National Organic Program Scope

Prepared by the Policy Development Committee for consideration by the NOSB
Approved by PDC - September 28, 2004
Revised October 13, 2004
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Background

On April 13, 2004 the U.S. Department of Agriculture issued a Directive defining the Scope of Enforcement for the certification for nontraditional products. As explained in that directive:

- The Organic Foods Production Act (OFPA) provides coverage for crops, livestock, and the products derived from them;
- OFPA does not extend to products over which USDA has no regulatory authority (see below for such products as personal care, health care products, fertilizers and their related products); and
- While OFPA provides coverage for products that are defined as agricultural by the
 Act, no standards have yet been developed for aquatic animals or for pet foods. Other
 agricultural products which are covered may need additional standards for their
 unique production and handling requirements (see below for mushroom, apiculture,
 greenhouse, and hydroponic operations).

This scope directive was among the documents covered by Agriculture Secretary Ann Veneman's May 26, 2004 announcement that she was directing the National Organic Program (NOP) to rescind the directive, and to work with the National Organic Standards Board (NOSB) and the organic industry in the development of new documents.

Accordingly, the Policy Development Committee of the National Organic Standards Board provides the following review and recommendations for the processes to be followed in addressing the specific areas identified in the April 13 Scope Document. Specifically, those issues are:

- Personal care products, body care products, cosmetics, and other related products.
- Dietary supplements, over-the-counter (OTC) medicines or health aids, and other related products.
- Fertilizers, soil amendments, manure, and related products.
- Fish and seafood, farm-raised or wild-caught.
- Pet Food.
- Mushrooms, apiculture and honey, greenhouse operations and greenhouse products, and hydroponic agriculture.

Applicable Regulatory Language

Organic Foods Production Act

6501 Purposes:

It is the purpose of this chapter to establish national standards governing the marketing of certain agricultural products as organically produced products.

6502 Definitions:

<u>Agricultural Product.</u> The term "agricultural product" means 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 or livestock consumption.

<u>Livestock.</u> The term "livestock" means any cattle, sheep, goats, swine, poultry, equine animals used for food or in the production of food, fish used for food, wild or domesticated game, or other nonplant life.

National Organic Program Final Rule Preamble

Page 80556 (2) Additional NOP standards for specific production categories. Many commenters asked that the NOP include in the final rule certification standards for apiculture, greenhouses, mushrooms, aquatic species, culinary herbs, pet food, and minor animal species (e.g., rabbits) food. The NOP intends to provide standards for categories where the Act provides the authority to promulgate standards. During the 18-month implementation period, the NOP intends to publish for comment certification standards for apiculture, mushrooms, greenhouses and aquatic animals. These standards will build upon the existing final rule and will address *only the unique requirements necessary to certify these specialized operations* [emphasis added].

We have not addressed the labeling of pet food within this final rule because of the extensive consultation that will be required between USDA, the NOSB, and the pet food industry *before any standards on this category could be considered* [emphasis added].

Page 80557 (3) Standards for Cosmetics, Body Care Products, and Dietary Supplements. A few commenters asked that the NOP include in the final rule certification standards for cosmetics, body care products, and dietary supplements. Producers and handlers of agricultural products used as ingredients in cosmetics, body care products, and dietary supplements could be certified under these regulations. Producers and handlers of these ingredients might find an increased market value for their products because of the additional assurance afforded by certification. The ultimate labeling of cosmetics, body care products, and dietary supplements, however, is outside the scope of these regulations.

Page 80557 (6) Nonedible Fibers Products in the NOP. Some commenters asked the NOP to clarify the certification status of fibers such as cotton and flax. The final rule

allows for certification of organically produced fibers such as cotton and flax. However, the processing of these fibers is not covered by the final rule. Therefore, goods that utilize organic fibers in their manufacture may only be labeled as a "made with ***" product; e.g., a cotton shirt labeled "made with organic cotton."

National Organic Program Final Rule

205.2 Terms Defined.

<u>Agricultural product</u> – 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 or livestock consumption.

<u>Certified operation</u> – A crop or livestock production, wild crop harvesting or handling operations, or portion of such operation that is certified by an accredited certifying agent as utilizing a system of organic production or handling as described by the Act and the regulations in this part.

<u>Livestock</u> – 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 aquatic animals or bees for the production of food, fiber, feed, or other agricultural-based consumer products. (Please note the difference between this definition and the definition of "livestock" in OFPA.)

NOSB Analysis, Review, and Proposed Actions

The NOSB and industry organizations have initiated steps to address each of the items identified in the Scope Directive. Those steps are listed as follows:

- 1. Personal care products, body care products, cosmetics, and other related products; and
- 2. Dietary supplements, over-the-counter (OTC) medicines or health aids, and other related products.

From the April Directive

The April directive notes that these categories are under the labeling and regulatory jurisdiction of the Food and Drug Administration (FDA) and may also be affected by applicable State laws.

The products listed above may not display the USDA organic seal and may not imply that they are produced or handled to the USDA NOP standards. Consumers should be aware that the use of labeling terms such as "100% organic," "organic," or "made with organic ingredients" on these products may be truthful statements. But these

statements do not imply that the product was produced in accordance with the USDA NOP standards nor that the producer is certified under the NOP standards.

Operations producing the products listed above that use labeling or other market information that implies or states that the products are in compliance with the USDA NOP standards, or products that carry the USDA seal, have until October 21, 2005, to use existing supplies of labels and packaging. Failure to comply with this requirement may result in an enforcement action.

Organic Trade Association

In the September 2004 edition of *The Organic Report*, the Organic Trade Association stated,

"OTA recognizes the limitations of the enabling legislation, and that the primary authority for non-food agricultural products may rest with other agencies. Applying standards developed for crops, livestock, and food products to such other products will no doubt be a complex task. Nonetheless, the clear authority of the Organic Foods Production Act and NOP over organic produced agricultural products should be the overarching factor to use in determining the scope of NOP. NOP should apply its authority to the maximum extent possible and provide any other agencies that might have some authority over final products with a definition of organic production and rules for the use of organic ingredients.

The absence of specific standards for such products should not become a reason for allowing the organic claim to be made for such products <u>if they do not meet the standard</u>. Until standards are developed, USDA should not allow the organic claim to be made regarding these products if they do not meet the standard."

NOSB Consideration

Many individuals have provided public testimony at NOSB meetings expressing a desire for consistency in the organic labeling of cosmetics, body care products, and dietary supplements. Also, many manufactures have indicated the benefit of USDA organic certification for domestic and international trade.

The agencies that are responsible for the labeling of cosmetics, body care products, and dietary supplements may regulate the term "organic" on such products. If the word "organic" is used to identify an agricultural product or ingredient, then the agricultural product or ingredient must have been produced and handled in accordance with the Act and regulation.

If the words "organic" or "Made with Organic" are used on the principle display panel, such usage shall comply with the product content requirements of \$205.300, \$205.301, \$205.308, and \$205.309 of the Final Rule.

In order to understand the depth of interest in certification and regulation of these product categories, the NOSB encourages the Organic Trade Association, consumer groups, affected industries, and other stakeholders to solicit information concerning the certification, regulation, and labeling of "organic" personal care, cosmetic, and dietary supplements.

Specifically, the NOSB recommends that the following general questions be addressed:

- 1. Should legislation be adopted and rules written to regulate the labeling of "organic" personal care, cosmetic, and dietary supplement?
- 2. Should legislation be adopted to prohibit the use of the word "organic" on products not covered by the Organic Foods Production Act of 1990, including personal care, cosmetic, and dietary supplements?

In addition, the NOSB recommends that the following specific questions be asked:

Do you presently manufacture organic -

- A. Personal care products?
- B. Cosmetics?
- C. Dietary supplements?

Personal Care Products or Cosmetics

Do you manufacture personal care products or cosmetics that would benefit from certified organic labeling? If yes, what benefits are realized from certified organic labeling of personal care products or cosmetics?

What are the consequences of not standardizing the organic labeling of personal care products or cosmetics?

Could the regulation of "organic" labeling of personal care products and cosmetics provide an adverse effect on the industry? If yes, please describe.

What economic and administrative burdens are imposed by the regulation of "organic" labeling of personal care products and cosmetics?

How would producers of organic agricultural ingredients benefit from market incentives realized by the regulation of "organic" labeling of personal care products and cosmetics?

Would lack of regulation of personal care products and cosmetics provide a disincentive for handlers of personal care products and cosmetics labeled as "organic" to seek agricultural ingredients certified to the USDA regulation? What impact could this have on producers of agricultural ingredients?

Dietary Supplements

Do you manufacture dietary supplements that would benefit from certified organic labeling? What benefits are realized from certified organic labeling of dietary supplements?

What are the consequences of not regulating the organic labeling of dietary supplements?

Could the regulation of "organic" labeling of dietary supplements provide an adverse effect on the industry? If yes, please describe.

What economic and administrative burdens are imposed by the regulation of "organic" labeling of dietary supplements?

How would producers of organic agricultural ingredients benefit from market incentives realized by the regulation of "organic" labeling of dietary supplements?

Would lack of regulation of dietary supplements provide a disincentive for handlers of dietary supplements labeled as "organic" to seek agricultural ingredients certified organic to the USDA regulation? What impact could this have on producers of organic agricultural ingredients?

3. Fertilizers, soil amendments, manure, and related products.

From the April Directive

Fertilizers and soil amendments are regulated by applicable State laws. Although there are no NOP standards for labeling these products as organic, there are explicit NOP standards regarding their use by certified organic operations.

The products listed above may not display the USDA organic seal and may not imply that they are produced or handled to the USDA NOP standards. Consumers should be aware that the use of labeling terms such as "100% organic," "organic," or "made with organic ingredients" on these products may be truthful statements. But these statements do not imply that the product was produced in accordance with the USDA NOP standards nor that the producer is certified under the NOP standards.

Operations producing the products listed above that use labeling or other market information that implies or states that the products are in compliance with the USDA NOP standards, or products that carry the USDA seal, have until October 21, 2005, to use existing supplies of labels and packaging. Failure to comply with this requirement may result in an enforcement action.

AAPFCO Consideration

The Association of American Plant Food Control Officers maintains a vital role in developing the regulations governing the labeling and use of fertilizers, soil amendments, manure, and related products.

In its meeting of August 3, 2004, AAPFCO considered the following amendment to its Model Regulation:

"T-63 "For organic production" - a term that may be used to describe fertilizer or soil amendments whose ingredients comply with the requirements of the USDA National Organic Program (NOP) as specified in 7 CFR Part 205.

SUIP-28 Products intended for use in organic production may use the label claim according to T-63, provided sufficient information is provided to demonstrate compliance. Evidence of compliance may be verified by agencies such as USDA accredited certification agencies, State Organic Programs, or independent materials compliance verification operations, and may bear the logos of these agencies. This term may be used alone, or in conjunction with the established terms T-12 (organic), T-13 (natural organic), or T-39 (organic base fertilizer) provided all requirements are met for all terms. A label may include specific reference to the applicable section(s) of 7 CFR Part 205."

The amendment has been referred to the AAPFCO labeling committee for further consideration.

NOSB Consideration and Recommendation

The Policy Development Committee recommends the NOSB acknowledge that the labeling of fertilizers, soil amendments, manures, and related products is regulated by State authorities. The PDC further recommends that the NOSB endorse the draft AAPFCO labeling definition of "for organic production" presented above.

4. Fish and seafood, farm-raised or wild-caught

From the April Directive

Although OFPA provided coverage for organic aquatic animal standards, NOP has not developed any standards for proposal to the public for comment.

The products listed above may not display the USDA organic seal and may not imply that they are produced or handled to the USDA NOP standards. Consumers should be aware that the use of labeling terms such as "100% organic," "organic," or "made with organic ingredients" on these products may be truthful statements. But these statements do not imply that the product was produced in accordance with the USDA NOP standards nor that the producer is certified under the NOP standards.

Operations producing the products listed above that use labeling or other market information that implies or states that the products are in compliance with the USDA NOP standards, or products that carry the USDA seal, have until October 21, 2005, to use existing supplies of labels and packaging. Failure to comply with this requirement may result in an enforcement action.

NOSB Consideration

The Livestock Committee of the National Organic Standards Board recommends the establishment of a new task force on standards for wild-caught and farmed aquatic animals. The task force would be structured similar to the earlier Task Force on Aquatic Animals, with two working groups -- one on wild caught and one on farmed species. These working groups will develop recommendations for consideration by the full task force, which will in turn issue recommendations to the NOSB.

The new task force will be directed to take into consideration the report issued by the previous aquatic animal task force and the subsequent NOSB recommendation.

Task force participants will be drawn from the NOSB and elsewhere. Non-NOSB participants should include fishermen, fish farmers, feed experts, marine conservationists, consumer representatives, academics, and certifiers.

The recommendation to form a task force will brought forward for consideration by the full board at the October 2004 meeting.

5. Pet foods

From the April Directive

Although OFPA provided coverage for organic pet food standards, NOP has not developed any standards for proposal to the public for comment.

The products listed above may not display the USDA organic seal and may not imply that they are produced or handled to the USDA NOP standards. Consumers should be aware that the use of labeling terms such as "100% organic," "organic," or "made with organic ingredients" on these products may be truthful statements. But these statements do not imply that the product was produced in accordance with the USDA NOP standards nor that the producer is certified under the NOP standards.

Operations producing the products listed above that use labeling or other market information that implies or states that the products are in compliance with the USDA NOP standards, or products that carry the USDA seal, have until October 21, 2005, to use existing supplies of labels and packaging. Failure to comply with this requirement may result in an enforcement action.

Discussion

Pet food in the US is currently regulated by State laws and regulations, which are guided by the national Association of American Feed Control Officials. This body defines permitted feed ingredients in consultation with FDA, which has federal authority over ingredients and additives permitted in feed, including pet food. AAFCO has established model regulations for the labeling and content of pet foods.

There have been suggestions that the NOP livestock feed regulations be applied to pet foods. The NOP organic livestock feed regulations do not contain a provision for "made with organic" ingredients labeling claims, and do not permit certain amino acids commonly used in pet foods. Organic livestock feed regulations also prohibit mammalian or poultry products fed to mammals.

Pet food could be alternatively certified and labeled under NOP requirements for human food products, but this would limit use of additives and processing aids to natural substances approved for human food (205.605(a)) and synthetics currently listed at 205.605(b).

NOSB Consideration and Recommendation

In order to understand the depth of interest in certification and regulation of pet food products, the Policy Development Committee recommends that the NOSB solicit comments and information on a number of issues concerning the certification, and labeling of "organic" pet food.

Specifically, the NOSB should request comments and information addressing the following questions:

- 1. Should standards be written and rule change action be taken to regulate the labeling of "organic" pet food?
- 2. Should legislation be adopted to prohibit the use of the word "organic" on products not certified under the Organic Foods Production Act of 1990, including pet food?

The Policy Development Committee further recommends that the NOSB Handling Committee convene a pet food task force. If convened, the task force should include NOSB members and members of the public representing the organic trade, pet food industry, feed control officials, academics, and accredited certifying agents.

The pet food task force should: 1) take into consideration information generated by the request for comments above; 2) determine which aspects of the existing regulation pertain to pet foods; 3) if needed, draft amendments to the regulation for consideration by the full board; and 4) identify substances used by pet food manufacturers to be petitioned for possible addition to the National List.

6. Mushrooms, apiculture and honey, greenhouse operations and greenhouse products, and hydroponic agriculture

From the April Directive

These products may be certified to the existing NOP regulations which will be amended in future rulemaking to cover any unique production and handling requirements. We have received recommendations from the NOSB and, to ensure uniform certification among USDA accredited certifying agents, we will publish at the earliest possible date through notice and comment rulemaking any additional standards needed for these commodities. Interested parties are invited to consult with the NOP in preparation for the proposed rulemaking.

NOSB Consideration and Recommendation

The Policy Development Committee recommends that the NOSB agree with the NOP position that mushroom, apiculture, and greenhouse operations can be certified organic and the products of such can be labeled "organic" and carry the "USDA Organic" logo. Further, the NOP should proceed with rulemaking, using recommendations submitted by the NOSB to construct proposed rule amendments.

The PDC points out that the NOSB adopted, as part of an April 25, 1995 greenhouse recommendation, a section entitled, "Specialized Standards for Hydroponic Production in Soilless Media." The recommendation stated, "Hydroponic production in soilless media to be labeled organically produced shall be allowed if all provisions of the OFPA have been met."

Though the issue has been discussed, the NOSB has not submitted a recommendation on hydroponic production standards since the Final Rule was released. The PDC requests that the Crops Committee place the item on its work plan. Rulemaking for hydroponic standards should not proceed until the NOSB has submitted a final recommendation.

NOSB VOTE Oct 13, 2004

Motion to approve the scope document: Yes 12; No -0, 2 absent, 0 abstain