



**The Regulation and Labeling of Organic Personal Care Products:
Issues and Policy Approaches
Organic Trade Association (OTA) Personal Care White Paper Task Force
October 2009**

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**The Regulation and Labeling of Organic Personal Care Products: Issues and
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OTA Personal Care White Paper Task Force

The Organic Trade Association (OTA) Board created a task force charged with writing a White Paper to summarize and discuss the background and controversies affecting how organic personal care products are regulated and labeled in the U.S., and to discuss the pros and cons of different policy approaches. The White Paper is intended to create a common body of knowledge among OTA members and others with an interest in the subject.

Task Force volunteers were selected based upon their familiarity with the Organic Foods Production Act (OFPA), the USDA National Organic Program (NOP) and organic standards generally, materials issues specifically; expertise with writing, reviewing and analyzing regulations; and knowledge of international standards and international trade implications thereof.

The Task Force relied heavily on a group of technical advisors, including but not limited to those with a proficient knowledge of the world of cosmetics and other personal care products, including regulatory oversight, market and consumer issues, and the current landscape of the various “organic” personal care standards.

In the course of a little more than a month, the Task Force convened for weekly conference calls and reviewed several outlines and drafts of this White Paper. The resulting document was adopted as a draft document by the OTA Board at its meeting of September 23, 2009. The final version, including four Appendices, reflects changes suggested by the Board as well as Task Force members and Technical Advisors. A list of all Task Force participants and advisors is found in Appendix 4.

Executive Summary

U.S. companies making organic claims for personal care products and cosmetics are not legally required to be certified or even to adhere to the rules outlined in the USDA National Organic Program (NOP). It appears the cosmetics sector is similar to food in the 1990s: multiple private standards, proliferating unregulated organic claims and unclear regulatory authority provoking confusion among consumers about the meaning of the organic label, with a potential threat to the value of the organic brand as non-certified, potentially fraudulent organic claims proliferate.

The size of the U.S. market for organic personal care products is estimated to be between \$250 and \$500 million. *OTA's 2009 Organic Industry Study* found that the organic personal care products market was \$443 million in 2008 and accounted for 27% of organic non-food sales (less than 2% of the total organic market).

OTA has been closely involved in industry efforts to develop organic personal care standards, and has a significant number of members engaged in this sector as manufacturers, certifiers, ingredient suppliers and consultants. There are multiple and divergent viewpoints and great contention within OTA's membership about the best route to achieve standardization of the use of organic within this sector. At issue in the debate is whether or not public regulation is needed, and if so, whether NOP is the appropriate agency to regulate personal care products or whether private standards are preferable at this time.

At its November 2009 meeting, the National Organic Standards Board (NOSB) will consider a recommendation presented by its Certification, Accreditation and Compliance Committee (CACC) entitled, "Solving the Problem of Mislabeled Organic Personal Care Products." This recommendation suggests any organically labeled cosmetics or personal care product should be subject to the same rules governing other organically labeled agricultural products. There are currently a number of cosmetic and personal care products certified organic under NOP, primarily lip balms, massage oils and similar products, and soaps are also certified as "made with organic" oils. The latter is the subject of particular controversy, as some believe that certification of soap should not be permitted under NOP because of claims that the soap making process makes all soap a synthetic substance.

The proposal now before NOSB suggests NOP is the most appropriate regulatory authority for all organic label claims. The U.S. Food and Drug Administration (FDA) has regulatory jurisdiction over cosmetics labeling, but it does not currently include organic label claims under its enforcement activities. Some argue that all regulation of the cosmetics sector would be better suited to private standards, pointing to the consensus in the EU that organic cosmetics and personal care products should not be regulated under the same rules that apply to food products. This viewpoint argues that there are many synthetic ingredients, such as preservatives and surfactants, needed to make functional personal care products, and adding these substances to the National List, for use in organic personal care products, would pose multiple problems.

Congress has also recently expressed interest in organic label claims on personal care products. The House-Senate conference report to the FY 2010 Agriculture Appropriations Bill directs FDA

to forward any recommendations on the need to establish labeling standards to key Congressional committees.

There is a range of potential policy positions and approaches that could be taken to address the lack of standardization in the organic personal care sector. In addition to the “no action” approach (i.e., not advocating a change to the “status quo” of a partially regulated market with minimal enforcement against mislabeled organic products), this White Paper outlines three policy options OTA—and other interested parties—could consider advocating:

1. **Private Standard Approach** – Encourage organizations issuing private standards to move toward agreement on a unified standard, with some public enforcement against mislabeled organic claims.
2. **Public Regulation under USDA/NOP** – Authorize jurisdiction over cosmetics for NOP, including adopting appropriate standards.
3. **Public Regulation under FDA** – Request that FDA use its authority to regulate organic personal care claims, either on its own or in conjunction with NOP.

It should be noted that all approaches involving regulation will take some time to write and implement. The concern about mislabeling is more immediate. Additional research and discussion with stakeholders, including OTA members, consumers and their advocates, and other organizations involved in organic policy and standards (both domestic and internationally) would be helpful in weighing pros and cons and thoroughly identifying the implications of each approach. Shorter-term solutions might include more robust enforcement of the existing California Organic Products Act; educating and engaging retailers who carry personal care products with organic labels; and communicating with the general public about the distinctions between the various current standards and labels for organic personal care products.

Personal Care Products in the Organic Landscape

The Problem: Perceived Threat to Consumer Trust in “Organic” Labels

Companies making organic claims for personal care products and cosmetics are not legally required to be certified or even to adhere to the rules outlined in USDA’s National Organic Program (NOP). Many in the organic industry are concerned that the value of the word "organic" is being diminished as a result of the plethora of non-certified personal care products labeled as organic.

This situation arises because labeling of personal care products is regulated by the Food and Drug Administration (FDA), and FDA has yet to address regulating “organic” claims on personal care product labels. NOP lacks the legal authority to regulate “organic” label claims of personal care products, except when personal care operations choose to pursue organic certification under NOP, qualify for NOP certification and thus are able to use the USDA Organic seal.

While most within the organic personal care and organic food industries agree a resolution must be reached to maintain the integrity of organic products and consumer confidence in the organic label, consensus about how the labeling of personal care products as “organic” should be regulated has proven elusive.

Organic Trade Association (OTA) members seem to agree a vibrant market for personal care products that use certified organic ingredients is desirable; it helps increase organic acreage and brings the corresponding environmental and health benefits. However, while some members believe that personal care processing can be addressed within NOP—as is the case with those personal care products already certified under NOP—others hold firmly that NOP standards for processing are specifically designed for food products and are not suitable for personal care products. There are also divergent viewpoints about whether the current NOP policy permitting the certification of soap and other personal care products is consistent with the law and the regulations.

In 2001, when OTA formed its first Personal Care Organic Standard Task Force, it issued a press release that stated: “The major hurdle will be to develop standards for personal care products that safeguard the integrity of organic while considering the constraints of personal care production and processing.” This statement remains true today.

Opposing Viewpoints and Disputes

The range of positions espoused by OTA members includes, but are not limited to, the following:

- All organic label claims should be regulated under NOP, with no special allowances for personal care (or any non-food) ingredients/products.
- All organic label claims should be regulated under NOP, and existing private standards should be incorporated into it by amending the National List to include a separate

Materials List identifying synthetic substances permitted for use in personal care products.

- Private industry standards should regulate organic labeling of personal care products specifically, separate and apart from the existing NOP standards. Later these standards could be adopted by a public agency, whether FDA or NOP.

In addition, some members have voiced opposition to allowing an organic label claim on any personal care product. Other members are primarily concerned that any standard adopted in the U.S. should be consistent with the norms in existing international standards.

The debate has often been contentious. Philosophical beliefs about the meaning of “organic” as well as market share and competitive issues all come into play. It must be underscored that the issues of organic personal care regulation and labeling bring a high level of emotion.

Those who oppose USDA/NOP as the future regulatory agency for organic labeling of personal care products argue USDA/NOP standards and items on the National List were never intended to cover the processing of organic agricultural products into non-food products. In addition, they maintain USDA lacks the expertise to regulate cosmetic products. Some favor private standards and a few suggest FDA is the most appropriate agency to regulate this sector. Those who favor private standards say that the cosmetic industry has been self-regulated since the passing of the FD&C Act. In their eyes, private standards would solve the problem of international trade barriers that may arise as a result of a USDA mandate, address the problem of designing the standard to meet industry-specific needs, and deal with the issue of having a level of expertise by certification administrators.

Those who favor using the USDA/NOP standard argue it is the only way to ensure consistency and reduce consumer confusion. In addition, they maintain FDA lacks expertise in organic standards and certification, and that the current private standards are weak and inconsistent. All agree that having two different federal agencies that oversee organic label claims would multiply the complexity of the industry’s task of understanding and influencing two sets of regulations.

It is not clear whether either USDA/NOP or FDA is interested in regulating organic label claims for personal care products. In the European Union (EU) and in Canada, existing government organic standards do not apply to personal care products. This has led to the establishment of various private standards to serve the global organic personal care market. However, a lawsuit filed in 2008 in the California State courts challenges use of private organic labeling standards for personal care products. Some believe that as long as this litigation is pending, it will hinder further private certification of organic labeling for personal care products in the United States.

Current Factors Influencing the Landscape for “Organic” Personal Care

During its next meeting on Nov. 3-5, 2009, the National Organic Standards Board (NOSB) will consider a recommendation by its Certification, Accreditation, and Compliance Committee (CACC) on organic labeling of personal care products. CACC is recommending NOP regulations be amended specifically to cover personal care products. When the Committee

presented a Discussion Document to the Board in May 2009, OTA submitted a comment in response. (See Appendix 1A and B).

OTA's comment suggested creating an NOSB Task Force to gather facts and examine the various issues and concerns that would be raised by such a recommendation. The NOSB did not move forward with creation of a task force; therefore, OTA's Personal Care White Paper Task Force is an effort to develop a clear assessment of the situation.

Other external factors may change the prospects for regulation of organic personal care products in the next few years. NOP has hired a new Deputy Administrator, and plans to considerably expand its staff in the coming year. In addition, the current administration is very supportive of the organic sector, and the new Deputy Secretary of Agriculture thoroughly understands the issues and challenges facing the organic industry.

OTA's Role

OTA believes it is in the best interest of the association and of the industry to help resolve the issues around the regulation and labeling of "organic" personal care products, even knowing that it will be difficult to meet all stakeholders' needs. Timely and effective resolution of this issue is central to OTA's mission of promoting the industry while protecting consumers' trust in the integrity of the word "organic". Additionally, non-food sectors continue to be the fastest-growing segment of OTA's membership and of the industry. Resolution of the issues surrounding organic personal care products will improve the process of establishing standards for other currently non-regulated sectors, benefiting both the industry as a whole and consumers of organic products.

Personal Care Products Background: Definition

The Food and Drug Administration (FDA), in the Department of Health and Human Services, regulates labeling of cosmetics, such as personal care products and body care products, under the authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act). For regulatory purposes, the FD&C Act defines "cosmetics" as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance."¹ Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, hair colors, toothpastes, and deodorants, as well as any material intended for use as a component of a cosmetic product.

Personal care product categories are defined by the intended use of the product, not how it is manufactured. Products intended to confer health benefits or which make a health claim, such as sunscreen or mouthwash with a topical antiseptic, are categorized as drugs. Plain soaps (i.e., those intended simply for cleansing and not intended to confer health benefits) have a regulatory category all their own. Some products, such as toothpastes, can be drugs if they contain ingredients that confer health benefits (e.g., fluoride), or a cosmetic if they don't. For the

¹ FD&C Act, sec. 201(i)

purposes of this discussion, “cosmetic” and “personal care product” will be used interchangeably.

Personal Care Products Background: Organic Market and Stakeholders

Current Market Overview

Organic sales in the United States reached \$24.6 billion in 2008. Organic food is the largest segment of the organic products industry, totaling \$22.9 billion in sales and accounting for 93% of all organic product sales. The size of the U.S. market for organic personal care products is estimated to be between \$250² and \$500³ million representing one-quarter of non-food sales or 1-2% of the total market for organic products.

At the close of 2008, OTA’s *2009 Organic Industry Study* reported a growth rate for organic personal care products of 19%, with estimates from SPINS showing a growth rate slowed to 8%, as of August 2009. Organic personal care products are available in all channels of distribution, including the natural, food, drug and mass market channels, as well as non-traditional and direct to consumer sales. The market is expected to continue to grow at a strong rate. Growth will be fueled by both increased consumption by current purchasers, as well as by increased household penetration.

Regarding the number of organic personal care products in the market, one technical advisor cites figures from Organic Monitor (www.organicmonitor.com) as “...well over 10,000 certified organic cosmetic ingredients and finished retail products worldwide. At last count in the United States there were over 2,500 brands that make some sort of organic claim on a personal care item.”

Stakeholders

A membership organization, OTA represents businesses along the organic supply chain in both the food and non-food sectors. These businesses are OTA’s constituents. The entire organic supply chain—comprised of growers, ingredient suppliers, brokers, processors, brand marketers, distributors, retailers, etc.— have a stake in the issue of organic certification and labeling of personal care products.

As mentioned in the introduction, a widely held belief within OTA is that a growing and diverse organic finished products market is integral to the growth and vitality of organic farms and farming. Clearly those farmers who grow products that are used in organic personal care products, as well as the companies that process, trade, and market those products to the U.S.

² According to SPINS, the organic body care market is \$207 million across all channels and growing +8%; sales are split nearly 50/50 across the natural and conventional channels, while the growth is coming from the conventional channel, -1% vs. 18% respectively for the 52-week period ending 8/08/2009. Organic within in the SPIN scan data set is defined broadly as items with organic content between 1-100%.

³ OTA’s 2009 industry survey approximates industry size and includes all channels of distribution, not solely retail channels. The data also capture the value of ingredients sold throughout the supply chain.

public, have the most to gain or lose from a new direction in the regulation and labeling of organic personal care products in the United States.

It is consumer trust in the organic label, however, that ultimately sustains growth of the organic market. For this reason, the consumer is a key stakeholder in this discussion. Companies in the organic food trade, for whom growing public distrust of “USDA Organic” or “organic” could mean loss of purchase of their products, have a stake in the outcome of how organic personal care products are regulated and labeled.

The following sections give more detail about OTA’s personal care sector members and about organic consumers.

Overview of OTA’s Personal Care Sector Members

Over the past year, approximately 150-175 OTA members have indicated their primary business is in the personal care sector. To better understand the profile of members who compete in the personal care industry, OTA fielded three member surveys in September 2009 (one each for manufacturers who identified personal care as their primary business activity, certifiers and ingredient suppliers). Below are headlines from the surveys. ***Note: sample sizes are very small so results are directional versus statistically accurate.*** See Appendix 2 for the complete survey results.

1) Manufacturer Survey: 31 respondents out of 90 invited

Sales Overview

U.S. sales of those participating in the survey ranged from \$0 to >\$20 million and a majority of these sales are done in the United States (83%). This group owns a total of 62 brands, of which 13 have the word “organic” in their names. Collectively, they sell over 2,600 SKUs.

Category Overview

OTA members who responded to the survey make products in all PC categories. See table below for a summary of categories.

category	% of total respondents
soap	79%
hair care	48%
facial care	76%
body care	86%
mouth care	48%
other	62%

Processing

Eighty-seven percent of the respondents self manufacture their products and a third use private label labs/contract manufacturers.

Certification

Most of the SKUs (74%) are not certified to any standard; however,

- 8% of the SKUs are certified organic to NOP
- 6% are certified “made with” to NOP
- 12% are certified to private standards, including ACO, BDIH, Content Verified, Ecocert, IMO, NaTrue, NPA, OASIS, and Soil Association
- Interestingly, 11% of the non-certified SKUs are NOP compliant but not certified. For those few who responded to the question regarding why they aren’t NOP certified, reasons provided include: time, cost, and/or certification not perceived to be of value.
- 56% of the SKUs are compliant with the California Organic Products Act.
- A few of the respondents’ products are eco-labeled (e.g., Green-e)

2) Certifier Survey: 10 respondents out of 40 invited

Of the certifiers who responded, a vast majority (78%) certify personal care products to NOP. EcoCert and Fair Trade are the other types of certification done. Two-thirds of the certifiers certify 1-10 products.

3) Ingredient Supplier Survey: 18 respondents out of 206 invited

Sales Overview

The ingredient suppliers who responded to the survey sell over 325 ingredients certified organic to NOP. Their ingredients sold for use in “organic,” “made with” or “contains organic” personal care products are sold primarily to U.S. manufacturers (72%), with Canada accounting for most of the balance. For a majority of the suppliers, supplying ingredients for personal care is not their primary business. In fact, 65% said supplying ingredients for use in personal care accounts for less than 25% of their business

Sourcing

Seventy-nine percent of the suppliers contract directly with the growers. About 50% of these growers are in North America.

Consumers

According to the Natural Marketing Institute’s (NMI) *2009 LOHAS Consumer Trends Database*, 25% of U.S. adults purchased natural/organic personal care products in the past six months (including soap, body care, hair care, etc.). Fifty-two percent of consumers believe the personal care products they put on their skin are just as important as the healthy and natural foods they consume, according to NMI’s *2008 Health and Wellness Trends Database*.

The data available indicate that purchase motivations for organic personal care products differ from those for organic foods. While “health” is identified as the top reason for purchasing both organic foods and personal care products, consumers identify “safety” as the close second in terms of motivation to purchase personal care products compared to “avoidance of additives” for

food. In fact, one-third of parents buy organic personal care products because “they are safer than other products.”⁴

Organizations that represent consumers, such as the Organic Consumers Association (OCA) and Consumers Union (CU), have been engaged in the issue of organic personal care products.

OCA believes organic body care standards should mirror the organic food standard. Currently, OCA supports the use of the USDA NOP standard and the NSF International-American National Standards Institute (ANSI) 305 “Contains Organic Ingredients” standard. In 2007, OCA conducted a survey of over 5,000 consumers in its database. They are characterized as “shoppers who go out of their way for organic products.” Findings included: 60% respondents did not believe “synthetic ingredients” should be in organic personal care products, even “made with” products; 30% said synthetics should only be allowed if they are manufactured from organically derived sources. Over half of the respondents “most of the time” or always look for the USDA Organic seal or a statement of certification on a product that claims to be “organic.”

The Consumers Union (CU) provided comments on personal care products at the May 2009 NOSB meeting that reflect its longstanding view. CU believes personal care products ought to follow the same NOP standard as food, for all tiers of organic, and that there needs to be separate sections for personal care product ingredients, on the National List, for both “organic” as well as “made with organic.” It does not support private organic standards for personal care products and believes that this is misleading to consumers.

Personal Care Products Background: Product Formulation

There are different viewpoints on the chemistry of personal care products and the acceptability of various inputs, including processing aids and ingredients, in products that carry an organic label. While there is little controversy over certification of food-like products, such as massage oils or lip balms, the certification of soaps and other non-food processed materials has created debate.

Some argue many personal care products are different from foods in that they are based primarily on synthesis chemistry. Others argue the processing of personal care products is analogous to cooking food, and that cooking food is also done in part to create chemical changes. Differing beliefs about consumer expectations and perceptions of what the organic label means serve as back drop to the controversy.

The arguments put forth by each side of the debate go directly to the question of the meaning of “synthetic” under the Organic Foods Production Act (OFPA). Which kinds of chemical changes make a substance synthetic and which do not? If a food is chemically changed during processing, how is it different from a cosmetic ingredient that is chemically changed during processing? What kinds of synthetic ingredients are acceptable or unacceptable to consumers? How much do consumers understand or care about the difference between cosmetic ingredients and food ingredients?

⁴ OTA’s 2009 *U.S. Families’ Organic Attitudes & Beliefs Study*

In order to sort out the debate, it is essential to have some background about the kinds of substances commonly used or needed to manufacture personal care products, and an understanding of which of these substances are currently accepted for use in NOP-compliant products.

Personal Care Processing

While a final cosmetic product is generally manufactured through simple processing methods such as mixing, heating, or blending, the processes needed to produce the ingredients used in these products tend to be more complex. The processing of personal care products frequently requires inputs and processing aids not acceptable under NOP. Many personal care products rely on surfactants, emulsifiers, preservatives and/or emollients. Surfactants reduce the surface tension of water to aid with washing oils and dirt off skin and hair. Emulsifiers help to mix oil and water ingredients in a stable emulsion. Emollients are used to moisturize skin and hair.

Most surfactants are synthetic and may be derived from plant oils or petrochemicals. Even those surfactants derived from plant oils require reagents and catalysts not currently allowed under NOP (they are non-reviewed synthetics not on the National List) and would not be used to produce edible products. All private personal care standards accept limited inclusion of surfactants in organically labeled products. Advocates argue that surfactants are required for shampoos to perform as most consumers expect.

Preservatives are generally required to protect personal care products from microbial contamination or “adulteration,” because consumers expect long shelf life. Products that do not contain water (e.g., lip balms and massage oils) are less prone to microbial contamination than those that contain water (e.g., lotions, shampoos, and other emulsified products). Products which are very alkaline (e.g., concentrated soap) are inherently antimicrobial. Currently there are few effective antimicrobials permitted under the NOP, and the evaluation criteria for the National List in §205.600(b)(4) explicitly rules out inclusion of handling substances whose primary use is as a preservative.

NOP standards permit a wide range of processing methods, including the general phrase “otherwise manufacturing.” NOP's consideration of processing methods for processing aids or adjuvants used to manufacture organic processed products is limited to the general provisions of 205.600(b)(2) requiring environmental benign manufacture, use and disposal methods. Other than that, the distinction common to private personal care organic standards between acceptable and unacceptable processing methods is not relevant to NOP, which asks only whether the inputs used (both ingredients and processing aids) are allowed or prohibited. A processing method that relies on synthetic substances as processing aids, reagents, catalysts or solvents is unacceptable under NOP, unless the synthetic inputs are on the National List (allowed for use in organic processed products). Conversely, most private personal care standards specify allowed and prohibited processing methods, in addition to permitted substances lists, for both ingredients and finished products.

Most ingredients derived from petrochemicals are prohibited in current private personal care standards, with exceptions made on a similar basis to the National List. Where the private standards allow use of petrochemical substances, they are limited to a handful of types of

compounds (e.g., carboxylates, sarcosinates, amphotacetates, and amidopropyl betaine) that meet criteria established by the standard as being relatively benign.

If the regulation of organic personal care claims is to come under NOP, it has been strongly suggested that the chemical formulation needs discussed above be addressed through specific standards for handling personal care products, and by designating separate sections on the National List for permitted non-organic ingredients in organic personal care products. This would serve to distinguish between non-organic ingredients that would be allowed in organic food and those nonorganic ingredients that would not be allowed in food but would be allowed in organic personal care products.

Personal Care Products Background: Legal and Regulatory Jurisdiction

FDA's Jurisdiction over Cosmetics

A summary of the FDA's regulatory authority over cosmetics is found at the following web page:

<http://www.fda.gov/Cosmetics/CosmeticLabelingLabelClaims/CosmeticLabelingManual/ucm126438.htm>.

FDA's authority is limited to interstate commerce, and it does not regulate cosmetics advertising. However, when a cosmetic is found to have been "misbranded" under the FD&C Act, FDA has the authority to seize the product. NOP's jurisdiction, in contrast, applies to products that are sold, labeled or represented as organic anywhere in the United States but it lacks authority to seize product. FDA's regulations address product qualities such as safety and effectiveness; NOP addresses the process by which a product and its ingredients are produced.⁵

Here are some additional facts about FDA's rules and authority:

- FDA's regulations for cosmetic labeling do not address label claims that the cosmetic is "organic."
- FDA does not perform any premarket approval of labels of cosmetic products or ingredients, with the important exception of [color additives](#). This is an important difference between FDA's method of operations and NOP, under which labels are approved in advance by Accredited Certifying Agents.

⁵ The Federal Trade Commission (FTC) has jurisdiction over "truth in labeling" for claims used in interstate commerce. This is generally enforced by responding to a competitor's complaint.

USDA/NOP's Jurisdiction over the "Organic" Label Claim

The Organic Foods Production Act of 1990 (OFPA) directed USDA to establish an organic certification program for "agricultural products," which includes agricultural products used in food as well as non-food items such as feed and agricultural fibers.⁶

NOP currently allows cosmetic operations meeting the NOP standard, including the National List, for processed food products to be certified and display the USDA Organic seal. However, as mentioned above, a wide array of cosmetic operations are making "organic" claims without claiming to be "organic" under NOP. USDA does not have authority to regulate these operations. As USDA itself has stated, as long as "organic" personal care products do not make any claims that they meet USDA standards, USDA has no authority over these operations. So USDA does not—indeed, cannot—require personal care products making organic claims to be certified. Since FDA does not regulate these organic claims either, the result is that there is no general federal regulation of personal care products with regard to "organic" label claims.

When USDA published the NOP Final Rule in December 2000, it stated clearly, on page 80577 of the Preamble, the "ultimate labeling of cosmetics, body care products, and dietary supplements" was "outside the scope of these regulations." A number of personal care stakeholders believe that this is the appropriate policy approach, arguing that NOP was never intended to address anything other than food, or to extend farther than raw agricultural products for non-food products such as fiber and ornamentals.

However, from the time the NOP Final Rule was implemented in October 2002 until April 2004, NOP allowed soap and other personal care products to be certified. In April 2004, NOP issued a controversial policy statement that would have made these personal care products ineligible for organic certification. This policy was subsequently reversed following a lawsuit against USDA challenging the policy statement; OTA and many other organizations had also protested the policy.

NOP's current statements on the scope of the program related to personal care products are in two documents: an Aug. 23, 2005, memo (see Appendix 3) and an on-line fact sheet on labeling organic personal care products under the NOP rule, "Cosmetics, Body Care Products, and Personal Care Products"

(<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5068442&acct=nopgeninfo>). This fact sheet includes the following explicit policy statements:

- 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.

⁶ 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 or livestock consumption.

- 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.

Prior and Current Efforts to Regulate Organic Labeling of Personal Care Products in the U.S.

California

In 2003, California amended the 1990 California Organic Products Act to establish jurisdiction over personal care products making an organic claim. The amended law requires personal care cosmetic products making a front panel claim to contain at least 70% organic ingredients. However, it permits a 70% organic product to be called "organic" as opposed to "made with."

U.S. Congress

In 2004, U.S. Representative Peter DeFazio (D-OR) drafted federal legislation on organic labeling of personal care products that would have mirrored the California law by allowing a 70% organic personal care product to be called "organic." This draft legislation was never introduced.

In the FY 2010 Agriculture Appropriations Bill, the House and Senate conferees included the following language in their report accompanying the bill:

The conferees direct that the FDA provide to the Committees on Appropriations in the House and Senate; the Committees on Agriculture, Nutrition, and Forestry; and Health, Education, Labor, and Pensions in the Senate; and the Committees on Agriculture, and Energy and Commerce in the House of Representatives any recommendations on the need to establish labeling standards for personal care products for which organic content claims are made, including whether FDA should have pre-market approval authority for personal care product labeling.

NOP Policies

A policy that has generated controversy forms the basis for NOP's current allowance for the certification of soap as "organic."⁷ NOP's policy permits a certified processing operation to combine two or more allowed ingredients in the course of manufacturing a certified organic product, whether or not the resulting intermediate product is synthetic or on the National List. In the case of soap, a certified organic oil (e.g., organic coconut oil) is combined with either

⁷ See Appendix 3B for NOP's draft policy document with regard to the certification and labeling of soap.

Sodium or Potassium Hydroxide, both of which are on the National List as allowed for use in or on organic processed products.

Those who object to this policy in the case of soap point out that the permitted synthetic ingredients, also strong alkalis, constitute a larger percentage of the original ingredients (15%) than the 5% limit of non-organic ingredients in products labeled as “organic.” These substances, they argue, are only intended for use as processing aids⁸, not as major ingredients in organic products. Moreover, soap is a clearly synthetic substance, and is not included on the National List as a synthetic allowed for use in organic processed products. Others argue that, since the alkalis used are no longer present in the final product, this is not relevant, and that in any event such products should still qualify for the “made with organic” label.

A related concern is the inclusion of synthetic organic food additives (such as glycerin, which is on the National List as an allowed synthetic) as organic ingredients on personal care labels could potentially confuse consumers. However, like soap, glycerin is currently being certified as organic under NOP, and is a by-product of soap manufacturing. It is used as an organic ingredient as well as a processing aid in various certified organic food and non-food products. Allowing glycerin to be certified under NOP is similarly considered problematic by those who disagree with allowing soap to use an organic claim. Others point out that the NOP policy is consistent with both the law and the rule, and that the end use of a material cannot be a factor in preventing a certified operation from processing two or more ingredients that are allowed for use in organic products (e.g., organic oils and an allowed synthetic in the case of soap and glycerin).

Another argument is that, while there are synthetic processes that occur in foods, the product produced at that end of the process is food, and is not considered a synthetic food additive. Consumers recognize organic tortillas, for example, as foods processed using methods outlined in OFPA, although they may not know that that masa harina might theoretically be considered synthetic under a strict interpretation of the law.

Masa harina, which is used to make tortillas, is produced by combining organic corn with a strong base (generally Calcium Hydroxide or slaked lime, which is also on the National List). This process, called “nixtamalization,” both loosens the hull and chemically changes the structure of the corn protein to make its vitamin and mineral content more available. Calcium molecules from the slaked lime are incorporated into the corn protein, further enriching its nutritional value. This is clearly not the kind of chemical change that consumers understand as creating a synthetic product, and nobody is suggesting that masa harina should be added to the National List as an allowed synthetic. However, the definition of synthetic given in OFPA and

⁸ Processing Aid: (a) substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form; (b) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and (c) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.

NOP does not tell us what kinds of chemical changes make something synthetic and what kind do not, with the exception of “naturally occurring biological processes.”⁹

A related argument holds that under NOP, the terms “ingredient¹⁰,” “processing aid,” “substance” and “adjuvant” are confused and conflated. This has made it impossible to distinguish appropriately one from the other and to treat them distinctly depending on how they are being used in a specific instance. In the case of soap, the sodium hydroxide is used as an ingredient, not a catalyst or processing aid, but since there is no sodium hydroxide present in the final product, it would not therefore count as an “ingredient” as defined by NOP. Before an organic standard can be applied to organic personal care products, in this view, these distinctions must be clarified.

The problems associated with classifying materials (as synthetic/non-synthetic, agricultural/non-agricultural, etc.) for food ingredients are similar to those for personal care ingredients, and relate directly to the fact that OFPA broadly defines “synthetic” in a way that applies to a host of substances produced through a wide range of processing or manufacturing methods. Some believe that this is at the root of the controversies surrounding organic personal care products. Some private cosmetic standards specifically prohibit synthetic petrochemicals, which many believe is the relevant class of synthetic substances that are not, and should not be, permitted for use in organic production or as ingredients in organic products.

NOSB Discussions

As mentioned previously, NOSB’s Certification, Accreditation & Compliance Committee (CACC) has published a recommendation for consideration at the Board’s November meeting entitled, “Solving the Problem of Mislabeled Organic Personal Care Products.” The recommendation says that the NOP rule should be amended to incorporate personal care products. See Appendix 1C for the text.

Regardless of the merit of this proposal (discussed more fully in the “Policy Approaches” section), there is little likelihood that NOP will act on such a recommendation in the near future due to its regulatory workload. Absent an agreement with FDA, there is also no possibility that NOP could require any personal care or cosmetic product that makes an organic label claim to be certified in compliance with NOP. Products that do comply with NOP may continue to voluntarily seek certification and use the USDA Organic seal if they qualify.

As a related issue, NOSB will also offer a recommendation in November to try to resolve the long-standing problem of inconsistent interpretations of the terms “synthetic,” “nonsynthetic,” “agricultural” and “nonagricultural” with respect to substances being considered for inclusion on the National List.

⁹ Synthetic: A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

¹⁰ Ingredient: Any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.

This recommendation could have a significant impact on the prospects for including personal care products within NOP. For example, an agricultural ingredient that is determined to be synthetic by virtue of its manufacturing process, such as soap, might then be classified as nonagricultural, and therefore not eligible for organic certification. This dilemma is not fully resolved for food products, let alone personal care. If a food product is chemically changed by processes such as cooking, mixing, or “otherwise manufacturing,” it is not currently considered to be synthetic even though the OFPA offers no exemptions for synthetics created under “normal” processing conditions. Even if the NOSB finally approves a recommendation that resolves these issues, it is unclear whether or when the NOP will accept it and revise the regulations and/or its guidance documents accordingly.

Related NOP Non-Food Approaches

Although USDA does not have jurisdiction over the labeling of organic non-food products, there are examples of collaboration between NOP and other agencies that do have jurisdictional authority, specifically in the cases of textiles and alcoholic beverages.

With regard to organic label claims on textile products, NOP has issued guidance that is similar to that now in place for personal care products.

(<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5070818>). However, the Federal Trade Commission (FTC), which has jurisdiction over textile labeling, recognizes the role of NOP in regulating the organic label claim. FTC thus allows the type of fiber listed on textile labels to be modified with “organic,” as long as the fiber used is compliant with NOP. FTC does not, however, regulate the use of “organic” to describe a textile product itself. Fiber products that are processed in compliance with NOP are eligible for certification and use of the USDA Organic seal.

In the case of textiles, there are also two private standards that unify the disparate international standards that previously existed in the organic textile sector: GOTS (Global Organic Textile Standard)¹¹, which addresses processing methods as well as environmental and labor considerations, and OE (Organic Exchange), which addresses traceability of organic fiber content. Both require NOP compliance for any fiber content identified as organic for products marketed in the United States. NOP permits both standards to identify textile products that conform to these requirements, so long as the label claim does not imply that the product is processed in compliance with NOP. This is consistent with how NOP currently treats personal care products.

With regard to regulating the use of organic label claims on alcoholic beverages, which are not considered food products, NOP collaborates with the Alcohol and Tobacco Tax and Trade Bureau (formerly the Bureau of Alcohol, Tobacco and Firearms). A similar Memorandum of Understanding (MOU) with FDA could allow USDA to regulate organic label claims on cosmetics.

¹¹ OTA is a member of the International Working Group and as such not only supports GOTS but has a legal obligation to GOTS.

Government Regulations Outside of the United States

Canada

In the new Canadian organic regulation, the Canada organic seal cannot be used on personal care products. However, for the time being verifiable, third-party, industry-self regulated claims are acceptable under a "truth in advertising" policy. OTA in Canada is working to include personal care products under the Canadian Organic Regime, to be followed by a task force of the standards technical committee to review and propose specific standards for adoption under the national standards.

Europe

The current EU Organic Regulation, EU 889/2008, explicitly excludes cosmetics and personal care products from its scope. There appears to be a consensus in Europe that a different standard is needed for organic personal care products, including a separate list of allowed additives and preservatives that would not apply to food products.

Private Organic and Other “Eco” Standards¹²

In the United States, private organic personal care labeling standards include the recently finalized NSF International standard, which addresses only products labeled as “contains organic ingredients,” and defers to NOP for products labeled as “organic.” The NSF standard originally referred to “made with organic” products, but was changed at NOP’s instruction. The NSF standard is based largely on the draft standard developed by OTA’s previous Personal Care Task Force. More recently, OASIS (Organic and Sustainable Industry Standards) was launched as a trade association designed to represent the concerns and goals of companies that make sustainable and organic products for the health and beauty industry, including an organic personal care standard agreed to by its member companies. See: www.oasisseal.org.

Europe has the widest array of private organic and natural labeling schemes for personal care products, including organic standards promulgated by Ecocert (France), BDIH (Germany), ICEA (Italy), and Soil Association (UK). A working group of seven leading manufacturer associations, certifying bodies and organic consumer groups has formed to develop the COSMOS-standard (www.cosmos-standard.org) as a harmonized European cosmetic standard. A final draft of this standard was issued in May 2009 and is expected to be finalized by the end of the year, with certification to the new standard beginning in the summer of 2010.

NaTrue (www.natrue.org) represents a separate European effort to harmonize natural and organic cosmetic standards, including a three-tiered system for “natural,” “natural with organic ingredients” and “organic” cosmetics. This model has established a partnership with the U.S.-

¹² This information comes from various technical advisors, as well as two articles: “Eco-labels: Environmental Marketing in the Beauty Industry,” published in the August 2009 of the *Global Cosmetic Industry (GCI)* on-line magazine (<http://www.gcimagazine.com/marketstrends/segments/natural/52976687.html?page=1>); and “Cleaning Up Organic Personal Care,” in the September/October 2009 issue of *Organic Processing* magazine (<http://www.organicprocessing-digital.com/organicprocessing/20090910/?folio=34>).

based NSF standard to permit products certified to either one to be recognized by the other as equivalent.

Other “natural” labels (e.g., Natural Products Association standard for “natural” products), Whole Foods Market’s Whole Body™ and Premium Body Care™ standards, as well as eco-labels that address environmental or health issues, such as allergen free, carbon neutral packaging and animal welfare, in addition to the new USDA Biobased label, are all alternatives that play into the problem of consumer confusion about the meaning and value of organic personal care labels.

USDA published a proposed rule on July 31, 2009, with a comment period ending Sept. 29, 2009, entitled “Voluntary Labeling Program for Biobased Products.” Several OTA member companies that make organically labeled personal care products have already filed applications for this program. “Biobased products” are defined in a USDA Fact Sheet as “commercial or industrial products whose main ingredients are renewable plant or animal materials.” The proposed rule addresses two aspects of the program: requirements for manufactured products and a “federally preferred” procurement program for such products. More information about this program can be found at <http://www.biopreferred.gov/files/LabelFactSheet.pdf?SMSESSION=NO>.

Labeling Issues

Significant differences in labeling requirements that exist among the various organic and natural personal care standards are problematic for any progress toward consistency in labels. The cosmetic industry uses a common language to identify cosmetic ingredients through INCI (International Nomenclature of Cosmetic Ingredients), which is a dictionary program owned by the Personal Care Product Council (PCPC), a trade association. An INCI name is an internationally recognized ingredient name that does not need to be translated for different languages, as is required by the EU Cosmetic Regulation. FDA also recognizes the INCI name system.

Percentage calculations of organic content vary based on whether water is counted in the product weight. Under NOP, water and salt are excluded from the total product weight when calculating the percentage of organic content, but Ecocert, for example, counts the liquid volume of flower water (including the added water) as organic, not just the amount of plant extract it contains. Similar problems have arisen in calculating percentage of ingredients in multi-ingredient products under NOP. The problem is multiplied when a formulation containing a plant extract, such as an essential oil, is then used as an ingredient in another product.

Implications for International Trade

The cosmetics industry is highly globalized, both in the sourcing of ingredients and in the marketing of branded products. Harmonization between the EU and United States is particularly crucial, since they represent both the biggest markets and the locations of major manufacturers of cosmetics and personal care products. Ongoing problems with harmonizing current organic

standards between the EU and United States will undoubtedly create additional problems for reciprocity among competing organic personal care standards.

If federally regulated U.S. organic cosmetics standards come under NOP, it will be important to clearly differentiate cosmetic standards from food standards, especially on the National List. One of the most consistent impediments to negotiating international trade agreements is that NOP restricts the use of materials by annotations within the National List. Few, if any, countries take into consideration the limitation(s) of the annotation and generally view the inclusion of a material on the list as a *carte blanche* allowance of the material.

Policy Approaches

Preceding sections of this paper map out the problems to be addressed and offer extensive regulatory and technical information on various aspects of personal care product production. Some information about the current organic personal care product market is also provided.

What follows is a concise analysis of the range of potential policy approaches that could be taken to address the problems discussed previously. In addition to a “no action” or “status quo” option, three alternative approaches outline a combination of steps that would lead to either a regulatory landscape dominated by private standards or standard setting and enforcement under either NOP or FDA. These choices are not necessarily mutually exclusive, and in some cases can be considered short-term versus long-term strategies. In some cases, the choices made in an earlier step will determine the possibilities that follow. The situation is also very fluid, and simply delaying action could open up new possible scenarios. All public regulatory approaches will likely entail several years of development and implementation.

Pros and cons for each of these approaches are summarized in the chart that follows. They are based on input from various technical advisors as well as feedback from OTA Board members, and refer back to the ultimate goal of protecting the value of the organic label, as well as the feasibility of the option in question.

Overview of the Policy Approaches

- 1) “No Action” Approach– No intervention in the status quo.** The current organic personal care market is partly regulated under NOP and the 2003 California Organic Products Act (considered by many to be minimally enforced), partly regulated by various competing and evolving private standards, and partly unregulated. This means personal care products may be marketed as “organic” without having to comply with any standard. Some personal care products that meet NOP standards are NOP certified. Others are certified to private standards. Under one private standard, NSF, products are certified to “contain organic ingredients.” Other private standards allow use of the term “organic.”
- 2) Private Standard Approach – Encourage unification of private standards and public enforcement of mislabeled organic products.** This would require leadership within the private sector to unify disparate but similar standards, as was done with organic textile standards in developing the Global Organic Textile Standard (GOTS), and

reflects the situation of the organic food industry prior to implementation of NOP. This approach would also require the industry to take a stronger self-policing role. In order to avoid the organic mislabeling problem, this approach would also entail public enforcement measures that could include:

- ◆ Pressing for stronger enforcement of the California Organic Products Act (COPA), requiring a minimum of 70% organic content for any front-panel organic claim; and/or
- ◆ Adoption of policy guidance by FDA that it would accept an “organic” claim on personal care product labels, provided that the operation has been certified either under NOP or under a private standard with third-party certification. This is similar to NOP’s current policy on fish and seafood.

3) Public Regulation under USDA/NOP – Advocate that NOP receive authority to regulate organic labeling claims on cosmetics.

This could occur by legislation to amend the Federal Food, Drug, and Cosmetic Act to transfer FDA’s entire authority over organic label claims for cosmetics to USDA. Alternatively, FDA would retain its authority under the Act but would negotiate a Memorandum of Understanding (MOU) with NOP to set standards and provide for NOP certification of personal care products. Then FDA would enforce organic label claims as established by NOP.¹³

Conceivably, USDA/NOP could also attempt to assert jurisdiction on its own, and take action against fraudulently labeled (i.e., non-NOP compliant) personal care products under its own authority. However, it is not clear whether FDA or private parties would object to this unilateral action. The USDA/NOP approach could also entail amending the National List to include personal care products, either in a separate section identifying substances permitted for use only in organically labeled personal care products or through addition of new subsections to 205.605 and 205.606 for that purpose.

Once it receives jurisdiction, there are three possible levels at which the NOP could exercise its regulatory authority:

- ◆ NOP retains its current rules and allows only those personal care products that meet them to make an Organic or “Made With” claim, and allows materials intended for use in personal care products to be petitioned for the National List.
- ◆ NOP amends the National List to include separate sections that identify substances allowed only for organic personal care products. These could include both Organic and “made with organic” claims, or be restricted to only “made with,” using the example of the NSF standard.
- ◆ NOP develops and adopts a new organic personal care standard, incorporating the best of existing private standards.

¹³ This would then operate similarly to the relationship between NOP and the Alcohol and Tobacco Tax and Trade Bureau (TTB) in the Department of the Treasury, which is responsible for enforcing organic label claims on alcoholic beverages.

4) Public Regulation under FDA – Advocate for Congress to direct FDA to regulate organic labeling under its existing authority. This would require FDA to undertake rulemaking to require certification and premarket approval of the labeling of organically labeled cosmetics, which would take considerable time to draft and then implement regulations. This would also entail creation of a new standard by FDA, probably based on existing private standards, to distinguish organic cosmetics from organic food product claims.

We note that none of these approaches precludes an interim measure that calls for more effective enforcement of the California statute requiring a minimum of 70% organic content for any front-panel organic claim on a personal care product, regardless of whether or not the product complies with some private standard or what that standard requires. This would prevent the lowest-level organic content (or even no organic content) from being marketed with an organic claim, which solves the major problem in relation to fraudulent organic claims. Strong enforcement of the California act would also put companies on notice that the marketplace is changing.

Summary of Pros and Cons of the Policy Approaches

POLICY APPROACH	PROS	CONS
<p>1) “No Action” – No intervention in the status quo</p>	<ul style="list-style-type: none"> ◆ Allows broadest definition of the market; no barriers to entry. ◆ Comparable to organic food sector prior to implementation of NOP. ◆ Some public regulation already exists through NOP and California (COPA), which could be more effectively enforced. ◆ Private standards are more flexible and more quickly revised to reflect rapidly changing technology and market. 	<ul style="list-style-type: none"> ◆ Permits escalating consumer confusion and risks loss of confidence in the organic label. ◆ Most personal care products that require synthetics to manufacture could not currently qualify for either NOP Organic or Made With Organic label. ◆ COPA allows organic claim on 70% products, with possible consumer confusion. ◆ Internal conflict: Opposition to NOP regulation of personal care products and lawsuits that inhibit private standard development.

POLICY APPROACH	PROS	CONS
<p>2) Private Standard – Encourage unification of private standards and public enforcement of mislabeled organic products</p>	<ul style="list-style-type: none"> ◆ International organic cosmetics industry is moving towards unification. ◆ Private standards are more flexible and more quickly revised to reflect rapidly changing technology and market. ◆ International cosmetic trade would not be disrupted by equivalency issues. ◆ Similar to successfully implemented Global Organic Textile Standard (GOTS). ◆ Private standards include accreditation requirements that prevent conflict of interest. ◆ Shortest time frame to address the problem, may be first step towards more comprehensive public regulation. 	<ul style="list-style-type: none"> ◆ Weak and inconsistent interpretations are possible. ◆ Organic personal care industry is a long way from unification. ◆ Allows consumer confusion to continue with multiple standards and claims. ◆ Private standards depend on fees from companies using them, leading to conflicts of interest. ◆ COPA allows organic claim on 70% products, with possible consumer confusion.
<p>3) Public Regulation under USDA/NOP – Advocate that NOP receive authority to regulate organic labeling claims on cosmetics</p>	<ul style="list-style-type: none"> ◆ NOP has expertise in organic certification and labeling that FDA lacks. ◆ Some Accredited Certifying Agents (ACAs) already have the expertise to certify organic personal care products (under private standards as well as NOP); NOP could develop additional needed expertise. ◆ National List revisions could clearly distinguish substances allowed for personal care products only, possibly through a separate section. ◆ An additional mechanism can be established to expedite review of new personal care substances petitioned for the National List. ◆ Consumers already recognize the USDA Organic seal and OTA promotes it as the “gold standard.” 	<ul style="list-style-type: none"> ◆ NOP interest in or understanding of cosmetic chemistry, formulation analysis, and labeling is unknown. ◆ Very time consuming for additional rulemaking and adding new substances to the National List. ◆ Adding multiple synthetic personal care ingredients to National List can upset consumers, and create concern for integrity of organic in general. ◆ Could require significant changes to NOP definitions and use of the terms such as synthetic, non-synthetic, agricultural, non-agricultural, ingredient, processing aid and adjuvant. ◆ Could pose equivalency problems and put U.S. manufacturers at a disadvantage to products certified under foreign private standards, or prevent such products from being marketed in the U.S.

POLICY APPROACH	PROS	CONS
<p>4) Public Regulation under FDA – Advocate for Congress to direct FDA to regulate organic labeling under its existing authority</p>	<ul style="list-style-type: none"> ◆ FDA already has regulatory authority over cosmetics, and expertise in cosmetic chemistry and formulation analysis that NOP lacks. 	<ul style="list-style-type: none"> ◆ FDA interest in or understanding of organic certification or labeling is unknown. ◆ Long time frame – Congressional action, standards development and additional rulemaking would be needed. ◆ Consumers already recognize the USDA Organic seal and OTA promotes it as the “gold standard” ◆ Could pose equivalency problems, putting U.S. companies at a disadvantage to products certified under foreign private standards, or prevent such products from being marketed in the U.S.

Concluding Observations and Next Steps

While there is no immediate solution, any of the policy approaches outlined above (with the exception of the “no action” approach) could be used to move the industry toward the goals of achieving consistency in the organic certification and labeling of personal care products and cracking down on unsubstantiated “organic” label claims. The OTA Personal Care White Paper Task Force believes OTA has a valuable role to play in helping the industry determine the best approach. In light of the quickly changing regulatory landscape, lack of thorough information about consumer perceptions, and the level of contention within the industry, the Task Force suggests the following next steps:

- ◆ **Solicit additional input from OTA members and other industry stakeholders.**

Ask OTA members in both the food and personal care sectors to read and comment on this White Paper. OTA should also continue conversations with the Personal Care Products Council (PCPC), the trade association for the cosmetics industry, as well as with other organizations in the organic community who are active in the regulatory and legislative realm. It would also be helpful to clarify where the regulatory agencies themselves—USDA/NOP and FDA—stand.

- ◆ **Further explore consumer beliefs and knowledge about organic personal care products.** There are various perspectives held by OTA members about the degree and genesis of the “threat” to consumer trust in the organic label posed by the current “status quo” of personal care regulations and labels. In addition to conversations with consumer organizations, OTA might consider supporting additional consumer research. Is consumers’ trust in organic food labels and the USDA Organic label being affected by the status quo?

To what extent do consumers accept and trust a certified to private standards organic label?
To what extent would consumers accept and trust a FDA-backed organic label?

- ◆ **Monitor and engage as appropriate with FDA and its oversight committees.** As discussed previously, the Agriculture Appropriations Bill report language directs FDA to make recommendations on the need to establish labeling standards for organic personal care products.
- ◆ **Examine how the California law is currently enforced and whether there is an opportunity to support or encourage stronger enforcement.**
- ◆ **Further investigate the effects of various regulatory approaches on international trade.**
- ◆ **Continue exploring the implications of including personal care substances on the National List.**
- ◆ **Educate retailers about the issues.** Retailers could exercise their purchasing power to help crack down on products that are making unsubstantiated “organic” label claims.
- ◆ **Develop talking points to help OTA communicate with its members and the public about these issues in a clear and consistent way.** This would be necessary if OTA were to adopt any of the approaches discussed, but, in the short term, should emphasize the importance of third-party certification for organic claims and communicate the distinctions between different standards as well as the distinctions between “organic” on personal care labels versus food labels.

APPENDICES

APPENDIX ONE: National Organic Standards Board Activity

- A) March 13, 2009, NOSB CACC discussion document: “Solving the Problem of Mislabeled Organic Cosmetics & Personal Care Products”
- B) OTA’s May 3, 2009, Comment on NOSB’s March 13, 2009, document: “Personal Body Care Standards Discussion”
- C) August 30, 2009, NOSB CACC recommendation, “Solving the Problem of Mislabeled Organic Personal Care Products”

APPENDIX TWO: September 2009 OTA Personal Care Member Survey Results

- A) OTA Personal Care Manufacturers Survey Results
- B) OTA Ingredients Suppliers Survey Results
- C) OTA Certifiers Survey Results

APPENDIX THREE: National Organic Program Activity

- A) August 2, 2005, memo on the scope of the National Organic Program: “Certification of agricultural products that meet NOP standards”
- B) July 24, 2009, NOP draft policy on the Certification and Labeling of Soap Products Made From Agricultural Ingredients

APPENDIX FOUR: Task Force Participants

- A) List of Personal Care White Paper Task Force members
- B) List of Task Force Technical Advisors

APPENDIX ONE: National Organic Standards Board Activity

A) March 13, 2009, NOSB document,

“Solving the Problem of Mislabeled Organic Cosmetics & Personal Care Products” (3 pages)

B) OTA’s May 3, 2009, Comment on NOSB’s March 13, 2009, document

“Personal Body Care Standards Discussion” (2 pages)

C) August 30, 2009, NOSB recommendation,

“Solving the Problem of Mislabeled Organic Personal Care Products” (6 pages)

A) March 13, 2009, NOSB document

Certification, Accreditation, and Compliance Committee
USDA National Organic Standards Board

Discussion Document
March 13, 2009

Solving the Problem of Mislabeled Organic Cosmetics & Personal Care Products

Purpose

The Certification, Accreditation, and Compliance Committee (CACC) recommends that organic cosmetics/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. The purpose of this document is to present the topic for public discussion and comment and then to incorporate feedback into a CACC Recommendation for the NOSB Public Meeting in Fall 2009.

Background

The statement of the USDA on August 23, 2005 extended the USDA regulations to cover the organic claims made by cosmetic/ 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 cosmetic/ personal care products making organic claims continues to flow in to the market place. Please see the Appendix at the end of this document for a detailed text of the National Organic Program's current stance on the certification of cosmetics, body care products, and personal care products.

The Problem of Mislabeled Cosmetics and Personal Care Products

Consumers are not assured that organic claims are consistently reviewed and applied to this product class. Manufacturers of cosmetics/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. The USDA is responsible for the product organic claims but is not currently enforcing this in the area of personal care products

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

This recommendation takes the initial steps toward:

- 1) assuring consumers that the federal government is policing these claims
- 2) allowing for the development of a complete federal organic cosmetic program

For the sake of clarity, the recommendation language below will use the term "cosmetics" rather than "personal care products." The phrase "personal care products" does not have a federally recognized definition whereas "cosmetics" is already defined by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321i.

Recommendation

To facilitate the development of a single national standard for this product class, and to ensure consumers that organic cosmetic 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 Cosmetic:

(1) 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, and (2) an article, other than soap, intended for use as a component or ingredient of any such articles (Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321i).

2. §205.100(a) Add words “including cosmetics”

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 including cosmetics 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

3. §205.102 Use of the term “organic.”

Any agricultural product, including cosmetics, 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 cosmetics, described in paragraphs * * *

Appendix: The following information is currently 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

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.
 - ❑ “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.

*CACC motion to present this document at the May 2009 meeting of the NOSB approved on March 23, 2009
Motion: Tracy Miedema 2nd: Julie Weisman Votes: Yes 5, No 0, Absent 1, Abstain 0*

B) OTA's May 3, 2009, Comment on NOSB's March 13, 2009, document

PERSONAL BODY CARE STANDARDS DISCUSSION

OTA thanks NOSB for taking a helpful first step towards integration of Personal Care manufacturing into the NOP, and wishes the Board the best of luck in resolving the issues that have proved so difficult for so long. We hope that NOSB realizes that the term "cosmetics," as regulated under the Food Drugs, and Cosmetic Act, does not include soaps, and that is the reason OTA has preferred the term "personal care," which includes soaps. OTA stands ready to assist NOSB in any way we can.

Due to the widely diverging opinions about many of the issues related to organic personal care products, OTA recommends forming a Task Force to address the questions we have identified here, along with any other issues that may arise in the course of this endeavor. Before considering a recommendation for a rule change, we therefore urge the NOSB to charge a Task Force with making recommendations about the following issues and questions related to inclusion of cosmetics and personal care products within the NOP:

- The NOSB's discussions and recommendations around clarification of definitions of "agricultural," "nonagricultural," "synthetic," and "nonsynthetic" may have a major impact on whether certain ingredients in personal care products can be acceptable under the NOP. For example, should a product such as soap, which may have been derived from an organic agricultural substance, be labeled as "organic" or "made with organic" under the NOP if it meets the definition of synthetic?
- What are acceptable processing methods for organic personal care products? The potential breadth of organic personal care product lines seems to be a matter of contention, with OTA members divided on how many commercially viable products can be made under the current rule compared with other scenarios or standards. OTA supports the current NOP policy of allowing certified handling operations to process allowed substances in order to produce an organic product (e.g., in the production of sodium lactate). On this basis, the phrase "otherwise manufacturing," as used in the definition of "processing," might enable a broad enough line of product to meet both manufacturer and consumer expectations.
- Another item that needs further discussion is the calculation of the percentage of organic content in personal care products, for which soap provides an excellent example. OTA notes that there are many fine organic soaps produced by several OTA members, so that this question already has been answered for practical purposes, but suggest that the NOSB at least consider, and if possible affirm, the decisions now being made by certifiers.
- Could cosmetic ingredients produced through processes such as hydrogenation, which may not be suitable for foods, be annotated to specify the allowable processes? It is not

clear whether Section 205.605 can and should cover any and all materials or processing aids for cosmetics, similar to the treatment of pet foods. The possible wording of annotations is a related question, as some 205.605 materials are used for personal care products, and materials may be petitioned for use in organic handling without including an annotation specifying a particular product or type of product for which they would be permitted. Since NOSB has recommended that Section 205.606 include separate sections for human food and pet food, a similar division might be considered for personal care products. OTA further urges that a Task Force identify materials for possible petition to the National List, as was done in the pet food recommendation. While we recognize that proposing large numbers of synthetic substances for use in personal care products might cause some concern among consumers, some new synthetic substances might be needed for this sector. We hope that the NOSB will explore this subject in detail.

- If the regulation is amended to refer to cosmetics, why not include herbal and nutritional supplements, textiles, and other non-food agricultural products?
- Would it be adequate for the NOP to simply revise its policy statement on Cosmetics, Body Care Products, and Personal Care Products of April, 2008 to state that “Personal care products that are labeled as ‘100 percent organic,’ ‘organic’ or ‘made with organic’ must be compliant with the NOP”?
- Because cosmetics and personal care products are not generally refrigerated and may not be used for months after they are manufactured, use of substances specifically as preservatives is often advisable. The Task Force might revisit NOSB’s processing criteria and make a recommendation concerning an allowance for relatively benign personal care ingredients that are used primarily as preservatives.
- How would NOP enforce its label on products that are not within its jurisdiction, absent a formal agreement with FDA? How would sanctions be imposed on noncompliant cosmetic manufacturers or brand names that include the word “organic”? We again offer our support for the NOP to negotiate an MOU with FDA to address organically labeled cosmetic and personal care products as expeditiously as possible.
- What would be the impact of inclusion of cosmetics under the NOP on voluntary organic cosmetic standards? OTA suggests that NOSB request public comment on the current amount and kinds of organic personal care sales (such as products with ingredients certified to non-NOP standards) in order to begin examining the potential effects of regulation on the current market. Related to this is the question of a proposed timeline for implementation.

C) August 30, 2009, NOSB recommendation

**National Organic Standards Board
Certification, Accreditation, and Compliance Committee**

Recommendation

Solving the Problem of Mislabeled Organic Personal Care Products

August 30, 2009

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:

- 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

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) 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

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 including personal care 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

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 * * *

COMMITTEE VOTE:

CACC motions to accept recommendation and to bring to the NOSB for consideration at November 2009 Meeting

Moved: Tracy Miedema **Second:** Joe Smillie

Yes: 6 No: 0 Abstain: 0 Absent: 0

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.
 - ❑ “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

APPENDIX TWO: OTA Member Survey Results

A) OTA Personal Care Manufacturers Survey Results

B) OTA Ingredients Suppliers Survey Results

C) OTA Certifiers Survey Results

A) OTA Personal Care Manufacturers Survey Results

1. In what product categories do you compete? Check "Yes" for all that apply and, wherever you can, please indicate whether the product is anhydrous, emulsified or reacted, or water-based.				
Product	Yes	Anhydrous	Emulsified or Reacted	Water-based
Soap				
-Bar	17	2	10	4
-Liquid	16	2	6	11
-Formulated	11	2	6	6
Other:				
Hair Care				
-Shampoo	13	0	5	7
-Conditioner	11	0	5	6
-Styling products	9	1	4	5
-Hair color products	4	0	0	1
Other:	Hair masque treatment-anhydrous			
Face				
-Lotions and creams	17	2	8	7
-Cleansers/ exfoliants	18	2	10	11
-Toners and astringents	11	1	1	7
-Shaving creams, lotions, aftershave	12	2	3	5
- Masks	11	5	3	2
-Foundation/ powder	3	2	1	1
Other:				
Body				
-Lotions and creams	21	2	10	9
-Body wash, bath gel and bubble bath	18	2	5	11
-Sun protection/ tanning lotions	6	2	2	2
-Body and massage oils	20	10	2	5
-Deodorants	10	1	1	5
Other:	Bath herbs-anhydrous; baby powder-anhydrous; sugar scrub-anhydrous; bath salt-anhydrous; diaper balm-anhydrous			
Mouth				
-Toothpastes and powders	3	0	1	2
- Mouthwash	3	0	0	3
-Lip balm	13	8	2	1

Other:				
Other				
-Essential oils	10	5	0	0
-Fragrances/ perfumes	7	5	0	1
-Insect repellants	6	0	2	3
-Ointments/gels/ salves/ antiseptics	5	2	1	1
-Lubricants	2	1	1	1
-Nail polish	1	0	0	0
-Eye	6	2	2	4
Other:	Nail and hair oil products (anhydrous); Hair tonic (anhydrous); Blush, lip colors, deodorant, after sun, Aloe, baby products, Man's lines- scrubs, after shave lotion, after shave balms, scalp toning products, spa massage products, bath salts, body scrubs (salt and sugar), foot massage products, sport rubs, pet products, home cleaners; wet wipes (water-based)			

2. What is the approximate percent of your product sales by country? (total to 100%, please enter whole numbers, no decimal places or % signs)

Answer Options	Response Average	
a. % United States	83	
b. % Canada	13	
c. % Mexico	5	
d. % Other	19	
<i>answered question</i>		24
<i>skipped question</i>		7

If you select Other, please list the countries here:

1. england, itally. korea, taiwan
2. japan, korea, uk, denmark, australia, india
3. Panama
4. EU, New Zealand, Australia, Middle East, India.
5. BVI
6. Japan, England, Germany, Holland, Russia, China, Korea, Australia, Many others
7. Japan, Hong Kong, Taiwan, Singapore
8. UK
9. Japan (10%), UK, Germany, Austrailia, Korea, Taiwan, Singapore
10. Australia, New Zealand, Japan, Singapore, UK.
11. rest of the world
12. Europe

3. What were the total U.S. gross sales (from shipments) of your products in the 12 months ending July 2009?

Answer Options	Response Percent	Response Count
\$ 0	4.5%	1
\$ 1- \$100,000	31.8%	7
\$ 100,001 - \$999,999	22.7%	5
\$ 1- 5 million	9.1%	2
\$ 5 – 15 million	9.1%	2
\$ 15 – 50 million	18.2%	4
\$ 50 – 100 million	0.0%	0
Over \$100 million	4.5%	1
<i>answered question</i>		22
<i>skipped question</i>		9

4. What percent of your total U.S. gross sales is from products that are (total to equal 100%, please enter whole numbers, no decimal places or % signs)

Answer Options	Response Average	Response Count >0
% certified "organic" to the NOP?	30.87	12
% certified "made with" to the NOP?	34.09	8
% certified to a private standard?	46.11	6
% not certified at all?	81.93	14
<i>answered question</i>		24
<i>skipped question</i>		7

If your products are certified to a private standard, which private standard(s)?

1. NaTrue
2. BDIH, NPA, NaTrue, others
3. Australian Certified Organic (ACO)
4. Soil Association/ IMO
5. We are just beginning to formulate products for the NOP standard.

5. How many brands do you own?

Total	62
Range	0 - 21
Mean	3
Median	1
<i>response count</i>	
	21

6. How many of your brands use the word "organic" in their name?

Total	13
Range	1 - 3
Mean	2
Median	2
<i>response count >0</i>	
	8

7. What is your total number of SKUs sold?

Total	2612
Range	10 – 1350
Mean	137
Median	60
<i>response count >0</i>	
	19

8. How many of your SKUs are:

Answer Options	Response Count >0
certified "organic" to the NOP?	10
certified "made with" to the NOP?	7
certified to a private standard?	5
not certified at all?	9
compliant with the California Organic Products Act (COPA)?	6

If your SKUs are certified to a private standard, which private standard(s)?

1. Content Verified & OASIS
2. NaTrue
3. BDIH, NPA, NaTrue
4. ACO
5. soil association / IMO / ecocert

Of the non-certified SKUs, how many are NOP compliant?

Total	205
Range	20 - 100
Mean	51
Median	43
<i>response count >0</i>	
	4

If they are NOP compliant, why are they not certified?

1. time and money and it does not sell more the fact that it is certified organic
2. not sure how many skus NOP compliant. We are manufactured outside the U.S. so we don't have information on USDA certified ingredient conten.
3. I am the only full-time employee and we are still tiny. I haven't been able to set aside the time to get the certification yet. Most of our sales are from soaps and until recently, I was under the impression that soap could not be certified.
4. We (in America) just need to just MAKE A DECISION. Manufacturers are totally frustrated with the political nature of these certification arguments. Money wasted on multiple standards is simply that - a waste of money. The view that the NOP is the only standard that counts is simply not true. Ask anybody that resides outside the USA.
5. Because I am brand new, very small, and I purchase from NOP compliant distributors and do not grow the ingredients I use.
6. not deemed as necessary as already certified to a European organic standard by certifier which is NOP accredited. NOP means nothing outside of the USA

9. Do you self-manufacture your product?

Answer Options	Response Percent	Response Count
Yes	86.4%	19
No	13.6%	3
answered question		22
skipped question		9

10. Do you use private label labs/contract manufacturers?

Answer Options	Response Percent	Response Count
Yes	31.8%	7
No	68.2%	15
answered question		22
skipped question		9

If yes, is your private label lab certified?

Answer Options	Response Percent	Response Count
Yes	80.0%	8
No	20.0%	2
answered question		10
skipped question		21

If yes, to what standard?

- 1. NOP, OASIS
- 2. We are distributors, so all products manufactured in Germany.
- 3. California State
- 4. NOP
- 5. ACO
- 6. soil association / IMO
- 7. Ecocert
- 8. USDA NOP

11. Are any of your products "eco-labeled" (certified or not)?

Answer Options	Response Percent	Response Count
Yes	36.8%	7
No	63.2%	12
If yes, which eco label(s):		8
<i>answered question</i>		19
<i>skipped question</i>		12

If yes, which eco label(s):

- 1. green e certified
- 2. 100% PCW Matte Paper — Permanent. A white paper label made from 100% post consumer waste.
- 3. We don't use any seals, but we do state our environmentally-friendly manufacturing practices and materials on our labels.
- 4. eco-friendly? Yes. eco-Lotions, balms, Shea Butters
- 5. What is eco-label?
- 6. EPD and Nordic Ecolabel
- 7. Ecocert
- 8. EcoLogo

B) OTA Personal Care Ingredients Suppliers Survey Results

1. Approximately what percent of your business is in the trade of ingredients for use in personal care?		
range		1 - 100%
mean		37%
median		20%
<i>response count >0</i>		15

2. What is the approximate sale mix by country of the ingredients you sell for use in organic/made with organic/contains organic personal care products?		
Answer Options	Response Average	
a. % United States	72	
b. % Canada	27	
c. % Mexico	0	
d. % Other	23	
<i>answered question</i>		15
<i>skipped question</i>		3

If you select Other, please list the countries here:

1. Japan, South Korea, Malaysia, China, and others.
2. Japan, Australia, NZ
3. Hong Kong, Korea, UK,
4. Mainland Europe / Australia / Japan / Korea / S. Africa / Sweden
5. Europe-Germany, Holland
6. UK, France and Germany

3. What were the total U.S. gross sales (from shipments) of the ingredients you sell for use in organic/made with organic/contains organic personal care products in the 12 months ending July 2009?		
Answer Options	Response Percent	Response Count
\$ 0	13%	2
\$ 1- \$100,000	33%	5
\$ 100,001 - \$999,999	47%	7
\$ 1- 5 million	7%	1
\$ 5 – 15 million	0.0%	0
\$ 15 – 50 million	0.0%	0
\$ 50 – 100 million	0.0%	0
Over \$100 million	0.0%	0
<i>answered question</i>		15
<i>skipped question</i>		3

4. If you sell ingredients that are certified "organic" to the NOP. . .				
Answer Options	Range	Mean	Median	Total
a. How many?	1 - 160	35	5	457
b. What percent of your total U.S. gross sales is from these ingredients?	.5 - 100	46	30	
Response count >0				13
c. List examples of these ingredients:				
1. Sugars, Oils, Butters, Emulsifiers				
2. organic jojoba. (our only product) 100% organic				
3. Oils, Sugars, Cocobutter, Shea Butter, Essential oils.				
4. hydrosols, essential oils				
5. ORGANIC ESSENTIAL OIL BLENDS				
6. rolled oats, rolled spelt				
7. Essential Oils, Butters				
8. agave syrup, evaporated cane juice, tapioca syrup				
9. corn starch, oils, flavors				
10. carnauba wax, palmfruit stearin, ev coconut oil, palmfruit oil				
11. glycerin, ethyl palmate, flavors for lip				
12. organic glycerin				
13. hemp seed oil				

5. If you sell ingredients that are certified "made with" to the NOP. . .				
Answer Options	Range	Mean	Median	Total
a. How many?	1 - 20	10	10	21
b. What percent of your total U.S. gross sales is from these ingredients?	<1 - 20	<10	<10	
Response count >0				2
c. List examples of these ingredients:				
1. potassium cocoate				
2. infused oils, value added herbal products				

6. If you sell ingredients that are certified to a private standard. . .				
Answer Options	Range	Mean	Median	Total
a. How many?				
b. What percent of your total U.S. gross sales is from these ingredients?				
c. List examples of these ingredients:				
Response count >0				0

7. If you sell ingredients that are not certified at all but are allowed for use in NOP certified products. . .

Answer Options	Range	Mean	Median	Total
a. How many?	1 – 2.5	1.75	1.75	3.5
b. What percent of your total U.S. gross sales is from these ingredients?	0 – 10	5	5	
Response count >2				
c. List examples of these ingredients:				
1. Non-GMO Tocopherol				

8. Do you contract directly with growers?

Answer Options	Response Percent	Response Count
Yes	79%	11
No	22%	3
answered question		14
skipped question		4

9. Approximately what percent of the ingredients you sell for use in organic/made with organic/contains organic personal care products are

Answer Options	Response Average	
a. % Grown in the United States	57	
b. % Grown in Canada	21	
c. % Grown in Mexico	15	
d. % Grown elsewhere	73	
e. % Non-agricultural	0	
answered question		13
skipped question		5

If you selected "Grown elsewhere", please list the countries here:

1. Various European & African
2. Israel
3. Philippines, Malaysia, India, China, Spain, South America
4. India, China
5. Ghana / S.Africa / Nepal / India / Papua New Guinea / Albania / France / Spain
6. paraguay
7. Brazil, Peru, Philippines,
8. brazil
9. Colombia, Brazil

10. Are any of your ingredients "eco-labeled" (certified or not)?

Answer Options	Response Percent	Response Count
Yes	20.0%	3
No	80.0%	12
If yes, which eco label(s):		2
<i>answered question</i>		15
<i>skipped question</i>		3
If yes, which eco label(s):		
1. Fair Trade		
2. TransFair and IBD EcoSocial		

C) OTA Personal Care Certifiers Survey Results

1. Do you currently certify personal care products?		
Answer Options	Response Percent	Response Count
Yes	100%	9
No	0.0%	0
If No, why not?		0
answered question		9
skipped question		1

2. To what standard(s) are you currently certifying personal care products?		
Answer Options	Response Percent	Response Count
NOP	78%	7
Other	22%	2
answered question		9
skipped question		1
If you selected other (please specify)		
1. Fair Trade Certified		
2. Ecocert standard		

3. How many manufacturers of organic personal care products do you certify?		
Answer Options	Response Percent	Response Count
1-10	67%	6
11-20	11%	1
21-30	11%	1
Over 30	11%	1
answered question		9
skipped question		1

4. What are the products that you are currently certifying?

Product	Yes
Soap	
-Bar	4
-Liquid	3
-Formulated	3
Other (please specify)	
Hair Care	
-Shampoo	3
-Conditioner	2
-Styling products	0
-Hair color products	0
Other (please specify)	
Facial Care	
-Lotions and creams	6
-Cleansers/exfoliants	5
-Toners and astringents	1
-Shaving creams, lotions, aftershave	2
-Masks	2
-Foundation/powder	2
Other (please specify):	lip stick, lip balm, lip gloss
Body Care	
-Lotions and creams	5
-Body wash, bath gel and bubble bath	3
-Sun protection/tanning lotions	1
-Body and massage oils	3
-Deodorants	2
Other (please specify):	Sun protection only with minerals
Mouth Care	
-Toothpastes and powders	1
-Mouthwash	1
-Lip balm	6
Other (please specify)	
Other Personal Care	
-Essential oils	5
-Fragrances/perfumes	1
-Insect repellants	0
-Ointments/gels/salves/antiseptics	2
-Lubricants	1
-Nail polish	0
-Eye	2
Other (please specify):	Oils: jojoba, olive, etc.; Mineral make up for eyes

APPENDIX THREE: National Organic Program Activity

**A) August, 2, 2005 Memo on the Scope of the Program
“Certification of agricultural products that meet NOP standards”**

**B) July 24, 2009 NOP draft policy on the
certification and labeling of soap products made from agricultural ingredients**

A) Memo on the Scope of the Program

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.

B) DRAFT Policy on the Certification and Labeling of Soap Products Made From Agricultural Ingredients

July 24, 2009

This draft procedure is being posted for public input for 30 days prior to final review and implementation by the National Organic Program (NOP). Interested parties are encouraged to provide substantive comments to the NOP by August 24, 2009. Comments will be considered and final procedures posted for use on the NOP website. Please submit written comments to the attention of Mark Bradley, National Organic Program, 1400 Independence Avenue, SW; Room 4004-South, STOP 0268, Washington, DC 20250; or by fax to (202) 205-7808.

DRAFT FOR COMMENT ONLY: Certification and Labeling of Soap Products Made From Agricultural Ingredients

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.

Approval

[PENDING FINAL REVIEW]

Barbara C. Robinson
Acting Director
National Organic Program

APPENDIX FOUR: Task Force Participants

A) List of Personal Care White Paper Task Force members

B) List of Task Force Technical Advisors

A) List of Personal Care White Paper Task Force members

Task Force Co-Chairs

Sarah Bird, Annie's, Inc.
Laura Stravino, Organic Trade Association

Task Force Members

Bob Anderson, Sustainable Strategies - Advisors in Food & Agriculture
Jody Villeco, Whole Foods Market
Marty Mesh, Florida Organic Growers (FOG)
Phil Margolis, Neshaminy Valley Natural Foods Distributor, Ltd.
Richard D. Siegel, Dick Siegel Law Offices

Additional Support

Tom Hutcheson, Organic Trade Association
Grace Gershuny, GAIA Services

B) List of Task Force Advisors

The task force relied heavily on technical advisors, including but not limited to those with a proficient knowledge of the world of cosmetics and other personal care products, including regulatory oversight, market and consumer issues, and the current landscape of the various “organic” personal care standards.

John Ashby, California Natural Products	Sheila Linderman, Sheila Linderman Consulting
David Bronner, Dr. Bronner's Magic	Katherine Martin, Aveda Corporation
Alice Brooks, Hain Celestial Group	Tracy Miedema, Stahlbush Island Farms, Inc.
Peter Boncelet, Earth Supplied Products, LLC	Tony Moore, Flavor Producers, Inc.
Ma Cherry, Ayuroma	Mary C. Mulry, FoodWise, Inc.
James Hahn, Terressentials	Herbert Stein, Natural Flavors, Inc.
Jessica Iclisoy, California Baby	Gay Timmons, Oh, Oh Organic, Inc.
Bea James, Lunds & Byerly	Curt Valva, Aubrey Organics, Inc.
Shahin Kalantari, d'Avicenna, Inc.	Luke Vukmer, ORGANIC GROOMING, LLC
Tim Kapsner, Aveda Corporation	Sam Welsch, OneCert, Inc.