Task Group on Definitions
Meeting Summary
Wednesday April 23, 2008

Participants
Tim Kapsner- Chair- *Aveda Corp*; Gay Timmons- *Oh, Oh Organics*; Bob Durst-Simple *Organic Solutions*; & Lorna Badman – *NSF International*

Action Items

L. Badman will draft the response memos for T. Kapsner to complete.

Discussion

T. Kapsner called the meeting to order. The purpose of the teleconference was to address the comments received during the ballot and public comment period.

The following are the comments received on sections 3:

CTFA
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.

G. Timmons requested a statement be added to the proposed Standard informing users of the Standard to be aware of other definitions in the regulations. People using this Standard could be entrepreneurs and unaware of the definitions not used in the Standard.

Upon review of the document it was determined the term 'over-the-counter' was not used. Therefore the term will be deleted.

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.

Deleting the term 'personal care products' and replacing it with 'cosmetic' was discussed. The JC has struggled with this term. The Standard should use language consistent with federal regulation definitions. The term 'cosmetic' is self-contained. It was suggested to modify the term 'personal care products' to encompass the term 'cosmetic'. Two suggestions were made: replace the term 'personal care products' with the term 'cosmetic' throughout the document (harmonize with federal regulation) or request the JC to redefine personal care products to be functional and non-contentious. This issue will be discussed at the upcoming JC meeting.

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 TG on Scope made revisions to the scope to provide more clarity. Based on the above discussion, this topic will be tabled until the JC makes a decision regarding the term 'personal care products'

NATRUE

In our opinion the NSF draft should cover both natural and organic cosmetics. 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 cosmetic product that is still present in the final commercial product.*

G. Timmons indicated the FDA had published legal definitions for the terms 'ingredient' and 'component'. The following modification will be made based upon the outcome of the 'personal care product' and 'cosmetic' discussion:

3.28 ingredient: A substance used in the preparation of ~~an agricultural~~ a (cosmetic or personal care) product that is still present in the final commercial product.

1.1 Purpose
This Standard encourages participation in the manufacturing of personal care products using organically grown ingredients within the supply chain.

This sentence should be changed to: This standard encourages participation in the manufacturing of natural personal care products using organically grown ingredients within the supply chain.

Rationale:
The standard does not only define the content of “organic” raw materials, but also defines "natural cosmetics" according to the definition of the manufacturing processes and raw materials allowed.

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

This Standard does not address ‘nautral’ products. The term is not used in the U.S.

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.

The proposed language is consistent with the industry definition and will remain as written.

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.

Upon review of the document it was determined the term ‘ethoxylation’ was not used in the body of the Standard but was used in Annex G. Therefore the term will be moved to Annex G.

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 cosmetics the formulation should be adapted to refer to cosmetics.

The term is appropriately used in the body of the Standard. Therefore the term will remain as written.

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.

The following modification will be made:

3.56 salt: Sodium chloride, ~~unless otherwise specified~~ only containing any additives or flow agents specifically allowed on the NOP 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.

Salt is dealt with in the definition in mined minerals and salt.

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.

The proposed language is consistent with the industry definition and will remain as written.

4.2.2.1 *The labeling of whole products or ingredients as organic is prohibited if those products or ingredients are created using any of the following:*
(…) – Ingredients that have been processed with ionizing radiation;

Better: It is forbidden to treat raw materials of plant or animal origin and finished cosmetic products using ionizing radiation.

Ionizing radiation should be rejected because it causes structural changes. This is not the case for minerals. They are sterilised but their structure remains unchanged. For this reason the ban on ionizing radiation should refer to organic substances and finished products. This requirement is covered by the definition for "ionizing radiation“. It reads as follows:

3.31 ionizing radiation: *Electromagnetic radiation whose waves contain energy sufficient to overcome the binding energy of electrons in atoms or molecules. Also (imprecisely) called radioactivity.*

According to this definition the term irradiation can only be used when the input energy is greater than the binding energy of the electrons in the atoms or molecules. This is not true in the case of the irradiation of minerals.

This process is allowed for minerals. Only earth minerals are listed. This comment should be sent to the TG on Composition.

Bob Hamilton – 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 Standard will follow the recognized nomenclature of FDA regulation.

* GMP for cosmetic products is discussed by FDA and although there is not an official standard established. The guidance provided by FDA should be cited and the essential compliance that the product not be found to be adulterated should be cited as the goal for GMP.

Upon review of the document it was determined the term 'GMP' was not used in the body of the Standard but was used in Annex F. Therefore the term will be moved to Annex F.

* 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.

'Volatile content' is defined as it is used in the Standard.

TERRESSENTIALS

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.

The term 'nanoparticles' is not used in the Standard. If and when the term is used in the document, it will be defined.

3.40 -- Incorrect! The term "organic" does NOT apply to products in the "made with" category.

'Made with' products will have organic ingredients.

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.

The term 'synthetic' will be modified to the USDA NOP federal regulations definitions.

CRAIG MINOWA – 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.

The term 'synthetic' will be modified to the USDA NOP federal regulations definitions.

The following other changes will be made to the definitions section:

3 Definitions

Terms used in this Standard that have special technical meaning are defined here.

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3.36 National List: A list of allowed and prohibited substances as provided for in National Organic Program, *7 CFR 205.~~600~~605-606*.

Reason: Section 600 only contains the criteria for the evaluation of materials. Section 3.4 of this Standard refers to the actual substances listed, which are contained in 7 CFR 605-606.

3.37 National Organic Program (NOP): The program authorized by the Organic Foods Production Act of 1990 and implemented by the Code of Federal Regulations 7 CFR part 205.

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

Reason: 'Nonagricultural substance' is not used in the body of the document. Therefore the term has been deleted.

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3.68 water: A clear, colorless, odorless, and tasteless liquid, chemically H_2O, essential for most plant and animal life; the most widely used of all solvents. Water that meets or exceeds safe drinking water standards (USEPA National Primary Drinking Water Regulations (40 CFR part 141) or the WHO Guidelines for Drinking-Water Quality).

~~**3.68.1 non-agricultural water:** Water that has been added to a product or ingredient that was not included in the originating plant matter.~~

~~**3.68.2 plant water:** Water that has been absorbed by the plant during its growth and contained within the plant, and that could be counted as organic content within an ingredient or final product.~~

~~**3.68.3 tap water:** Water that meets or exceeds safe drinking water standards (USEPA National Primary Drinking Water Regulations (40 CFR part 141) or the WHO Guidelines for Drinking-Water Quality).~~

Reason: 3.68.1 – 3.68.3 are not used in the body of the document. Therefore the terms have been deleted.