



August 22, 2008

Carrie Gregory
Personal Care Products Council (formerly CTFA)
gregoryc@personalcarecouncil.org

RE: Public Review Comment
Proposed draft for NSF 305 – *Organic personal care products* (305i1r6)

Dear Ms. Gregory:

Thank you for your ballot and comment on NSF 305 – *Organic Personal Care Products*, issue 1. Below are your statements (*in italics*) and the responses of Task Group Chairs (**in bold**):

Comment#177

The Personal Care Products Council (the “Council”) (formerly the Cosmetic, Toiletry, and Fragrance Association) is providing these comments in response to the NSF Draft Standard 305: Organic Personal Care Products (“Draft” or “Draft Standard”).

Based in Washington, D.C., the Council is the leading national trade association representing the \$250 billion global cosmetic and personal care products industry. Founded in 1894, the Council's more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the U.S. As the makers of a diverse range of products that millions of consumers rely on everyday, from sunscreens, toothpaste and shampoo to moisturizer, lipstick and fragrance, personal care products companies are global leaders committed to product safety, quality and innovation. The Council represents the vast majority of stakeholders that would be affected by NSF's Draft Standard once adopted by the American National Standard (“ANS”). Thus, we urge NSF to seriously consider the comments contained herein.

Issues with the Draft NSF Standard for Organic Personal Care Products

The Council finds that the Draft Standard is substantially flawed and far from ready to advance to ANS at this time. We urge NSF to continue development of the Draft and allow for more opportunities for public comment prior to advancing the standard to ANS. While not an exhaustive list, we find examples of deficiencies in four major areas:

- 1. Draft Standard includes provisions that are in conflict with federal law.*
- 2. Draft Standard Annexes contain issues of concerns.*
- 3. The Draft Standard references sources that are not authoritative.*
- 4. Draft Standard contains confusing inconsistent information.*

1. Draft Standard includes provisions that are in conflict with federal law. The Draft Standard is not consistent with current federal law. NSF appears to recast a number of terms in a way that conflicts with longstanding statutory and regulatory standards.

a. Over-the-counter

In the Draft Standard, NSF defined “over-the-counter” as: “(Of drugs and non-drugs) Sellable without a prescription and without a visit to a medical professional.” This definition is in direct conflict with FDCA in that there is no legally recognized non-drug OTC.

The term “over-the-counter” is not used in the document. Therefore, the term “over-the-counter” has been deleted.

b. Order of ingredients

The Draft Standard's order of ingredient listing is not consistent with federal law and may be confusing or potentially misleading. In the Draft, NSF states:

Ingredients at a concentration of more than 1% shall be listed on the label in descending order of predominance, in their concentration by weight. Ingredients that are present at a concentration of 1% or less shall be listed in any order after the ingredients present at a concentration of more than 1% or as required by federal regulation.

This ingredient listing conflicts with FDA regulation and mandated by the Fair Package Labeling Act. Legally, a cosmetic product's order of ingredients may appear in one of three ways. The Draft Standard's ordering scheme is inconsistent with federal law and, if followed, may cause a product's label to be misleading.

The following modification has been made to 7.7.1 – Order of ingredients:

7.7.1 Order of ingredients

Order of ingredients shall be labeled according to federal regulation in the jurisdiction where the product shall be sold.

c. Ingredient Labeling

In the Draft Standard, NSF outlines ingredient labeling practices that augment current regulatory and INCI standards. NSF lacks authority to revise regulation or INCI nomenclature. In Section 7.7 of the Draft, NSF states:

Each organic personal care product shall list the ingredients on its label using the International Nomenclature for Cosmetic Ingredients (INCI) labeling system as found in the most recent edition of the International Cosmetic Ingredient (ICI) Dictionary and Handbook as applicable. The list of ingredients shall appear on the outer label of the personal care product. Extra descriptive or marketing terminology, unless specified in 7, shall not be deemed acceptable in the ingredient list.

Emphasis added. The wording in the Standard “unless specified in 7” indicates that there are exceptions to FDA labeling regulations.

Also, in Section 7.5.2 of the Draft Standard, NSF states:

products in packages described in 7 CFR 205.301(c) shall: – In the ingredient statement, identify each organic ingredient with the word “organic” or with an asterisk or other reference mark that is defined below the ingredient statement to indicate that the ingredient is organically produced.

NSF has no authority to make such changes to INCI nomenclature or federal regulation.

The standard will allow for qualifying ingredients as “organic” or using an asterisk. This information is necessary in order to inform the consumer which ingredients are organically produced.

2. Draft Standard Annexes contain issues of concerns.

The Draft Standard includes information on GMPs. This is well beyond the scope of this document, is of limited utility, and appears to be written for food handling. If a standard is to reference GMP, a much more thorough treatment would be needed and should be consistent with existing international standards (i.e., ISO 22716:2007).

The term ‘GMP’ is not used in the body of the document but is included in an informational annex. GMP has been deleted.

3. Draft Standard use of Annexes is inappropriate.

In the Draft Standard, some of the information contained in the Annexes appears to be an integral part of the meaning of the standard itself. In footnote format, NSF states:

The information contained in this Annex is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. As such, this Annex may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

NSF cannot exclude the annexes or separate them from the standards development process as they appear to contain information necessary for conformance to the Draft Standard. In addition, alkaline, alkylation, audit, batch, biodegradable, catalyst, and many other terms are defined within the Draft Standard, but never used within the document; and the definitions are not necessarily the same in the Draft Standard and the annexes.

Your comment has been reviewed and the annexes are compliant with ANSI requirements. The annexes are provided to the user of the Standard as guidance and do not contain requirements to meet the Standard.

The following terms are being deleted from the 3 – Definitions: alkaline, allowed synthetic, nonagricultural substance, over-the-counter, non-agricultural water, plant water, and tap water.

The following definitions are being moved to the appropriate annexes: alkylation, audit, biodegradable, company, contamination, ethoxylation, Good Manufacturing Practices (GMP), inspector, inspection, products, production location, records, and steam fractionation.

4. The Draft Standard references sources that are not authoritative.

The Draft Standard references sources that are not authoritative. For example, NSF's reference to EWG reports is not appropriate. To the extent that data or opinions are referenced, the source of the data or the opinions should be by a recognized, authoritative body. Environmental Working Group ("EWG") is not an authoritative body; but rather a nonprofit organization that synthesizes data from primary references in a way that is not necessarily consistent with the conclusions of authoritative bodies, such as the Cosmetic Ingredient Review or Europe's Scientific Committee for Cosmetic Products.

Annex E has been modified to remove all references to EWG, Soil Association, etc and the Safe Campaign.

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5. Draft Standard contains confusing inconsistent information.

Providing accurate and consistent information is critical to the development and use of a meaningful standard. We found a number of deficiencies throughout the Draft Standard including confusing definitions and inconsistent use of terms.

a. Personal Care Product and Cosmetics

The Draft Standard uses the terms "cosmetics" and "personal care products" interchangeably. Specifically, NSF states, "[t]his Standard does not differentiate between requirements for personal care products and requirements for cosmetics. Therefore, for the purposes of this Standard, cosmetics are considered personal care products." However, each term has a different meaning and it is not appropriate to treat them synonymously.

The following are NSF's definitions for "cosmetics" and "personal care products":

· "Personal care product: A non-medicinal consumable product that is intended to be used in the topical care and grooming of the body and hair and that is rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to a body, human or animal, for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions. Personal care products are specifically for use in such activities as cleansing, toning, moisturizing, hydrating,

exfoliating, conditioning, anointing, massaging, coloring/decorating, soothing, deodorizing, perfuming, and styling.”

· *Cosmetic: (1) an article intended to be rubbed, 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 of any such articles.*

Furthermore, NSF’s definition for “personal care product” appears internally flawed. For example, the term is defined as a product “...intended to be used in the topical care and grooming...” but then states it can be “... introduced into... a human or animal...” *Emphasis added.*

The following modification has been made to the definition for “personal care products”:

3.45 personal care product: A Non-medicinal consumable cosmetic products (as defined in 3.16) and soap products (as defined in 3.59) that is intended to be used in the topical care and grooming of the body and hair and that is rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to a body, human or animal, for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions. Personal care products are specifically for use in such activities as cleansing, toning, moisturizing, hydrating, exfoliating, conditioning, anointing, massaging, coloring/decorating, soothing, deodorizing, perfuming, and styling.

b. Section 1.2 Scope

The scope of the Draft Standard (as defined by NSF) renders the standard confusing and its application unclear. The Federal Food, Drug, and Cosmetic Act (“FFDCA”) defines cosmetics by their intended use, 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.” However, in the Draft Standard the NSF changes the fundamental definition of cosmetic to one of end use application:

Items covered by this Standard include, but are not limited to, rinse-off and leave-on personal care and cosmetic products that are applied or used externally on any part of the body (e. g., hair, face, hands, and feet) as well as oral care and personal hygiene products.

This scope also creates internal confusion within the Draft Standard as it does not appear to comport with NSF’s (or FDA’s) definition for cosmetics.

The following modification has been made to 1.2 – Scope:

1.2 Scope

This Standard specifies materials, processes, production criteria, and conditions that shall be met in order for personal care products to make organic label and marketing claims under this Standard.

Items covered by this Standard include, but are not limited to, ~~rinse-off and leave-on personal care and cosmetic products that are applied or used externally on any part of the body (e. g., hair, face, hands, and feet) as well as oral care and personal hygiene products.~~ cosmetic products; rinse-off and leave-on personal care products; oral care products; and personal hygiene products. These products may be applied to or used externally on any part of the body (e.g., hair, face, hands, and feet). This Standard does not differentiate between requirements for personal care products and requirements for cosmetics. Therefore, for the purposes of this Standard, cosmetics are considered personal care products.

Submitter Proposed Solution

In light of the non-exhaustive list of examples we have highlighted above, we believe NSF has a considerable amount of development work to undertake before finalizing the Draft Standard; allowing for several opportunities for public comment and following the ANSI Essential Requirements: Due process requirements for American National Standards.

Thank you for reviewing the document and providing comments.

Please provide a written response via e-mail to Lorna Badman, Joint Committee on Personal Care Products Secretariat, indicating whether your comment has been addressed. She can be reached at badman@nsf.org. If a response is not received by September 5, 2008, NSF will consider your comment addressed.

Sincerely,

Ray Green

Ray Green
Chairperson
Joint Committee on Organic Personal Care Products

Cc: L. Badman