March 18, 2013

National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2648-So, Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-12-0070
RE: Livestock Sub-Committee – Pet Food Amino Acids

Dear Friends:

These comments today are being filed on behalf of the Pet Food Institute, the major voice of pet product manufacturers in the United States.

The Pet Food Institute has been directly engaged with the deliberations surrounding the development of a regulatory framework for organic pet food since 2006, when the NOP established the Pet Food Task Force. That task force included representatives of pet food companies that have diligently worked to produce certified organic and "made with organic" products despite having to manufacture those products in accordance with the human food standards, and with ingredients intended for human food as limited by §205.605 of the National Organic Standards.

We are therefore pleased that the National Organic Program is in the process of rulemaking to establish specific pet food regulations pursuant to the National Organic Standard Board's unanimous adoption of the Pet Food Task Force report in November 2008.

In anticipation of those regulations, we filed a petition in January 2012 to allow required amino acids to be utilized as a category in pet food, similar to the manner in which vitamins and trace minerals are allowed for use as a category in §205.603(d), livestock feed additives. We are deeply concerned by the NOSB Livestock Committee's recommendation to limit the allowance of synthetic required amino acids to the use of taurine in cat food. This recommendation is based upon flawed reasoning in the TAP Report, and by a lack of recognition of the inability to source some pet food ingredients in organic form.

We accept that some of the required amino acids can be obtained by food ingredient sources. However, the committee's recommendation to limit the allowance of required amino acids to taurine for cats is far too limiting, and will eliminate the ability of responsible manufacturers to formulate certified organic products that meet the nutritional requirements of all life stages for both dogs and cats.

The TAP analysis cited examples of commercial pet food products that are labeled as complete and balanced without the use of synthetic amino acids. However, the companies cited do not

market any certified organic dry food formulations, and only a limited scope of wet or raw organic formulations. Additionally those products to not take into account the higher minimums for amino acids in the upcoming update to the AAFCO Dog Food Nutrient profiles.

The reason for this absence is that critical ingredients that allow for production of complete and balanced formulations are simply unavailable in certified organic form.

The challenge for pet food manufacturers stems in large part from the fact that it is not only important to include all of the required amino acids, but it is important to include them in the correct balance of proper nutrition after any degradation that occurs during heat processing. And, those nutrients must be in a form that is bioavailable to the pet.

The ability to properly balance the required amino acids in pet food formulations is critically important in producing any food that can be labeled as a *complete and balanced* diet for dogs and cats. Simply put, we have one or two chances each day to "get it right" when feeding our pets. The food we provide in their bowls is their sole source of nutrition.

We recognize that the NOSB Livestock Committee opposes the allowance of the required amino acids as a category. We therefore, convened a working group of nutritionists to identify those required amino acids that must be available in synthetic form to allow for certified organic pet food formulas.

At the least, we believe that the following must be allowed in synthetic form:

- Taurine (both dogs and cats)
- Methionine
- Lysine
- Threonine

To understand the basis for this determination, it is important to review the food sources of these amino acids, and then to consider whether those food sources can be included in a natural or organic form.

As cited in the TAP, there are natural sources for the four required amino acids. The following table lists those sources, and describes the issues involved in utilizing those sources in organic formulations:

Amino Acid	Natural Sources (as listed in the TAP Report 8/12)	Issues in Organic Formulation
Taurine	Taurine is completely absent in cereal grains and is found in high quantities in meat proteins such as seafood (highest), poultry, and beef (Spitze et al., 2003).	It is present only in tissues of animal origin. Additionally processing has been shown to have an adverse effect on taurine availability. Most commercial cat foods cannot reach these required minimum levels without taurine supplementation. Because the highest levels are found in rendered animal meals (which are not currently certified organic) and dry food are very limited

		as to how much fresh meat they can contain (up to approximately 25%), the use of synthetic taurine is required in order to produce organic pet foods that are complete and balanced.
Methionine	Methionine is found in eggs, fish meal (tuna, white, and menhaden), milk, poultry byproduct meal, corn gluten meal, what germ, and yeast (NRC, 2006).	Good sources of methionine in commercial pet foods include fish meals (not available in organic form) and both corn gluten meal and dried eggs, both of which are available as organic ingredients. Unfortunately, the use of high levels of dried egg in dry commercial pet foods is limited by its high fat content. The use of high levels of corn gluten meal in commercial pet foods is limited by its relatively unbalanced amino acids profile with extremely low levels of both lysine and tryptophan. Additionally synthetic methionine is an excellent urinary acidifier making it a useful ingredient for use in organic dry cat foods when trying to reduce the risk of FLUTD.
Lysine	Pet food dietary sources of lysine include beef (including the meat, broth, kidney, heart, liver, and tripe), chicken (including the meat, broth, gizzard, and liver), eggs, fish meal (tuna, white, and menhaden), lamb (including ground, meat, and liver), poultry byproduct meal, shrimp, turkey, milk, whey, beet pulp, yellow corn grain, gluten meal, oats, and rice bran (NRC, 2006).	While lysine is rich in many pet foods containing high levels of meat, poultry or fish (wet foods) or rendered meat, poultry or fish meals (dry foods) most plant based ingredients are poor sources of lysine. Since animal meals are not currently certified organic and dry pet foods can contain only limited amounts of fresh meat, lysine rich ingredients for dry foods are extremely limited. Soybean meal and other soy products are excellent sources of lysine, but their use is limited in pet food due to their detrimental effect on stool quality in dogs and their adverse effect on urine pH in cats. Cat foods containing high amounts of soy products produce a relatively high urine pH predisposing the cat to urinary tract problems or FLUTD (Feline Lower Urinary Tract Disease). Ingredients such as broth, beet pulp, gluten meals, and rice bran are poor sources of lysine.
Threonine	Threonine is found in pork bacon, beef (including the meat, broth, kidney, heart, liver, and tripe), chicken (including the meat, broth, gizzard, and liver), eggs, fish meal (tuna, white, and menhaden), lamb (including ground, meat, and liver), poultry byproduct meal, shrimp, turkey, milk, whey. Grain barley, dried gluten feed, gluten meal, beet sugar, oats, rice bran, soybean flour, and wheat (Germ, germ meal, and middlings) (NRC, 2006).	Pending changes in the recommended minimum levels under AAFCO will increase the amount of threonine required to be included in complete and balanced pet foods.

There are other key issues that underscore the need for these amino acids for both dogs and cats.

1. **A growing body of literature is documenting the need for taurine in the diets of certain breeds of dogs.**

Scientific and clinical evidence supports the hypothesis that dilated cardiomyopathy (DCM) is associated with low blood taurine concentration in dogs. That taurine deficiency in dogs is being linked to the consumption of certain dietary ingredients. (Delaney, 2003). Supplementation with taurine can improve taurine status (A. J. Fascetti, unpublished data), but care must be taken that the added taurine is in sufficient quantities to overcome the increased microbial degradation associated with heat processing and the formation of Maillard reaction products (Kim et al., 1996; Backus et al., 1998).

Consequently, while the NRC lists taurine as an essential dietary nutrient for cats, but dispensable for dogs, additional reading of that section notes, "Dietary taurine is essential for the fox, and there are breed differences in dogs susceptibility to DCM and probably also to taurine deficiency."

As noted in the TAP report, a study of Newfoundland dogs found a high incidence of low plasma taurine in the population. Additional studies have identified the dangers of taurine deficiency in other large breed dogs.

Dilated cardiomyopathy is one of the most prevalent acquired heart diseases of dogs, only surpassed by degenerative valve disease and, in some parts of the world, heartworm disease as a major cardiovascular cause of morbidity and mortality. It most commonly affects large-breed dogs and far less commonly small-breed dogs (with a few exceptions such as American Cocker Spaniels, Springer Spaniels, and English Cocker Spaniels). Doberman Pinschers, Boxers, Great Danes, German Shepherds, Irish Wolfhounds, Scottish Deerhounds, Newfoundlands, Saint Bernards, and Labrador Retrievers, among other large-breed dogs, are particularly at risk. The disease is typically seen in middle-aged dogs; males are affected more than females.

Further, the prohibition of any other synthetic required amino acid will present similar difficulties, and will prohibit manufacturers from supplying their customers with a full selection of organic food to meet the dietary needs of their dogs and cats.

2. **The amino acids must be in sufficient quantity after processing, and must be bioavailable to the pets**

Fresh meat and poultry contain sulfur amino acids, but not at the levels of the meat and poultry meals that cannot be sourced in a certified organic form. Vegetable protein sources vary in their sulfur amino acid content and bioavaibility. This can impact the bioavailability of the sulfur amino acids in the overall diet.

The production of commercial pet foods generally involves a series of heat treatments including sterilization, extrusion, cooking, and baking. Heat processing has been shown to have a negative impact on the nutritional value of the amino acids in animal feeds.

This has been particularly well documented for lysine. Thermal processing of high-protein materials generally reduces lysine availability, with the total effect depending on the temperature levels and the time of exposure to the heat. Although extrusion enhances the nutritional value of cereal grains, it is likely to reduce the lysine availability. In foods that are heat processed or stored for long periods of time, the free e-amino group of lysine can react with the carbonyl group of other compounds such as reducing sugars. The complex that is formed Maillard complex) may be partially absorbed but cannot be utilized by the animal. (Williams, et. al (2006)

3. The requirements in the NRC, not AAFCO, should be used as the basis for evaluating the nutrient requirements in pet food.

The TAP Report mentions the AAFCO Nutrient Profiles as the basis for manufacture and labeling of complete and balanced formulations. While this is technically correct, our petition referenced the National Research Council's 2006 edition of *Nutrient Requirements of Dogs and Cats.*

As noted in the June 27 memorandum to the National Organic Program from the FDA Center for Veterinary Medicine the NRC tables are considered the reference source for the model regulations that are enforced throughout the country in regard to complete and balanced formulas. It's important to note that the NRC contains six distinct tables listing separate nutrient requirements for:

- Growth of Puppies after Weaning (Table 15-3);
- Adult Dogs for Maintenance (Table 15-5);
- Bitches for Late Gestation and Peak Lactation (Table 15-8);
- Kittens after Weaning (Table 15-10);
- Adult Cats for Maintenance (Table 15-12); and
- Queens in Late Gestation and Early Lactation (15-14).

In other words, AAFCO endeavors to establish its nutrient requirements to conform to the requirements documented by the NRC.

Earlier this year, the Canine and Feline Nutrition Expert Subcommittees proposed new AAFCO nutrient requirements for dog and cat foods based on the 2005 NRC for dogs and cats. While there were no significant changes to the amino acids minimums for cats, the values for dogs for all life stages changed significantly as shown below

Amino Acid(s)	Current AAFCO minimum	Proposed AAFCO minimum	Change (%)
Lysine	0.77%	0.90%	17%
Methionine-Cystine	0.53%	0.70%	32%
Threonine	0.58%	1.04%	79%

These changes further increase the need to have the option of using synthetic methionine and lysine for organic pet foods. Additionally while synthetic threonine is currently rarely used in commercial pet foods the 79% increase in the AAFCO minimum for dogs means most current dry dogs foods on the market today would not meet the proposed 2014 minimum for threonine without the use of additional synthetic threonine. As such we would request that threonine be added to the list of synthetic amino acids available for use in organic pet foods.

4. Raw diets are not a viable alternative

The TAP report cites raw food diet as an alternative practice to supply the required amino acids without synthetic ingredients. Again, the brand cited by the reviewers does not offer any products certified under the USDA organic standards. More important, the reviewers acknowledge potential health risks involved in raw food diets, saying,

> "Concerns with feeding pets a raw food diet include the risk of contamination from Salmonella, E. coli and other pathogenic bacteria, dietary imbalances and internal injuries from sharp bones. Some dogs have reportedly died from bacterial poisoning."

Any alternative that includes these types of dangers cannot be considered a viable option. The American Veterinary Medical Association just released a position statement strongly opposed to the feeding of raw diets due to these contamination concerns.

Formulators in the pet food business subscribe to three ethical tenets:
1. Know the nutrient requirements of the animal in terms of AVAILABLE nutrients
2. Know the composition of the ingredients used to formulate the diet
3. Know the bioavailability of the nutrients in the dietary ingredients

Small manufactures—in particular—rely heavily on the empirical data regarding the level of required nutrients in the ingredients they utilize in their formulations. The inability to use targeted supplementation will likely lead to marketing of diets, which promote nutrient deficiencies, suffering and animal death.

To date, nearly all organic products in the marketplace have been manufactured under the "made with" category. The companies offering products that are certified organic have only been able to meet the complete and balanced threshold in a very limited range without using synthetic amino acids.

Specifically, developing complete and balanced formulas that will meet the dietary requirements of all life stages of both dogs and cats (including different breeds and sizes) will require manufacturers to have access to synthetic sources of at least the amino acids mentioned above.

The opportunity to expand the availability of certified organic pet food in the marketplace not only holds strong benefits for pets and consumers, but for agricultural producers as well. The growth of the organic livestock sector has been stymied in large part because producers face significant

challenges in capturing the organic value for the whole animal. Selling organic tenderloins strip steaks and burgers alone will not return the income required to cover the additional costs of production inherent with small scale, pasture based organic livestock production. Capturing value for items such as hearts, liver, B trim and other items help increase the economic viability of the organic livestock sector.

In summary, the member companies involved with the PFI's Organic Pet Food Working group all have a strong commitment to providing their customers seeking that option with a nutritious, wholesome line of certified organic products. Those companies have diligently worked to develop organic offerings compliant with the USDA organic standards, even as they are forced to produce those products under the human food standards. The emerging pet food regulations will be a help. But that help may be minimal unless manufacturers have access to the required nutrients that will allow them to produce a full line of complete and balanced products.

Sincerely,

Dave Carter
On Behalf of the Pet Food Institute

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