NATURAL AND ORGANIC INGREDIENTS AND PRODUCTS: ISO 16128 STANDARD

Alain KHAIAT PhD
Chairman ISO TC 217 Cosmetics 2014-19
President Seers Consulting
I want to develop an ingredient/a product that is natural and I want it to be recognized as such around the World!

Before the publication of ISO 16128, there was no unique criteria to define what is a natural (or organic) ingredient nor how to determine the natural index of a cosmetic product.
Consumer’s perceptions

• It’s natural thus it is safe!
• Safety evaluation of natural ingredients is mandatory!
Consumer’s perceptions

• There is an increase interest in natural and organic cosmetic products who now represent close to 10% of the total market...but...
Consumer’s perceptions

• There is total confusion!

Too many logos, consumers are confused
Total confusion

• At the international level there are several certification norms which, sometimes, are conflicting;

• The industry and the consumers want clarity, transparency and the end to “greenwashing”;

• With more than 30 logos around the World, no wonder we’re all confused!
Why do we need an ISO standard?

• ISO, the International Standardization Organization is an emanation of the World Trade Organization (WTO) which role is to help develop and publish international standards;

• Independent non-governmental organization with a membership of 163 national standards body;

• Nominated experts share knowledge and develop voluntary, consensus based, market relevant international standards that support innovation and provide solutions to international challenges;
How does it work?

• Along the years technical committees have been created to deal with one topic: TC 217 deals with cosmetics;

• Each TC decides to create Working Groups (WG) to deal with specific areas;

• In each country there is a Mirror Committee i.e. a committee of experts reviewing the work done at the TC level, discussing the content of the standards, and casting the country vote;
How does it work? TC 217

• Chairman for the period 2014-2016 renewed for 2017-2019 Dr. Alain Khaiat representing Singapore;

• Participating (P) countries: 39

• Observing (O) countries: 27

• Only P countries can vote on the different milestones of a standard and send experts to any WG. O countries receive the information;

• Liaison: TC 217 has 9 associations representatives who can participate in the meetings but cannot vote;
Standards and Regulations

• The WTO TBT (Technical Barrier to Trade) specifies that when a product meets an international standard, countries cannot prevent it from entering except for human safety, environmental safety or religious reasons. As such ISO standards are facilitating international trade;

• Compliance to standard is voluntary but can be made mandatory by regulations: we see more and more countries adopting ISO 22716 as the standard for cosmetic GMP and many have also adopted ISO 24444 as the official measure for SPF;
Objectives of the standard

• For the consumers: transparency, easy interpretation of the claims;

• For the industry: simple way to determine the percentage of naturalness of an ingredient, of a product;

• For the regulators: simple way to determine the validity of claims made;

• ISO standards are International as such recognized all over the World;
ISO TC 217 WG 4 Terminology

  - Part 1: Definitions for Ingredients (published in February 2016)

The two parts have to be used together
The standard

• Is specially developed for cosmetics;

• Is a logical and consistent reference for ingredients and products;

• Is promoting a better choice of natural or organic ingredients;

• Is promoting innovation;
The standard

• Is not touching on communication, claims or human or environmental health;
• Is not touching on socio-economic areas like fair trade or Nagoya Protocol;
• Is not touching on packaging or legal matters;
Ingredient definition categories

• Natural and derived natural;
• Mineral and derived mineral;
• Organic and derived organic;
  - Constitutive
    - Water
      - Reconstitution
      - Extraction
  - Non natural ingredients;
Natural ingredients definition

• Natural ingredients are cosmetic ingredients obtained only from plants, animals, microbiological, or mineral origin, including those obtained from these materials by:
  — physical processes (e.g. grinding, drying, distillation, etc.),
  — fermentation reactions occurring in nature and leading to molecules which occur in nature, and
  — other procedures of preparation including traditional ones (e.g. extraction using solvents) without intentional chemical modification.

• The following materials and materials originating from them may be considered to fall under the general heading of natural origin: plants including fungi and algae; minerals, animals, microorganisms;

Ingredients obtained from fossil fuels are excluded from the definition.
Examples of Natural Ingredients

- Shea butter;
- Aloe Vera juice;
- Water and Calendula officinalis extract;
- Carnauba wax;
- Rubus idaeus (raspberry) seed powder;
- Ylang Ylang oil;
- Ethanol;
- Hyaluronic acid;
Different types of water exist:

- **Constitutive water**: the liquid (juice) content of fresh plants;
- **Reconstitution water**: is equivalent to the water found in the original material and is used to restore the dry material to its original content;
- **Extraction water**: is the water used to physically extract ingredients from a material mixture;

Water which is not defined above is designated as “formulation water”;

**Water: Water is natural**
Derived natural ingredients

• Derived natural ingredients are cosmetics ingredients of greater than 50% by molecular weight natural origin, obtained through defined chemical and/or biological processes with the intention of chemical modification;

• The degree of natural origin is generally quantified by molecular weight or by renewable carbon resulting in certain cases of ingredients of wholly natural origin;
Derived Natural ingredients: examples

- Derived natural ingredients:
  - Hydrogenated olive oil;
  - Cocamidopropylbetaine;
  - Octyldodecyl beeswax;

- Derived natural ingredient of 100% natural origin:
  - Glycerin;
  - Apricot Kernel oil Polyglyceryl-6 Esters;
  - Caprylic capric triglyceride;
  - Lecithin;
  - Squalane;
  - Dihydroxyacetone;
  - Hydrolyzed wheat proteins;
Natural Mineral ingredients

Natural mineral ingredients are natural ingredients which are **inorganic substances** (i.e. non-carbon derived and carbonate salts) occurring naturally in the earth having a **distinctive chemical formula** and a **consistent set of physical properties** (e.g. crystalline structure, hardness, colors);

**Example:** sea salt, talc, tourmaline powder
Derived Mineral ingredients

Derived mineral ingredients are cosmetic ingredients obtained through chemical processing of inorganic substances occurring naturally in the earth, which have the same chemical composition as natural mineral ingredients;

**Examples:** Titanium dioxide, Bismuth oxychloride, Iron oxides, Mica, Zinc oxide...
Organic Ingredients

- **Natural ingredients** originating from organic farming methods *(defined by national jurisdictions)* or from wild harvesting in compliance with national legislation or equivalent International Standards where applicable;

- Water, except for constitutive water, and minerals are outside the scope of organic farming;
Derived Organic ingredients

Derived organic ingredients are cosmetic ingredients of organic or mixed organic and natural origin obtained through defined chemical and/or biological processes with the intention of chemical modification, which do not contain any fossil fuel origin moiety.
Non natural ingredients

- Ingredients obtained from fossil fuel or ingredients having more than 50% of non-natural moiety: propylene glycol, mineral oil, dimethicone...
Indexes for ingredients

<table>
<thead>
<tr>
<th>Ingredient category</th>
<th>Index &amp; Value</th>
<th>Natural index</th>
<th>Natural origin index</th>
<th>Organic index</th>
<th>Organic origin index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constitutive water</td>
<td></td>
<td>1</td>
<td>1</td>
<td>1&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Reconstitution water</td>
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<td>1</td>
<td>1</td>
<td>1&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Extraction water, with exclusion of reconstitution water</td>
<td></td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Formulation water</td>
<td></td>
<td>1</td>
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<td>0</td>
</tr>
<tr>
<td>Natural</td>
<td></td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Natural mineral</td>
<td></td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Organic</td>
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<td>1&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1&lt;sup&gt;a&lt;/sup&gt;</td>
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<tr>
<td>Derived natural</td>
<td></td>
<td>0</td>
<td>Should be more than 0,5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Derived organic</td>
<td></td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>To be calculated&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Derived mineral</td>
<td></td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Non natural</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

<sup>a</sup>Only if the material is organic
Annexes

- The annexes give examples and explanations:
  - Annex A: solvents used for the manufacturing or processing of ingredients;
  - Annex B: list of chemical or biological processes for the derived ingredients;
  - Annex C: examples of calculation when the molecular weight is known or unknown;
  - Annex D: list of derived natural minerals;
Part 2: criteria for ingredients and products

- Explains the principles used to determine the indices of natural, natural origin, organic or organic origin which apply to the ingredients defined in part 1;
- Offers a way to calculate the natural, derived natural, organic, derived organic indices of products based on the definitions in part 1;
Indexes for calculating Natural or natural origin index of ingredients: **NATURAL INDEX**

- Value indicating whether a cosmetic ingredient meets the definition of natural ingredients (ISO 16128-1);

- **The value is assigned to each ingredient according to the following guidance:**
  - **Natural Index = 1**: Ingredient meets the definition of natural ingredients;

  *The Natural Indexes of constitutive, reconstitution, extraction and formulation water are each considered to equal 1.*

  - **Natural Index = 0**: Ingredient does not meet the definition of natural ingredients;
Index of Plant extracts

Plant extracts have a Natural Index of 1 if the solvents used are natural, including water. In other cases, the Natural Index is calculated according to the following:

$$\text{Natural Index} = 1 - \frac{\text{NDS}}{\text{E}}$$

*Where:*

NDS: Weight of Natural Derived Solvent in the final extract

E : weight of the final extract.
Natural origin index

- The Natural Origin Index is a value indicating whether a cosmetic ingredient meets the definitions in ISO16128:1 of either natural ingredients, derived natural ingredients or derived mineral ingredients (from corresponding sections);

- The value is assigned to each ingredient according to the following guidance:

$$0.5 < \text{Natural Origin Index} \leq 1$$

$$\text{ingredient} = \frac{\text{natural origin moiety}^*}{\text{Total molecular composition}}$$

* determined by molecular weight, renewable carbon content or any other relevant methods
Annex D Examples of calculations

• Cocamidopropylbetaine

MW of the natural part = 183
MW of the molecule = 342
% of natural origin = \( \frac{183}{342} \times 100 = 53.5\% \)
Organic index

• The value is assigned to each ingredient according to the following guidance:
  ✓ Organic Index = 1: Ingredient meets the definition of organic Ingredients;

  ✓ Organic Indexes of constitutive water or reconstitution water used in processing organic ingredients are considered to equal 1;

  ✓ Plants extracts have an Organic Index of 1 if plant and solvents used are organic;
Organic Origin index

- The value is assigned to each ingredient according to the following guidance:

\[ 0 < \text{Organic Origin Index} \leq 1: \]

\[ \text{ingredient} = \frac{\text{organic origin moles}}{\text{Total molecular composition}} \]

- The Organic Origin Indexes of organic ingredients, and constitutive water or reconstitution water present in either organic ingredients or derived organic ingredients are considered to equal 1;

* determined by molecular weight, renewable carbon content or any other relevant methods
Finished product indexes

- Different indexes have been developed to determine:
  - Percentage of naturalness of the product with and without the formulation water;
  - Percentage of natural origin of the product with and without the formulation water;
  - Percentage of organicity of the product with and without the formulation water;
  - Percentage of organic origin of the product with and without the formulation water;

All the indexes are based on the sum of the index for each ingredient $\times$ the percentage of the ingredient in the formula.
<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Example</th>
<th>% (w/w)</th>
<th>Natural index</th>
<th>Natural content</th>
<th>Natural origin index</th>
<th>Natural origin content</th>
<th>Organic index</th>
<th>Organic content</th>
<th>Organic origin index</th>
<th>Organic origin content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formulation water</td>
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<td>60</td>
<td>1</td>
<td>60</td>
<td>1</td>
<td>60</td>
<td>0</td>
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<td>Natural Vegetable oil</td>
<td></td>
<td>10</td>
<td>1</td>
<td>10</td>
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<td>0</td>
<td>0</td>
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<td>0</td>
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<tr>
<td>Extract</td>
<td>extract of fresh natural plant by a mix 30% natural derived glycerin / 70% water</td>
<td>2</td>
<td>0,7</td>
<td>1,4</td>
<td>1</td>
<td>2</td>
<td>0</td>
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<tr>
<td>Mineral Salt</td>
<td></td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>0</td>
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<tr>
<td>Derived natural ester</td>
<td>ester with 70% natural origin</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>0,7</td>
<td>3,5</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Derived mineral Titanium dioxide</td>
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<td>0</td>
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<td>5</td>
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<tr>
<td>Organic Vegetable oil</td>
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<td>5</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Organic extract</td>
<td>extract of dry organic plant by 50% organic ethanol / 50% water</td>
<td>4</td>
<td>1</td>
<td>4</td>
<td>1</td>
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<td>1</td>
<td>4</td>
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<td>4</td>
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<tr>
<td>Derived organic ester</td>
<td>ester with 20% natural origin and 80% organic origin</td>
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<td>3,2</td>
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<td>Non natural Silicon oil</td>
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<tr>
<td>Content with formulation water (%)</td>
<td></td>
<td>83,4</td>
<td></td>
<td></td>
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<tr>
<td>Content without formulation water (%)</td>
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<td>58,5</td>
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</tbody>
</table>
Claims

• Claims are not considered in the ISO standards;
• It is important to note though that the standards will most probably serve as the basis for control of claims;
• Certification: there are many certifying bodies like Ecocert, BDHI, Natrue, Cosmos, etc. their criteria are slightly different but always more stringent than ISO;
Conclusions ISO standard 16128

• Provides a clear, transparent, scientific way of calculating the natural, derived natural, mineral, derived mineral, organic, or derived organic indexes of ingredients and finished products;
• It allows companies to claim the percentage without the need for costly certification (which are always possible);
• It allows consumers a clear, transparent choice;
• It gives regulators a basis for controls;
• Promotes innovation in always pushing for higher content;
Thank you