# USDA RESPONSE TO NOSB FEEDBACK ON ISSUE STATEMENTS: FISHMEAL, INERTS, ANTIBIOTICS, AND SCOPE OF AUTHORITY

Below are the summaries of feedback from the NOSB on four issue statements related to: fishmeal as a feed supplement; the use of approved pesticidal treatments that may contain unknown inert ingredients; the use of antibiotics and other synthetic medical treatments for livestock; and the scope of authority for NOP organic standards regarding eligibility.

The summary of each of the NOSB feedback statements is followed by the Department's response in bold and italics. The full statements issued by the NOSB can be found at: http://www.ams.usda.gov/nosb/meetingbooks/Oct2004/tableofcontents.htm.

All USDA certifying agents and certified operations should consider the USDA response as the most current guidance on each of these matters.

## ISSUE 1. FISHMEAL

## NOSB Statement:

- o Fishmeal is nonsynthetic.
- o Fishmeal preserved with natural substances and that would not be harmful to human health or the environment should be allowed as a feed additive or feed supplement for organic production, in accordance with 7 CFR §205.237(a), 7 CFR §205.237(b)(2) and 7 CFR §205.238(a)(2).
- o The use of fishmeal must comply with all applicable requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. 301 et seq.), as required by 7 CFR §205.237(b)(6).
- o Nonsynthetic (natural) preservative ingredients are allowed in fishmeal used in organic production.
- o Synthetic preservative ingredients may only be used in fishmeal after petition, review, and placement on the National List.

# **USDA-NOP Response to NOSB Statement:**

- 1. NOP concurs that fishmeal is nonsynthetic and that fishmeal preserved with natural substances may be allowed as a feed additive or feed supplement;
- 2. NOP further concurs that use of fishmeal must comply with FFDCA requirements; and
- 3. NOP concurs that any synthetic preservatives added to fishmeal must first be added to the National List through rulemaking; however, the issue of added synthetics is currently the subject of Federal court litigation and final action on this issue must await the outcome of the litigation.

#### NOSB Statement on Future Work:

- The status of fishmeal for use in organic aquaculture should be considered during the development of NOP aquaculture standards. Issues including the sustainability of fisheries exploited for fishmeal production and possible heavy-metal, PCB, dioxin, and pesticide contaminants in fishmeal should be addressed during the development of aquaculture standards.
- o If NOP standards and definitions are developed for the production of organic fishmeal, then only organic fishmeal can be used as a feed, feed supplement, or feed additive for any organic livestock, in accordance with 7 CFR §205.237(a), which requires the use of organic feed.

- o A clear, predictable policy needs to be developed concerning when incidental substances in livestock and crop production materials make an otherwise natural substance a synthetic.
- To help clarify the distinction between natural and synthetic substances, the Livestock Committee recommends that the current definition of "nonsynthetic (natural)" in the regulations be revised. The Association of American Plant and Feed Control Officials (AAPFCO) definition of "natural" and "natural organic" fertilizers should be considered in the revision process.
- To clarify the differences between "feed," "feed additives," and "feed supplements," the NOP and NOSB should provide guidance concerning the types of nutrients (carbohydrates, proteins, fats, amino acids, vitamins, and minerals) allowed in each category and whether limits should be set on the quantities of nonorganic feed additives or supplements allowed in organic feed rations.

# USDA-NOP Response to NOSB Statement on Future Work:

- 1. The NOSB should place these issues on their working plans for future Board meetings. If any recommendations from these future meetings result in proposed regulatory changes, NOP will consider issuing a proposed rule for public comment.
- 2. NOP has published a notice in the Federal Register calling for nominations for a taskforce to help develop standards for farm-raised and wild-caught fish. This task force may address issues related to fishmeal.

## **ISSUE 2. UNKNOWN INERTS**

#### **NOSB Statement:**

- o The NOSB encourages pesticide manufacturers who want to market their products for organic production to take advantage of the Environmental Protection Agency (EPA) organic labeling program. They are also encouraged to disclose all product ingredients, including inert or other ingredients on the pesticide label.
- Pesticide manufacturers of products that contain allowed active ingredients and List 3 inert ingredients are encouraged to reformulate those products to contain only List 4 inerts, which are allowed under NOP regulations. Other options are to notify EPA of a need for expedited review, and to petition the NOSB for review of the specific List 3 inert.
- o Since the EPA regulates use claims, directions for use, and composition of a pesticide product as a pre-market condition, the NOP should establish functional lines of communication with EPA in order to provide EPA consistent information about organic standards and updates to the National List, and to obtain advice from EPA on the status of petitioned materials.
- O Certification agents who find that producers are reporting use of pesticide products with unknown inert ingredients should instruct producers to discontinue use immediately unless the ingredients can be verified as compliant with the NOP regulation. Discontinuation of use will be considered sufficient corrective action for use of pesticide products with approved active and unknown inert ingredients.

- 1. The NOP regulations allow only List 4 inert ingredients in the formulation of pesticide products used in organic production, and List 3 inerts that appear on the National List.
- 2. Certifying agents should ensure that certified operations use pesticides that are known to them to contain only List 4 (and any approved List 3) inert ingredients.
- 3. USDA-NOP may initiate enforcement actions against any certified operation using a pesticide that USDA-NOP can show contains an inert ingredient other than a List 4 (or approved List 3) inert.

## **ISSUE 3. ANTIBIOTICS**

#### **NOSB Statement:**

- NOP should issue a statement clarifying that the use of antibiotics and other prohibited substances is not allowed for organically produced livestock or edible organic livestock products once a producer is certified organic.
- o NOP should adopt the May 14, 2003, NOSB recommendation on Origin of Livestock as either a technical correction (preferable) or as a rule change.
  - o This action will unify and clarify the standard for dairy herd replacement stock.
  - The vast majority of organic dairy producers and accredited certifying agents endorse this recommendation.
- The approval of NOSB recommended health care materials for livestock must be a priority for the USDA.
  - NOP should publish the amendment to the regulations that will allow the use of all livestock materials recommended by the NOSB.
  - NOP should provide to the industry the opportunity to petition for inclusion of calf-hood medications on the National List.

- 1. NOP concurs that the use of antibiotics and other prohibited substances is not allowed for organically produced livestock or their edible products once a producer is certified organic.
- 2. NOP is processing the rulemaking docket addressing NOSB-recommended livestock materials for publication in the Federal Register. Operators and certifying agents are reminded that unless and until the final rule containing NOSB-recommended materials is published in the Federal Register and becomes effective, the recommended materials may not be used.
- 3. For USDA's response to the NOSB recommendation on the origin of replacement dairy stock, see issue 3a below.
- 4. Producers and manufacturers are directed to the NOP website for procedures on how to petition to add medications and other materials to the National List.

## ISSUE 3A. ORIGIN OF LIVESTOCK

#### NOSB Statement:

The NOSB recommends that 7 CFR §205.236(a)(2)(iii) be amended to read:

## 7 CFR § 205.236 Origin of livestock.

- (2) <u>Dairy animals conversion of conventional dairy herds</u>. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of the milk or milk products that are to be sold, labeled, or represented as organic, Except, That, when an entire, distinct herd is converted to organic production, the producer may:
  - (i) For the first 9 months of the year, provide a minimum of 80-percent feed that is either organic or raised from land included in the organic system plan and managed in compliance with organic crop requirements; and
  - (ii) provide feed in compliance with 7 CFR § 205.237 for the final 3 months.
- (3) Replacement dairy stock -- Once a dairy herd has been converted to organic production, all dairy animals shall be under organic management from the last third of gestation.

NOSB also recommends that for purposes of conformity existing 7 CFR § 205.236(a)(3) be renumbered to 7 CFR § 205.236(a)(4).

- 1. The exception related to the 80-20 feed provision is currently the subject of Federal court litigation and final action on this issue must await the outcome of that litigation.
- 2. NOP will consider drafting an advance notice of proposed rulemaking (ANPR) to obtain information from the public on the issue of dairy livestock, including the length of time that dairy livestock must be managed organically before dairy products may be sold as organic.

## **ISSUE 4. SCOPE OF NOP REGULATIONS**

## A. NOSB Statement: Personal Care Products, Cosmetics, and Dietary Supplements

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 products, cosmetics, 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 products, cosmetics, and dietary supplements?
- 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 (OFPA), including personal care products, cosmetics, and dietary supplements?

- 1. OFPA and the NOSB charter establish the duties and functions of the NOSB, which do not include soliciting recommendations from private citizens or organizations regarding legislative initiatives.
- 2. If legislation to amend OFPA with respect to personal care products and cosmetics is enacted, the NOP will enter into notice and comment rulemaking to propose standards for the production, handling, and labeling of these products. Until such time, these finished products may not display the USDA seal or be represented as NOP-certified. Only the organic agricultural ingredients contained in these products may be represented as certified to NOP standards. These products may be certified to other, private standards.
- 3. Regarding dietary supplements, no determination has been made at this time concerning their labeling under the NOP regulations.

## B. NOSB Statement: Soil Amendments, Fertilizers, Manures, and Related Products

The NOSB recommends acknowledgement that the labeling of fertilizers, soil amendments, manures, and related products is regulated by State authorities. The NOSB further recommends endorsement of the draft AAPFCO labeling definition of "for organic production…."

# **USDA-NOP Response to NOSB Statement:**

1. NOP concurs that the labeling of these products is regulated by State authorities. However, the OFPA gives USDA jurisdiction over the use of the word "organic" to the extent such products may be agricultural products. NOP will await the Board's recommendations based on AAPFCO's review of labeling for these products. At its March 2005 meeting, the NOSB tabled its recommendation regarding the labeling of these products pending further review.

# C. NOSB Statement: Farm-Raised and Wild-Caught Fish and Seafood

The NOSB recommends the establishment of a new task force on standards for wild-caught and farmed-raised fish and seafood. The task force would be structured like the earlier Task Force on Aquatic Animals, with two working groups -- one on wild-caught and one on farmed-raised fish and seafood. 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 consider the report issued by the previous Task Force on Aquatic Animals 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.

- 1. NOP concurs with the formation of a task force with two working groups to consider and develop standards to be presented to the NOSB for its consideration for farm-raised and wild-caught fish and seafood.
- 2. NOP published a Federal Register notice calling for nominations to a task force for farmraised and wild-caught fish and seafood. The task force is charged with developing draft standards to propose to the NOSB for consideration.

## D. NOSB Statement: Pet Food

In order to assess the degree of interest in certification and regulation of pet food products, the NOSB recommends solicitation of 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 regulatory action be taken with respect to the labeling of "organic" pet food?
- 2. Should legislation be adopted to prohibit the use of the word "organic" on products not certified under OFPA, including pet food?

The NOSB further recommends that a pet food task force be convened. If convened, the task force should include NOSB members and members of the public representing the organic trade, the 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; 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 for possible addition to the National List through the petition process.

- 1. NOP concurs with the establishment of a pet food task force that can address labeling issues for pet food and make recommendations to the NOSB and NOP for amending the regulations to include pet food as an organically-produced product. NOP published a Federal Register notice calling for nominations for a pet food task force to develop draft standards on the handling and labeling of pet food products to be proposed to the NOSB.
- 2. With regard to legislative proposals, OFPA and the NOSB charter establish the duties and functions of the NOSB, which do not include soliciting recommendations from private citizens or organizations regarding legislative initiatives.

# E. NOSB Statement: Mushrooms, Apiculture and Honey, Greenhouse Operations and Products, and Hydroponic Agriculture

The NOSB agrees with the NOP position that mushroom, apiculture, and greenhouse operations can be certified as organic, and that the products of such operations can be labeled "organic" and carry the USDA organic seal. Further, the NOP should proceed with regulatory amendments, using recommendations submitted by the NOSB.

The NOSB points out that it 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 adoption of the final rule. NOSB recommends 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.

# **USDA-NOP Response to NOSB Statement:**

1. NOP concurs with the NOSB and agrees to proceed with additional rulemaking for mushrooms, apiculture and honey, and greenhouse operations and their products, and not to propose hydroponic standards until the NOSB has submitted a final recommendation.