

The scientific and regulatory approach: the impact of the international standard ISO 16128

Why do we need a standard?

What is the ISO 16128 Part 1&2?

Advantages on using ISO 16128

The scientific and regulatory approach: the impact of the international standard ISO 16128

Why do we need a standard?



Demand for natural and organic ingredients in personal care products is a major trend that parallels interest in foods, dietary supplements, and related products.

In most markets, there is no regulated definition of "natural" or "organic" with respect to cosmetics, and no health authorities have issued formal positions on how such claims should be substantiated.



#### Why do we need a standard











A number of private organizations have developed certifications to support natural and organic claims.

While there are similarities in private certifiers' approaches, there are critical technical differences in how ingredients are defined, how content is calculated, and which ingredients are prohibited.





























### CONSUMERS

Increased interest in cosmetic products perceived as natural and organic.

Difficulties in the interpretation of natural & organic claims

CONTROL

Difficulties to evalue ethe or piant = 5

INTERNATIONAL RECOGNITION....

Difficulties to evaluate the consistency from country to country





## GENERAL PERCEPTION



At international level, there is currently a plethora of divergent, often conflicting and competing 'standards' and 'certification schemes'

Industry/consumers voiced concerns over apparent lack of clear rules and international coherence



## INDUSTRY WANTS ....



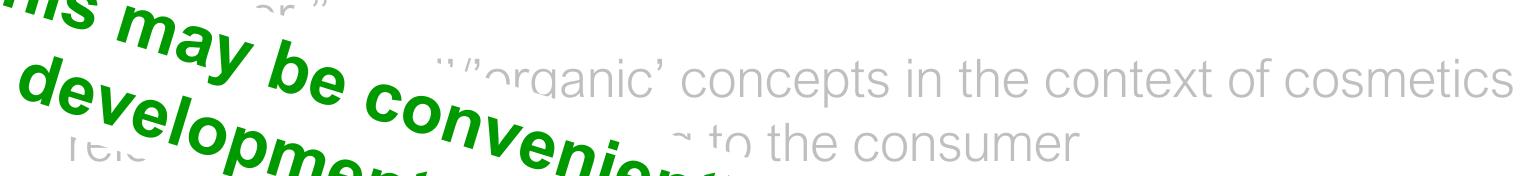
- ✓ To have a highly credible, transparent and scientifically-sound set of definitions and criteria for natural and organic cosmetic products, in order to communicate with sincerity to the consumer.
- ✓ Promote 'natural'/'organic' concepts in the context of cosmetics, relevant and not misleading to the consumer
- ✓ Improve the value of 'natural'/'organic' cosmetics for the consumers by assuring product quality.
- ✓ Ensure fair competition and proper functioning of the market at international level by aligning technical criteria and underlying principles at ingredient and product level among existing initiatives.



## INDUSTRY WANTS ....

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"This may be conveniently achieved through the



- development of the consumer

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  International level by aligning technical. principles at ingredient and product level among initiatives.





#### Why do we need a standard









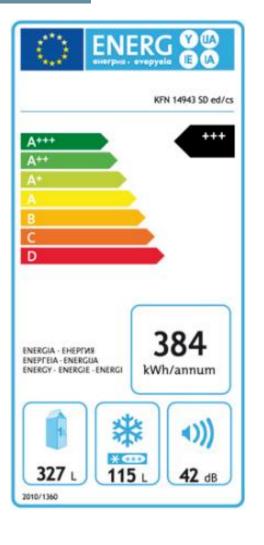
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The scientific and regulatory approach: the impact of the international standard ISO 16128

What is the ISO 16128

## 189 TC217 Cosmetics - a brief

STANDARDIZATION: Consistently ensures fair competition and adequate functioning of the international market by aligning, among the initiatives of the different countries, the technical criteria and the fundamental principles at the level of ingredients and products.



#### ISO

- ✓Integrates National Standardization Bodies
- ✓ International forum open to all stakeholders
- ✓ Transparency
- ✓ Consensus driven process
- ✓ Widely recognized at international level
- ✓ Organized in TC's





## ISOTC217 WG4 TERMINOLOGY

ISO 16128: "Guidelines on definitions and criteria for natural and organic cosmetic ingredients and products"

Divided in two Parts to enable a better understanding and application



INTERNATIONAL ISO
STANDARD 16128-1

STANDARD 16128-1

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Services

Cosmetics - Guidelines on Technical Definitions and Criteria for Nat
& Organic Cosmetic Ingredients
Part 2:
Criteria for ingredients and Products

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Region of this data with the comments, addition of any relevant patient of
which they are seen and to provide supporting documentation.

Statements and the Standard of the

ISO 16128: "Guidelines on definitions and criteria for natural and organic cosmetic ingredients and products" Part 1&2

Both parts are intended to be used together

Part 1 ingredient characterization

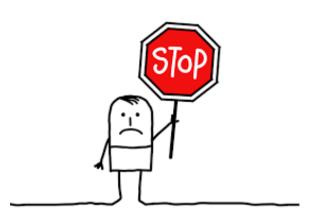
Part 2 approaches to determine indexes that apply to the ingredient categories defined in Part1. Framework to determine the natural, natural origin, organic and organic origin content of products based on the ingredient characterization.

NB: the annexes are only informative

#### The guidelines:



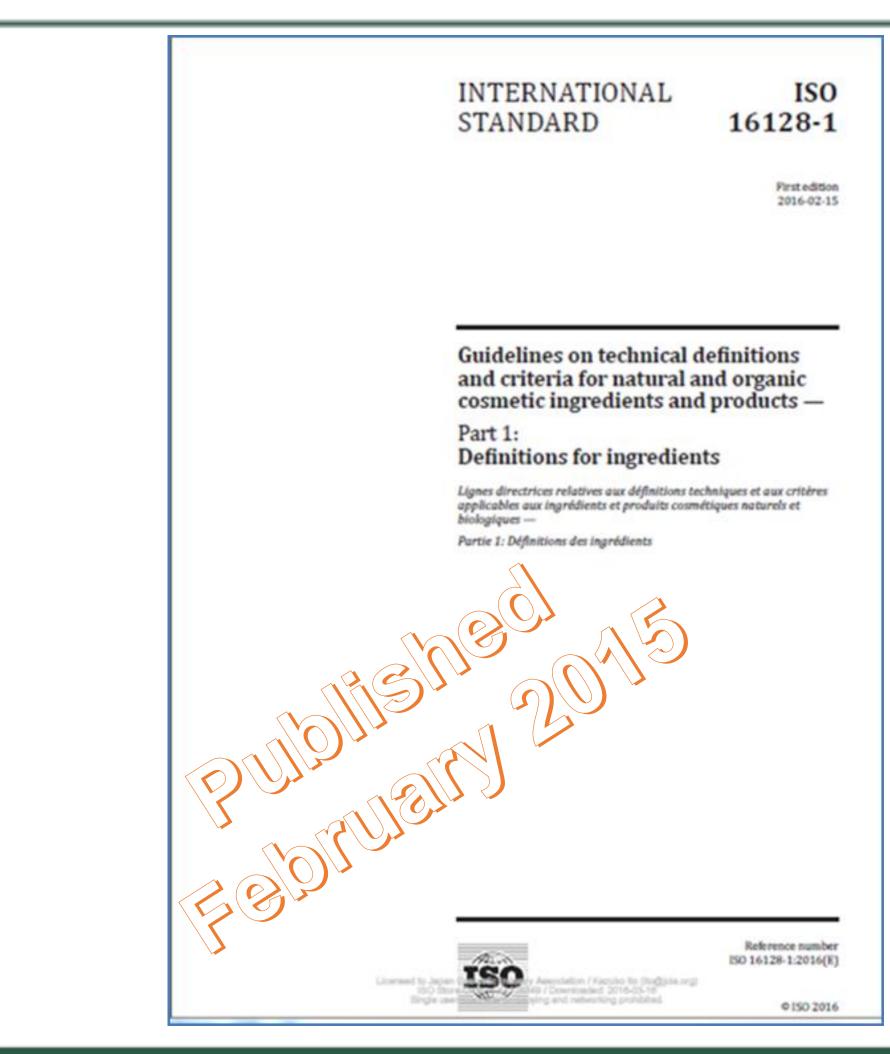
- specific to the cosmetics sector
- apply scientific judgment
- offer principles towards a consistent & logical framework for natural and organic cosmetic ingredients and products
- > encourage a wider choice of natural and organic ingredients
- encourage innovation (no positive or negative lists)
- Voluntary not linked to any certification / approval system.



#### Do not address

- Product communication (how to claim or label a products), human or environmental safety
- > Does not commit to values (no exclusion of certain ingredients depending on the media coverage or the expectations of consumers)
- Does not consider socio-economic aspects (fair trade, animal well being, sustainable development)
- Does not deal with packaging materials or regulatory requirements
- Does not set a threshold limit for a product to be considered natural / organic



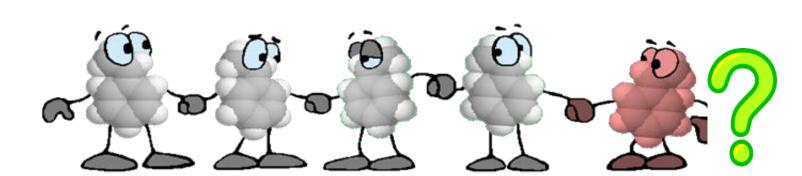


## Part 1 - INGREDIENTS FIRST - definition

- Natural and Derived natural ingredients
- Natural and Derived mineral ingredients
- Organic and Derived organic ingredients

ConstitutiveWaterReconstitutionExtraction

- Non-natural
- Informative annexes











#### NATURAL INGREDIENTS ARE:

Cosmetic 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 of preparation including traditional ones (e.g. extraction using solvents) without intentional chemical modification).

The following materials, and materials originating from them, shall be considered to fall under the general heading of natural origin:

- a) plants including fungi and algae;
- b) minerals;
- c) animals;
- d) micro-organisms.

Ingredients obtained from fossil fuels are excluded from the definition.





# Squalan sourced from oliver

#### DERIVED NATURAL INGREDIENTS ARE:

Cosmetic ingredients of greater than 50 % natural origin, by molecular weight, by renewable carbon content, or by any other relevant methods, obtained through defined chemical and/or biological processes with the intention of chemical modification.

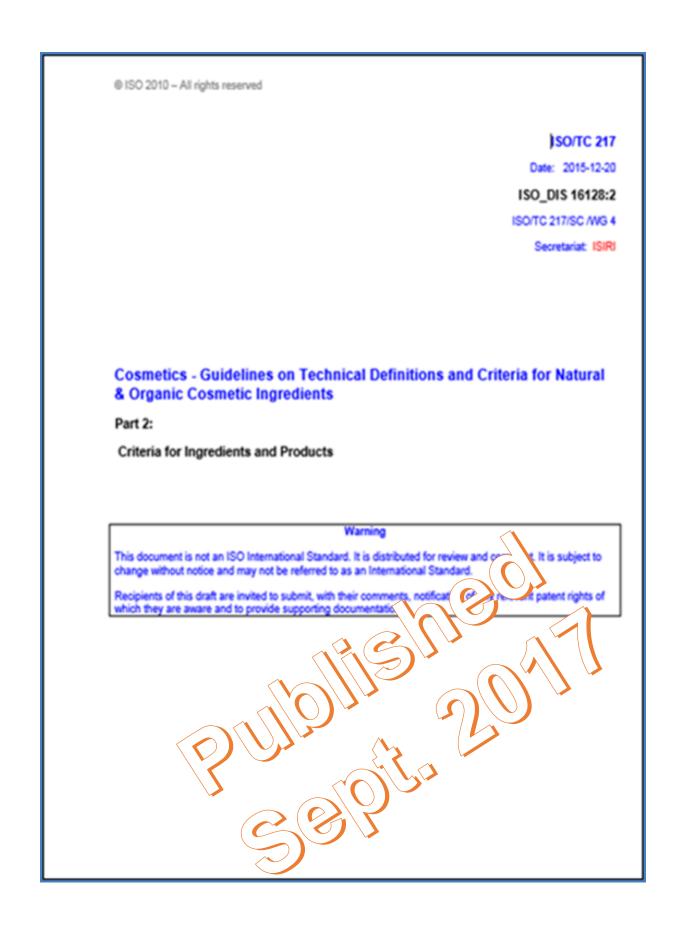
An informative list of such processes is provided in Annex B. Enzymatic and microbiological processing may also give rise to derived natural ingredients, where an intentional chemical modification takes place.



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.

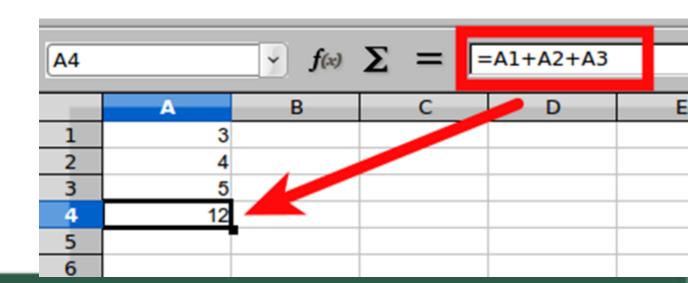
Processes compliant with Green Chemistry are recommended <a href="https://www.epa.gov/greenchemistry">https://www.epa.gov/greenchemistry</a>





## Part 2 - CRITERIA - indexes and calculations

- ✓ Part 2 is intended to be used in conjunction with Part 1. Builds on and enhances ISO 16128:1 (Part 1).
- ✓ Describes approaches to determine natural, natural origin, organic and organic origin indexes that apply to the ingredient categories defined in Part 1.
- ✓ Offers a framework to determine the natural, natural origin, organic and organic origin content of products based on the ingredient characterization.





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)SO/TC 217 Date: 2015-12-20

ISO\_DIS 16128:2

ISO/TC 217/SC /WG 4

Secretariat: ISIRI

Cosmetics - Guidelines on Technical Definitions and Criteria for Natural & Organic Cosmetic Ingredients

Part 2:

Criteria for Ingredients and Products

#### Warnin

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

### INDEXES FOR CALCULATING NATURAL AND NATURAL ORIGIN CONTENT OF INGREDIENTS

Index is a value indicating whether a cosmetic ingredient meets the definition from the corresponding Section of ISO 16128-1.

NATURAL INDEX
NATURAL ORIGIN INDEX
ORGANIC INDEX
ORGANIC ORIGIN INDEX

Natural Index  $(I_n)$ = 1: Ingredient meets the definition of natural ingredients.  $I_n$  constitutive, reconstitution, extraction and formulation water =1.

Natural index  $(I_n)$ = 0: Ingredient does not meet the definition.

Plant extracts:  $I_n=1$  if solvents used are natural, including water. In other cases,  $I_n$  needs to be calculated  $I_n=1-\frac{m_{\rm DNS}}{m_{\rm T}}$ 



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 $P_{\alpha}$ 

#### APPROACHES TO DETERMINE NATURAL AND/OR ORGANIC CONTENT OF FINISHED COSMETIC PRODUCTS

+ Formulation

water

2 ways

#### **Natural content**

$$C_{+H_2O}^{N} = \sum_{\alpha=1}^{n} (P_{\alpha} \times I_{n\alpha})$$

#### Natural origin content

$$C_{+H_2O}^{no} = \sum_{\alpha=1}^{n} (P_{\alpha} \times I_{no\alpha})$$

- Formulation water

$$C_{-\text{H}_2\text{O}}^{\text{N}} = \sum_{\beta=1}^{\text{n}} \left[ \frac{P_{\beta}}{1 - \frac{H_2O_F\%}{100\%}} \times I_{\text{n}\beta} \right]$$

$$C_{-\text{H}_2\text{O}}^{\text{no}} = \sum_{\beta=1}^{n} \frac{P_{\beta}}{\left(1 - \frac{H_2O_F\%}{100\%}\right)} \times I_{\text{no}\beta}$$

natural origin content of a product, as calculated by including formulation water as an  $C_{+\mathrm{H}_2\mathrm{O}}^{\mathrm{no}}$ ingredient;

> percentage, by mass, of each ingredient,  $\alpha$ , in the product and includes formulation water as an ingredient;

natural origin index corresponding to each ingredient,  $\alpha$ , in the product.

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Advantages on using ISO 16128

#### The STANDARD



- Based on sound scientific judgment
- > Developed by consensus among the different actors in this field (companies, private certifiers, academics, authorities, suppliers of raw materials ...). Forty participating countries.
- Takes into account existing regulations and common practices
- Transparent
- > Supports innovation
- > Integrates the principles of green chemistry
- Improves the image of natural / organic cosmetics for consumers by ensuring the quality of the product.
- Guarantees greater transparency for consumer
- Ensures fair competition
- Allows existing labels to persist and compete fairly.
- Ensure that the market operates at the international level by aligning technical criteria and underlying principles with regard to ingredients and products among existing initiatives
- international recognition
- Consumer confidence and credibility





#### **COMPANIES & SUPPLIERS**



- The ingredients are fully categorized in ISO 16128
- Clearly defined and verifiable criteria
- Suppliers of natural and organic ingredients will be able to respond to the demands of their customers on the characterization of the ingredient or extract
- The use and production of natural and organic ingredients will be favoured The use and cultivation of natural and organic ingredients will be encouraged
- > Transparency and homogeneity in the market
- Companies marketing cosmetic products will have a scientific basis for calculating the natural and/or organic content of their products



#### THE CONSUMER



- > Harmonization in the market . A global approach will unify the current jungle of definitions and values
- Clarity and transparency
- > The comparison between product categories for an informed choice will be easy
- > It will allow the supervisory authorities to evaluate the allegations on the same basis

#### **CONTROL AUTHORITIES**



- Transparency
- > It will allow the CONTROL authorities to evaluate the allegations on the same basis



ISO 16128-1

Advantages on using ISO 16128

First edition 2016-02-15

Guidelines on technical de fincions and criteria for naturalla de organic cosmetic ingrediants in products —

Part 1:
Definitio 1 ingredients

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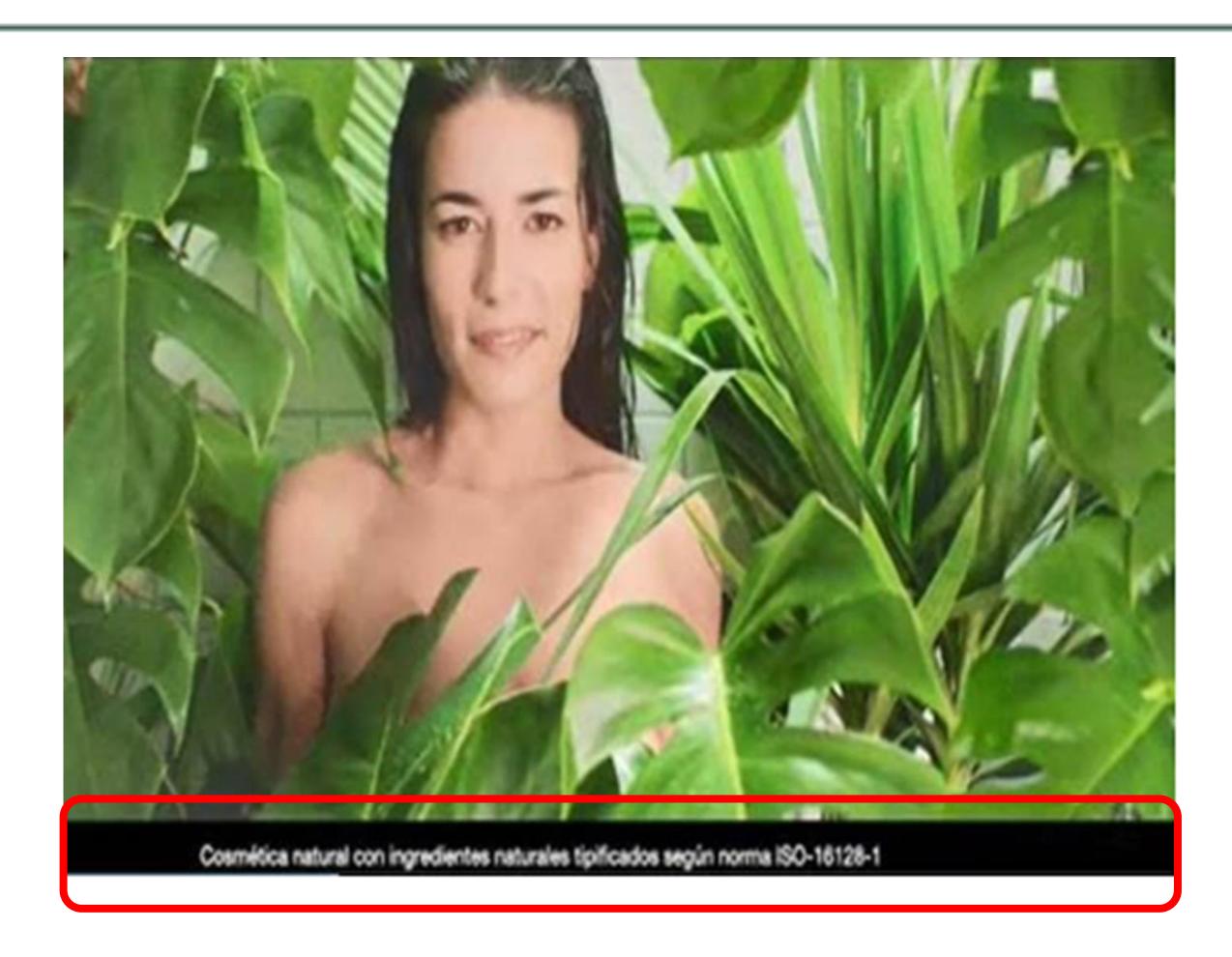
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