



August 24, 2009

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1400 Independence Ave., SW
Room 4004-South, STOP 0268
Washington, DC 20250

Via Hand Delivery and Email: mark.bradley@usda.gov

Re: Comments on Draft: Certification and Labeling of Soap Products Made from Agricultural Ingredients

Dear Mr. Bradley,

This correspondence provides comments of the American Herbal Products Association (AHPA) on the draft document issued by the National Organic Program (NOP) titled, Draft for Comments Only: Certification and Labeling of Soap Products Made from Agricultural Ingredients (the draft document). According to the draft document, it “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].”

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA’s members include companies that manufacture and market, among other things, soap products and products that contain soap as an ingredient, including such products made with or from agricultural ingredients, including herbal and organic agricultural ingredients. AHPA and its members therefore have an interest in the issues identified in the draft document.

AHPA has taken an active role in the past in providing input to NOP on various issues, and specifically with regard to scope issues, such as the scope of the NOP regulations in relation to dietary supplements, cosmetics, body care products, and personal care products. AHPA appreciates the opportunity to provide comments on the issues addressed in the draft document.

The scope of the NOP should extend to soap products and ingredients

AHPA's position on NOP scope issues can generally be described as supporting a very broad scope for the application of the NOP to all agricultural products. AHPA believes that NOP was exactly correct when, in August 2005, it issued a memorandum to all USDA accredited certifying agencies on the subject of certification of agricultural products that meet NOP standards to address "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**" (emphasis added). This August 2005 memorandum clarified that "agricultural commodities or products that meet the NOP standards for certification under the Organic Foods Production Act of 1990 ... can be certified under the NOP and be labeled as 'organic' or 'made with organic' pursuant to the NOP regulations...."¹ AHPA strongly supports this broad application of the Organic Foods Production Act (OFPA), and believes that it reflects the intent of Congress when this important legislation was adopted.

Consistent with AHPA's previous support for applying the NOP broadly to agricultural products that meet the NOP program standards, irrespective of the end use of the product, AHPA strongly supports the draft document insofar as the document disagrees that allowing certification and labeling of soap as organic is a violation of the OFPA. AHPA also strongly supports the draft document insofar as it puts forth as guidance that "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]," and that, when such certified soap products are provided to downstream processors, "they may be further processed into 'organic' or 'made with' products." AHPA requests that NOP clarify that such downstream processors may include both the manufacturer of the soap, when using it as an ingredient in other of their own products, and other companies that purchase an organic soap ingredient for inclusion in cosmetic products.

Along with this expression of support for NOP's recognition that the scope of the NOP should extend to soaps that meet the NOP program standards, whether as a product in and of itself or as an ingredient in other products, AHPA is

¹ Robinson BC. August 23, 2005. Memorandum – To: All USDA Accredited Certifying Agents; Subject: Certification of agricultural products that meet NOP standards.

providing here comments on how such products can comply with both the NOP and other existing federal regulations that govern the labeling of soap products. In addition, AHPA is also addressing a concern that acknowledgement that the scope of the NOP extends to soap products and soap ingredients that meet the NOP program standards may lead inadvertently to perceptions that NOP is applicable to other products and categories where organic labeling may not be appropriate.

Labeling of “organic” soap must comply with other federal labeling regulations

The U.S. Food & Drug Administration (FDA) has authority over the labeling of cosmetics under both the Federal Food, Drug and Cosmetic Act (FFDCA) and the Fair Packaging and Labeling Act (FPLA).

Regulations for designation of cosmetic ingredients on labeling are maintained in Title 21, Part 701.3 of the Code of Federal Regulations (21 CFR 701.3). Soap, however, is excluded from the FFDCA’s definition of cosmetic (21 U.S.C. 321(i)), though this exclusion is limited for regulatory purposes only to soap articles that meet the following conditions: “(1) the bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the detergent properties of the article are due to alkali-fatty acid compounds²; **and** (2) the product is labeled, sold, and represented **only** as soap” (21 CFR 701.20, emphasis added; hereinafter non-cosmetic soaps³). Thus, any soap that, for example, makes any cosmetic claim, such as moisturizing or deodorizing (hereinafter cosmetic soaps), is included in the FFDCA’s definition of cosmetic and so must comply with 21 CFR 701.3.

Most soap products in the marketplace, including presumably most organic soap products as envisioned by the draft document, are marketed as cosmetic soaps and must comply with all FDA requirements for a cosmetic, including listing each ingredient on the label with a name specified by the cosmetic labeling regulations at 21 CFR 701.3. Under these regulations, each cosmetic ingredient

² FDA clarifies elsewhere that what is meant by this is “the traditional composition of soap.” <http://www.fda.gov/Cosmetics/CosmeticLabelingLabelClaims/CosmeticLabelingManual/ucm126444.htm#clgl> (“Page Last Updated: 5/16/2009”); accessed August 19, 2009.

³ Non-cosmetic soaps fall under the jurisdiction of the U.S. Consumer Product Safety Commission (CPSC), and need not comply with FDA regulations.

is required to be “identified by the name established by the Commissioner for the purpose of cosmetic ingredient labeling or, in the absence of a name established by the Commissioner, the name adopted for that ingredient in the editions and supplements of the compendia listed below,” in a prescribed order. The compendium identified as primary is the Cosmetic, Toiletry and Fragrance Association (CTFA)⁴ Cosmetic Ingredient Dictionary, 2nd edition (1977)⁵ which assigns International Nomenclature Cosmetic Ingredient (INCI) names. INCI names are recognized by the United States, the European Union, and other countries as the labeling names that must be used on cosmetic and personal care product packages.

FDA has communicated its position that in designating cosmetic soap ingredients a labeler may declare its ingredients either as the starting materials that went into making the soap, or the resulting reaction products.⁶ In other words and for example, the ingredients in a soap may be designated either as “coconut oil⁷, potassium hydroxide,” referring to the starting materials, or as “potassium cocoate,” referring to the reaction product. FDA’s regulations also require that all ingredients added to a cosmetic soap are listed on labels.

⁴ CTFA is now the Personal Care Products Council.

⁵ The current version of this document is the 12th edition, published in 2008 and now titled *International Cosmetic Ingredient Dictionary*. FDA’s regulation, however, still cites the 2nd edition, and the agency’s website states: “The third edition of the CTFA Cosmetic Ingredient Dictionary published in 1982 and the Supplement published in 1985 have not yet been recognized. However, FDA has informed the CTFA that the agency will not take regulatory action against products labeled in accordance with these editions while their review is in progress.” This FDA site also states: “The ... second edition ... is recognized only in part, i.e., not all names listed in the second edition have been adopted.” Accessed August 19, 2009 at <http://www.fda.gov/Cosmetics/CosmeticLabelingLabelClaims/CosmeticLabelingManual/ucm126444.htm#cl> (“Page Last Updated: 5/16/2009”).

⁶ Email communication between Lark Lambert, FDA Biologist, Office of Cosmetics and Colors, and Michael McGuffin, President, AHPA; August 17-21, 2009 (transcript attached and incorporated by reference in these comments).

⁷ Recent editions of CTFA’s *International Cosmetic Ingredient Dictionary* list botanical ingredients by their Latin names. For example, the current INCI name for “coconut oil” is “Cocos Nucifera (Coconut) Oil.” FDA, however, informed CTFA in 1995 that, “The use of Latin names as the primary identifying term for plant extract ingredients, with the current common name appearing imbedded in parenthesis, would not be consistent with the FPLA,” and that the agency “cannot accept” CTFA’s proposal that the Latin name of a plant be listed in the primary position on cosmetic labels with the English plant name in parenthesis to declare botanical ingredients on products sold in the United States. Accessed August 19, 2009 at <http://www.fda.gov/Cosmetics/CosmeticLabelingLabelClaims/IndustryRequestsFDAResponses/ucm075032.htm>.

NOP's draft document's discussion of labeling of organic soap products in its "Discussion" section, states:

"Labeling of these [soap] 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 [and] ... 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.

It is apparent from this language that NOP would require the listing on a soap label of the "starting materials" that were used to make a soap, and is therefore consistent with one of the two options that FDA allows for labeling soap. The draft document provides an example of labeling for finished products containing organic saponified oils (i.e., soaps), and states that if a saponified oil is produced as part of a separate process, it may be listed as a parenthetical statement, such as "saponified organic oil (organic coconut oil, potassium hydroxide), water, glycerin, beet juice color."

As discussed above, any cosmetic soap must comply with 21 CFR 701.3 and use the common or usual name for each ingredient, identifying either its starting materials or reaction products. The parenthetical portion of the above example of NOP's proposed labeling appears to be consistent with FDA's regulations. It is AHPA's understanding, however, that FDA reads its cosmetic ingredient labeling rule to require the listing of all ingredients in a cosmetic, including all of the ingredients in a soap ingredient within a cosmetic, but does not believe that terms that describe an intermediate product (such as "soap" or "saponified oil") need to be, or even should be identified in labeling. In fact, FDA has communicated to AHPA that "neither the terms 'soap' nor 'saponified oil' are in the INCI dictionary."⁸ It therefore appears that the correct labeling under FDA's rules in NOP's example cited above would be to list each of the ingredients (organic coconut oil, potassium hydroxide, water, glycerin, beet juice color) in their order of predominance in the finished cosmetic product, but without use of

⁸ Email communication between Lark Lambert, FDA Biologist, Office of Cosmetics and Colors, and Michael McGuffin, President, AHPA; August 17-21, 2009 (transcript attached and incorporated by reference in these comments).

the term “saponified oil.” AHPA encourages NOP to initiate communication with FDA to clarify this issue.

In addition, the draft document, in its “Guidance” section, provides information on labeling of saponified oils that 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, stating that such products:

“... must be accompanied by a complete ingredient statement which gives the actual percentage of the organic ingredients contained in the ‘made with’ product.”

The “Guidance” section of the draft document also provides information on labeling of further processed products produced with saponified oil, stating:

“... 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.”

It is AHPA’s view that both of the above cited statements in the Guidance section of the draft document provide guidance for labeling of organic soap when used as an ingredient in another product that is consistent with FDA’s labeling requirement to identify all ingredients in a cosmetic. As discussed above, however, AHPA believes that this guidance should be revised to remove the described option to identify a “saponified oil” as an ingredient with a parenthetical statement, as this appears to be inconsistent with FDA’s cosmetic labeling rules.

It is also AHPA’s view that the latter-cited guidance statement provided here should apply to further processed products produced with saponified oils, whether such downstream products are manufactured by the same company that manufactures the organic saponified oil or by some other company that purchases this ingredient from its manufacturer. AHPA suggests that NOP clarify the applicability of this section to all downstream products.

In addition, AHPA notes that the Guidance section does not provide any guidance as to the labeling of soap sold simply as soap. AHPA therefore recommends that language be added to provide such guidance, and that such guidance maintain consistency with FDA’s labeling regulations for cosmetic soap.

USDA must ensure that its policy on organic soap is not misunderstood as broadly applicable

AHPA is concerned that acknowledgement that the scope of the NOP extends to soap products and soap ingredients that meet the NOP program standards may lead to an assumption that allowing certification and labeling of soap as organic may have the effect of also allowing certification and labeling of any other product that is manufactured by processing an organic agricultural ingredient with an allowed synthetic ingredient by a process that may be described as a “chemical process.”

AHPA therefore recommends that the draft document be revised to specifically state that it does not, in fact, establish such a precedent, and to specifically state that it is relevant only to soap. While AHPA believes that there may be other such products or product categories where organic labeling under NOP may be appropriate and consistent with the OFPA, AHPA believes at this time that each such product or category must be dealt with separately in order to avoid any supposition that any specific example has broad application to other products or categories.

AHPA appreciates the opportunity to comment on the NOP’s draft document regarding the certification and labeling of soap products made from agricultural ingredients. Thank you in advance for considering the information provided in these comments.

Sincerely,



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