AAFCO Official Publication. See www.aafco.org for ordering information. The other OFPA criteria at 6518(m) would also apply (lack of organic alternatives, toxicity, environmental contamination, etc.)

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products, <u>including pet food,</u> labeled as "organic" or "made with organic (specified ingredients or food group(s))."

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products, <u>including pet food.</u> labeled as "organic."

Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as "organic," only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.

a) <u>Allowed for all processed products</u>

<u>(1)</u>Casings, from processed intestines…..
<u>(23)</u> Whey protein concentrate.

<u>b) Allowed for pet food only</u>

Appendix 2

	AAFCO Dog Food Nutrient Profiles			
		Growth	Adult	
	Units	Reproduct	Maintena	
	Basis	Minimu	Minimu	Maxim
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	
Phenlyalanine-	%	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 1000 M	Growth & Reproduct Minimum	Adu Maintenan Minimum	Maxim
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	
Phenlyalanine-	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			
	Units Basis	Growth & Reproduct Minimum	Adu Maintenan Minimum	Maxim
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	1.5
Phenlyalanine-	%	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 1000 M	Growth & Reproduct Minimum	Adu Maintenan Minimum	Maxim
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	

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Methionine-	g	2.75	2.75	
Methionine	g	1.55	1.55	3.7
Phenlyalanine-	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	g	0.50	0.50	

Appendix 3

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-(1*H*-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