ISO standard 16.128, an international harmonization for natural and organic cosmetic products

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

Bologna - September 2018

CARMEN ESTEBAN
Project leader ISO 16128: "Guidelines on definitions and criteria for natural and organic cosmetic ingredients and products"

TRENDS

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

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What is the main characteristic/differentiation of a natural/organic cosmetic?

Composition

Ingredients

This is the characteristic to be communicated to the consumer in order to meet his expectations.

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What is the main characteristic/differentiation of a natural/organic cosmetic?

Composition

Ingredients

How this can be achieved?

This is the characteristic to be communicated to the consumer in order to meet his expectations.

DOES THE CONSUMER RECOGNIZE A TRUSTFULL CLAIM?

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What is the main characteristic/differentiation of a natural/organic cosmetic?

Composition

Ingredients

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.

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What is the main characteristic/differentiation of a natural/organic cosmetic?

Composition

SO WHAT?????

Ingredients

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.

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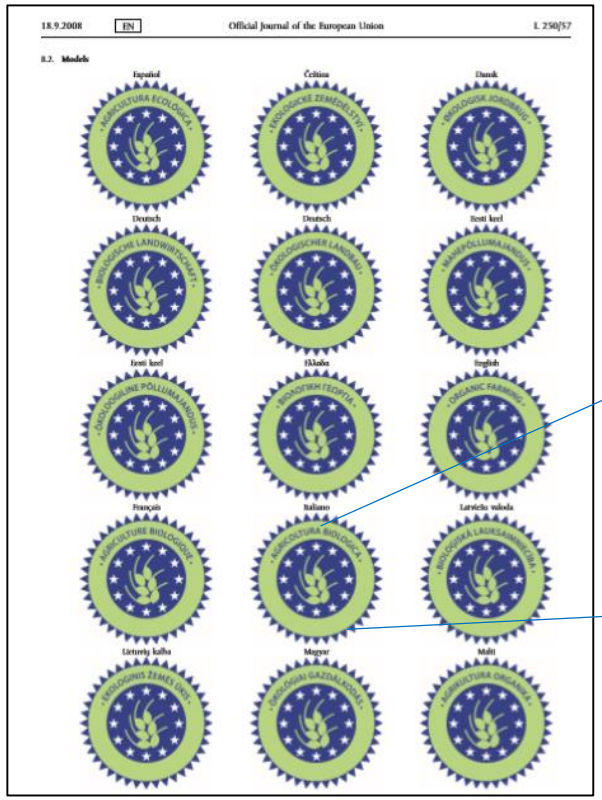
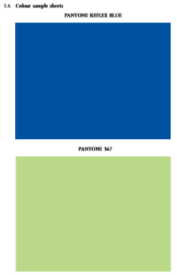
Informing our consumers/customers

Organic farming. Production, labelling and control of organic products in the plant and livestock sector.

Regulatory frame

- *Council Regulation (EC) Nr 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control*
- *Commission Regulation (EC) Nr 889/2008 laying down detailed rules for the implementation of Council*





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Informing our cosmetic consumers

CONTAINS: GLUCOSINOLATES (2-PROPENYL GLUCOSINOLATE (SINIGRIN), 3-METHYLTHIOPROPYL GLUCOSINOLATE, 3-METHYLSULFINYLPROPYL GLUCOSINOLATE, 3-BUTENYL GLUCOSINOLATE, 2-HYDROXY-3-BUTENYL GLUCOSINOLATE, 4-METHYLTHIOBUTYL GLUCOSINOLATE, 4-METHYLSULFINYLBUTYL GLUCOSINOLATE, 4-METHYLSULFONYLBUTYL GLUCOSINOLATE, BENZYL GLUCOSINOLATE, 2-PHENYLETHYL GLUCOSINOLATE, PROPYL GLUCOSINOLATE, BUTYL GLUCOSINOLATE); **INDOLE GLUCOSINOLATES AND RELATED INDOLES**: 3-INDOLYLMETHYL GLUCOSINOLATE (GLUCOBRASSICIN), 1-METHOXY-3-INDOLYLMETHYL GLUCOSINOLATE (NEOGLUCOBRASSICIN), INDOLE-3-CARBINOL, INDOLE-3-ACETONITRILE, BIS(3-INDOLYL)METHANE); **ISOTHIOCYANATES AND GOITRIN**: (ALLYL ISOTHIOCYANATE, 3-METHYLTHIOPROPYL ISOTHIOCYANATE, 3-METHYLSULFINYLPROPYL ISOTHIOCYANATE, 3-BUTENYL ISOTHIOCYANATE, 5-VINYLOXAZOLIDINE-2-THIONE (GOITRIN), 4-METHYLTHIOBUTYL ISOTHIOCYANATE, 4-METHYLSULFINYLBUTYL ISOTHIOCYANATE, 4-METHYLSULFONYLBUTYL ISOTHIOCYANATE, 4-PENTENYL ISOTHIOCYANATE, BENZYL ISOTHIOCYANATE, PHENYLETHYL ISOTHIOCYANATE); **CYANIDES**: 1-CYANO-2,3-EPITHIOPROPANE, 1-CYANO-3,4-EPITHIOBUTANE, 1-CYANO-3,4-EPITHIOPENTANE, THREO-1-CYANO-2-HYDROXY-3,4-EPITHIOBUTANE, ERYTHRO-1-CYANO-2-HYDROXY-3,4-EPITHIOBUTANE, 2-PHENYLPROPIONITRILE, ALLYL CYANIDE, 1-CYANO-2-HYDROXY-3-BUTENE, 1-CYANO-3-METHYLSULFINYLPROPANE, 1-CYANO-4-METHYLSULFINYLBUTANE); TERPENES: MENTHOL, NEOMENTHOL, ISOMENTHOL, CARVONE **PHENOLS**: (2-METHOXYPHENOL, 3-CAFFOYLQUINIC ACID (CHLOROGENIC ACID), 4-CAFFOYLQUINIC) 4-CAFFOYLQUINIC ACID, 5-CAFFOYLQUINIC ACID (NEOCHLOROGENIC ACID), 4-(P-COUMAROYL)QUINIC ACID, 5-(P-COUMAROYL)QUINIC ACID, 5-FERULOYLQUINIC ACID)

RED = CARCINOGENIC
ORANGE = MUTAGENIC/CLA

James Kennedy posters

INGREDIENTS: AQUA (82.2%), **SUGARS (12.8%)** (GLUCOSE (52%), FRUCTOSE (42%), GALACTOSE (5%), MALTOSE (<1%), SUCROSE (<1%)), FIBRE E460 (2.1%), ASH, **FATTY ACIDS (1.6%)** (OCTADECAENOIC ACID (24%), OMEGA-6 FATTY ACID: OCTADECADIENOIC ACID (24%), OMEGA-3 FATTY ACID: OCTADECATRIENOIC ACID (23%), HEXADECANOIC ACID (14%), OCTADECANOIC ACID (<1%), HEXADECAENOIC ACID (<1%), TETRADECANOIC ACID (<1%)) **AMINO ACIDS (<1%)** (ASPARTIC ACID (57%), GLUTAMIC ACID (9%), PROLINE (4%), SERENE (3%), LEUCINE (3%), ALANINE (3%), LYSINE (3%), PHENYLALANINE (2%), GLYCINE (2%), THREONINE (2%), VALINE (2%), ARGININE (2%), HISTIDINE (2%), ISOLEUCINE (2%), TYROSINE (1%), METHIONINE (1%), CYSTEINE (1%), TRYPTOPHAN (1%)), **COLOURS** (E160a, E161b, E161c), E300, E307, CHOLINE, PHYTOSTEROLS, **FLAVOURS** ((Z)-3-HEXENOL, 2-HEPTANONE, CINNAMIC ALCOHOL, CINNAMIC ALDEHYDE, (E)-2,6-NONANEDIENAL, (E)-2-HEXENAL, HEXANAL, EUGENOL, LINALOOL, BENZALDEHYDE, PHENYLACETALDEHYDE).

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Informing our consumers/customers

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.

PRIVATE CERTIFICATIONS?????

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Informing our consumers/customers

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

….”fragmented market with no clear rules, lack of international coherence and increased awareness of mislabeling issues”…….

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Informing our consumers/customers

GENERAL PERCEPTION

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

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Informing our consumers/customers

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.

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Informing our consumers/customers

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.
- ✓ ...organic' concepts in the context ... not misleading to the consumer
- ✓ Improve the value of 'natural' ... for the consumers by assuring product...
- ✓ 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.

....” This has been conveniently achieved through the development of an ISO standard”.....

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Informing our consumers/customers

Why do we need a standard?

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.

A STANDARD IS A TECHNICAL DOCUMENT

- **voluntary** application,
- based on **consensus**
- results of **experience** and technological development
- approved by a recognized standardization body.
- Trustful
- Reliable

Why an ISO standard?

Internationally recognized

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Why do we need a standard

International Organization for Standardization

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

UNI ENTE ITALIANO DI NORMAZIONE

UNE NormalizaciónEspañola

ANSI American National Standards Institute

afnor CERTIFICATION

STANDARDS Australia

SASO
الهيئة السعودية للمواصفات والمقاييس والجودة
Saudi Standards, Metrology and Quality Org.

JISC 日本工業標準調査会
Japanese Industrial Standards Committee

Ministry of Industry
สมอ
THAI INDUSTRIAL STANDARDS INSTITUTE (TISI)

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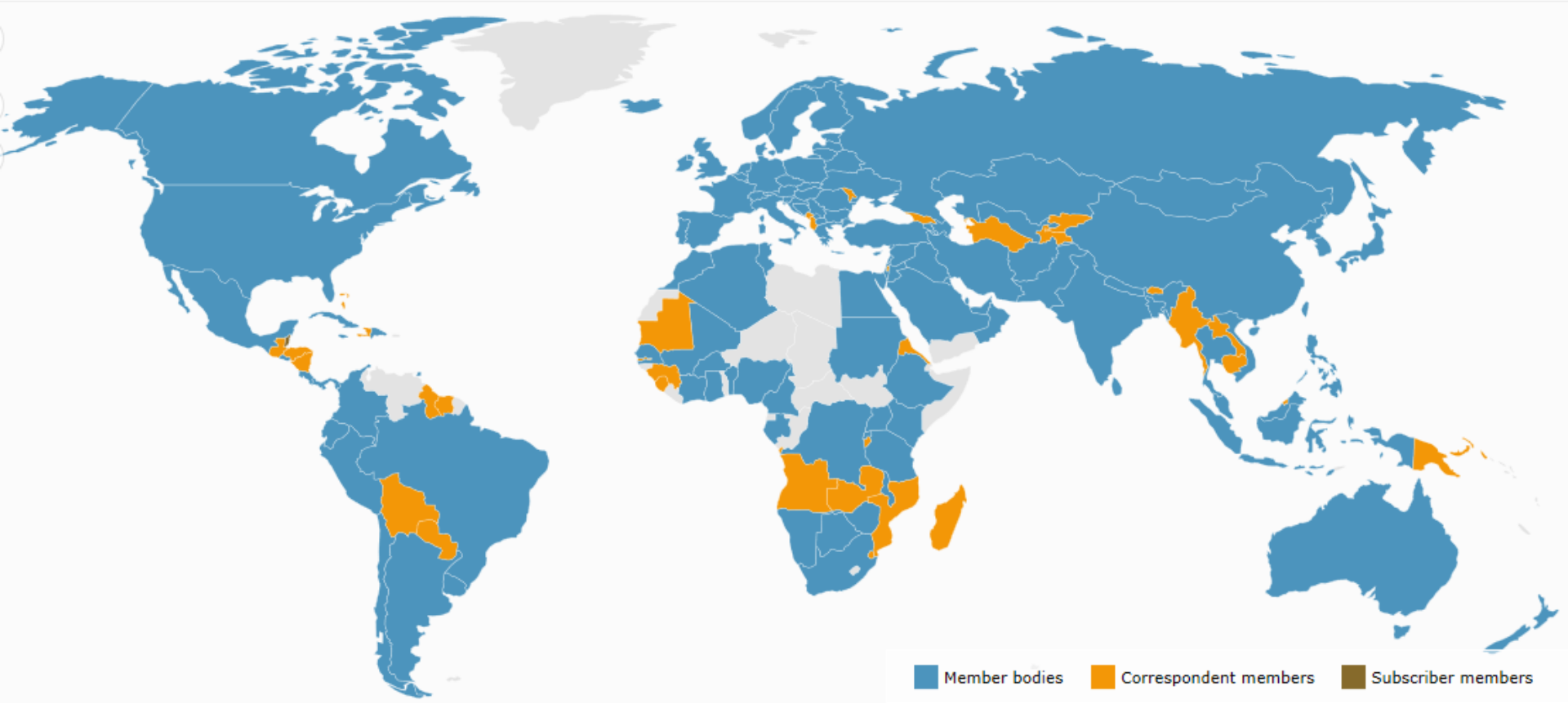
ISO TC217 Cosmetics - a brief introduction



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ISO TC217 Cosmetics - a brief introduction

✓Organized in TC's

ISO TC217 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

More than 40 experts from different countries (also certifiers)

"The purpose of these guidelines is to encourage a wider choice of natural and organic ingredients in the formulation of a diverse variety of cosmetic products to encourage innovation".

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ISO 16128 - the international alternative

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. Framework to determine the natural, natural origin, organic and organic origin content of products based on the ingredient characterization.

Part 2: approaches to determine indexes that apply to the ingredient categories defined in

Both parts have Informative annexes

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ISO 16128 - the international alternative

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

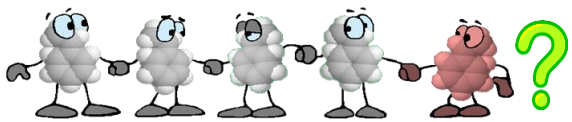
- Product communication (how to claim or label products), human or environmental safety
- Does not commit to values (no exclusion of certain ingredients depending on the media coverage or the expectations of consumers)
- Does not consider socio-economic aspects (fair trade, animal well being, sustainable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

What is ISO 16128? Part 1

Part 1 -INGREDIENTS FIRST - definitions

Published February 2015

- Natural and Derived natural ingredients
- Natural and Derived mineral ingredients
- Organic and Derived organic ingredients
- Water
  - Constitutive
  - Reconstitution
  - Extraction
- Non-natural
- Informative annexes



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What is ISO 16128? Part 1

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.

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What is ISO 16128? Part 1

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 (1) with the intention of chemical modification.

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

https://www.epa.gov/greenchemistry

(1) An informative list of such processes is provided in Annex B.

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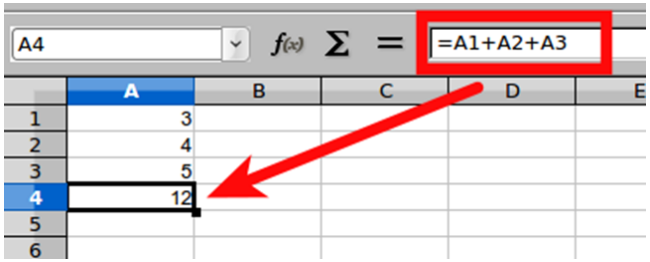
What is ISO 16128? Part 2

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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What is ISO 16128? Part 2

INDEXES FOR CALCULATING NATURAL AND NATURAL ORIGIN CONTENT OF INGREDIENTS


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

Reference number ISO 16128-2:2017(E)

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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.

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

FINISH PRODUCT

Natural content

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

Natural origin content

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

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Advantages of ISO 16128

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Advantages of 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

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Advantages of ISO 16128

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 crop of natural and organic ingredients will be encouraged (no positive or negative list)
- 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

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Advantages on using ISO 16128

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 easier

CONTROL AUTHORITIES

- Transparency
- It will allow the control authorities to evaluate the allegations on the same common basis
- Authorities to challenge unsubstantiated and unclear claims

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Advantages on using ISO 16128

How does the standard fit in EU Regulation

Regulation 1223/2009 of the European Parliament and the Council

- Contrary to common consumer perception, 'natural' or 'organic' ingredients & products are not intrinsically safer than synthetic ingredients and products.
- Products and claims should not imply that the product is safer because it is 'natural' or 'organic'.
- Safety for human health of cosmetic products has to be ensured according to existing cosmetic regulations

Art. 2: Definitions: cosmetic. Natural / organic products are cosmetics in the definition of the EU regulation and they must comply with the requirements related to safety and product information

Natural/organic is a claim ➔ Article 20 apply
"In the labelling, making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have"

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Advantages on using ISO 16128

How does the standard fit in EU Regulation

Commission Regulation 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products

- Legal compliance
- Truthfulness
- Evidence support
- Honesty
- Fairness
- Allowing informed decision making

All six criteria can be met with the standard ISO 16.128 Part 1 & 2

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Summary

Comments on ISO 16128

- ISO 16.128 is based on sound scientific judgment
- ISO 16.128 is internationally recognized
- ISO 16.128 does not represent a communication tool, it is a technical tool based on a set of criteria internationally agreed by consensus.
- ISO 16.128 comes to be in the contest of natural/organic cosmetic products, a market segment in which many private standards already coexist.
- ISO 16.128 is not developed for product certification
- European cosmetic industry is working on understanding how to use practically ISO 16128
- It is company decision to use any of the alternatives on the market to inform the consumer.

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THANKS FOR YOUR ATTENTION AND QUESTIONS!!!!!

Bologna September 2018

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