FORMAL RECOMMENDATION BY THE NATIONAL ORGANIC STANDARDS BOARD (NOSB) TO THE NATIONAL ORGANIC PROGRAM (NOP)

TO THE NATIONAL ORGANIC PROGRAM (NOP)
Date: November 19, 2008
Subject: _Organic Pet Food Standards Recommendation
Chair:Rigoberto Delgado
Recommendation
The NOSB hereby recommends to the NOP the following: Rulemaking Action: Guidance Statement: Other:
Summary Statement of the Recommendation (including Recount of Vote): This recommendation proposes changes in the organic regulations to support labeling of organic pet food. It provides clarity where any conflicts may exist between organic labeling claims and the existing state requirements for pet food labeling. And it proposes remedies that have been developed in collaboration with state officials. The intent of this proposed regulation is to create a pet food label that is consistent with labeling for human food. We recognize that these requirements will present challenges for pet food manufacturers, especially sourcing non-genetically engineered ingredients in the non-organic fraction of the products.
NOSB Vote: Yes Motion: Joseph Smillie Second: Hubert Karreman Board vote: Yes - 13 No- 0 Abstain- 1 Absent - 2
Summary Rationale Supporting Recommendation (including consistency with OFPA and NOP): This recommendation sets forth that pet food regulations are a better fit under the livestock section of the organic rules. Pet food is currently regulated by states as a subset of livestock regulations. Ingredients and additives permitted in pet food are regulated similarly to livestock feed. We have recommended that the product composition requirements for organic pet food be similar to those for livestock, but that labeling categories be the same as for processed human food. Further, this recommendation proposes that eligible label claims for organic pet food match the requirements for human food: i.e. a minimum of 70% organic ingredients for a "made with organic" claim, and at least 95% organic content for an "organic" claim. See pages 5-10 for recommended regulatory changes and citations. Response by the NOP:

National Organic Standards Board Handing Committee Organic Pet Food Recommendation

November 19, 2008

Executive Summary

The National Organic Standards Board recommended in October 2004 that a Task Force be formed to develop labeling standards for organic pet food. A Federal Register notice was posted on January 24, 2005 to solicit nominations, and the Pet Food Task Force was selected by NOP in May 2005. The Task Force included individuals experienced in organic and conventional pet food manufacture, consultants with organic expertise, as well as state and federal regulatory authorities (please see *Acknowledgements* at the end of this document for a complete list of Task Force members). The NOP has acknowledged in the Federal Register notice that pet food is "unregulated" by NOP regulations, but that further consultation with the pet food industry and NOSB was needed to craft specific regulations for organic pet food. The NOSB noted that the existing organic livestock regulations may not be suitable for pet food application, as they restrict the use of mammalian products fed to mammals, and do not allow a "Made with Organic" label claim. The existing human food processing standards do not allow for use of natural feed additives and processing aids that are allowed in livestock feed.

In establishing the regulatory objectives for the Pet Food Task Force, the NOSB specifically asked the Task Force to:

- Determine which aspects of the existing regulation pertain to pet foods;
- If needed, draft amendments to the regulation for consideration by the full board; and
- Identify substances used by pet food manufacturers to be petitioned for possible addition to the National List. ¹

The organic Pet Food Task Force (PFTF) decided that the primary tasks should be undertaken in two phases:

- 1) Propose changes in the organic regulations to support labeling of organic pet food, and
- 2) Evaluate where any conflicts may exist between organic labeling claims and the existing state requirements for pet food labeling, and propose remedies in collaboration with state officials.

The PFTF completed a draft proposal for organic regulation changes for public and NOSB consideration in April 2006. During the more than 2 years since this work was completed, the PFTF has collaborated with the Handling Committee of the NOSB to refine this Organic Pet Food Recommendation. Organic pet food manufacturers will have to comply with both the NOP regulations and existing state pet food regulations. This recommendation seeks to reconcile any conflicts between the two sets of regulations and propose guidance for the AAFCO officials in interpreting organic claims.

Highlights of the Proposed Rule Changes

This recommendation sets forth that pet food regulations are a better fit under the livestock section of the organic rules. Pet food is currently regulated by states as a subset of livestock regulations. Ingredients and additives permitted in pet food are regulated similarly to livestock feed. We have recommended that the product composition requirements for organic pet food be similar to those for livestock, but that labeling categories be the same as for processed human food. Further, this recommendation proposes that eligible label claims for organic pet food match the requirements for human food: i.e. a minimum of 70% organic ingredients for a "made with organic" claim, and at least 95% organic content for an "organic" claim.

¹ Recommendation on "National Organic Program Scope", adopted by NOSB, as revised Oct.13, 2004

<u>Definitions:</u> This recommendation proposes a number of new definitions that are based on existing AAFCO definitions for pets, and specialty pets. It is important to know that the definitions of "pets" and "specialty pets" do not include horses, llamas, alpacas, rabbits, or wild birds. Feed for such animals must meet the NOP livestock feed standard in order to carry an organic claim. Please also note that, for the purposes of this regulation unless specifically noted, the term "pet food" will include both pet and specialty pet food. We do not intend that pets include large cats such as tigers and lions or other zoo animals.

We have also proposed some definitions for slaughter products and various types of meat feed ingredients. This will aid in further discussions about suitability of slaughter products and by-products in pet food.

Slaughter products: We have clarified that prohibition for feeding mammalian and poultry slaughter by-products to animals applies only to livestock, but not to pets. We would like to solicit further comments on the proposed changes to 205.237. (This is particularly important because cats are obligate carnivores (do not produce taurine or arachidonic acid in their bodies) and dogs are preferential carnivores, but can be omnivores.)

These proposed changes allow non-organic meat, meat products, poultry and poultry products in the non-organic fraction of an "organic" (95%) or "made with organic" (70%) product. This will address the pet food manufacturers' concern that lack of organic animal protein sources would limit their ability to formulate products.

We did include a requirement that organic and non-organic sources for the same ingredient cannot be included in the same product. This will prevent a product with organic meat or poultry from also including the same type of non-organic meat or poultry. Identification of specific types of meat or poultry ingredients should be based on standardized AAFCO feed ingredient definitions.

Description of product composition requirements:

- Products labeled "100% Organic" must have 100% organic ingredients and additives, including processing aids.
- Products labeled "Organic" must have 95% organic agricultural ingredients, and the remainder may be nonsynthetic substances or synthetic substances on the National List at 205.603 (substances allowed for livestock) or 205.605 (nonsynthetic or synthetic substances approved for food use, provided they are also FDA approved for livestock).
- Products labeled "Made with organic" must have 70% organic agricultural ingredients, and the remainder may be non-organic agricultural ingredients, nonsynthetic substances or synthetic substances on the National List at 205.603 or 205.605.
- All products labeled as "Organic" or "Made with Organic Ingredients" can **not** include ingredients that are genetically engineered (produced using "excluded methods"), be produced using sludge or irradiation, synthetic substances not on the National List, contain sulfites, nitrates or nitrites, or include organic and non-organic forms of the same ingredients.
- Products labeled "organic" cannot contain non-organic ingredients when organic sources are available.

The intent of this proposed regulation is to create a pet food label that is consistent with labeling for human food. We recognize that these requirements will present challenges for pet food manufacturers, especially sourcing nongenetically engineered ingredients in the non-organic fraction of the products.

We have also provided an appendix with a list of substances that manufacturers believe may need inclusion on the National List specifically for pet or specialty pet food, subject to the existing petition process for adding substances.

Additional comments are provided in footnotes to the proposed regulatory changes.

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

Suggested additions to 7 CFR Part 205 are included in <u>underline format</u>. 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, <u>pet</u>, <u>specialty pet</u> 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."

<u>Meat</u> (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

<u>Pet food</u> - 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."

<u>Poultry</u> (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. 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.

<u>Slaughter by-products</u> 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.

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 <u>f</u>) 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 <u>h</u>) 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

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 <u>livestock</u> 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 poultry⁹; 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

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. <u>Products sold, labeled, or represented as "100 percent organic."</u> 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. 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.

should be made in concert with change to the requirements for human food.

Recommendation for Rule Change Concerning Made with Organic Ingredients", March 18, 2005. This pet food requirement

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"

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 <u>livestock</u> 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)

(de) 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]

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, including pet food, 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, including pet food, 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) Allowed for all processed products
- (1) Casings, from processed intestines.....
- (23) Whey protein concentrate.
- b) Allowed for pet food only

Committee Recommendation:

The Handling Committee recommends the acceptance of this document and the rule changes described in it as the initial plan to implement the regulation of Organic Pet Food into National Organic Program.

Moved: Tracy Miedema Second: Katrina Heinze

Yes - 5 No - 0 Absent - 1 Abstain - 0

Appendix

Materials for possible petition to the National List for use in Pet Food

205.603(d) Feed additives

1-arginine - for pet food (amino acid)

d-l Methionine for pet food (amino acid)

Carnitine for pet food (amino acid)

1-cysteine for pet food (amino acid)

1-lysine, 1-lysine monochloride for pet food (amino acids)

Taurine for pet food (amino acid)

l-tryptophan for pet food (amino acid)

Phosphoric acid – used as acidifier for pet food, and for metabolic purposes for cats (already approved as mineral source)

Tocopherols – for pet food (Vitamin E) derived from vegetable sources

205.604 Non-synthetic substances – prohibited for use in organic livestock and pet food production.

Propionic acid – prohibited except as preservative in pet food (and possibly livestock feed)

Sorbic acid – prohibited except as preservative in pet food (and possibly livestock feed)

205.605(b)

Magnesium stearate – add pet food to the annotation - for use only in pet foods labeled "made with organic (specified ingredients or food group(s))," prohibited in pet foods labeled "organic,"

Acknowledgement

The Handling Committee of the National Organic Standards Board would like to acknowledge the excellent Initial Report of National Organic Program Organic Pet Food Task Force.

Members of the Organic Pet Food Task Force

Nancy K. Cook: TF Chair

Emily Brown Rosen: TF Secretary

Brian Connolly

E. Rod Crossley

Rochelle A. Lavens

Robert S. Lepp

Lois Luthy

Gerald G. May

Edward Moser, DVM

Dr. Rodney J. Noel, for

Sharon Sherman

Anthony Zolezzi