Interim Report of the

National Organic Program

ORGANIC PET FOOD TASK FORCE

April 7, 2006

Recommendations for Regulatory Change 7 CFR Part 205

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Executive Summary

Background

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 includes individuals experienced in organic and conventional pet food manufacture, consultants with organic expertise, as well as state and federal regulatory authorities. 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.

At the present time, the PFTF has completed a draft proposal for organic regulation changes for public and NOSB consideration. The PFTF will continue to work further on evaluating any conflicts with state requirements, as embodied in the Association of American Feed Control Officials (AAFCO) model Pet and Specialty Pet Food regulations. Organic pet food manufacturers will have to comply with both the NOP regulations and existing state pet food regulations, so the goal will be to reconcile any conflicts and propose guidance for the AAFCO officials in interpreting organic claims.

Highlights of the Proposed Rule Changes

In general, the PFTF finds 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. There was strong agreement by the PFTF that the 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>: We have proposed 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 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.

<u>Slaughter products</u>: 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.

These proposed changes allow non-organic meat and meat 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 from also including the same type of non-organic meat. Identification of specific types of meat ingredients should be based on standardized AAFCO feed ingredient definitions. It would be possible to have organic beef and non-organic chicken in the same product, or organic chicken and non-organic chicken meal in the same "made with organic" product, so long as both are correctly identified in the product's ingredient statement.

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 non-genetically 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.

Proposed Changes in 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, 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 <u>pets or specialty pets.</u> aquatic animals or bees for the production of food, fiber, feed, or other agricultural based consumer products."³

<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.

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.

<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.⁵

<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, milk or milk products. ⁶

<u>Specialty pet</u>- 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.

<u>Specialty Pet food</u>: 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,

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.

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.

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, <u>pet food</u> 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, <u>Provided</u>, 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; g
- (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 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;

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).

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.

- (3) Feed plastic pellets for roughage;
- (4) Feed formulas containing urea or manure;
- (5) Feed mammalian or poultry slaughter by-products to mammals or poultry; or
- (6) Use feed, feed additives, and feed supplements in violation of the Federal Food, Drug, and Cosmetic Act.
- (c) Pet food must be composed of agricultural products that are organically produced and, if applicable, organically handled: Except that, nonsynthetic substances, and synthetic substances allowed under §205.603, and 205.605 provided they are allowed by FDA in animal feed, may be used as feed additives and supplements.

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.⁹

§ 205.301 Product Composition

- (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.

⁹ 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).

(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. Any remaining product ingredients or processing aids must be organically produced, unless not commercially available in organic form, or must be nonsynthetic substances or synthetic substances 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))." Multiingredient 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 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 § 205.304.¹¹
- 4. Products with less than 70 percent organically produced ingredients. The organic ingredients in multiingredient 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. Multiingredient agricultural products containing less than 70 percent organically produced ingredients may represent the organic nature of the product only as provided in § 205.305.

 $^{^{10}}$ Product labeled "organic" may contain multiple organic agricultural ingredients.

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.

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. ¹²

§205.603 Synthetic substances allowed for use in organic livestock <u>and pet food</u> 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.

- (c) 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)

$(\mathbf{d} \mathbf{e})$ 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 <u>and pet food</u> production.

The following nonsynthetic substances may not be used in organic livestock production:

- (a) Strychnine
- (b)-(z) [Reserved]

¹² 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.)

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)

1-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 <u>and pet food production</u>. 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,"

Potassium iodide – 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."