AVANT Institute Symposium
International Standards:
ISO and Natural - Organic Cosmetics

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Personal Care Products Council

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Agenda

- Section 1 – Standardization & ISO
  - An Introduction to ISO
- Section 2 – ISO TC 217 Cosmetics Standards
  - High Impact Standards Published and Under Development
- Section 3 – ISO 16128: Parts 1 & 2 -- Guidelines on Natural and Organic Cosmetics
- Section 4 – Dec 2019 Natural/ Organic Update
  - HR 5017 - Natural Cosmetic Act

The views and opinions expressed are mine and do not necessarily reflect the official policy or position of PCPC or it's members.

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A Global Industry

- Raw Materials
- Manufacturing
- Distribution
- Sales

Harmonization is essential to the free movement of goods on a global basis.

A History of Global Harmonization

- CTFA Cosmetic Ingredient Dictionary (1973)
  - Today >26,000 Monographs
  - Recognized by US, EU, Canada, Japan & acknowledged by many more
- International Cooperation on Cosmetic Regulations (2007)
  - ICCR - Voluntary initiative of cosmetic regulatory authorities from Brazil, Canada, Japan, EU and US.
    - 2019 ICCR-13 Observers: Colombia, Israel, South Korea, Taiwan, and Thailand
  - Overall Goal to Remove Regulatory Obstacles while maintaining highest standards in consumer protection

http://www.iccr-cosmetics.org/

ISO

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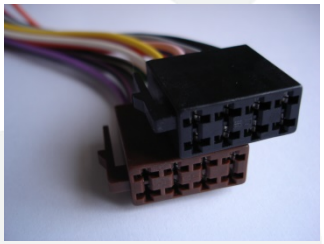
ISO – A SNAPSHOT



- What ISO does
  - Develops International Standards and other deliverables for products, services, processes, materials and systems, for conformity assessment, managerial and organizational practice.
- What ISO does not do
  - Carry out certification of conformity.
- ISO – the organization

  - The most representative national standards body, on the basis of 1 per country
- ISO's origins
  - Founded in 1946 by delegates from 25 countries.

Purpose Remains: Facilitate Trade

- Make world market requirements transparent.
- Sets standards and defines conformity assessment mechanisms checking products meet standards.
- Improve Human Health and Safety.
- Spread knowledge, and share technological advances and good management practices.

Everyone to Compete on an Equal Basis Everywhere.

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ISO Today

ίσος

- Today 164 members with Central Secretariat in Geneva.
- 22,208 International Standards covering almost all aspects of technology and manufacturing.
- Because 'International Organization for Standardization' would have different acronyms in different languages the short form is ISO, derived from the Greek isos, meaning equal.

Whatever the country, whatever the language, it is always ISO.

Standards Development

- Standards developed by Technical Committees.
- **TC** is comprised of experts who participate as members of national delegations representing the ISO national member institute.
- In the US the national member institute is ANSI
- Experts come from the industrial, governmental, technical and business sectors, or others with specialized knowledge.
- Today there are 780 Technical Committees & Subcommittees ~50,000 experts working on Standards worldwide.

International Recognition

- ISO standards are voluntary and have no regulatory or statutory standing in and of themselves.
- The power of an ISO Standard arises from the inclusive development process.
- Standards are broad based consensus documents, reflecting the agreement of international experts from all 164 participating member nations.

Thus ISO Standards are widely respected and accepted by public and private sectors, and are regularly adopted explicitly or recognized in regulatory activities internationally.

Technical Committee – 217 Cosmetics

- TC 217 formed in 1998, to develop international standards in the area of cosmetics. US joins 2000.
- As of December 2019 Published 30 Standards.
- 41 Full members (P); 28 Observing countries (O); & 9 liaison
  - ASEAN Cosmetics Association (ACA), The Latin American Cosmetics, Toiletry and Perfumery Association (CASIC), International Commission on Illumination (CIE), COSMOS-Standard AISBL, Cosmetics Europe, International Federation of Organic Agriculture Movement (IFOAM Head office), International Fragrance Association (IFRA), NATRUE, and Small Business Standards (SBS).

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Participating Countries

Argentina (IRAM); Australia (SA); Austria (ON); Bahrain (BSMD), Belgium (NBN); Brazil (ABNT); China (SAC); Colombia (ICONTEC); Czech Republic (CNI); Egypt (EOS); Ethiopia (ESA); France (AFNOR); Germany (DIN); Ghana (GSB); India (BIS); Indonesia (BSN); Iran(ISIRI); Ireland (NSAI); Italy (UNI); Japan (JISC); Jordan (JISM); Korea (KATS); Lebanon (LIBNOR); Lithuania (LST); Mexico (DGN); Netherlands (NEN); New Zealand (NZSO); Poland (PKN); Portugal (IPQ); Saudi Arabia (SASO); Singapore (ESG); South Africa (SABS); Spain (AENOR); Sri Lanka (SLSI); Sweden (SIS); Switzerland (SNV); Thailand (TISI); Turkey (TSE); United Arab Emirates (ESMA);United Kingdom (BSI); USA (ANSI)

Observing Countries

Algeria (IANOR); Armenia (SARM); Belarus (BELST); Botswana (BOBS); Brunei Darussalam (NSC); Bulgaria (BDS); Cameroon (CDNQ); Canada (SCC); Congo (OCC); Côte-d'Ivoire (CODINORM); Croatia (HZN); Ecuador (INEN); Finland (SFS); Hong Kong (ITCHKSAR); Hungary (MSZT); Kenya (KEBS); Mongolia (MASM); Nigeria (SON); Oman (DGSM); Romania (ASRO); Russian Federation (GOSTR); Serbia (ISS); Slovakia (SUTN); Slovenia (SIST); Uganda (UNBS); Ukraine (DSSU); Uzbekistan (UZSTANDARD); Zimbabwe (SAZ)

ISO TC 217 – Cosmetics Structure

- The work of the TC 217 has been divided into Working Groups (WG):
  - WG 1 Microbiological standards and limits;
  - WG 3 Analytical Methods;
  - WG 4 Terminology;
  - WG 7 Sun protection test methods
  - *WG 2 Packaging, labeling and marking;*
  - *WG 6 GMP;*

Standards Activity

Working Group	Standards Completed*	Under Development
1- Microbiology	12	1
2- Labeling	1	
3- Analytical	7	4
4- Terminology	4	1
6- GMP	2	
7- Sun Protection	4	7

* Published Standards are reviewed every 5 years to assure currency and continued relevance.

Section 2 – TC 217 Cosmetics

High Impact Standards Published & Under Development

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WG 1 Microbiology – Highlights

- ISO 11930:2012 comprises a preservation efficacy test and a procedure for evaluating the overall antimicrobial protection of a cosmetic product.
- ISO 29621:2017 gives guidance to help define those finished products that, based on a risk assessment, present a low risk of microbial contamination during production and/or intended use, and therefore, do not require the application of microbiological International Standards for cosmetics.
- ISO 17516:2014 recommends limits applicable for all cosmetics and assists interested parties in the assessment of the microbiological quality of the products.

WG 3 Analytical Methods – Highlights

- ISO/TR 18811:2018 gives guidelines for the stability testing of cosmetic products reviewing readily available bibliographic references for assessing the stability and can serve as a technical/scientific framework to identify the most suitable methods for the assessing the stability of cosmetics.
- ISO/ TS 22176 proposes a characterization protocol for the validation of a quantitative analysis method in the cosmetic field and thus respond to the requirements of ISO/IEC 17025:2017 specifying the general requirements for the competence, impartiality and consistent operation of laboratories.
- ISO 21392; ISO 23821 & ISO 23674 Quantification of heavy metal trace elements in finished cosmetic products applicable to numerous number of elements but this standard refers only Chromium, Cobalt, Nickel, Arsenic, Cadmium, Antimony and Lead and 2 methods for Mercury with CEN.

WG 6 GMP – Highlights

- ISO 22716:2007 Cosmetics -- Good Manufacturing Practices (GMP) -- Guidelines on Good Manufacturing Practices Guidelines for the production, control, storage and shipment of cosmetic products.
- ISO TR 24475:2010 Cosmetics -- Good Manufacturing Practices (GMP) -- Training document on GMP contributing to the training of personnel in cosmetic production plants within the context of the GMPs. It is intended to complement personal involvement and reasoning in the implementation of ISO 22716.

International Recognition

ISO 22716 has been or is intended to be adopted as a national standard or other publication and is identical to the International Standard.

Adopted (Modified*)

Austria ASI
Bahrain BSMD
Belgium NBN
Colombia ICONTEC
Croatia HZN
Czech Republic UNMZ
Ecuador INEN
Finland SFS
France AFNOR
Germany DIN
Indonesia BSN
Iran, Islamic Republic of ISIRI
Italy UNI
Korea, Republic of KATS
Jordan* JSMO
Lebanon LIBNOR
Lithuania LST
Netherlands NEN
Poland PKN
Romania ASRO
Singapore* SPRING
South Africa SABS
Spain AENOR
Sri Lanka* SLSI
Sweden SIS
Switzerland SNV
Thailand TISI
United Arab Emirates ESMA
United Kingdom BSI

ASEAN Countries Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam.

WG 7 Sun Methods Highlights

- ISO 24442(2011) Cosmetics -- In Vivo determination of UVA protection
- ISO 24443(2012) Cosmetics -- In Vitro determination of UVA protection
- ISO 24444(2010) Cosmetics -- In Vivo determination of SPF (sun protection factor)
- ISO WD 23675 Cosmetics -- Sun Protection Test Methods - In Vitro determination of SPF

Section 3: ISO 16128:1 (2016) & ISO 16128:2 (2017)

"Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products"

Part 1: Definitions for ingredients

Part 2: Criteria for ingredients and products

The Naturals Evolution

- U.S. Market for natural & organic cosmetics largest in the world
- The global natural cosmetics market size is expected to reach a value of $48 B by 2025 , at a CAGR of 5.01% from 2019 to 2025*
- ~ 2 out of 3 Woman age 35-54 say buying all-natural beauty products is important
- Consumer confusion is apparent+:
  - Does the word “Organic” have the same meaning for a Shampoo as an Apple? 41% Yes; 31% No; 28% Just didn’t know
  - There are Regulations Governing the Claim for a Shampoo. 37% Yes; 33% No; 30% Just Not Sure

*) Grand View Research, found 12/01/2019 at https://www.bloomberg.com/press-releases/2019-06-11/natural-cosmetics-market-worth-48-04-billion-by-2025-cagr-5-01-grand-view-research-inc

+) FTC USDA “Consumer Perception” Study, August 10, 2016

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State of Play

- Many private, NGO and Governmental organizations have developed natural and organic standards and for fee certifications
- There are similarities but also critical technical differences in how ingredients are defined, how content is calculated, and which ingredients are prohibited.

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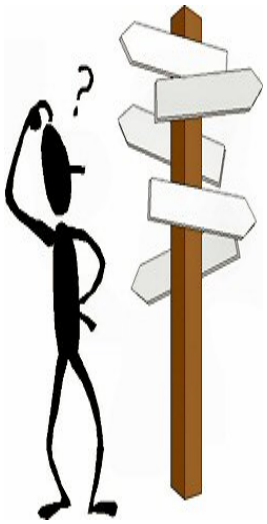
Why an International Standard?

Claim	USDA	CARTV Quebec	DAFF Australia	Retailer
100% Organic	100%	--	100%	100%
Organic	≥95%	≥95%;	≥95%;	≥95%
Made with organic Ingredient	≥70%	70-95% Contains X% organic ingredients: <70% contains X	≥70% <70% contains X	≥70%
No Claim	<70%	--	--	--



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What was Needed

- Credible, transparent and scientifically-sound set of definitions and criteria for natural and organic products at an international level.
- Provide this guidance in the **context of cosmetics.**

ISO 16128: “Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients”

Part 1 (2016): Definitions for Ingredients

Part 2 (2017): Criteria for ingredients and products”.

INTERNATIONAL STANDARD

ISO 16128-1

First edition
2016-02-15

Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products —

Part 1:
Definitions for ingredients

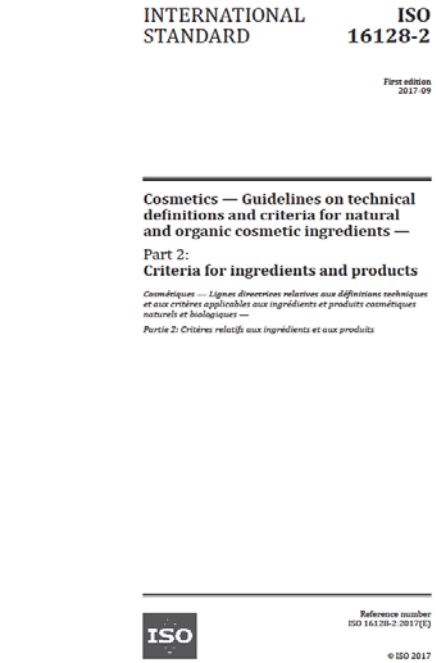
Lignes directrices relatives aux définitions techniques et aux critères applicables aux ingrédients et produits cosmétiques naturels et biologiques —

Partie 1: Définitions des ingrédients

ISO

Reference number
ISO 16128-1:2016(E)

© ISO 2016



INTERNATIONAL STANDARD

ISO 16128-2

First edition
2017-09

Cosmetics — Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients —

Part 2:
Criteria for ingredients and products

Cosmétiques — Lignes directrices relatives aux définitions techniques et aux critères applicables aux ingrédients et produits cosmétiques naturels et biologiques —

Partie 2: Critères relatifs aux ingrédients et aux produits

ISO

Reference number
ISO 16128-2:2017(E)

© ISO 2017

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Scope ISO 16128: Parts 1 & 2

- ISO 16128 provides guidelines on definitions and criteria for natural and organic cosmetic ingredients (Part 1) and products (Part2).
- These guidelines are specific to the cosmetics sector.
- They apply scientific judgment to establish principles for a consistent framework for natural and organic cosmetics
- Represent a consensus of all the different stakeholders that have been part of its development (cosmetics companies, academics, authorities, supplier & certifying bodies…)
- Recognizes and aligns to the extend possible existing definitions and technical criteria for ingredients and products with established schemes
- Voluntary – To respect the right of companies to utilize internal requirements developed under a common set of technical definitions and criteria

Scope: ISO 16128: Parts 1 & 2

ISO 16128 Doesn't

- Explain National or State claims/advertising regulations covering natural and organic
- Assessing human or environmental safety
- Pronounce a value on GMOs
- Address socio-economic considerations (e.g. Fair Trade, animal testing, Precautionary Principle)
- Deal with packaging materials or regulatory requirements
- ➢ Does Not Set a threshold for finished products to be considered natural or organic

Overview ISO 16128: Parts 1 & 2

Part 1: Ingredient Definitions for:

- Natural & Derived Natural ingredients
- Organic & Derived Organic ingredients
- Natural & Derived Mineral ingredients
- Non-natural ingredients
- Natural fragrances must comply with ISO 09325

Part 2: Calculates indexes for product content

- Natural & Natural origin
- Organic & Organic origin

Definitions: Natural & Natural Derived

- Ingredients obtained only from plants, animals, micro-organisms or minerals, including those obtained from these materials by physical processes (e.g. grinding, drying, distillation), fermentation reactions occurring in nature and leading to molecules which occur in nature, and other procedures including traditional ones (e.g. extraction using solvents) without intentional chemical modification.
- Ingredients of >50 % natural origin, by MW, by renewable carbon content, or by any other relevant methods, obtained through defined chemical and/or biological processes with the intention of chemical modification.

Definitions Organic & Organic Derived

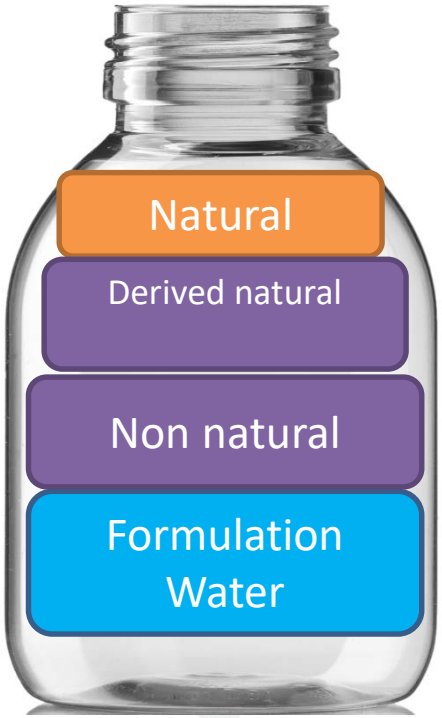
- Organic ingredients are natural ingredients originating from organic farming methods or from wild harvesting in compliance with national legislation or equivalent International Standards where applicable.
- Derived Organic ingredients are of organic or mixed organic and natural origin obtained through defined chemical and/or biological processes with the intention of chemical modification, which do not contain any fossil fuel origin moiety.

Informative Annexes

- Part 1: Annexes
  - Solvents for ingredient processing and manufacturing
  - List of chemical and biological processes for derived natural, derived organic, and derived mineral ingredients
  - Examples of calculations for molecular weight is known or not known
  - List of derived mineral ingredients
- Part 2 Annexes
  - Examples of calculations
  - Examples of organic and organic origin index determination for extracts
  - Results of index determination and content calculation

Supporting Documents

- ISO TR 22582:2019 Cosmetics — Methods of extract evaporation and calculation of organic indexes — Supplemental information to use with ISO 16128-2
- ISO TR 23199:2019 Cosmetics — Calculation of organic indexes of hydrolates — Supplemental information for ISO 16128-2
- ISO DTR 22750 Cosmetics – Answers to Frequently Asked Questions on Ingredients and Product Characterization According to ISO 16128



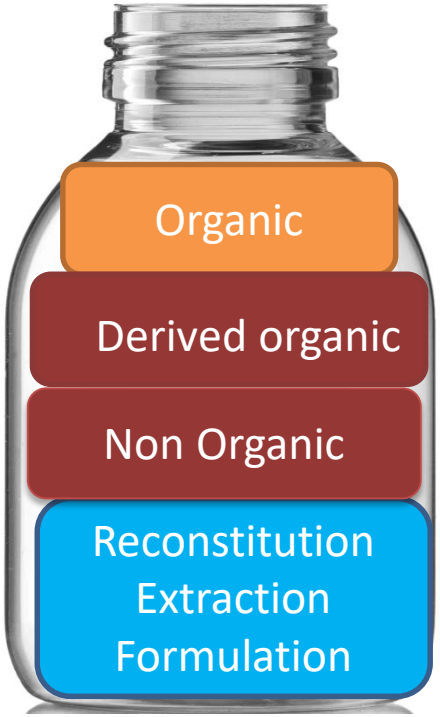
Formula **including** water

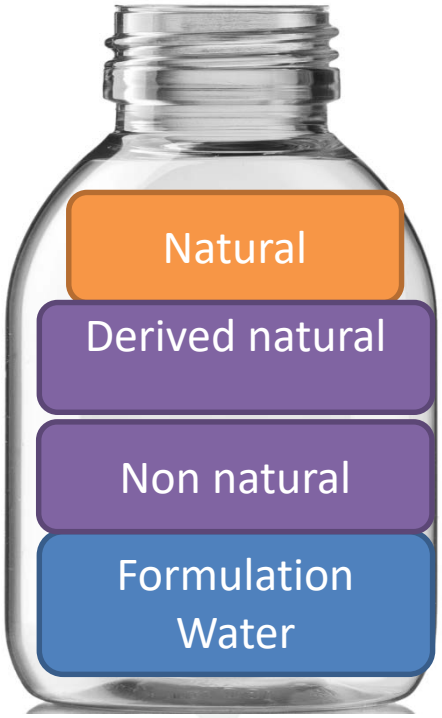
$$\frac{\text{Sub total} + \text{Water}}{\text{Sub total} + \text{Sub total} + \text{Water}} \times 100$$

Natural Index

Organic Index

$$\frac{\text{Sub total}}{\text{Sub total} + \text{Sub total} + \text{Water}} \times 100$$





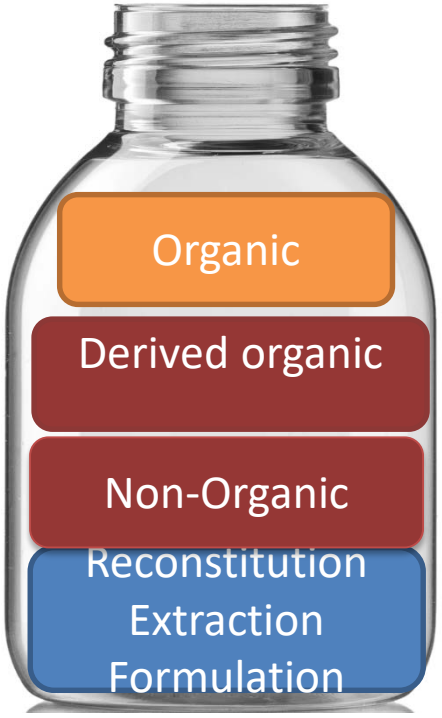
$$\frac{\text{Sub total}}{\text{Sub total} + \text{Sub total}} \times 100$$

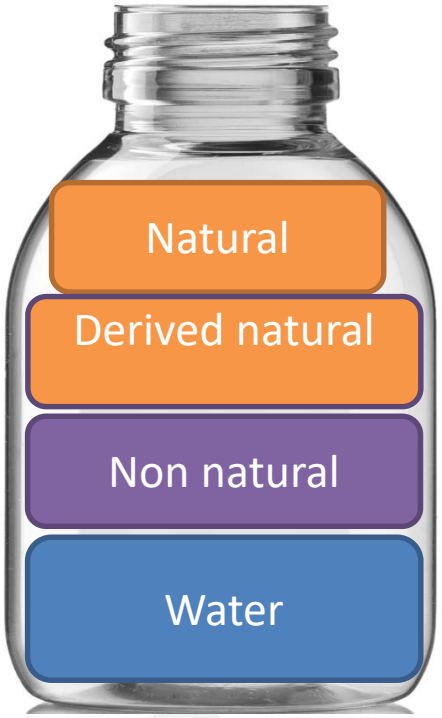
Formula **excluding** water

Natural Index

Organic Index

$$\frac{\text{Sub total}}{\text{Sub total} + \text{Sub total}} \times 100$$





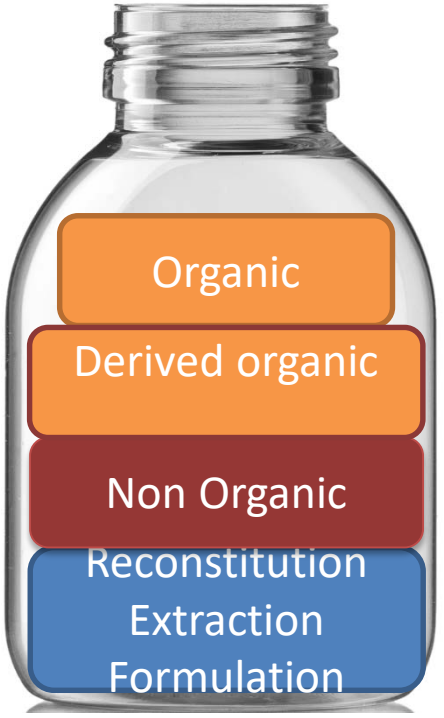
$$\frac{\text{Sub total} + \text{Water}}{\text{Sub total} + \text{Sub total} + \text{Water}} \times 100$$

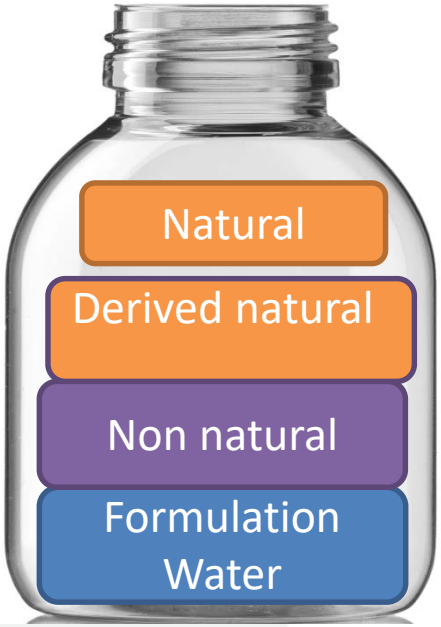
Formula **including** water

Natural Origin Index

Organic Origin Index

$$\frac{\text{Sub total}}{\text{Sub total} + \text{Sub total} + \text{Water}} \times 100$$

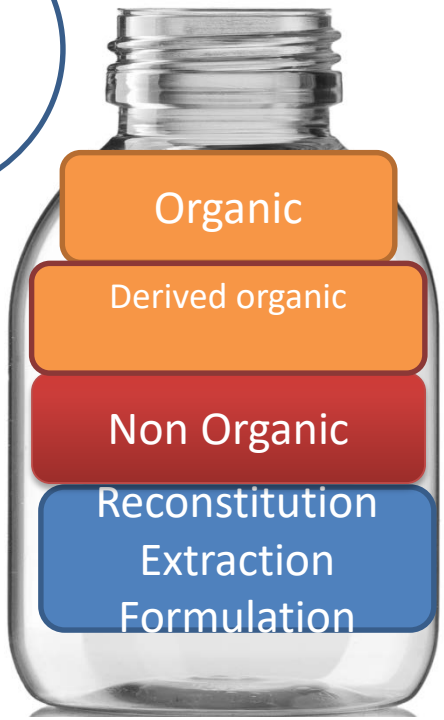




Natural Origin Index

$$\frac{\text{Sub total}}{\text{Sub total} + \text{Sub total}} \times 100$$

Formula **excluding** water



Organic Origin Index

$$\frac{\text{Sub total}}{\text{Sub total} + \text{Sub total}} \times 100$$

Natural origin **30%** | Non Natural origin **70 %** → Not added

>50% of non natural origin components are regarded as non-natural

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Summary ISO: 16128 Part 1 & 2

- International, voluntary standards specific to natural and organic cosmetics and their ingredients;
- Delivers a credible and transparent set of definitions and criteria, for natural and organic cosmetic ingredients & products
- Establish a common basis to communicate objectively between consumers, industry and authorities.
- Does this by using sound scientific judgement, providing logical framework, to translate natural and organic content in a cosmetic product into a numeric value
- The standard sets a minimum requirement and does not prevent a company from having a more rigorous or expansive set of internal requirements.

Todays Goal

AWARNESS!

- Next Steps: Additonal Implementation Support
- Systematic Review: 2021 & 2022

Section 4: Dec 2019 Natural/ Organic Update

ISO 16128 Part 2: Correction

- Proposed change of the formula and other changes aligning text with formula.
- Amendment approve by TC 217 by simple resolution.
- Are these changes considered as critical?
  - If not they may be kept for a future full revision.

HR 5017 Natural Cosmetics Act 2019

- Introduced in the House November 8, 2019
- Sponsored by Representatives Sean Maloney (D-NY) and Grace Meng (D-NY) & Jan Schakowsky (D-IL)

A Bill to amend the Federal Food, Drug, and Cosmetic Act to treat as misbranded cosmetics with packaging or labeling using the term ‘‘natural’’ unless the product meets certain standards, and for other purposes.

Provisions: HR 5017 - Natural Cosmetics Act

- Establishes that in Cosmetics the claim “Natural” means
  - ≥70 % Natural substances (excluding H_2O and Salt)
  - No Fragrance other than Natural & Naturally-Derived (N-D)
  - Remainder only N-D, with few exceptions (required for functionality or not feasible)
- Requires Natural Ingredients
  - Be identified in Ingredient Declaration by ‘mark’
  - Labeling includes definitions
- Prohibited Reactions
- Record Keeping (including ^{14}C dating), Enforcement

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Definitions: Natural

- The term ‘natural’ means any chemical substance that is naturally occurring and which is—
  - Unprocessed or processed only by manual, mechanical, naturally derived solvent or gravitational means, by dissolution in water or steam, by flotation, or by heating solely to remove water; or extracted from air by any means.
  - Excludes petroleum and petroleum derived ingredients

Definitions: Naturally-Derived

- Any substance where the starting material is of mineral, plant, microbe, or animal origin, but:
  - has been chemically processed; or
  - has been chemically processed and combined with other ingredients, excluding petroleum and fossil fuel-derived ingredients;
- Derived from a plant feedstock and bio-manufactured using processes like fermentation, saponification, condensation, or esterification in order to improve performance or make the ingredient biodegradable or sustainable.’’.

Forbidden Reactions

- Alkoxylation (including ethoxylation and propoxylation) using EO or PO or other alkylene oxides.
- Deterpenation (other than with steam).
- Halogenation as the main reaction.
- Ionizing radiation.
- Sulphonation as the main reaction.
- Treatment with ethylene oxide.
- Treatment using mercury.’’.

Natural Cosmetics Act v. ISO 16128

- Natural more restrictive as ingredients from “fermentation reactions occurring in nature and leading to molecules which occur in nature” not be allowed.
- Derived Natural possibly less restrictive; ISO requires D-N be >50% from Natural starting materials; NCA allows combination without regard to final contribution.
- Natural claim limited to N & D-N natural ingredients. ISO allows certain non-natural components with a 50% maximum.
- ISO lists allowed reactions; NCA lists prohibited reactions.
- NCA additional obligations to the ingredient disclosure statement
- Does not address organic
- ➢ Sets a 70% natural Ingredients bright line on the term Natural for the formulated product excluding water and salt from the calculation.

Progress Toward The Ideal State

QUESTIONS?

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