Organic and Sustainable Industry Standards, Inc.

Health and Beauty Products

Beta Version #4 – March 15, 2009

OASIS Standard #100
Organic Production Standards (for Health and Beauty Products)
A Voluntary Standard

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Standard #100 / Organic Health & Beauty Production

Comment [DB1]: Inconsistent Title and regulation. Recommend changing title of section "Labeling of Retail Packages" or something of that sort and using the "Health and Beauty Products in retail packages must:' statement as part of the regulation.

Organic Production Standard for Health & Beauty Products

1. Introduction

This Organic Production Standard for Health and Beauty Products is based on 8 years of collective work and thought about how we measure “organic” as it applies to the cosmetic industry. Thanks are extended to all of the participants in those various efforts.

There are no Federal regulations or guidelines for the use of the word/claim “organic” on the labeling of Health & Beauty Products. The State of California does enforce the Calif. Organic Products Act (COPA) of 2003 which sets a minimum requirement of 70% organic content, the other 30% is not restricted in any way. A few comments:
The phrase “Health & Beauty” is used because it encompasses everything in the category; Personal Care, make-up, body and skin care, candles, cotton swabs, anything that may be sold in the “beauty” world that does not fall under the USDA National Organic Program (NOP) for food and is not ingestible.
The OASIS Standard includes a method for the membership to propose and pass amendments to The Oasis Standard as time and technology provide for more organic and sustainable raw ingredient alternatives.
Most cosmetics cannot be certified organic according to the USDA NOP as they are not solely based on agriculture; they are primarily the combination of organic feedstock using “green chemistry” to make ingredients safer and more sustainable.
The goal of Oasis is to create a standard utilizing organic feedstocks and green chemistry to make ingredients for health and beauty products safer and more sustainable.

The Oasis Standard 100 was created for the following purposes:
Consumers: Consumers need a consistent system of labeling for “organic” Health and Beauty Products. The Oasis Standard and the OASIS certification seal will provide verifiable reliability for Organic and Sustainability claims.
Manufacturers: Manufacturers of Health and Beauty Products need a consistent, credible, and responsive standard for the production of products claiming the use of organic raw materials on their labels. The Oasis Standard will provide the guideline to both manufacturers of ingredients and finished Health and Beauty Products.
Retailers: The Oasis Standard will provide the marketplace with a tool to ensure verifiable organic manufacturing and label claims.
Raw Materials Vendors: Manufacturers of raw materials are in need of a method to evaluate the market demand of organic ingredients. The Oasis Standard and its associated members will provide that baseline information.

2. History, Principles, Scope, and Regulatory References

2.1. History. Most Health and Beauty Products are produced by using ingredients made by applying chemical processes to petrochemical materials. Soaps, surfactants, emulsifiers and preservatives are used to create functional products that are useful and affordable. The Oasis Standard incorporates two primary principals: (1) promote the increased use of organic raw materials in the manufacturing of Health and Beauty Products, and (2) to acknowledge that there is good and bad chemistry for our health and environment. The Oasis Standard includes a review process to exclude chemistry that results in non-sustainable products wherever possible. The combination of organic feedstock and benign or “Green” chemistry is the goal of the OASIS Standard.

2.2. Principles. The Oasis Standard is based on the following Principles:

2.2.1. The use of certified organic agricultural ingredients contributes to improved environmental conditions worldwide by increasing the use of and demand for organic raw materials as feedstocks for organic cosmetic ingredients.

2.2.2. The principals of "Green Chemistry", as defined by the US Environmental Protection Agency, provide an environmentally responsible framework for the production of the materials used in the Health and Beauty Products.

2.2.3. Transparency to both consumers and manufacturers as viewed through The Oasis Standard and the claim of "organic" labels is fundamental for credibility.

2.2.4. Manufacturers with a desire to improve the sustainability of their products and operations.

2.2.5. Voluntary Standards should be flexible enough to reflect changes in consumer demand, technological advances, and "commercial availability".

2.2.6. The integrity of the word "organic" as a label claim is only as good as the faith of consumers in the meaning of the word.

2.3. Scope

2.3.1. The Oasis Standard includes validation and verification of materials, processes, production criteria and conditions required for health and beauty ingredients and products to use various verified organic label claims. The Oasis Standard may not be used to certify food products for human or animal consumption nor may it be used to certify to the USDA NOP regulations.

2.3.2. The Oasis Standard includes products defined under State and Federal regulations of cosmetics and cosmetic ingredients, as well as other products that may be sold in a health and beauty retail setting, such as, soaps, candles, aromas, and other non-ingestible products.

2.3.3. Oasis Organic certification is process verification; the ability of a manufacturer or handler to demonstrate their ability to meet the process criteria described in The Oasis Standard may allow the use of agreed upon label claims on final products.

2.3.4. The Oasis Standard does not verify product quality.

2.3.5. The organic content of all OASIS Standard #100 certified products (raw materials and/or finished processed products) must be certified to the USDA-NOP 7 CFR Part 205 by an accredited certifier. Minor ingredients, such as essential oils and other materials used in less than 1%, may be added and described by their original certification but may not be counted toward the organic content.

Is this the proper place for this comment.?

Comment [DB2]: My opinion- Move to Section 4: General Requirements.for Organic Health and Beauty Products.
Does this also apply to processing aids and intermediates that must be 100% organic as per section 5.3.1. and that are not included in the calculation of organic content?

Comment [DB3]: This statement is in conflict with section 5.4.3.
In addition, if this is a condition for content calculation, is should be included in that same section.

2.4 Regulatory References. Listed documents include provisions that may affect the ability of an applicant to meet The Oasis Standard. The editions indicated are subject to revision and applicants are directed to use the most recent version of the document.

California Organic Products Act of 2003
http://www.dhs.ca.gov/fdb/HTML/food/organreq.htm

Code of Federal Regulations, *Title 21, Chapter 29, Federal Food, Drug, and Cosmetic Act*
www.fda.gov

Federal Food, Drug, and *Cosmetic Act*
www.fda.gov

International Cosmetic Ingredient (INCI) Dictionary and Handbook, 11th edition, 2006 (www.ctfa.org)

National Organic Program, *7 CFR Part 205*
www.ams.usda.gov/nop

Organic Food Production Act of 1990
http://agriculture.senate.gov/Legislation/Compilations/AgMisc/OGFP90.pdf

USFDA, Good Manufacturing Practices (GMPs for Cosmetics)
www.fda.gov

EU Directive 2092/91
http://eur-lex.europa.eu

EPA – List 4, EPA List 3, etc.
www.epa.gov

REACH - Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants} {SEC(2003 1171} /* COM/2003/0644 final - COD 2003/0256
http://eur-lex.europa.eu

The 7th Amendment (EU allergen list, etc.) Find official name.

3. Definitions

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.

Alkylation (protein acylation): A chemical process in which an alkyl group (containing only carbon and hydrogen) is added or substituted in a compound.
This needs work (alkylation and acylation are not the same).

Allowed synthetic: A substance that is allowed within The Oasis Standard for use as annotated

Audit: A means to verify compliance with a standard or set of standards, rules, regulations, or other requirements against which a company or product is being measured and that the company must meet. Audits can range in duration depending on size or organization, and can be performed as a desk audit (review of documents and records) only, an on-site audit only, or a combination of both.

Authorized certifying agent: A business entity that has been authorized by the Board of OASIS to provide and maintain certification to the OASIS Standard(s) to its' members.

Batch or lot: A specific quantity of a finished product or other material that is intended to have uniform character and quality, within specified limits, and/or is produced according to a single manufacturing order during the same production run.

Comment [DB4]: should be listed directly with the definition for "Lot (or batch) number" and formatted the same (i.e. Batch or lot number or Lot (or batch)).

Catalyst: A non-agricultural processing material that is used in small quantities to modify or increase the rate of chemical change in an agricultural material, but which does not itself become consumed in the process or incorporated into the modified material/ingredient.

Claims: Oral, written, or symbolic representations, statements, labeling, advertising, or other forms of communication presented to the public or to buyers of Health and Beauty Products that relate to the organic certification process.

Commercially available: The ability to obtain a production input or material in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic Health and Beauty Products production or handling.

Commingling: Physical contact between unpackaged organically produced and non-organically produced products, processing intermediates or ingredients during production, processing, transportation, storage, or handling, other than during the manufacture of a multi-ingredient product containing both types of ingredients.

Company: A public or private organization, group, individual, or other entity seeking conformance to The Oasis Standard, or a subsidiary or division of such an entity.

Compliance: Conformance to a regulatory standard.

Concentration: The removal of water from a liquid ingredient.

Component (or ingredient component): Materials that are physically mixed together into a multi-component ingredient.

Contamination: The presence of prohibited materials or deleterious substances in an organic product.

Cosmetic: Articles 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) articles intended for use as a component of any such articles; except that such term shall not include soap.

Essential oil: Concentrated, volatile, fragrant pure plant extracts obtained by steam distillation, expression or extraction.

Ester: The reaction product of an acid and an alcohol.

Esterification: The process of producing an ester from an acid and an alcohol.

Etherification: The process of forming an ether bond (C-O-C) between two compounds, such as an alcohol and glycerin or glucose.

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 process is prohibited under The Oasis Standard due to the downstream result of dioxin pollution.

Excluded method: A method not permitted under The Oasis Standard.

Extract: Soluble material of plant origin that is dissolved out of the plant material by soaking the plant in a suitable solvent.

Glucosidation: A specific type of etherification in which glucose is combined with another compound, usually a fatty alcohol.

Good Manufacturing Practices (GMP): The practice of maximizing the purity of products and materials by maintaining and practicing appropriate quality control and quality assurance procedures, over raw materials, processing, handling, packaging, storage, and distribution of the finished product.

Green Chemistry or Sustainable Chemistry: Environmentally friendly chemicals and processes that result in: reduced waste, eliminating costly end-of-the-pipe treatments; safer products; and reduced use of energy and resources—all improving the competitiveness of chemical manufacturers and their customers.(Def Spource: US - EPA We Site/Green Chemistry).

Handle: To sell, process, re-label, or package products covered by Oasis Standard #100.

Handling operation: An operation or portion of an operation that receives or otherwise acquires and processes, packages, or stores products covered by Oasis Standard #100.

Health and Beauty Products: Everything in the following categories; make-up, body and skin care, candles, cotton swabs, anything that may be sold in the “beauty” world that does not fall under the NOP and is not ingestible.

Hydrogenation: A chemical reaction in which all or some unsaturated (double or triple) bonds between carbon atoms are reduced by attachment of a hydrogen atom to each carbon. The process results in the saturation of the carbon atoms, meaning that each carbon atom has four other atoms attached to it. When the process is carried to completion, it converts unsaturated fatty acids to saturated ones, creating waxes from vegetable oils.

Hydrogenolysis: A reaction between hydrogen and an organic compound in which chemical bonds in the compound are broken, with subsequent reaction with and addition of hydrogen to the molecular fragments. The most common example is the conversion of a fatty acid to a fatty alcohol.

Hydrolysis: Decomposition of a chemical compound by reaction with water.

Hydrosol: An aqueous colloidal solution derived from a plant source.

Ingredient: Materials that are added directly to a multi-ingredient finished cosmetic product. An ingredient can be a single component, such as stearyl alcohol, or it can be a mixture of components, such as stearyl alcohol and cetyl alcohol, or hydrolyzed protein, water and preservatives.

Inspector: A person or auditor employed to conduct inspections of applicants or of production or handling operations.

Inspection: The act of examining and evaluating the production or handling operation, process products and records of an applicant to determine conformance with The Oasis Standard.

Ionizing radiation: limited to:

Gamma rays from sealed units of the radionuclides cobalt-60 or cesium-137.
Electrons generated from machine sources at energies not to exceed 10 million electron volts.
X-rays generated from machine sources at energies not to exceed 5 million electron volts.

Juice: Un-concentrated liquid, predominantly aqueous, expressed from a plant material, (see single strength).

Label/labeling: any display of written, printed, or graphic matter on the immediate container of any article, or any such matter affixed to any consumer commodity, affixed to, or appearing upon a package containing any consumer commodity. (CFR Title 21 Sec. 1.3)

Labeling: includes all written, printed, or graphic matter accompanying an article at any time while such article is in commerce or held for sale after shipment or delivery in interstate commerce.

Lot (or batch) number: A unique code consisting of letters, numbers, or symbols, or any combination thereof from which one can determine the complete history of the manufacturing, processing, packaging, holding, and distribution of a batch or lot covered by The Oasis Standard.
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Comment [DB5]: should be listed directly with the definition for "Batch or lot" and formatted the same (i.e. Batch or lot number, Lot (or batch)).

Comment [DB6]: Maybe….

A unique code consisting of letters, numbers, symbols, or any combination thereof, utilized to document the complete history of the manufacturing, processing, packaging, holding, and/or distribution of an individual batch or lot.

Mined minerals: Naturally occurring homogeneous substances (such as stone or salt) extracted from a hole or system of holes in the ground.

National list: A list of allowed and prohibited substances as defined in 7 CFR 205.600.

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.

Neutralization: Combination of an acid and a base to produce a salt and water.

Nonagricultural substance: A substance that is not a product of agriculture, such as a mineral or a bacterial culture that is used as an ingredient in an agricultural product.

Non-compliance: Lack of conformance with Oasis Standard #100.

Organic: a term used to describe a finished health and beauty product or cosmetic ingredients within a product that has been produced and or processed according to The Oasis Standard or the NOP regulations.

Organic content: That portion, expressed as a percentage, of the finished product, ingredient, ingredient component or processing intermediate that comes from certified organic agricultural material.

Organic label: The specific labeling guidelines contained within The Oasis Standard or the NOP regulations.

Organic production: A production system that is managed in accordance with The Oasis Standard or the NOP regulations.

Organic system plan: A plan of management of an organic production or handling operation that has been agreed to by the producer or handler and the certifying agent and that includes written plans concerning all aspects of production or handling described in The Oasis Standard or the NOP regulations.

Over-The-Counter (OTC): Drugs and non-drugs that may be sold without a prescription and without a visit to a medical professional.

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, styling, etc.

Petroleum compound: A carbon compound derived/synthesized from a petroleum source that is part of a larger health and beauty product ingredient. Example: ethylene oxide in ethoxylated fatty alcohol.

Principal display panel (PDP): The portion of the package label that is most likely to be seen by the consumer at the time of purchase..

Processing: Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing; includes packaging, canning, jarring, or otherwise enclosing in a container and other processing allowed in The Oasis Standard.

Processing aid: Any substances intentionally used in the processing of raw materials or their ingredients, to fulfill a certain technological purpose during treatment or processing, and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product.

Processing Intermediate: An agricultural material that is being, or has been, changed chemically into a new molecule by an approved process, but is not used directly in a finished cosmetic product.

Products: Finished goods or ingredients covered by The Oasis Standard.

Production location: A location or site that is involved in handling, processing, or final point of production or assembly of products or of ingredients to be included in a final product.

Prohibited practice: Any practices not specifically allowed within The Oasis Standard for the production of any final product or ingredient to be labeled under The Oasis Standard.

Prohibited substance: A substance not allowed in any aspect of organic production or handling or not provided for in The Oasis Standard.

Records: Information in written, visual, or electronic form that documents the activities undertaken by a producer, handler, or certifying agent to comply with The Oasis Standard.

Reagent: A non-agricultural material that is added to an agricultural material in a processing step in order to change its chemical structure into a more useful form. The reagent is incorporated into the agricultural material in the process and becomes part of the new material/ingredient.

Salt: sodium chloride, unless otherwise specified

Saponification: The hydrolysis of a fat or oil with alkali to form a soap and glycerin.

Soap: from the FDA Title 21 701.20: the term ``soap'' is to apply only to articles that meet the following conditions:

The bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the detergent properties of the article are due to the alkali-fatty acid compounds;

The product is labeled, sold, and represented only as soap.

Solvent: A substance that dissolves one or more other substances or that causes another substance to disperse.

Split handling operation: An operation that handles both conventional and organic products.

Standard: The document that is the basis for the compliance.

Steam fractionation: Splitting a compound with steam to produce new compounds, such as the use of steam to split a vegetable oil into fatty acids and glycerin.

Sulfation: The manufacture of a sulfate ester of a fatty alcohol that is then neutralized with an alkali such as sodium hydroxide to produce a surfactant.

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.

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 or processes traditionally used in the production of food.

Transesterification: The process of exchanging the alcohol or acid group of an ester with another alcohol or acid.

Volatile content: The amount of moisture and other compounds present in plant material generally measured by gentle drying (oven or microwave) until a constant weight is achieved. The loss on weight is considered the volatile content; similar to moisture content.

4. General requirements for Organic Health and Beauty Products

4.1. Scope. A Health and Beauty Product or ingredient using any organic claim and the logo, name or verification seal of this organization shall be produced and handled in conformance with The Oasis Standard.

4.2. Allowed and Prohibited Substances (non-organic ingredients, and other substances)

4.2.1. The labeling of finished products or ingredients as "organic" is prohibited if those products or ingredients are created using any of the following:

4.2.1.1. Ingredients, reagents, catylysts, or processing aids produced using excluded methods except as specificaly allowed in The Oasis Standard;

4.2.1.2. Ingredients that have been produced using applications of sewage sludge (at the farm level);

4.2.1.3. Ingredients that have been processed with ionizing radiation as described in Food and Drug Administration regulation, 21 CFR 179.26;

4.2.1.4. Ingredients that have been made using engineered genetic modification or from raw materials derived from plants grown from genetically modified raw materials;

4.2.1.5. Ingredients with petroleum compounds, except as specifically allowed in Oasis Standard #100;

4.2.1.6. Formaldehyde or formaldehyde donors;

Comment [DB7]: Title Inconsistent
The regs in this section list only prohibited substances and does not define allowed substances. Should section 4.3 Nonorganic ingrediients be included as a subpart of this since it references non organic ingredients in the title?

4.3. Non-Organic Ingredients

4.3.1. All allowed non-organic ingredients will be listed on Annex 1, OASIS Allowed Materials List.

4.3.2. New materials may be added to this list by submitting information as required by the review process to demonstrate conformance with this Standard.

Comment [DB8]:

4.4. Recordkeeping. An Oasis verified operation must maintain records concerning the production and handling of Health and Beauty Products or ingredients that are sold or that are intended to be sold, labeled, or represented using an organic label claim and the Oaisis Seal. The records must:

4.4.1. Be adapted to the particular business that the verified operation is conducting;

4.4.2. Fully disclose all activities and transactions of the verified operation in sufficient detail as to be readily understood and audited;

4.4.3. Be maintained for not less than 5 years beyond their creation;

4.4.4. Be sufficient to demonstrate conformance with Oasis Standard #100 and with applicable Federal and State regulations; and

We need comment on the above line. Do we want OASIS responsible for this? Can we, instead, require that OASIS is only responsible for the claims covered under Standard #100 for organic contet and materials related statements?

4.4.5. Be available for inspection and verification during normal business hours by authorized representatives of OASIS.

Comment [DB9]: Additional comment
As this is stated, it would be a huge liability as well as time consuming and perhaps difficult to find reviewers and/or inspectors that are proficient in ALL Fed and State regulations. Seems this is above and beyond the OASIS standards intention. Should be revised.

If you removed the Fed/State regs statement from here, records required for verification would still be covered since the OASIS standard does reference other standards where it's applicable, (i.e. NOP certification for org content) (my recommentdation) Or perhaps you could indicate OASIS and applicable Federal and State "Organic" regulations. (this may be valid, depending on the intent of the OASIS standard?)

Comment [SM10]: We don't like this becuase it is vague and we aren't going to verify to other state and/or federal regulations. We think this should be removed.

5. Organic Health and Beauty Product Production and Handling Requirements

5.1. General. The producer or handler of a production, handling or warehouse operation intending to sell, label, or represent Health and Beauty Products as “100 percent organic,” “organic,” or “made with organic” shall comply with the applicable provisions of The Oasis Standard. Production practices implemented in accordance with The Oasis Standard shall maintain or improve the natural resources of the operation, including soil and water quality.

5.2. Organic System Plan (OSP). The producer or handler of a production or handling operation intending to sell, label, or represent cosmetic products as “100 percent organic,” “organic,” or “made with organic” shall develop an organic production or handling system plan. This section specifies the requirements for such a plan. An organic production or handling system plan shall include:

- **5.2.1.** A description of activities, practices and procedures to be performed including the frequency with which they will be performed;
- **5.2.2.** A list of substances and/or ingredients to be used as production or handling input, indicating their compositions, organic content (expressed as a whole percentage, rounded down to the closest percent and excluding all non-organic materials), sources, location where they will be used, and documentation of commercial availability, as applicable;
- **5.2.3.** A description of the monitoring activities, practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;
- **5.2.4.** A description of the record keeping system implemented to comply with section 4.4;
- **5.2.5.** A description of the plan to implement the general improvement of the manufacturing environment and or its immediate environs.
- **5.2.6.** A description of the management activities and practices and the physical barriers established to prevent commingling of organic and non-organic products in a split operation, to prevent adulteration of the product and to prevent contact of organic production and handling operations and products with prohibited substances; and
- **5.2.7.** Additional information as applicable that is required in order to demonstrate conformance with The Oasis Standard.
- **5.2.8.** An applicant may use any plan prepared to meet the requirements of another program for the organic system plan provided that the submitted plan meets all the requirements of this section.

5.3. Product Composition

- **5.3.1. 100% Organic.** Health and Beauty Products or ingredients sold, labeled, or represented as "100 percent organic": Any health or beauty product sold, labeled, or represented as "100 percent organic" shall contain (by weight or fluid volume, excluding water, and salt) 100 percent organically produced ingredients.
  - **5.3.1.1.** If labeled as organically produced, such product shall be labeled pursuant to section 6.
  - **5.3.1.2.** Any processing aids, catalysts, reagents, or other materials to come in contact with this product must also be certified to the 100% organic level and must be plant derived.
- **5.3.2. Organic.** Health and Beauty Products or ingredients sold, labeled, or represented as "organic":
  - **5.3.2.1.** Shall contain (by weight or fluid volume, excluding water, and salt) not less than 85 percent organically produced raw or processed agricultural products

Comment [DB11]: “made with organic” claim is not consistent with sections5.1, 5.2, 5.3.3, 5.4.1, 5.5.4, 6.1.2, 6.2.1 6.2.1.5, and 6.2.2

Comment [DB12]: “made with organic” claim is not consistent with sections5.1, 5.2, 5.3.3, 5.4.1, 5.5.4, 6.1.2, 6.2.1 6.2.1.5, and 6.2.2

Comment [DB13]: Section verbiage is not consistent with same section in Organic 5.3.2.3 and MWO 5.3.3.3

Section 6 does not describe how the “100% Organic” claim is to be displayed in the PDP. This section doesn’t specify the 100% Organic label claim either.

Comment [DB14]: Per above comment, maybe replace this with “100% Organic”

Comment [DB15]: See comment for 2.3.5.

Also, , it appears this is a higher standard than the NOP- which states in 205.301(f)(4) …products labeled as “100 percent organic,” if processed, must be processed using organically produced processing aids;
The additional statement “and must be plant derived” would be a mute point if the material was certified organic
If this is referring to OASIS Verified as Shannon asked about, it’s a whole other beast.

Comment [SM16]: is this referring to Oasis verified or NOP certified?

intended for use in Health and Beauty Products UNTIL JAN. 1, 2010. THIS NUMBER WILL MINIMALLY MOVE UP TO 90% ON THAT DATE. *Except that:* Soap and other products that, by their inherent nature will always be below 95% organic content, shall remain in the "made with" category regardless of this section.

5.3.2.2. Any remaining ingredients shall be:

5.3.2.2.1 organically produced, unless not commercially available in organic form, or;

5.3.2.2.2 nonagricultural substances or;

5.3.2.2.3 non-organically produced agricultural products produced consistent with the Administrative List in The Oasis Standard.

5.3.2.3. Products labeled as organically produced must be labeled according to the requirements specified in the Oasis Standard.

5.3.2.4. Any processing aids, catalysts, reagents, or other materials that come in contact with this product must also be in conformance with The Oasis Standard.

THE EXCLUSION OR INCLUSION AND LABELING TREATMENT OF MINED MINERALS IS TO BE ASSESSED, WRITTEN AND VOTED UPON BY THE MEMBERS.

Will call for a vote of members on irradiation.

5.3.3 Made with Organic. Health and Beauty Products or ingredients sold, labeled, or represented as "made with organic":

5.3.3.1. Shall contain (by weight or fluid volume, excluding water, and salt) not less than 70 percent organically produced raw or processed agricultural products.

5.3.3.2. Any remaining ingredients shall be:

5.3.3.2.1. organically produced, unless not commercially available in organic form, or;

5.3.3.2.2. nonagricultural substances or;

5.3.3.2.3. non-organically produced agricultural products produced consistent with the Administrative List in The Oasis Standard.

5.3.3.3. Products labeled as organically produced must be labeled according to the requirements specified in the Oasis Standard.

5.3.3.4. Any processing aids, catalysts, reagents, or other materials that come in contact with this product must also be in conformance with The Oasis Standard.

5.4. Calculation of Organically Produced Materials. In order to perform the organic content calculations a statement of organic content must accompany all raw materials or ingredients bearing an "organic" label claim of any category from a recognized certifier of the original material or the handler. Without a statement from an accredited certifier the percentage of organic content recognized for formulation calculation will be set at the lowest percentage associated with the label claim.

5.4.1. The percentage of all organically produced ingredients in a health and beauty product sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)," or as including organic ingredients must be calculated by:

5.4.1.1. Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of the finished product;

5.4.2.2. Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of the finished product (excluding water and salt) if the

Comment [DB17]: Inconsistent. Any non-ag ingredients are allowed? Or only those consistent with OASIS standards? (section 4.2 and Annex 1, OASIS Allowed Materials List, etc)

Comment [DB18]: Needs section # reference Annex 1, OASIS Allowed Materials List

Comment [DB19]: Section verbiage is not consistent with same section in 100% Organic 5.3.1.1
Needs section # reference Labeling-Section 6

Section 6 does not describe how the "Organic" claim is to be displayed in the PDP. This section doesn't specify the "Organic "label claim either.

Comment [DB20]: Per above comment, maybe replace this with "Organic"

Comment [DB21]: Needs section # reference?

Comment [DB22]: There is no numbering assigned to this comment. Is this a completed regulation? The formatting (all caps and spacing between the line above and below) is different from other regulations. Would this apply to both the "Organic" and "Made with Organic" Categories?

Comment [DB23]: "made with organic" claim is not consistent with sections5.1, 5.2, 5.3.3, 5.4.1, 5.5.4, 6.1.2, 6.2.1 6.2.1.5, and 6.2.2

Comment [DB24]: This is the same requirement as "organic" claim 5.3.2 and is higher standard than NOP? Is this what you intended?

Comment [DB25]: Inconsistent. Any non-ag ingredients are allowed? Or only those consistent with OASIS standards? (section 4.2 and Annex 1, OASIS Allowed Materials List, etc)

Comment [DB26]: Needs section # reference Annex 1, OASIS Allowed Materials List

Comment [DB27]: Section verbiage is not consistent with same section in 100% Organic 5.3.1.1
Needs section # reference Labeling-Section 6

... [1]

Comment [DB28]: Per above comment- maybe replace this with "Made with Organic"

Comment [DB29]: Needs section # reference?

Comment [DB30]: MWO claim is not consistent with 5.3.3 and 6.2.1

product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation shall be made on the basis of single-strength concentrations of the ingredients and finished product; or

5.4.2.3. For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of the finished product.

5.4.2. The percentage of all organically produced ingredients used in any label claims in a health and beauty finished product shall be rounded down to the nearest whole number.

5.4.2.1. The handler who affixes the label on the consumer package shall determine the organic percentage of the product. The handler shall use information provided by the compliant operation in determining the percentage.

5.4.2.2. The handler who affixes the label on the bulk or wholesale container shall determine the organic percentage of the ingredient. The handler shall use information provided by the compliant operation in determining the percentage. The certifier must verify these numbers and such documentation shall be provided on request.

5.4.3. The percentage of all organically produced ingredients in a health and beauty ingredient shall be calculated to the nearest 10^{th} of one percent for the purpose of the total formula calculation.

5.5. Organic Handling Requirements

5.5.1. Mechanical, or biological methods, including but not limited to cooking, heating, drying, mixing, grinding, churning, separating, distilling, extracting, cutting, fermenting, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the packaging, jarring, or otherwise enclosing in a container may be used to process an organically produced health and beauty product for the purpose of retarding spoilage or otherwise preparing the product for market except for those processes prohibited under section 4.2.

5.5.2. Allowed processes as defined in section 7.2 and in other sections of The Oasis Standard.

5.5.3. Non-organic materials allowed under Annex 1, OASIS Allowed Materials List of The Oasis Standard may be used as annotated in that section.

5.5.4. The manufacturer of Organic Health and Beauty Products or ingredients must not use in or on those ingredients or products intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specific ingredients or botanical groups)," or in or on any ingredients labeled as organic:

5.5.4.1. Practices prohibited under section 4.2.

Comment [DB31]: "made with organic" claim is not consistent with sections 5.1, 5.2, 5.3.3, 5.4.1, 5.5.4, 6.1.2, 6.2.1 6.2.1.5, and 6.2.2

5.6. Commingling and contact with prohibited substances prevention practice standards

5.6.1. The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and non-organic products and protect organic products from contact with prohibited substances.

5.6.2. The following are prohibited for use in the handling of any organic health and beauty product or ingredient: Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant.

5.7. Facility pest management practice standards

5.71. The producer or handler of an organic facility must use management practices to prevent pests, including but not limited to:

5.7.1.1. Removal of pest habitat, food sources, and breeding areas;

5.7.1.2. Prevention of access to handling facilities; and]

5.7.1.3. Management of environmental factors, such as temperature, light, humidity, atmosphere, and air circulation, to prevent pest reproduction.

5.7.2. Pests may be controlled through:

5.7.2.1. Mechanical or physical controls including but not limited to traps, light, or sound; or

5.7.2.2. Lures and repellents using non-synthetic or synthetic substances consistent with the NOP National List.

5.7.3. If the practices provided for in paragraphs 5.7.1 and 5.7.2 of this section are not effective to prevent or control pests, a non-synthetic or synthetic substance agreed to by the certifier may be used.

5.7.4. If the practices provided for in paragraphs 5.7.1, 5.7.2, and 5.7.3 of this section are not effective to prevent or control facility pests, a synthetic substance not on the National List may be applied, Provided, That, the handler and the Oasis Representative agree on the substance, method of application, and measures to be taken to prevent contact of the organically produced products or ingredients with the substance used.

5.7.5. An organic handling operation, which applies a non-synthetic or synthetic substance, to prevent or control pests must update the operation's organic handling plan to reflect the use of such substances and methods of application. The updated organic plan must include a list of all measures taken to prevent contact of the organically produced products or ingredients with the substance used.

5.7.6. Notwithstanding the practices provided for in paragraphs 5.7.1, 5.7.2, 5.7.3, and 5.7.4 of this section, a handler may otherwise use substances to prevent or control pests as required by Federal, State, or local laws, Provided, that, measures be taken to prevent contact of the organically produced products or ingredients with the substance used.

6. Labels, Labeling, and Market Information

6.1. Health and Beauty Products in retail packages must:

6.1.1. In the ingredient statement, identify each organic ingredient in a truthful manner. This language may utilize acceptable chemical name(s) for the material. Labels may use an asterisk or other reference mark, placed below the ingredient statement to indicate the certification standard used for each ingredient or other acceptable methods of labeling. Water, mined minerals or salt included as ingredients must not be identified as organic.

6.1.2. On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, " Verified (100% organic, organic, or made with organic) to OASIS Standard 100.

6.1.3. Display the production lot number of the product.

6.2. Labeling of non-retail containers used for only shipping or storage of raw or processed

Comment [DB32]: Section 6 does not describe how the "100 % Organic" "Organic" or "Made with Organic" claim is to be displayed in the PDP nor if the MWO statement must or may identify ingredients or a percentage claim.
(also described in section 5.3)

Comment [DB33]: I don't see any place in section 6.1 that refers to the use of the OASIS seal or identification of the "accepted verification agency".

Comment [DB34]: Incomplete. There is no verb (i.e. display…) identifying the action required.

This was pulled directly from NOP where it additionally states "identify the accredited certifying agency" This is not a requirement for this standard (accepted rather than accredited)?

Comment [DB35]: "made with organic" claim is not consistent with sections 5.1, 5.2, 5.3.3, 5.4.1, 5.5.4, 6.1.2, 6.2.1 6.2.1.5, and 6.2.2

Comment [KET36]: There are two instances that refer to bulk, wholesale, and ingredinets. It appears that these would all fall under the same labeling requirement, so do we need them in here twice with different labels. It comes accoress as confusing. IS there something we need to know regarding labeling and cosmetics that would reqyire this differenciation.

6.2.1. Health and Beauty Products or ingredient products labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" MUST display:

6.2.1.1. The production lot number of the product.

6.2.1.2. The name and contact information of the handler/shipper that sold the finished product.

6.2.1.3. The name and contact information of the certifying agent that certified the handler that assembled the final product (if regulated).

6.2.1.4. Identification of the product as organic;

6.2.1.5. The phrase "Verified (100% Organic, Organic, Made with Organic) to the OASIS Standard 100 must be clearly visible on the container of any ingredients certified to The OASIS Standard.

6.2.2. Non-retail containers used only to ship or store raw or processed cosmetic ingredients labeled as 100% org., organic, or made with organic MAY display the following terms or marks;

6.2.2.1. Special handling instructions needed to maintain the organic integrity of the product;

6.2.2.2. The seal, logo, or other identifying mark of the certifying agent that certified the organic production or handling operation that produced or handled the finished product.

6.3. Prohibited Labeling Practices. The following labeling practices are prohibited for finished/retail products and for bulk/wholesale ingredients:

6.3.1. Use of the phrase, “organic when available,” or similar statement on labels or in market information when referring to products composed of non-organic ingredients used in place of specified organic ingredients;

6.3.2. Labeling as “organic” any product containing both organic and non-organic forms of an ingredient specified as “organic” on the label.

7. Administrative

7.1. Evaluation criteria for allowed substances, processes, and ingredients. The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the Administrative List:

7.1.1. Synthetic and nonsynthetic substances and processes considered for inclusion on or deletion from the Allowed Processes or the Allowed Materials List will be evaluated using the criteria specified in section 7.1.2.

7.1.2. In addition to the criteria set forth in the The Oasis Standard, any substance used as a processing aid, processing intermediate, catalyst, reagent, ingredient, or adjuvant will be evaluated against the following criteria:

7.1.2.1. The substance cannot be produced from a non-sustainable source and there are no organic or sustainable substitutes;

7.1.2.2. The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;

7.1.2.3. The substance is essential for the handling of organically produced Health and Beauty Products.

7.1.2.4. Materials and processes may be added and deleted based on a submission presented to the Technical Review Committee. Submissions must minimally include:

Comment [DB37]: **This statement appears to apply to ALL verified product (retail and non-retail) making organic claims, but is perhaps under the wrong heading for non-retail packaging????????**
This would address comments noted on section 5.3, 6. And 6.1
And if applies to all- should be move up to 6.1 w/ a new heading and added to the table of contents

Comment [DB38]: “made with organic” claim is not consistent with sections 5.1, 5.2, 5.3.3, 5.4.1, 5.5.4, 6.1.2, 6.2.1 6.2.1.5, and 6.2.2

Comment [DB39]: Isn’t that what this standard verifies? Also, this states “certifying agent” but does not distinguish “accepted” or “accredited” as defined in section 3- Definitions.

Comment [DB40]: “made with organic” claim is not consistent with sections 5.1, 5.2, 5.3.3, 5.4.1, 5.5.4, 6.1.2, 6.2.1 6.2.1.5, and 6.2.2

Comment [DB41]: “made with organic” claim is not consistent with sections 5.1, 5.2, 5.3.3, 5.4.1, 5.5.4, 6.1.2, 6.2.1 6.2.1.5, and 6.2.2

Comment [KET42]: Does this need to be removed or since a MAY leave. Is this in reference to OASIS organic or NOP organic?

Comment [DB43]: As written, this could only apply if the product was certified to NOP.
I don’t see any place in this standard that refers to the use of the OASIS seal or “accepted” verification agency.

Comment [DB44]: Changed section reference to 7.1.2.

7.1.2.4.1. Review to the Criteria stated in The Oasis Standard
7.1.2.4.2. Supporting information as supplied or requested to further justify the addition or deletion.
7.1.2.4.3. Other information as determined by the Technical Review Committee.
7.1.2.4.4. These reviews will be performed once every 4 to 6 weeks.

7.2. Processes allowed to make ingredients for use in Health and Beauty Products

7.2.1. Hydrolysis
7.2.2. Hydrogenation
7.2.3. Hydrogenolysis
7.2.4. Esterification
7.2.5. Transesterification
7.2.6. Etherification
7.2.7. Saponification
7.2.8. Sulfation
7.2.9. Protein Acylation
7.2.10 Glucosidation
7.2.11 Neutralization

7.3. Label changes based on materials changes

7.3.1. Certified entities with retail product and labels on the shelf will be allowed 18 months in which to revise formulas and labels to reflect changes in allowed materials or processes.
7.3.2. Certified entities with ingredient products and labels in distribution will be allowed 12 months in which to revise formulas and labels to reflect changes in allowed materials or processes.

7.4. Adjudication committee procedures

7.4.1. The adjudication committee will hear all reasonable appeals. If the committee refuses an appeal, the refusal must be submitted to the Board of Directors for review, inclusion in the minutes and a detailed explanation of the refusal to hear the appeal.
7.4.2. All appeals will be submitted in writing. The Committee chair will review the appeal, set a date for the committee meeting and respond to the member bringing the appeal within 14 days.
7.4.3. The appeal will be fully documented in the minutes of the committee hearing.
7.4.4. The response of the committee will be submitted in writing to the member.
7.4.5. In the event of an additional appeal, the request must be sent to the OASIS Board of Directors.
7.4.6. The Directors or a sub-set of the Directors must meet with the Chair of the adjudication Committee to review the appeal and to determine a written outcome.

7.5. Technical Review Committee: Materials and processes review procedures

7.5.1 The Technical Review Committee will review all reasonable and well-supported requests for process or materials amendments to The Oasis Standard. If the committee refuses a request, the refusal must be submitted to the Board of Directors for review, inclusion in the minutes and a detailed explanation of the refusal to hear the request.
7.5.2. All amendment requests will be submitted in writing.
7.5.3. All amendments shall minimally include:
7.5.3.1. An MSDS.
7.5.3.2. A flow chart for the material or process.

7.5.3.3. A review of the literature regarding the environmental effects of the final material.

7.5.3.4. A review of the literature regarding the environmental effects of any new materials necessary to complete a proposed process.

7.5.3.5. A listing of the human impact of the process or materials: carcinogenicity, mutagenicity, toxicology, reproductive toxin status, and any other known issues associated with the process or material.

7.5.4. The Committee chair will review the request, set a date for the committee meeting and respond to the member bringing the request within 14 days.

7.5.5. The request will be fully documented in the minutes of the committee hearing.

7.5.6. The Technical Review Process Procedures shall be defined in a written procedure no later than six months from the implementation of The Oasis Standard.

7.5.7. The response of the committee will be submitted in writing to the member.

7.5.8. The Technical Review Committee shall submit and documented recommendation to the Board regarding the results of its review process.

Page 13: [1] Comment [DB27] **Donna Bice**

Section verbiage is not consistent with same section in 100% Organic 5.3.1.1
Needs section # reference Labeling- Section 6

Section 6 does not describe how the “Made with Organic” claim is to be displayed in the PDP nor if the MWO statement must or may identify ingredients or a percentage claim. This section doesn’t specify the MWO Organic label claim either.