Section 3 - Definitions

Personal Care Products Council

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 FFDCA in that there is no legally recognized non-drug OTC.

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 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.

Na True

In our opinion the NSF draft should cover both natural and organic <u>cosmetics</u>. However in certain areas it covers foodstuffs and is not thoroughly adapted to the situation in cosmetics. This for example can be seen in point 3.28, where it is written:

ingredient: A substance used in the preparation of an agricultural product that is still present in the final commercial product.

This formulation would have to be changed for a cosmetic standard to: *ingredient:* A substance used in the preparation of a <u>cosmetic</u> product that is still present in the final commercial product.

The term "natural" should be explained under *3 – Definitions*

- **3.4 allowed synthetic:** A substance that is included on the National List (National Organic Program, 7 CFR Part 205) of synthetic substances allowed for use in organic production or handling, and/or that is further allowed within this Standard for use in specific situations.
- **3.36 National List:** A list of allowed and prohibited substances as provided for in National Organic Program, 7 CFR 205.600-606.
- 3.39 non-synthetic (natural): A substance that is derived from mineral, plant, animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, non-synthetic is used as a synonym for natural as the term is used in the Act. (National Organic Program, 7 CFR Part 205).

3.66 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. This term shall not apply to substances created by naturally occurring biological processes permitted under the NOP, nor does it apply to Ecological Agricultural-Based Oleochemical Ingredients defined and allowed in this Standard for products labeled "made with organic".

3.17 essential oil: The non-aqueous oil obtained from plant matter that may be volatilized by steam. Citrus oil is considered an essential oil because of its composition (to be adopted to point 6.4.2)

In this formulation other manufacturing processes are missing such as e.g. extraction using CO_2 or the extraction of resins. This is why the wording should be changed and the definition under 6.4.2 included:

6.4.2 Essential oil

Essential oils expressed, distilled, or extracted from organic plant material shall be considered fully organic.

3.19 ethoxylation: A chemical process in which a raw material is catalyzed with potassium hydroxide and dried under vacuum, after which ethylene oxide is added as a reagent to form a new material.

This wording only describes a selection of possibilities. It would be better to use the generally applicable formulation:

A chemical process in which ethylene oxide or another alkyl epoxide is added as a reagent to form a new material.

3.20 excluded method: A method not permitted in this Standard, including genetically engineered organisms (GEO) or their products.

Reason: Clarification. GEOs are excluded in 4.2.2 - Prohibited labeling practices in all categories.

3.38 nonagricultural substance: A substance that is not a product of agriculture, such as a mineral.

Non-agricultural covers a great deal more (salt, water, wild-crafted plants etc.). It would be more precise to offer a definition of "agricultural".

3.40 organic: A term used to describe a finished product or ingredients within a product that have been produced and or processed according to this Standard or the NOP regulations.

This formulation should definitely be changed to:

A term used to describe a finished product or ingredient that has been produced and/ or processed according to this Standard, the NOP regulations or equivalent organic regulations (e.g. the European "COUNCIL REGULATION (EEC) N° 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs").

Rationale:

Most of the producers of agricultural raw materials outside the USA are not certified according to NOP. If the only raw materials that count as "organic" are those which were cultivated according to NOP then US-American firms will only be able to draw on very few agricultural raw materials that have been cultivated in other countries. It would still be the case that no European natural cosmetic articles could be labelled with the NSF

label since they primarily utilize organic raw materials that that are cultivated according to the European standards for organic farming.

3.42 organic production: A production system that is managed in accordance with this Standard or the NOP regulations.

See note on 3.4. Here the IFOAM should count as the collective standard.

3.49 processing aid: (a) 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; or (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.

This formulation is another example of the exclusive reference to foodstuffs. Since the NSF draft is supposed to deal with the definition of natural und organic <u>cosmetics</u> the formulation should be adapted to refer to cosmetics.

3.56 salt: Sodium chloride, unless otherwise specified **6.3.2 Salt**

Salt is sodium chloride, not containing any additives or flow agents that are not specifically allowed on the National List.

For a standard for cosmetics the definition of salt should include all inorganic salts not just table salt as for a foodstuffs standard.

3.65 surfactant: A compound designed to reduce the surface tension of a liquid or to reduce the interfacial tension between two liquids, or between a liquid and a solid.

The wording should be changed to:

A compound designed to reduce the interfacial tension.

Access Business Group

"cosmetics", as "soaps" and as "drugs". These are long standing categories. Introducing a new formal category in this standard is likely to result in confusion for consumer/users of the standard. Therefore, I propose the standard follow the recognized nomenclature of FDA regulation.

- * The definition section should agree with and cite agreement with the official definition of cosmetic and soap as used by the FDA.
- * The definition section on several occasions redefines standard terms when it is not necessary to have a definition unique to the standard. An example is "volatile content".

This is defined under a number of analytical standards with descriptive conditions. This standard limits it to volatile content of plant materials. This is not appropriate since volatile content could be used with its normal meaning and plant materials specified within the standard instead of in the definition. This makes the standard more plainly readable without having to refer to a key unexpectedly.

TerrEsentials

- 3.355 -- There must be a definition of nanoparticle. This is particularly important as the UK Soil Association has implemented a complete ban on nanoparticles in organic personal care products.
- 3.40 -- Incorrect! The term "organic" does NOT apply to products in the "made with" category.
- 3.66 -- The definition of the word "synthetic" should be unchanged from the USDA National Organic Program federal regulations definitions. It should NOT be changed to allow synthetics as "non-synthetics." It would be unethical to do so.

OCA

The definition of "non-synthetic" (3.39) and "synthetic" (3.66) are contradictory. Section 3.39 states that a non-synthetic ingredient is one that does not undergo a synthetic process. Yet Section 3.66 states that ingredients that go through the various synthetic processes allowed under this new NSF "made with standard" are not considered "synthetic". It's misleading to consumers to suggest that highly processed ingredients not found in nature can be considered "non-synthetic" under this standard, simply because it benefits the majority of industry players in this group.