FORMAL RECOMMENDATION BY THE NATIONAL ORGANIC STANDARDS BOARD (NOSB) TO THE NATIONAL ORGANIC PROGRAM (NOP) Date: December 10, 2009 Subject: Organic Personal Care Chair: Jeff Moyer Recommendation The NOSB hereby recommends to the NOP the following: Rulemaking Action: X

Summary Statement of the Recommendation (including Recount of Vote):

The National Organic Standards Board recommends that organic personal care products be recognized explicitly by the National Organic Program to ensure consumers and businesses alike that the products have an unquestioned home in the USDA National Organic Program.

This recommendation takes the initial steps toward:

Guidance Statement:

Other:

- 1) assuring consumers that the federal government is policing organic claims on personal care products
- 2) allowing for the development of a complete federal organic personal care product program

NOSB Vote: Motion: Joe Smillie Second: Barry Flamm

Board vote: Yes - 12 No- 1 Abstain- 0 Absent - 2

Summary Rationale Supporting Recommendation (including consistency with OFPA and NOP):

The organic personal care policy statement of the USDA on August 23, 2005 extended the USDA regulations to cover the organic claims made by personal care products which meet the composition requirements for organic food. With this recognition has come the full force of certification and enforcement. While this is an improvement over what previously existed, an ever-increasing stream of personal care products making organic claims continues to flow in to the market place. In an April 2008 news bulletin, the NOP further explained USDA organic certification of cosmetics, body care products, and personal care products. Most recently, in July 2009, the NOP published a "DRAFT FOR COMMENT ONLY: Certification and Labeling of Soap Products Made From Agricultural Ingredients." None of these statements were developed through the Federal Rulemaking process, neither is it certain how durable these various statements will be at NOP.

The USDA is responsible for product organic claims but is not currently enforcing this in the area of personal care products. Consumers are not assured that organic claims are consistently reviewed and applied to the class of products known as personal care products. For instance, at a given retailer, one may find personal care products such as shampoos and lotions labeled as "organic" with no clear standards or regulatory underpinning for the organic claim--and unless the product is specifically labeled as "USDA Organic," the word "organic" may be used with impunity. Manufacturers of personal care products that contain organic ingredients are hindered by a thicket of competing private standards and confusion regarding the applicability of the NOP to their products. Transactions lack the regulatory clarity that applies under the NOP to food products that contain organic ingredients. Given the pace of development of this marketplace, and the important but uneven development of private standards, the NOP should take the necessary initial steps to bring this product class into a coordinated existence with organic food products under the regulation.

Response by	v the NOP:
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USDA National Organic Standards Board

November 5th, 2009

Solving the Problem of Mislabeled Organic Personal Care Products

Purpose

The Certification, Accreditation, and Compliance Committee (CACC) recommends that organic personal care products be recognized explicitly by the National Organic Program (NOP) to ensure consumers and businesses alike that the products have an unquestioned home in the USDA National Organic Program.

Background

The policy statement of the USDA on August 23, 2005 extended the USDA regulations to cover the organic claims made by personal care products which meet the composition requirements for organic food. With this recognition has come the full force of certification and enforcement. While this is an improvement over what previously existed, an ever-increasing stream of personal care products making organic claims continues to flow in to the market place. In an April 2008 news bulletin, the NOP further explained USDA organic certification of cosmetics, body care products, and personal care products. Most recently, in July 2009, the NOP published a "DRAFT FOR COMMENT ONLY: Certification and Labeling of Soap Products Made From Agricultural Ingredients." The Appendix contains these 3 NOP statements. None of these statements were developed through the Federal Rulemaking process, neither is it certain how durable these various statements will be at NOP.

The Problem of Mislabeled Personal Care Products

The USDA is responsible for product organic claims but is not currently enforcing this in the area of personal care products. Consumers are not assured that organic claims are consistently reviewed and applied to the class of products known as personal care products. For instance, at a given retailer, one may find personal care products such as shampoos and lotions labeled as "organic" with no clear standards or regulatory underpinning for the organic claim--and unless the product is specifically labeled as "USDA Organic," the word "organic" may be used with impunity. Manufacturers of personal care products that contain organic ingredients are hindered by a thicket of competing private standards and confusion regarding the applicability of the NOP to their products. Transactions lack the regulatory clarity that applies under the NOP to food products that contain organic ingredients.

Given the pace of development of this marketplace, and the important but uneven development of private standards, the NOP should take the necessary initial steps to bring this product class into a coordinated existence with organic food products under the regulation.

This recommendation takes the initial steps toward:

- 3) assuring consumers that the federal government is policing organic claims on personal care products
- 4) allowing for the development of a complete federal organic personal care product program

Recommendation

To facilitate the development of a single national standard for this product class, and to ensure consumers that organic personal care products meet a consistent standard, the CACC recommends that the following amendments be made to 7 CFR Part 205. Underlined text is to be added to the current rule.

1. §205.102. Add Definition of Personal Care Products:

(1) <u>An article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance</u>

2. §205.100(a) Add words "including personal care products"

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, or other agricultural products <u>including personal care</u>

<u>products</u> 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.

3. §205.102 Use of the term "organic."

Any agricultural product, including personal care products, that is sold, labeled or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s)) must be: * * *

4. §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 of any product, without regard to the end use of the product, that is sold, labeled or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s)) must be: * * *

5. §205.311 USDA Seal

(a) The USDA seal described in paragraphs (b) and (c) of this section may be used only for farm or processed agricultural products, including personal care products, described in paragraphs * * *

Appendix

The following information has been provided to the public by the USDA NOP

United States Department of Agriculture Agricultural Marketing Service National Organic Program www.ams.usda.gov/nop ph 202-720-3252

- 1) August 2005 NOP MEMORANDUM
- 2) April 2008 NOP Statement Cosmetics, Body Care Products, and Personal Care Products
- 3) July 2009 NOP DRAFT FOR COMMENT ONLY: Certification and Labeling of Soap Products Made From Agricultural Ingredients

1) August 23, 2005 MEMORANDUM

TO: All USDA Accredited Certifying Agents FROM: Barbara C. Robinson Deputy Administrator Transportation and Marketing Programs Agricultural Marketing Service

SUBJECT: Certification of agricultural products that meet NOP standards

The National Organic Program (NOP) has received numerous inquiries regarding its current thinking on the issue of products that meet the NOP program standards for organic products based on content, irrespective of the end use of the product. This statement is intended to clarify the NOP's position with respect to this issue, and will be provided to all of our accredited certifying agents.

Agricultural commodities or products that meet the NOP standards for certification under the Organic Foods Production Act of 1990, 7 U.S.C. §§ 6501- 6522, can be certified under the NOP and be labeled as "organic" or "made with organic" pursuant to the NOP regulations, 7 C.F.R. part 205.300 et seq. To qualify for certification, the producer or handler must comply with all applicable NOP production, handling, and labeling regulations.

Operations currently certified under the NOP that produce agricultural products that meet the NOP standards to be labeled as "organic" and to carry the USDA organic seal, or which meet NOP standards to be labeled as "made with organic," may continue to be so labeled as long as they continue to meet the NOP standards. Such certification may only be suspended or revoked after notice and opportunity for hearing.

There are agricultural products, including personal care products, that, by virtue of their organic agricultural product content, may meet the NOP standards and be labeled as "100 percent organic," "organic" or "made with organic" pursuant to the NOP regulations. Businesses that manufacture and distribute such products may be certified under the NOP, and such products may be labeled as "100 percent organic," "organic" or "made with organic" so long as they meet NOP requirements. Additionally, products that may be labeled "100 percent organic" or "organic" may also carry the USDA organic seal. If additional rulemaking is required for such products to address additional labeling issues or the use of synthetics in such products, the NOP will pursue such rulemaking as expeditiously as possible.

2) Cosmetics, Body Care Products, and Personal Care Products, April 2008

- FDA does not define or regulate the term "organic," as it applies to cosmetics, body care, or personal care products.
- USDA regulates the term "organic" as it applies to agricultural products through its National Organic Program (NOP) regulation, 7 CFR Part 205.
- If a cosmetic, body care product, or personal care product contains or is made up of agricultural ingredients, and can meet the USDA/NOP organic production, handling, processing and labeling standards, it may be eligible to be certified under the NOP regulations.
- The operations which produce the organic agricultural ingredients, the handlers of these agricultural ingredients, and the manufacturer of the final product must all be certified by a USDA-accredited organic certifying agent.
- Once certified, cosmetics, personal care products, and body care products are eligible for the same 4 organic labeling categories as all other agricultural products, based on their organic content and other factors:
 - ¶ "100 percent organic"--Product must contain (excluding water and salt) only organically produced ingredients. Products may display the USDA Organic Seal and must display the certifying agent's name and address.
 - □ "Organic"--Product must contain at least 95 percent organically produced ingredients (excluding water and salt). Remaining product ingredients must consist of nonagricultural substances approved on the National List or nonorganically produced

agricultural products that are not commercially available in organic form, also on the National List. Products may display the USDA Organic Seal and must display the certifying agent's name and address.

If "Made with organic ingredients" -- Products contain at least 70 percent organic ingredients and product label can list up to three of the organic ingredients or "food" groups on the principal display panel. For example, body lotion made with at least 70 percent organic ingredients (excluding water and salt) and only organic herbs may be labeled either "body lotion made with organic lavender, rosemary, and chamomile," or "body lotion made with organic herbs." Products may not display the USDA Organic Seal and must display the certifying agent's name and address.

Less than 70 percent organic ingredients--Products cannot use the term "organic" anywhere on the principal display panel. However, they may identify the specific ingredients that are USDA-certified as being organically produced on the ingredients statement on the information panel. Products may *not* display the USDA Organic Seal and may *not* display a certifying agent's name and address. (Water and salt are also excluded here.)

• Any cosmetic, body care product, or personal care product that does not meet the production, handling, processing, labeling, and certification standards described above, may not state, imply, or convey in any way that the product is USDA-certified organic or meets the USDA organic standards.

However:

- USDA has no authority over the production and labeling of cosmetics, body care products, and personal care products that are not made up of agricultural ingredients, or do not make any claims to meeting USDA organic standards.
- Cosmetics, body care products, and personal care products may be certified to other, private standards and be marketed to those private standards in the United States. These standards might include foreign organic standards, eco-labels, earth friendly, etc. USDA's NOP does not regulate these labels at this time.
- 3) DRAFT FOR COMMENT ONLY: Certification and Labeling of Soap Products Made From Agricultural Ingredients
 United States Department of Agriculture 1400 Independence Avenue SW. NOP 5010 Agricultural Marketing Service Room 4004-South
 Building National Organic Program Washington, DC 20250 Distribution: Public, Approval: PENDING

Background

The Organic Foods Production Act of 1990 (OFPA), 7 U.S.C. Section 6501, et. seq., as amended, and implemented in 7 CFR Part 205, National Organic Program (NOP) Final Rule, regulates the production, handling, processing, and labeling of all raw or processed agricultural products to be sold, labeled, or represented as organic in the United States. In an August 23, 2005 policy statement issued by the NOP, the Program clarified that agricultural products may be certified and labeled in accordance with the Act and its implementing regulations regardless of end use. The statement allows for certain products, such as soaps, to be certified under the NOP, providing they comply with 7 CFR 205.

This document describes the interim procedures to be used by certified operations and certifying agents accredited by the U.S. Department of Agriculture (USDA) to certify and label soap products as "organic" or "made with organic [specified ingredients]", referred to throughout this document as "made with" products.

Discussion

Soap is produced by a process called saponification, whereby oils are hydrolyzed by the addition of an alkali, yielding soap, glycerin, water and other byproducts. Glycerin is produced by this process and has been determined by the National Organic Standards Board (NOSB) to be a synthetic and appears on the National List of Allowed and Prohibited Substances as such. (Insecticidal soaps are permitted under 205.601 for crop production.)

The NOP has been asked to provide guidance on the labeling of soap that has been formulated and produced in accordance with the NOP regulations.

Some in the industry have expressed concern that allowing certification and labeling of soap as organic is a violation of OFPA. We disagree. The processing of agricultural products in accordance with NOP regulations often results in chemical or physical changes, many of which may involve the synthesis of new compounds. For example, the processes of baking bread or cooking meat create changes in the products that may involve the creation of new compounds. However, neither of these common products are viewed as synthetic under the regulations.

Our interest is to create a consistent, fair policy that can be applied uniformly in a variety of situations. Therefore, we base our analysis of the process on the NOP regulations. The NOP regulations describe the inputs and processing which take place in the formulation and

manufacturing of a finished product; they do not prescribe the nature of the finished product itself. This allows agricultural products and allowed synthetics to be used to create a wide variety of products which may be eligible for certification, regardless of end use. Further, identification of products produced in compliance with the NOP regulations, and the percentage of organic products that they contain, allows for subsequent formulation into products which retain their eligibility for labeling as organic or "made with" organic products, depending upon the percentage of organic ingredients used to create the product. This allows producers to retain the added value of organic products throughout the production process and provides consumers with a choice when searching for products that contain organically produced ingredients.

In general, products that have been formulated in compliance with the NOP regulations may be eligible for certification as "organic" or "made with" products. Further, products produced in compliance with the regulations should be eligible for further processing and certification based on their true organic component content. Thus, a formulated product produced using 75% organic ingredients and 25% allowed synthetics is eligible for certification as a "made with" product. In addition, the "made with" products should carry a certified organic content of 75% when used in subsequent down-stream processing, under the condition that full disclosure of its organic content and other ingredients is provided by the manufacture. If a soap is produced using 80% certified organic oil and 20% sodium hydroxide, the soap would be eligible for certification as a soap "made with organic oils." Further, the soap "made with organic oils" may be processed downstream into other products using 80% as the organic content for those calculations.

Labeling of these products should be consistent with labeling done for any other certified organic processed product, with full disclosure of the ingredients in the ingredient statement on the information panel. This should include all certified organic ingredients and any synthetics used to produce the product. Although Food and Drug Administration (FDA) regulations allow downstream processors to list "saponified organic oils" in the ingredient statement, FDA does not prohibit full disclosure of the organic and synthetic ingredients, consistent with NOP regulations. Therefore, ingredient statements for products containing saponified oils must include the name of the actual organic ingredient and the synthetic ingredients used to create the soap. If the saponified oils are produced as a part of a separate process, they may be listed as a parenthetical statement, such as "saponified organic oils (organic coconut oil, potassium hydroxide), water, glycerin, beet juice color."

Guidance

Soap products formulated using certified organic oils and materials included on the National List may be certified and labeled as "organic" or "made with organic [specified ingredients]." Further, when manufacturers of saponified organic oils produce such products in compliance with the regulations and provide certified formulations to downstream processors, they may be further processed into "organic" or "made with" products.

When saponified oils are produced by a certified organic handler and are to be sold as "made with organic oils" for further processing into certified "organic" or "made with" products, they must be accompanied by a complete ingredient statement which gives the actual percentage of the organic ingredients contained in the "made with" product.

When labeling products produced with saponified oil, the ingredient statement of the further processed product must include the ingredients used to produce the saponified oil. As an option, the saponified organic oil may be stated on the ingredient statement followed by a parenthetical statement. Listing the saponified oils without listing the ingredients used to produce the saponified oils is not sufficient.

Procedures

As always, certifiers must review and approve all organic handling plans for products produced with saponified oils, including the ingredient statements for the saponified oils themselves, prior to issuing certification for handling operations producing these products.

Producers of saponified oils to be further processed into other personal care products must provide statements of the type and percent of all ingredients used to produce the saponified oils so that this information may be included in the ingredient statement of the finished product.

All labels for certified organic soaps and products containing saponified oils must be reviewed and approved by the certifying agent prior to printing and labeling.

Barbara C. Robinson, Acting Director National Organic Program

August 31, 2009 CACC Motion to Approve, Vote Tally: 6 yes, 0 no, 0 absent, 0 abstain