

NSF COMMENTS ~ DEFINITIONS

1) 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.

REJECT. WHO CARES.

Definitions / Scope

TKapsner: Accept. We must be consistent with existing regulations. We do not need to define terms that are regulated. Recommendation: if the term is left in, refer to FDA regulations.

2) CTFA

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.

REJECT: IT'S CLEAR ENOUGH AND FINE. THIS IS STUPID QUIBBLING.

Definitions

TKapsner: Do we need the term “personal care product”? The intention is to allow the standard to be used for products that do not fall into the FDA definition of “cosmetic”. We may be able to accomplish this without needing to define this category of “non-cosmetic products we want the standard to cover”. This is a scope issue also.

3) CTFA

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.

REJECT: SEEMS LIKE ANOTHER NON-ISSUE

Scope Definitions

TKapsner: Accept. We need to be consistent with FDA definition of “cosmetic”.

4) 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.*

ACCEPT: I'M FINE EITHER WAY

DEFINITIONS

TKapsner: Accept. This slipped through and should be changed.

5) NATRUE

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*

REJECT: WE’VE BEEN DANCING AROUND THIS AND I THINK WE SHOULD LET SLEEPING DOGS LIE. NATRUE IS SAYING SULFATION AND SULFATED INGREDIENTS, OR ANY OTHER INGREDIENT PRODUCED BY AN ACCEPTABLE PROCESS, SHOULD BE DEFINED AS ‘NATURAL’ AND THE PRODUCTS THEY ARE IN AS “NATURAL”. THIS IS CONTROVERSIAL IN NSF (ALTHOUGH WHAT THE NPA STANDARD DOES) AND I DON’T THINK WORTH THE TIME FIGHTING OVER. RIGHT NOW WE’RE ROLLING WITH “Ecological Agricultural-Based Oleochemical Ingredients” IN PRODUCTS “MADE WITH ORGANIC [SPECIFIED] INGREDIENTS” OR “__% ORGANIC”

DEFINITIONS

TKapsner: We have been attempting to create a standard that does not depend on a definition or perception of the meaning of the word “natural”. We should try to avoid any use of this term if possible.

6) NATRUE

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 CO₂ 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.

ACCEPT: SOUNDS GOOD

DEFINITIONS

TKapsner: The term “essential oil” is fairly clearly defined and used in the industry in the way we have defined it. We may need to create another term for the other aroma extracts such as CO₂, but we should not simply lump all of them under the term “essential oil”.

7) NATRUE

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.

ACCEPT: SOUNDS GOOD TO ME

DEFINITIONS

TKapsner: We shouldn't need to refer to or define any excluded methods, such as ethoxylation or GEO's. I recommend we eliminate these definitions and any references to them in the text of the standard.

8) NATRUE

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.

ACCEPT

DEFINITIONS

TKapsner: we may not need the term “processing aid” if we don’t need to use it in the standard., unless there are processing aids that are used and do not fit into any of our other definitions. This definition came directly from the food standard.

9) NATRUE

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.

ACCEPT

DEFINITIONS

TKapsner: Accept

10) NATRUE

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

REJECT, SODIUM CHLORIDE IS UNIQUE IN BEING UBIQUITOUS AND THUS EXEMPT LIKE WATER FROM CALCS

DEFINITIONS

TKapsner: This question should be addressed in composition and calculation. We may want to include other salts, but a blanket discounting of all inorganic salts from the organic calculation may not be practical because of the widely different uses of these materials. The best way to deal with them may be to change the way we deal with sodium chloride and lump it in with other inorganics such as clays.

11) NATRUE

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.

EITHER WAY

DEFINITIONS

TKapsner: I don’t think they understand the use of the terms surface tension vs. interfacial tension. The definition is correct.

12) NATRUE

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.

**ACCEPT
DEFINITION**

TKapsner: This issue brings up the question of whether the ban on ionizing radiation is more philosophical or practical. There does not appear to be a health issue with using inorganic materials that have been irradiated. This should be discussed in composition.

13) 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.

**ACCEPT
DEFINITIONS**

TKapsner: Accept

14) Bob Hamilton – Access Business Group

* 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.

**ACCEPT
DEFINITIONS**

TKapsner: Accept.

15) Bob Hamilton – Access Business Group

* 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.

UNSURE, MIGHT BE RIGHT: BUT THE RELEVANT ISSUE IS ABOUT WHEN AND HOW REGULAR WATER CAN BE ORGANIC IN ORGANIC WATER EXTRACTS, NOT VOLATILITY PER SE.

DEFINITIONS

TKapsner: Accept. We should be using terms in their common usage whenever possible.

16) 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.

ACCEPT: WE NEED TO LIMIT PARTICLE SIZE.

DEFINITIONS

TKapsner: Good luck on this issue.

17) TERRESENTIALS

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

NOT SURE THE REFERENCE

DEFINITIONS

18) TERRESENTIALS

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.

REJECT: NSF IS ABOUT "ECOLOGICAL OLEOCHEMICAL" ALLOWANCES THAT CAN BE MADE FROM AND SUPPORT ORGANIC AGRICULTURE, THAT SHOULDN'T BE LUMPED TOGETHER WITH PETROCHEMICALS.

DEFINITIONS

TKapsner: If we could avoid the use of the term "synthetic" we would have a better standard.

19) 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.

REJECT: OLEOCHEMICAL ECOLOGICAL INGREDIENTS PRODUCED BY ALLOWED PROCESSES CAN BE MADE FROM AND SUPPORT ORGANIC AGRICULTURE, AND SHOULD NOT BE LUMPED TOGETHER WITH PETROCHEMICALS. THIS IS THE POINT OF NSF 305 DEFINITION

TKapsner: See 18.