IBHA-CE-PCPC Cosmetics Workshop

Indian Beauty & Hygiene Association
IBHA

Cosmetics Europe
the personal care association

Personal Care Products Council
Committed to Safety, Quality & Innovation

September 27, 2019

Delhi

WELCOME ADDRESS & OPENING REMARKS

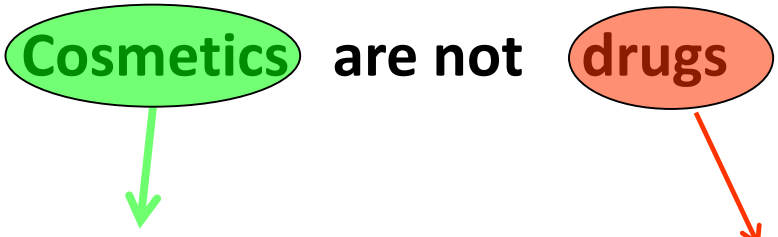
- Mr Dinesh Dayal, President, IBHA
- Mr Christophe De Vroey, First Counsellor, Trade and Economic Affairs, Delegation of the European Union to India
- Mr Chris Priddy, International Relations Specialist, US FDA

REGULATORY BEST PRACTICES

PRIMARY LEGISLATION vs. SECONDARY LEGISLATION vs. GUIDELINES/STANDARDS

Clarification of the role, status and objective of the different level of legislation
Role of standards in modern cosmetics legislation
Best practices for industry-regulator cooperation

John Chave, Director General, Cosmetics Europe



- Fast moving consumer goods
- Low biological / systemic activity
- Inherently low risk
- Well-being benefit

- Slow moving goods
- High biological / systemic activity
- Inherently high risk
- Health/medical benefit

Legislation needs to find the right balance to ensure:

High level of consumer safety **AND** fast innovation / high product diversity

Developed and developing cosmetics legislations world-wide adopt an in-market control approach to fulfil these criteria

Success Criteria of Cosmetics Legislation

There are a three key success criteria for a successful safety legislation of fast-moving consumer goods :

- *Safe products that comply with the legislation can quickly enter the market without administrative lead times.*
- *Unsafe products don't reach the market, or in the rare cases that they do, are quickly detected and removed*
- *A transparent and predictable regulatory environment, ensuring business continuity in times of regulatory change*

Developed and developing cosmetics legislations world-wide adopt an in-market control approach to fulfil these criteria

Typical tiers of cosmetics legislation

- **Primary legislation (Basic requirements)**
  - Scope & Definitions
  - Basic Safety Requirement
  - Allocation of responsibility for safety and compliance
  - Basic process requirements (e.g. follow GMP)
  - Requirement for Product Notification (or Registration*)
  - Mandatory labelling elements
  - Cosmetovigilance and Market surveillance (and/or Registration dossier inspection*)

- **Implementing legislation (Detailed requirements)**
  - Specific substance restrictions
  - Notification (or Registration*) content
  - Content of Technical / Safety Documentation
  - Pictures / symbols required for labelling

- **Guidance on practical implementation and compliance**
  - Technical and process related information

*depending on fundamental approach taken

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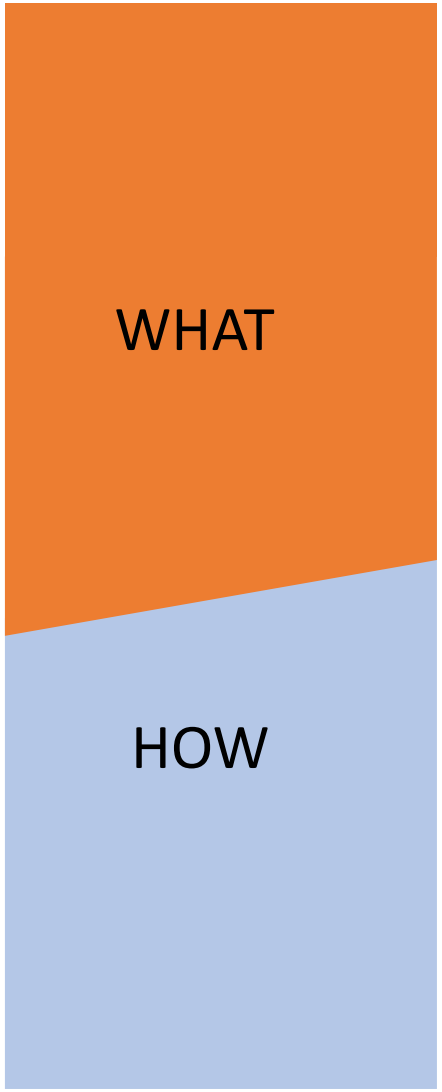

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Rarely changed – requires policy decisions

- **Implementing legislation (Detailed requirements)**
  - Specific substance restrictions
  - Notification (or Registration*) content
  - Content of Technical / Safety Documentation
  - Pictures / symbols required for labelling

Updated regularly according to scientific progress– requires scientific knowledge

- **Guidance on practical implementation and compliance**
  - Technical and process related information

Developed/changed when needed – requires practical experience

*depending on fundamental approach taken

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- **Implementing legislation (Detailed requirements)**
  - Specific substance restrictions
  - Notification (or Registration*) content
  - Content of Technical / Safety Documentation
  - Pictures / symbols required for labelling

- **Guidance/standard on practical implementation and co**
  - Technical and process related information

Rarely changed
policy de

Where do Standards fit in?

arly according to
rogress– requires
ntific knowledge

Developed/changed when needed – requires practical experience

*depending on fundamental approach taken

What is a “Standard” ?

A Standard is a means of determining what a thing should be.

Standards usually deal with technical aspects in a narrow, detailed scope.

Two uses of standards:

- Something established by authority, custom, or general consent as a model or example (“Standards as a guidance”)
- Something set up and established by authority as a rule for the measure of quantity, weight, extent, value, or quality (“Standards as an obligation”)

Can legislation be based on mandatory standards ?

- “Bottom-up” approach to legislation
- Specific and detailed requirements for technical characteristics of product (groups) and processes :
  - pH, composition, GMP…
- Standard is the only recognised/permitted way to achieve safety and compliance
- Need to translate policy drivers/objectives into detailed technical “cooking recipes”
- Requires strong co-ordination and collaboration between health regulator and standardisation body
- Low product differentiation on the market
- Stifling innovation – locks industry in the stage of development of the time when the Standard was written
- Safe products falling outside the Standard are prohibited

EU Cosmetics Regulation Approach on Technical Guidance and Standards

- Cosmetics Regulation (Basic and Detailed requirements)
  - Scope & Definitions
  - Requirement for products to be safe
  - Allocation of responsibility for safety and compliance
  - Basic process requirements (e.g. follow GMP)
  - Requirement and content of Product Notification
  - Mandatory Technical / Safety Documentation
  - Mandatory labelling elements
  - Cosmetovigilance
  - Market surveillance requirements for Authorities

  - Specific substance restrictions
  - Pictures / symbols required for labelling

WHAT

=

Mandatory

- Guidance **and Standards** on practical implementation and compliance
  - GMP Standard
  - Safety Assessment Guidelines
  - Claim Substantiation Guidelines
  - Recommendation on Sun Protection testing and labelling
  - Guideline on Cosmetovigilance

HOW

=

Advisory

EU Technical Guidance

- Mandatory requirements for safety and efficacy must be respected, but technical characteristics of product (groups) and processes are not strictly prescribed
- Technical Guidance is not mandatory but advisory
- It provides one recognized way to achieve safety and compliance – but other ways are acceptable, as long as the same legal objective (e.g. safety, efficacy) is achieved
- Guidance defines a “best practice” reference for industry and control authorities
- Within the mandatory requirements for safety and efficacy, this approach
  - Allows for wide product differentiation
  - Incentivises innovation
  - Enables “best practice” to evolve together with the stage of industry development

EU Harmonised Standards

- Special case of technical guidance
- Two sources of EU Standards:
  - Developed by the European Norming Institute (CEN) upon request by the EU Commission
  - Transposed by CEN from ISO Standards, following the Vienna Agreement

- EU Standards are not mandatory, but following an EU harmonized Standard provides the industry user with the benefit of “presumed compliance”

GMP Standard ISO 22716 → CEN EN ISO 22716:2007

Harmonised Standards also foreseen in the area of analytical methods

Principle also applied de-facto for sun protection testing

International Standards (ISO TC 217)

- Important tool for international regulatory compatibility
- Are frequently considered in EU Technical Guidance documents
- Do not provide the industry user with “presumed compliance”, but are recognized by control authorities as Best Practice reference
- Examples:
  - Microbiology
  - Analytical methods
  - Natural y organics cosmetics products

Development of Technical Guidance and Standards

No Regulation is self explanatory

Wording often reflects political compromise :

Issues are emotional (→ trigger of regulatory process)	Solutions are technical (→ proposals for regulation)	Decisions are political (→ compromise text achieved at the end)

The Regulator is not the Regulated - need common understanding and interpretation between those who wrote the law and those who need to apply it

Development of Technical Guidance and Standards

- Legislation is usually drafted and decided with a general objective (e.g. ‘high level of consumer safety’) but without intimate technical knowledge of manufacturing and distribution practices.
- If a smooth application is wished the input is needed of those who will apply the law in practice
- Otherwise, risk of ‘unintended consequences’
- Oversight by the health regulator to ensure that the resulting guidance satisfies the wording and the spirit of the law

Example: EU Approach implementing the Cosmetics Regulation "Preventive Dialogue"

- Development of implementation guidance was integrated into the planned transition time (3 ½ years)
- Dialogue initiated immediately after the adoption of the Regulation (→ avoid problems before the application date, not 'fix them later')
- Brought together the addressees of the EU Cosmetics Regulation (→ Member States, industry, poison control centers)
- Identified potential problem areas and priorities:
  - Persistence of national requirements
  - Misunderstandings of new requirements
  - Needs for technical guidance/training
  - Possibility for synergies
- Open discussions – solution oriented – respecting the wording and spirit of the adopted text

Preventive Dialogue “Working Process”

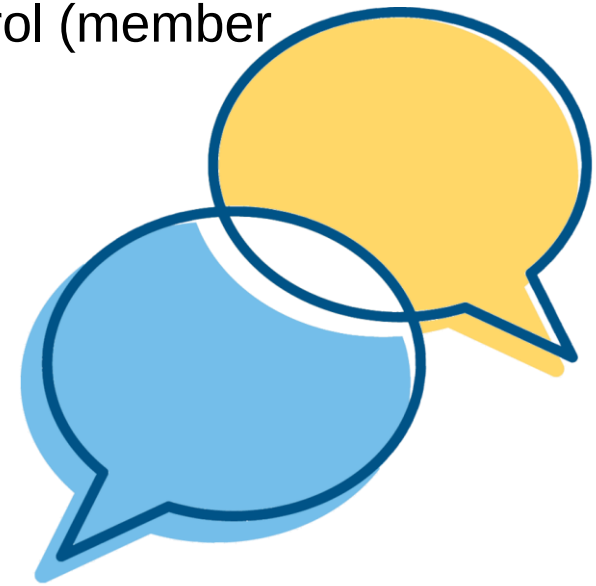
For each topic of the new Regulation, Cosmetics Europe (representing the main addressee of the Regulation) developed a strawman paper :

- Scope and interpretation of the relevant article(s)
- What industry sees as the practical implementation actions and potential issues
- Unintended consequences to be avoided
- What needs clarification / guidance / training

These documents were shared with the Commission and Member States authorities to kick off the discussions

Preventive Dialogue “Working Process”

- All stakeholders sent experts into the Preventive Dialogue Working Groups
- Intensive discussions on interpretation and practical implementation
- Moderated by the EU Commission, to guarantee consistency with the wording and spirit of the law.
- Ultimate Deliverable: A set of practical guidelines, i.e. common basis to ensure (industry) and control (member states) compliance with the Regulation



Conclusion

- Unlike drugs, cosmetics are fast moving consumer goods with inherent low risk
- Legislation needs to ensure high level of consumer safety **AND** fast innovation / high product diversity
- Most cosmetics legislation models distinguish between requirements and objectives (WHAT) and the ways to achieve them (HOW)
- Detailed Technical Guidance and Standards are necessary to enable practical implementation
- To allow continued product innovation and improvement, Technical Guidance and Standards should provide a reference way on how to achieve safety and compliance, but other ways should remain possible (advisory vs mandatory)
- In the develoment of Technical Guidance and Standards, input is needed of those who will apply the law in practice - otherwise, risk of ‘unintended consequences’

Questions?

REGULATORY BEST PRACTICES

SUN PROTECTION METHODOLOGY

ISO 24444 In Vivo Sun Protection Factor (SPF) method and its relevance for Indian phototype IV- VI

Dr. Dominique Moyal, Sun Expert

OBJECTIVES OF THE PRESENTATION

Role of the standard to provide adequate international methodology: ISO in vivo SPF method and its relevance for Indian skin types (IV to VI)

OBJECTIVES OF THE PRESENTATION

- In vivo SPF test method history
- Presentation of the ISO 24444 in vivo SPF test method
- Relevance for Indian skin types
- Benefits of ISO standards

IN VIVO SPF TEST METHOD HISTORY

- 1978 FDA USA
- 1984 German DIN 67501
- 1991 JCIA
- 1994 COLIPA guidelines
- 1993/1998 Australian Standard
- 1998 SABS method
- 1999 FDA USA

➢ **first step of harmonization**

- 2003 International SPF test method (Colipa, JCIA, CTFA-SA)
- 2006 International test SPF method (Colipa, JCIA, CTFA-SA, supported by PCPC (USA)

ISO TC217 - COSMETICS

- 1998
  Established following proposition from Iranian Standards Organisation, ISIRI

- 2000
  6 Working Groups formed (WG1 to WG6)

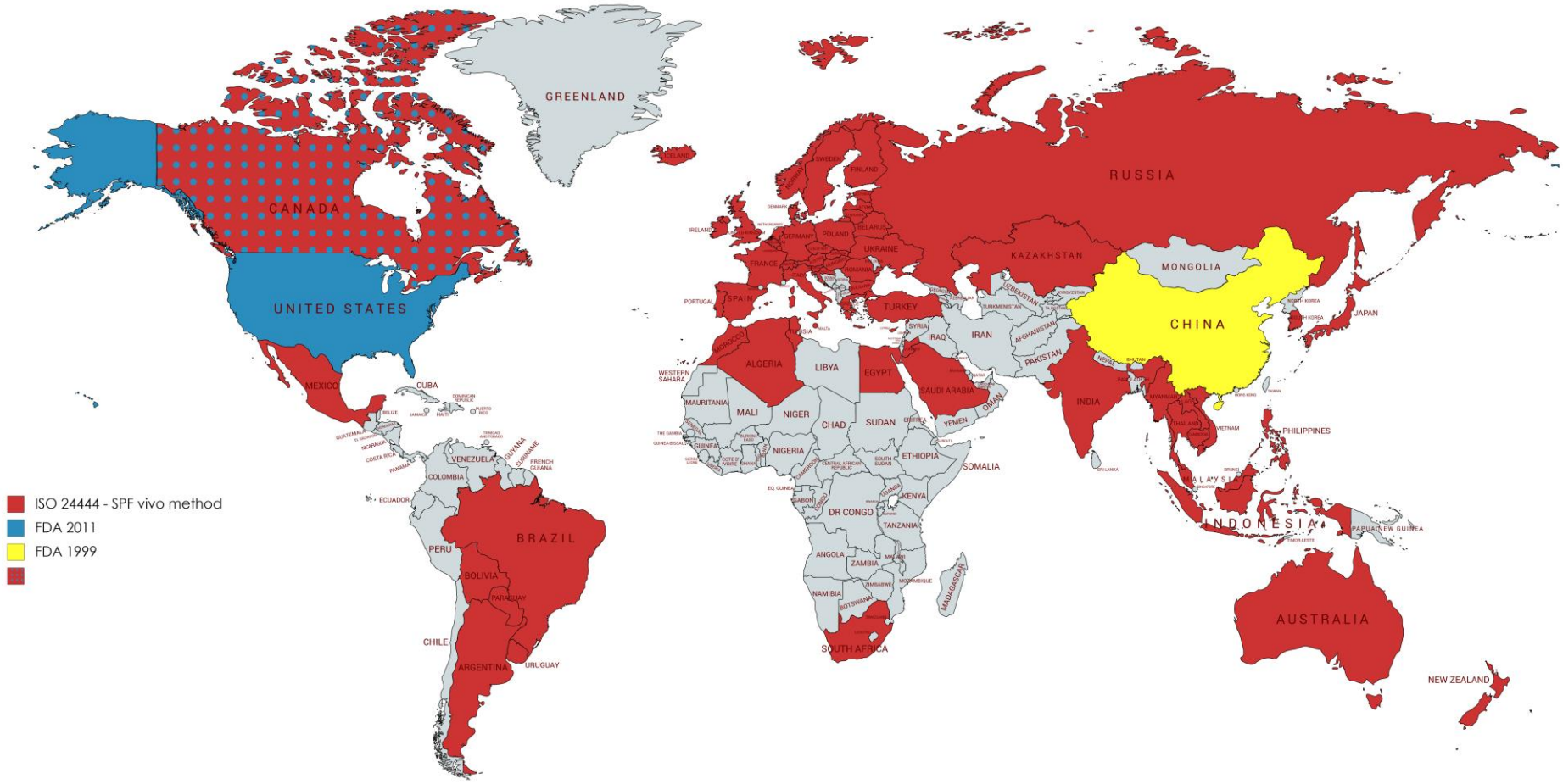
- 2006
  Sun protection working group (WG7) including European countries, USA, Latin America countries, Asian countries, Australia, NZ, South Africa…

SPF TEST METHOD: ISO PROPOSAL

- Decision was taken to work on SPF in vivo method but first to do a review and evaluation of the methods used
- A technical report ISO/TR 26369:2009 was finalized end of 2007 and published in 2009
- This TR served as a technical/scientific framework to identify the most suitable methods for standardization
- The International SPF test method 2006 was selected as basis for standardization

IN VIVO SPF TEST METHOD: ISO WORK

- *In vivo* SPF test method: ISO 24444
  - Published on November 15, 2010
  - This method is very similar to the International SPF test method 2006 published by Colipa, JCIA, CTFA-SA



ISO 24444 – In vivo determination of the sun protection factor (SPF)
published in 2010

IN VIVO SPF TEST METHODS

- US FDA published a new rules in 2011
- ISO 24444 and FDA 2011 In vivo SPF test methods are both based on the 2006 International SPF test method and then are very close
- Few differences which cannot induce different results
- FDA 2011 is “compliant” with ISO 2010

SUN PROTECTION FACTOR MEASUREMENT

- Selection of subjects (phototypes I, II and III or ITA° > 28°)
- Number of subjects (at least 10, max 20)
- Standard products (for validation of the test)
- Quantity of product applied (standardized, 2mg/cm², weighing by loss)
- Test site (on the back)
- Product application (standardized , low pressure , duration between 20 and 50 sec)
- UV exposures (solar simulator calibration each 18 months)
- Reading of MEDp and MEDu in standardized illumination conditions
- Calculation of SPF (statistical criteria, 95% CI ≤ 17% of the mean and standard in the acceptance range)

SUN PROTECTION FACTOR MEASUREMENT

DEFINITION OF THE SPF:

SPF is a Ratio of:

- the individual minimal erythemal dose on skin protected by the product (MEDp)

And

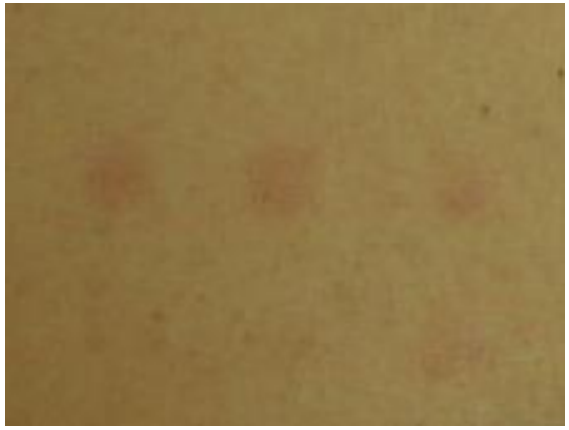
- the individual minimal erythemal dose on unprotected skin (MEDu)

$$\mathbf{SPF_i = MEDp/MEDu}$$

Individual SPF takes into account the individual sunburn sensitivity

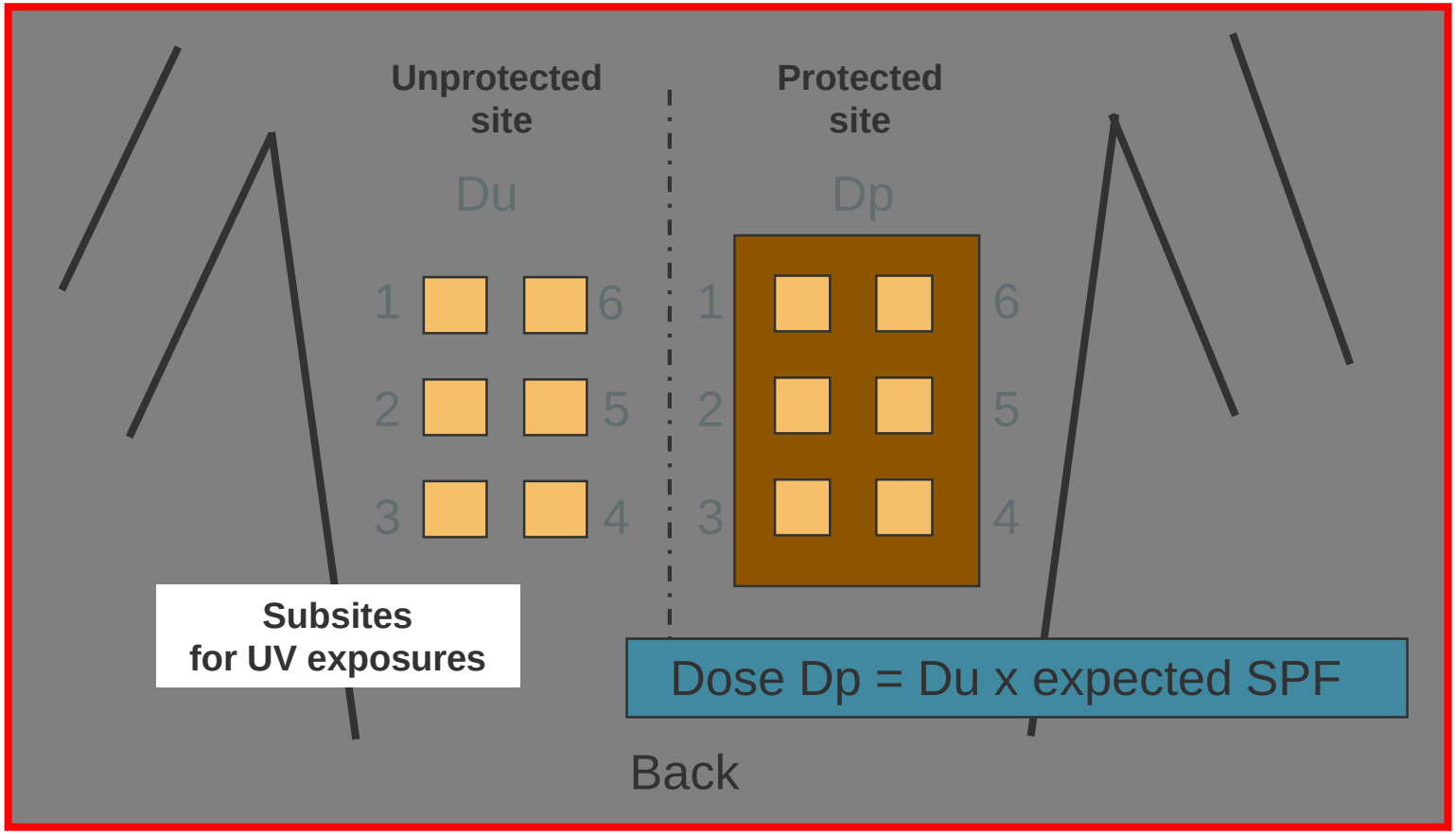
SUN PROTECTION FACTOR MEASUREMENT

- DEFINITION OF MEDs:
  - MEDu: lowest dose of UVR that produces the first perceptible unambiguous erythema with defined borders appearing over most of the field of UV exposure on the unprotected skin, 16 to 24h after UV exposure
  - MEDp: lowest dose of UVR that produces the first perceptible unambiguous erythema with defined borders appearing over most of the field of UV exposure on the skin protected by the product, 16 to 24h after UV exposure



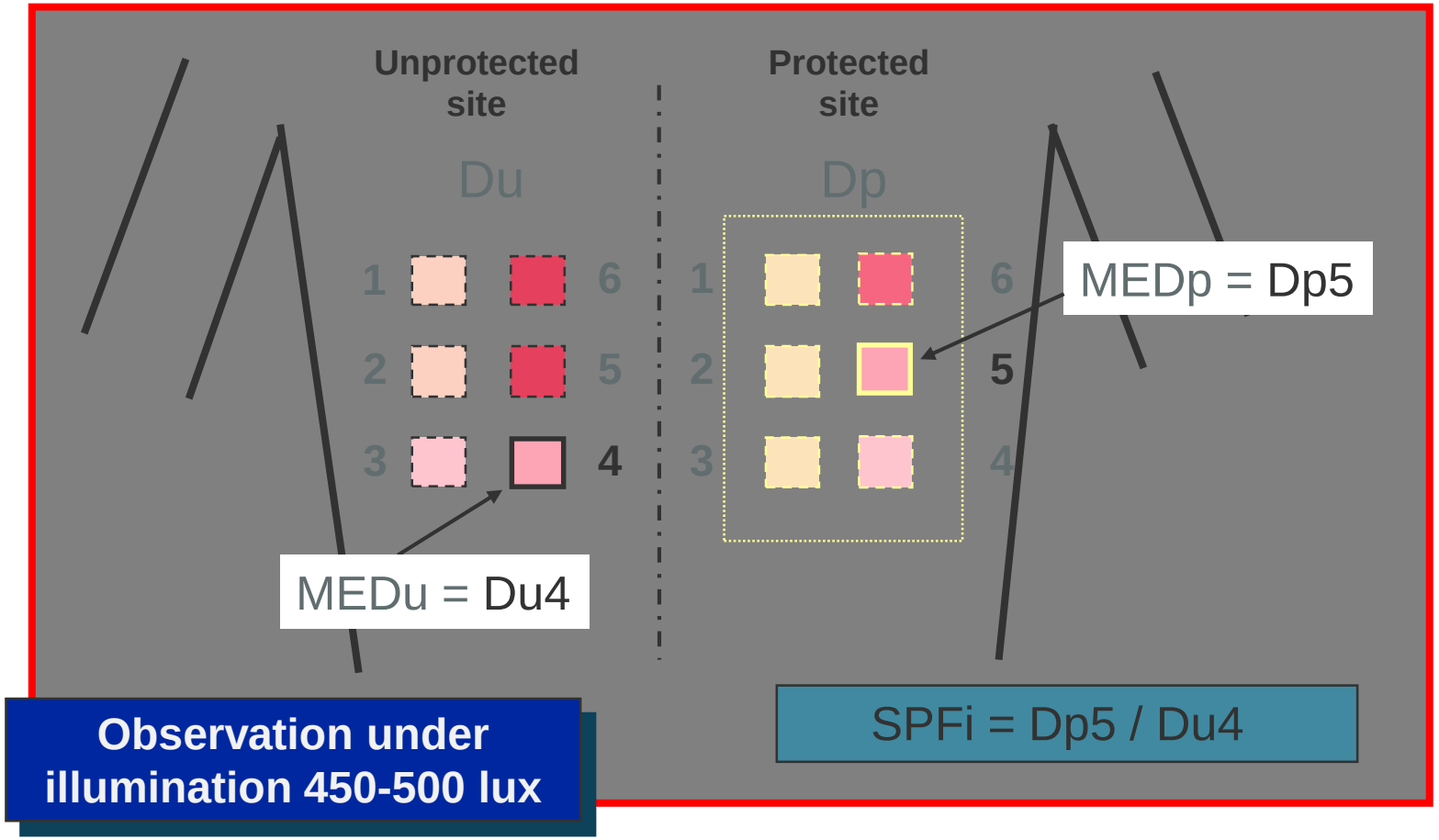
SUN PROTECTION FACTOR MEASUREMENT

UV exposure: sites, subsites and UV doses



SUN PROTECTION FACTOR MEASUREMENT

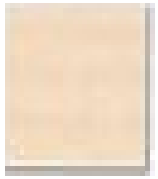
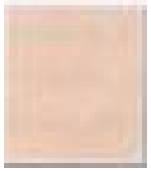
Reading of MEDu and MEDp 16 to 24 hours after exposure



INCLUSION OF VOLUNTEERS

- **PHOTOTYPES FITZPATRICK CLASSIFICATION (1975)**

based on sunburn sensitivity (questionnaire*)

Phototype I Porcelain	Phototype II Beige	Phototype III Intermediate	Phototype IV Medium Brown	Phototype V Brown	Phototype VI Black
					
Burns always easily Never tans	burns always easily slightly tans	burns Moderatly Progressively tans	Burns slightly Easily tans	Burns rarely Tans immediately	Never burns Highly pigmented

[Determined after 45mn 1st sun exposure after winter)

INCLUSION OF VOLUNTEERS

MEDs values from phototypes I to V

- We can find in the litterature values and we confirm that it is possible to induce sunburn in phototypes IV and V
- Depending on the laboratory (radiometer, spectroradiometer)

  MEDs for phototypes IV and V compared to phototypes I can be X 2.25 to 3.8.
- So it is possible to induce sunburn on phototypes IV to V under laboratory conditions
- However, from a practical point of view, determination of SPF on phototypes IV/V is quite unrealistic
- To determine a SPF 50+ (at least 60) it takes 1 hour under a solar simulator for phototypes I/III, so it would take 2 to 4 hours for phototypes IV/V

INCLUSION OF VOLUNTEERS

Why all SPF test methods have only included phototypes I to III ?

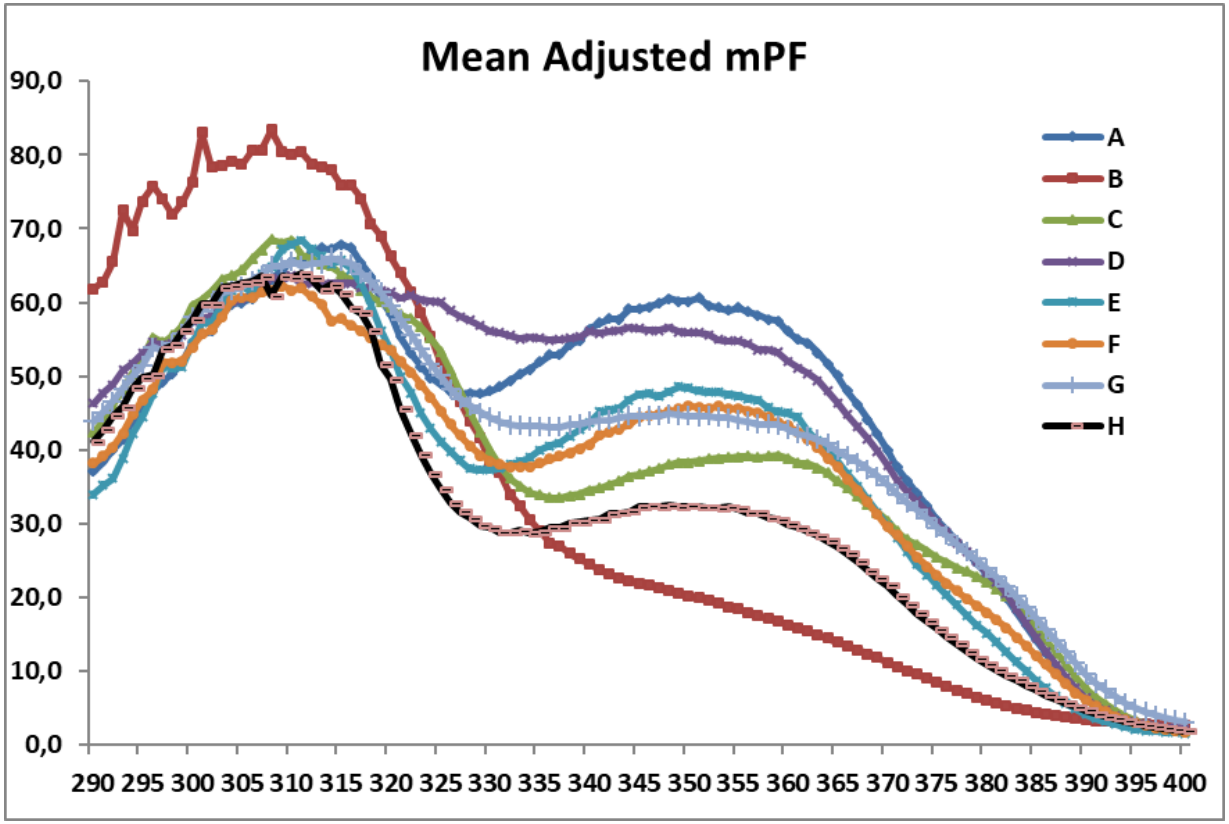
- Because the methods have been developed first in Europe and USA and because a higher risk for the population with fair skin
- It is also easier in laboratory conditions to include volunteers with fair skin and to produce sunburn in a short time of UV exposure and in an acceptable duration with product
- It is easier to evaluate the redness on fair skin
- Because evaluation of MED is done visually by technicians and not by objective measurements, variability was observed between technicians especially when pigmentation is present

LINK BETWEEN SPF AND PHOTOTYPES

Are SPF values different depending on the phototypes?

- There are data showing that SPF can vary between phototypes , higher SPF on phototypes I compared to IV/V
- However, that is not always true, there are different factors which can explain such results:
- it depends on the sunscreen product: level of SPF and filtering system
- Important point is the UVA absorption, if UVA protection is adequate, there is no pigmentation induced by the solar simulator on the dark skin
- I remind you dark skins are able to develop persistent pigment darkening (PPD) under UV exposure, so pigmentation can disturb the erythema reading

THE IMPORTANCE OF UVB+UVA WELL BALANCED FILTERING SYSTEM



All products have the same SPF, however they have different UVA protection factors
So UVA pigmentation can be produced during UV exposure

LINK BETWEEN SPF /PHOTOTYPES/ITA°

EXAMPLE OF SPF RESULTS

SPF MEAN +/- SD	Caucasian subjects (phototypes I to III, ITA° > 28°)	Indian subjects (Phototypes IV and V ITA° 16° to 39°)
P3 STANDARD	[13.8 – 18.7] ISO range	13.9 +/- 2.7

SPF MEAN +/- SD	Caucasian subjects (Phototypes I TO III, ITA° > 41°)	Indian subjects (Phototypes IV AND V , ITA° < 28°)
SUNSCREEN A	25.2 +/- 4.5	22.5 +/- 7.6

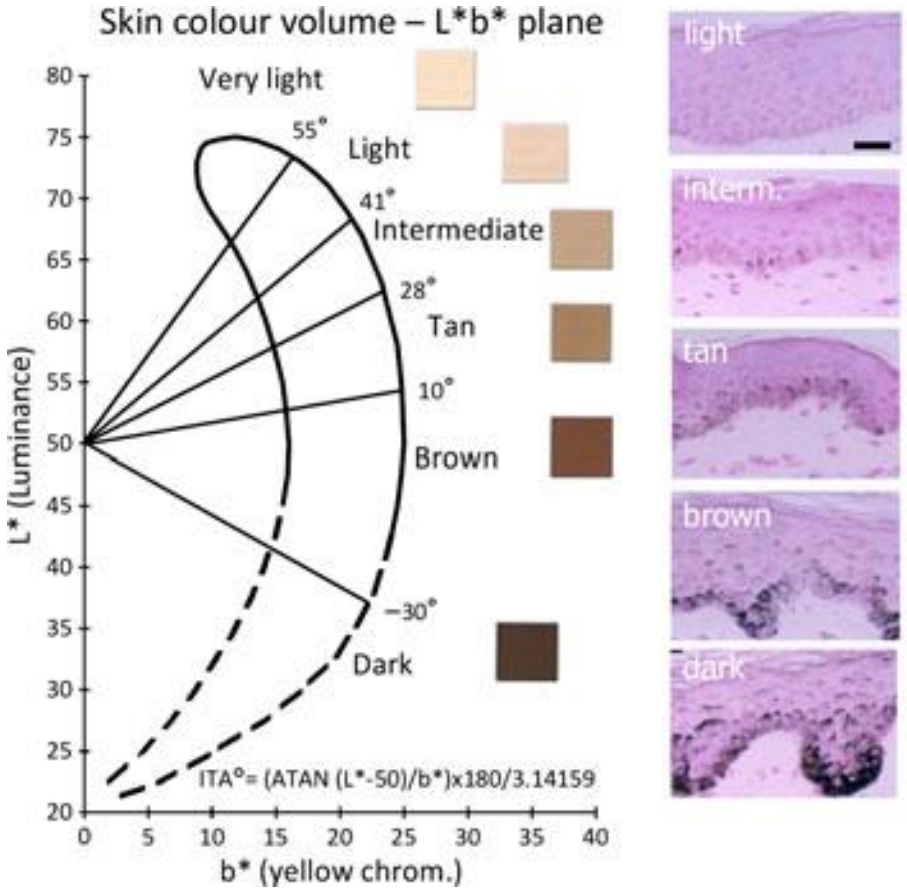
PHOTOTYPES AND SKIN COLOR

- To avoid some bias, it has been requested that Phototypes I, II and III should be mixed in the ISO 24444:2010 standard
- To select more precisely the subjects, in the ISO 24444:2010, there is the possibility to use the ITA°

Individual Typologic Angle:
ITA° = (ArcTan(L* - 50) / b*) x 180 / π

L* = Lightness
b* = Chroma Yellow-Blue
a* = Chroma Red-Green

SKIN COLOR : ITA°



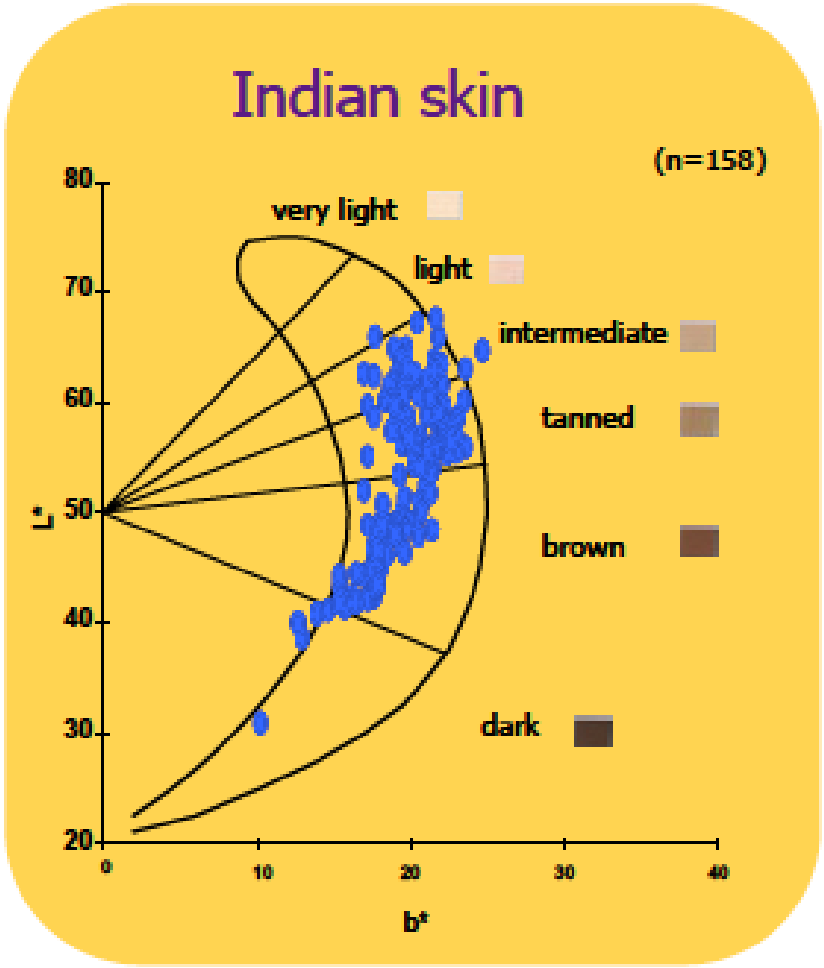
Individual Typology Angle ITA°	Skin classification
ITA° > 55°	Very light
41° < ITA° < 55°	Light
28° < ITA° < 41°	Intermediate
10° < ITA°< 28°	Tan
−30° < ITA°< 10°	Brown
ITA° < −30°	Dark

ISO 24444:2010 ITA° should be higher than 28° so only very light, light and intermediate skin color on the back should be selected.

SELECTION OF SUBJECTS BASED ON ITA°

- Revised proposed standard: selection of the volunteers based on ITA° values, no more on phototypes because ITA° are more objective and skin color is precisely measured when the subject is participating to the test (e.g. exclusion of phototypes II or III who are tanned)

INDIAN SKIN COLOR : ITA° VALUES



It is possible to find intermediate skin color in India even if the phototype has been qualified as IV

LINK BETWEEN SPF /PHOTOTYPES/ITA°

- Even for phototypes IV and V with ITA< 28° , the SPF values for the standard P3 and for a product SPF20 are equivalent to the SPF values determined in Caucasian skin with phototypes I, II and II and ITA > 28°

- Determining the SPF for sunscreens with higher SPF in dark skin is very difficult because of the duration of the test and of the pigmentation induced by UVA especially when the product doesn't absorb correctly the UVA

- Inclusion of phototypes IV and V with ITA° < 28° is a risk of error on the SPF determination

- Inclusion of phototypes IV and V with intermediate skin color ITA° > 28° on the back is possible in India

Questions?

TRACES

How traces are regulatory managed over the world and best practices for trace management

ISO works to develop harmonized analytical methods

Elsa Dietrich, International relations Manager, Cosmetics Europe

Dr. Jay Ansell, Vice President Cosmetic Programs, PCPC

Why traces can be found in finished cosmetics products?

Minerals & Beauty

MINERALS THROUGHOUT THE CENTURIES

1990

1928

Optical Effect

Interdiction of Ceruse

1915

Romantics

Transparent Skin

1st compact powders

Restauration

Milled Pearls, ZnO, Chalk,

Starch,

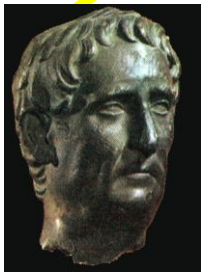
Gypsum

Ceruse ($PbCO_3$), Minium (Pb_xO_y)

Vermilion,

Lampblack

Rome



J C

Ovide

Natural Ochers ,

Kohl (PbS - Galenit)

Malachite Powder

Calcined Umber

Yellow Ocher from Apt

Iron Oxides

(natural)

From 2500 bf JC ***20th century*** ***21st century***

The Skin: a very complex support

- **LIVING**
- **COLORED**
- **MOBILE**
- **3D**

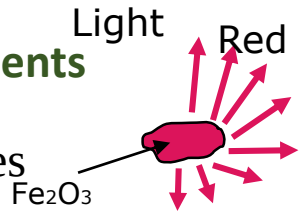
INHOMOGENOUS
COLOR,
SURFACE
RELIEF

The properties of the mineral ingredients allow to achieve changes & reply to the consumer's expectations

Optical Properties, Sensorial Properties, Mechanical properties
→ CORRECTION OF IMPERFECTIONS,
→ COLOR, → IMPROVEMENT OF SHINYNESS

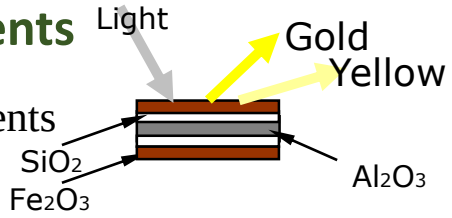
Diffusing Pigments

ex: Iron Oxides



Iridescent Pigments

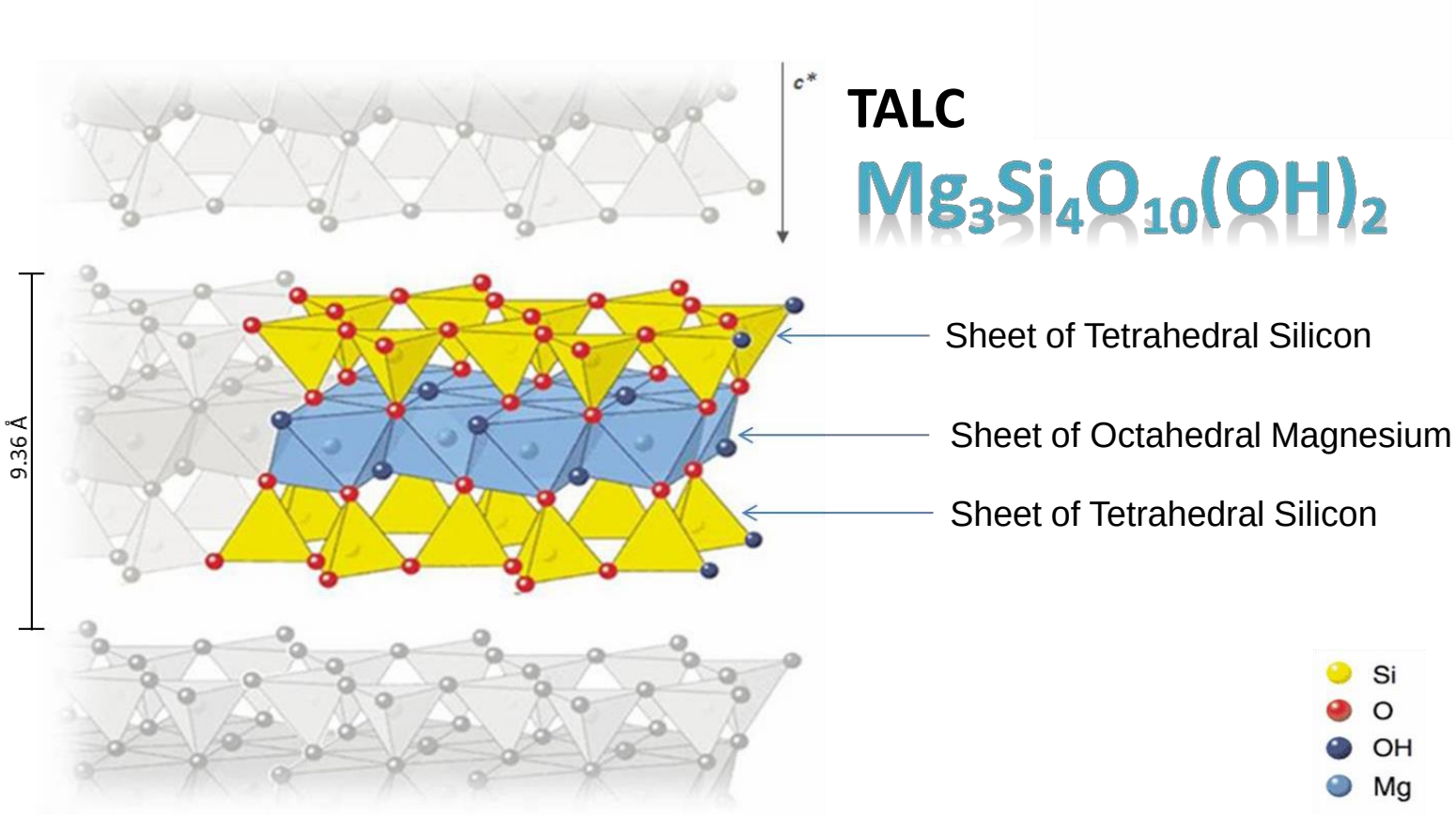
ex: multilayer pigments



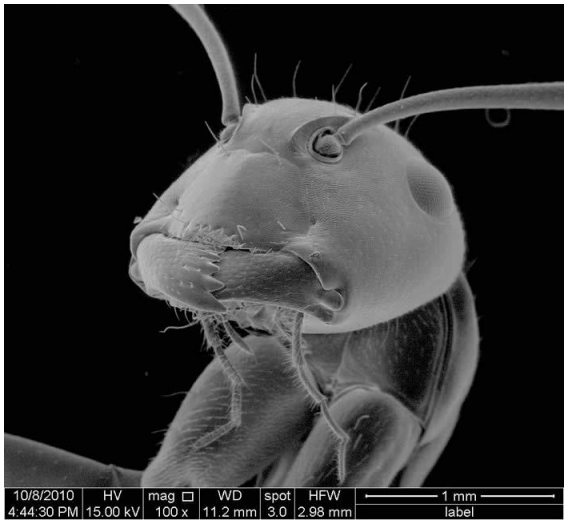
MINERAL INGREDIENTS = INTEGRAL AND INDISPENSABLE PART OF THE COSMETIC RAW MATERIAL PORTFOLIO

Minerals & Metallic Elements

- **EXAMPLE OF CRYSTAL STRUCTURE OF TALC**



Which one is more dangerous ?



Advances in instrumental techniques allow for ever greater detail. The risks to the human population however remains unchanged.

Best regulatory practices for trace management

Context

- ever increasing sensitivity of analytical methods
- lower levels of traces of unwanted substances may be detected in cosmetic products, even when produced according to state-of-the-art sourcing and manufacturing practices
- Such traces can originate from a variety of sources
- appropriate management of traces in cosmetic products is required, primarily based on safety considerations

NB: Very few substances may present a risk for the consumer when they are present in trace concentrations in a cosmetic product

INTERNATIONAL MAPPING - regulations having the concept of “acceptable traces of prohibited substances under particular condition to fulfill.

Condition to fulfill for acceptance

presence is non-intended = not intentionally added, the substance may be naturally occurring, it is unwanted, it is not an ingredient

small quantity = residual level subject to interpretation < 0,1% ? 0,01% 0,001%

technically unavoidable in good manufacturing practice = even the application of GMPs doesn’t allow to avoid traces of substance; its presence occurs naturally or is unavoidable.

Non-functional = The trace doesn’t provide any technical benefit to the cosmetic.

the product shall be safe for consumer uses = the safety evaluation of the product takes into consideration the presence of the prohibited substance during the evaluation process

COUNTRY	REGULATION	Concept of "acceptable traces if technically unavoidable" is approved: YES / NO
EUROPEAN UNION	CPR 1223/2009/EC	YES - Art.17 The non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3.
TURKEY	Cosmetics Regulation	YES - Article 7 identical to the EU
CANADA	Canadian Food and Drugs Act (F&DA)	YES – Substances known to cause injury or that are not appropriate for use in cosmetics are reflected on Health Canada's Cosmetic Ingredient Hotlist. Substances found on the Cosmetic Ingredient Hotlist may find their way into finished cosmetic products at trace levels. These trace levels may be acceptable if they do not pose a hazard to human health and are technically unavoidable.. + Guidance on Heavy Metal Impurities in Cosmetics published in 2012
BRAZIL & MERCOSUR (Argentina, Brazil, Paraguay, Uruguay)	MERCOSUR/GMC/RES. N° 62/14	YES - Annex §3 Prohibited substances will only be permitted as traces if they are technologically unavoidable with correct manufacturing procedures, and provided that the finished product is safe.
USA	21CFR701.3	NO BUT Concept of incidental ingredient : (l) The provisions do not require the declaration of incidental ingredients that are present in a cosmetic at insignificant levels and that have no technical or functional effect in the cosmetic.
ASEAN (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore Thailand. and Vietnam)	ASEAN Directive	YES - Article 4 The presence of traces of the substances listed in Annex II shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms with Article 3 [safety]. But there are some limits for HM in the ASEAN Guidelines on Limits of Contaminants
CHINA	Safety & technical standard on cosmetic products 2015	YES – Cosmetics prohibited ingredients including but not limited to the ones in this table 1. The substance listed in this table 1 may exists non-purposely in cosmetics finish products, such as comes from the impurity in natural or synthetic material, packaging, production or storage process etc.. In line with national compulsory conditions of production, if it's technically non-avoided prohibited ingredient, cosmetics finish products must ensure that no harm is created to human health under the normal, reasonable and predictable use conditions.
SAUDI ARABIA UNITED ARAB EMIRATES KOWEIT	GSO - 943/2016	YES - Paragraphs 4.7 & 4.12 The non-intended presence of small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 4.2 [safety]. But In the case of presence of HM as an impurity, they should not exceed some limits.

What technically unavoidable under GMP means in practice?

Why not the same level of traces is found across the different product categories

Only a few traces of prohibited substances have regulatory concentration limits

In the absence of specific limits, the manufacturer must:

- Justify the presence & provide evidence of the technical unavoidability of the levels under GMP
- Obtain reassurance from the safety assessor that the levels are toxicologically evaluated and the product is safe

The justification must be plausible, comprehensible and complete (so that the authorities can understand)

CRITERIA TO EVALUATE THE TECHNICALLY UNAVOIDABLE PROFILE OF TRACES

Origin of raw materials

- Ingredients from mineral origin extracted from earth crust
- e.g. lead is naturally present in rocks, soil and water

Raw material selected for its cosmetics function or benefit

- Each raw material is used at least for one cosmetic function in a formula
- e.g. clays used as major ingredient in rinse-off face mask formulas may contain traces of heavy metals. Clay bring a specific purifying action to the formula and cannot be directly and easily substituted by another ingredient by another one when the formulation challenge is to keep a similar galenic with a similar cosmetic function

Sourcing of raw material

- Multi sourcing of raw materials (high concentration level purchase, geographical reason…) can explain slight variability between raw material ➔ company must ensure quality certificate from supplier and perform quality audit

Manufacture under GMP

- Respect of GMP should support the demonstration that safe traces can be considered as acceptable because their presence is fully managed during the manufacture
- e.g. compliance with ISO 22716 ➔ equipment should be suitable and cleaned, raw material and packaging material should be purchased based on quality criteria and carefully audited, at each stage of the production the product should be checked (sample testing)

Finished product stability

- presence of traces can originate from interaction and/or migration of substances in the product that could occur under normal storage condition and / or through contact with the packaging material
- e.g. antimony may occur in time in oral-care products due to the release from the PET packaging

ICCR and ISO work on Traces

Traces in ICCR

- Principles for Handling Traces in Cosmetics (2011)
- Considerations on Acceptable Lead Levels in Cosmetic Products (Excluding products used in the oral cavity) (2013)
- Recommendation for Acceptable Trace Mercury Levels in Cosmetic Products (2016)
- Considerations on Acceptable Trace Level of 1,4-Dioxane in Cosmetic Products (2017)

Traces in ISO TC 217 Cosmetics

Standard	Title
ISO 10130:2009	Nitrosamines: Detection and determination of N-nitrosodiethanolamine (NDELA) in cosmetics by HPLC, post-column photolysis and derivatization
ISO 15819:2014	Nitrosamines: Detection and determination of N-nitrosodiethanolamine (NDELA) in cosmetics by HPLC-MS-MS
ISO/TR 18818:2017	Detection and quantitative determination of Diethanolamine (DEA) by GC/MS
ISO/TR 17276:2014	Analytical approach for screening and quantification methods for heavy metals in cosmetics
ISO/CD 21392	Measurement of traces of heavy metals in cosmetic finished products using ICP/MS technique
ISO/AWI 23674	Determination of traces of mercury in cosmetics by integrated mercury analytical systems
ISO/AWI 23821	Determination of traces of mercury in cosmetics by atomic absorbtion spectrometry (AAS) cold vapour technology after pressure digestion

ICCR Joint Working Group on Traces

Principles for the Handling of Traces of Impurities and/or Contaminants in Cosmetic Products (2011)

- Serves as a guidance tool for any person responsible for handling traces in cosmetic products.
- It includes a number of definitions and describes important management principles for traces in cosmetic products.
- Will also help guide the development of any recommendations for trace impurity limits set out by the International Cooperation on Cosmetic Regulation (ICCR).

Key Principles

- **The Product Must Be Safe:**
  - Trace substances that may present a potential safety issue must be considered in the cosmetic product safety assessment and it may be appropriate to set a maximum acceptable concentration in the finished product.
- **Identification Of Traces:**
  - All Potential Sources Must be Considered: Ingredients should be assessed for their potential to introduce trace substances into the finished cosmetic products. This should include an evaluation of the source of the ingredient, the method of manufacture and/or the interaction with the primary packaging material.
- **Quantification of Trace:**
  - Attention should be paid to determining if the levels in the finished product are below a level that is considered sufficiently protective for human health, based on reasonable evidence such as available safety data.

Key Principles – Safety Assessment

- **Establish Maximum Acceptable Trace Exposures:**
  - A level established by recognized scientific organization may be used or if none exists established by appropriate risk-assessment methods including in vivo, in vitro, in silico data or methodology (read-across, TTC)
- **Determine Consumer Exposure:**
  - Considering potential categories of product use, consumer habits and practices data for the product potential consumer exposure to the trace substance through the use of the product may be calculated.
- **Set Acceptable Trace Concentration:**
  - The safe limit can then be determined based on the maximum acceptable trace exposure, and consumer habits and practices for the product or product category.
- **Manufacture Responsibility**
  - Manufacturer should ensure that levels of traces are below the safe limit.

Key Principles - As Low As Reasonably Achievable "ALARA"

- The ALARA principle must always be evaluated as part of the deliberations.
- ALARA levels will not exceed the safe level but may well be below the level determined to be safe and may differ by manufacturer and region.
- When setting a target concertation for trace company should also consider:
  - Currently achievable quality under Good Manufacturing Practices (GMP); the quality of the raw material, analytical testing capability, even external relations issues
- The ALARA levels are part of a continuing process and can evolve over time, even within a company.

Recommendations 1,4-Dioxane (2017)

- Set Maximum Tolerable Levels & Usage Patterns
  - As one example 10mg/kg/day was set as the MTD and from that the authority assessing the safety of consumer products concluded that that the presence of 1,4-dioxane as an impurity at < 30ppm was not considered to pose a significant health risk to the general public. Others found 50 ppm pose no significant health risk
- ALARA
  - The WG notes that a summary of the data that has been published since 2001 shows that the values are all <50 ppm, 96 % are <25 ppm, and 90% are ≤ 10 ppm. This constitutes evidence that the levels of 1, 4-dioxane can be controlled and maintained at low levels, which are considered "reasonably achievable".
- Recommendation:
  - The WG recommends that the target level of 1,4-dioxane in cosmetics is achieved in two phases by industry: Phase 1: A target level of ≤ 25 ppm in finished products; and Phase 2: A target level of ≤ 10 ppm in finished cosmetic products should be phased in over a suitable transition period.

https://www.iccr-cosmetics.org/files/2414/8717/1555/ICCR_14-Dioxane_Final_2017.pdf

Recommendations for Acceptable Trace Levels in Cosmetic Products

- Lead (2013)
  - Based on the findings of the ICCR Traces WG, trace levels of lead in finished cosmetic products (excluding products used in the oral cavity), should be kept below a target level of ≤ 10 ppm total lead, using a lead control system (through raw materials or finished products) described in section 4. https://www.iccr-cosmetics.org/files/4314/2495/6253/2013-12_Recommendation_on_Lead_Traces_in_Cosmetics.PDF
- Mercury (2016)
  - Based on the levels found, and the tolerable levels identified by authoritative agencies, the ICCR Regulators-Industry Traces Working Group concluded that mercury levels in cosmetic products should be kept below a target level of ≤ 1 ppm mercury, determined as total mercury, in finished cosmetic products using either approach of mercury control system (raw materials or finished products). https://www.iccr-cosmetics.org/files/2914/7461/8872/ICCR_WG_report_Recommendation_for_Acceptable_Trace_Mercury_Levels_in_Cosmetic_Products.pdf

ICCR Traces Recommendations

- Trace substances and trace levels are topics of interest for both the industry and regulatory authorities worldwide.
- Industry and regulators are working together at the ICCR level on traces in cosmetic products to maintain the highest level of global consumer protection, to facilitate convergence to the fullest extent possible and to minimize barriers to international trade.
- The ICCR recommendations may be taken and/or adopted by ICCR members for implementation as appropriate, respecting the boundaries of their legal and institutional constraints.
- The ICCR recommendations are considered to be non-binding on the members.

Traces in ISO

- Ideal topic to be addressed Internationally
- Increasing sophistication analytical methods means ever lower levels of traces of substances may be detected in cosmetic products leading to potential confusion
- Experts work collaboratively through ISO & ICCR to establish common framework:
  - Best Management Practices
  - Best Techniques to Identify and Quantify
  - Applicable across all regions facilitating international trade
- Agreed approaches to facilitate dialogue, compare results, etc.
- IMPROVE HUMAN HEALTH AND SAFETY.

ISO TR 17276:2014:
Analytical Approach For Screening And Quantification Methods For Heavy Metals In Cosmetics

- Heavy metals are ubiquitous occurring naturally in the environment.
- Some heavy metals play key roles in biological systems and in small amount are essential minerals to life.
- However heavy metals, even essential minerals, can be a concern when human exposure is too high
- As such, heavy metals are both unavoidable and must be monitored closely to assure the safety of cosmetic products
- TR 17276 introduces most common and typical analytical approaches for screening and quantification of heavy metals of interest at both raw material and finished product level.
- TR covers techniques from the simple to the more sophisticated allowing detection at µg/kg (PPB) level; covering the advantages and disadvantages so that a suitable approach can be chosen.
- This TR does not set or suggest acceptable concentration limits of heavy metals

ISO TR 17276:2014 - Screening

- Quantification of heavy metals content requires technical knowledge and experience, and often expensive facilities and vigorous condition of sample preparation
- However, screening as a 1st step allows a determination if identifying and quantification using more quantitative methods is needed
- Screen for heavy metals in cosmetics products and raw materials consists of sample preparation method and detection method.
- Preparation methods:
  - leaching; digestion
- Detection tests and methods:
  - colorimetric reaction
- This approached are limited but may be sufficient.

ISO TR 17276:2014

- **X-ray fluorescence**
  - The advantage of this technique is that it is non-destructive analysis. Various sample forms such as solid, liquid, or powder are applicable and measurements are performed easily and quickly without complicated sample preparation. Complexity would be realized in quantitative or semi-quantitative analysis and for certain elements, sufficient sensitivity can not be obtained
- **Atomic absorption spectrometry**
  - AAS is a very common technique with a good sensitivity and a good specificity. Interference can occur for some elements in the presence of nitric acid with high amounts of iron, aluminum, and silica. The main disadvantages are its mono-elemental capability requirement for complete dissolution of the samples and the relatively high cost.
- **Inductively coupled plasma (ICP)**
  - The great advantages of the ICP are the multi-element capability and the linear dynamic range. Cost and samples typically should be in solution are the main disadvantages.

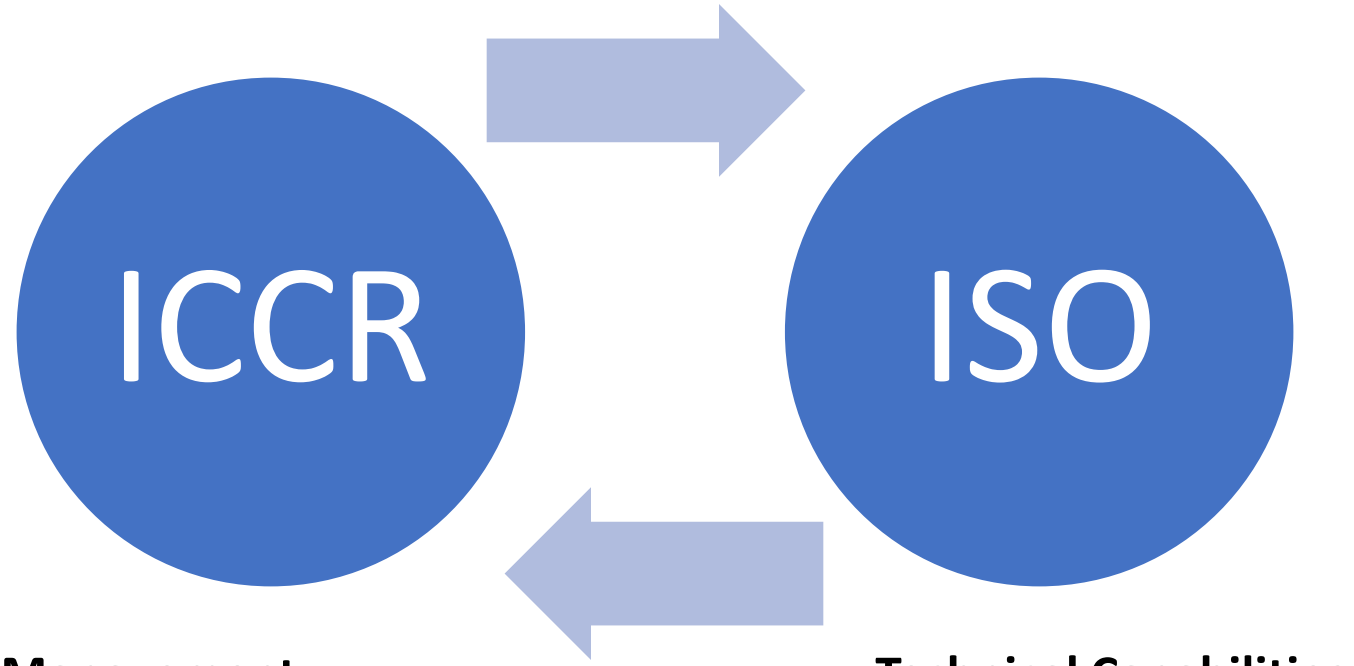
ISO CD 21392 *Measurement of traces of heavy metals in cosmetic finished products using ICP/MS technique*

- ISO 21392 builds on ISO TR 17276 to provide a method for determination of trace levels of heavy metals based on ICP/MS.
- The work program will involve:
  - Selection of metallic elements
  - Review of the available analytical methods (mainly on sample preparation)
  - Selection of the best method
  - Validation and characterization of the method by determining its accuracy profile

Status

- Good progress on ISO 21392 traces in cosmetic finished products using ICP/MS technique effective with Chromium, Cobalt, Nickel, Arsenic, Cadmium, Antimony and Lead
- Launched two new work items for Mercury
- Joint ISO/TC 217 & CEN/TC 392 products
  - ISO 23674 – *Determination Of Mercury In Cosmetics By Integrated Mercury Analytical Systems* for development as an ISO standard under Vienna Agreement under ISO-Lead
  - ISO 23821 – *Determination Of Mercury In Cosmetics by Atomic Absorption Spectrometry (AAS) Cold Vapour Technology After Pressure Digestion* for development as an ISO standard under Vienna Agreement under CEN-Lead

International Cooperation



TAKE AWAY

- The manufacturer is responsible of the safety of the product and must follow the GMP.
- The approach for handling unavoidable traces in cosmetics product should be consistent with the ICCR guidelines.
- The current ISO/CEN project on measurement for heavy metal traces in cosmetic finished products will allow consistent and reliable identification and quantification of traces
- The importance of the topic at the international level is clear and will benefit from an open dialogue and cooperation between the industry and the authorities on this topic.

Value to Harmonization

- Industry
  - Transparency – Compete Fairly Everywhere in the World
- Government
  - Efficiency – Leveraging Best Practices Developed by International Experts
- Consumers
  - Satisfaction – Delivering the High Quality and Safety they Expect.

Working together

Delivering Safe High Quality Cosmetics to Consumers around the World

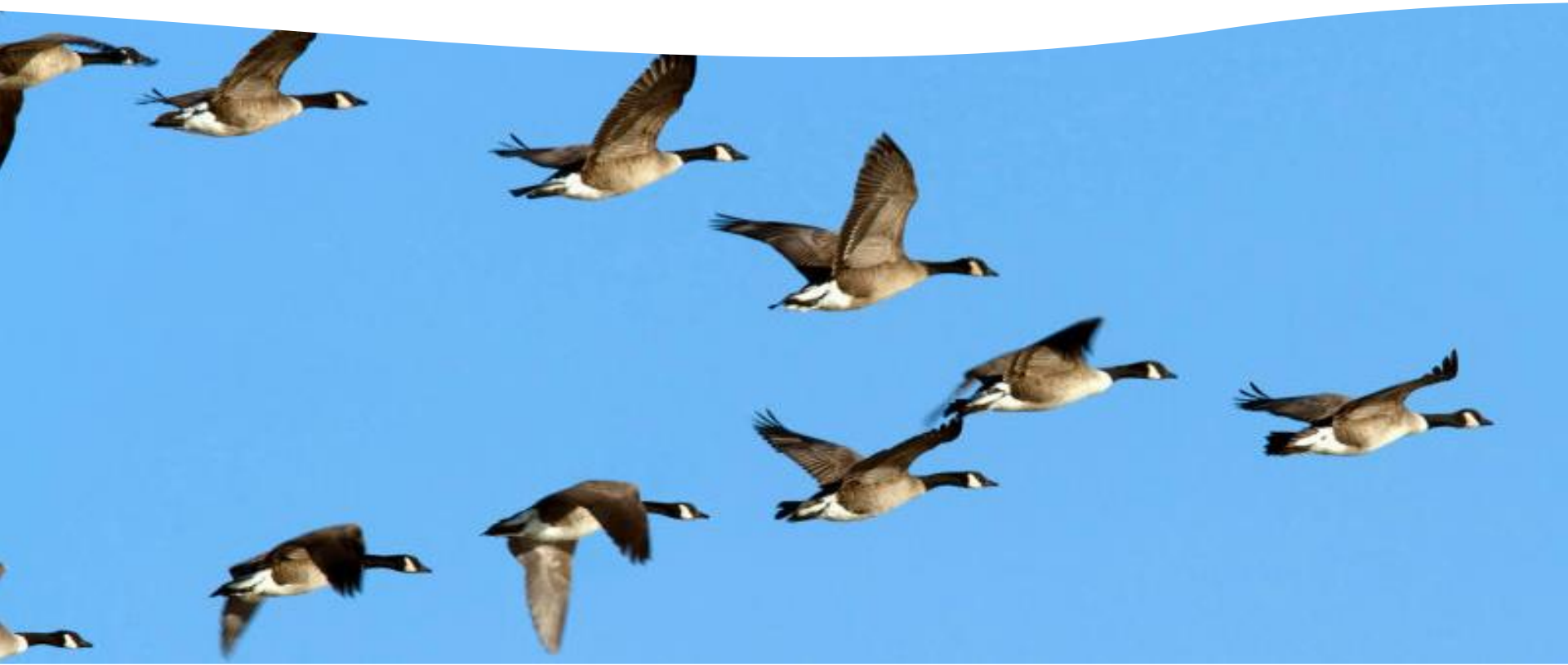
Questions?

REGULATORY BEST PRACTICES

ROLE OF THE ICCR IN INTERNATIONAL ALIGNMENT & BEST PRACTICES

Role and objective of the ICCR
Main guidelines published by ICCR; future work programs of special interest

Dr. Jay Ansell, Vice President, Cosmetic Programs, PCPC



AGENDA
International Cooperation on Cosmetic Regulations

- Introduction
- ICCR
  - History
  - Structure
  - Responsibilities
  - Processes
- Work Products
- How to Join
- Value to Participation
- Questions

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International Harmonization

- Many overarching goals:
  - Experts working collaboratively to establish common International processes and procedures for products, services or systems ensuring quality, safety and efficiency
  - Spreading knowledge leverages technological advances and good management practices across all regions
  - Facilitate International Trade

➢IMPROVE HUMAN HEALTH AND SAFETY.

International Standards Make Things Work

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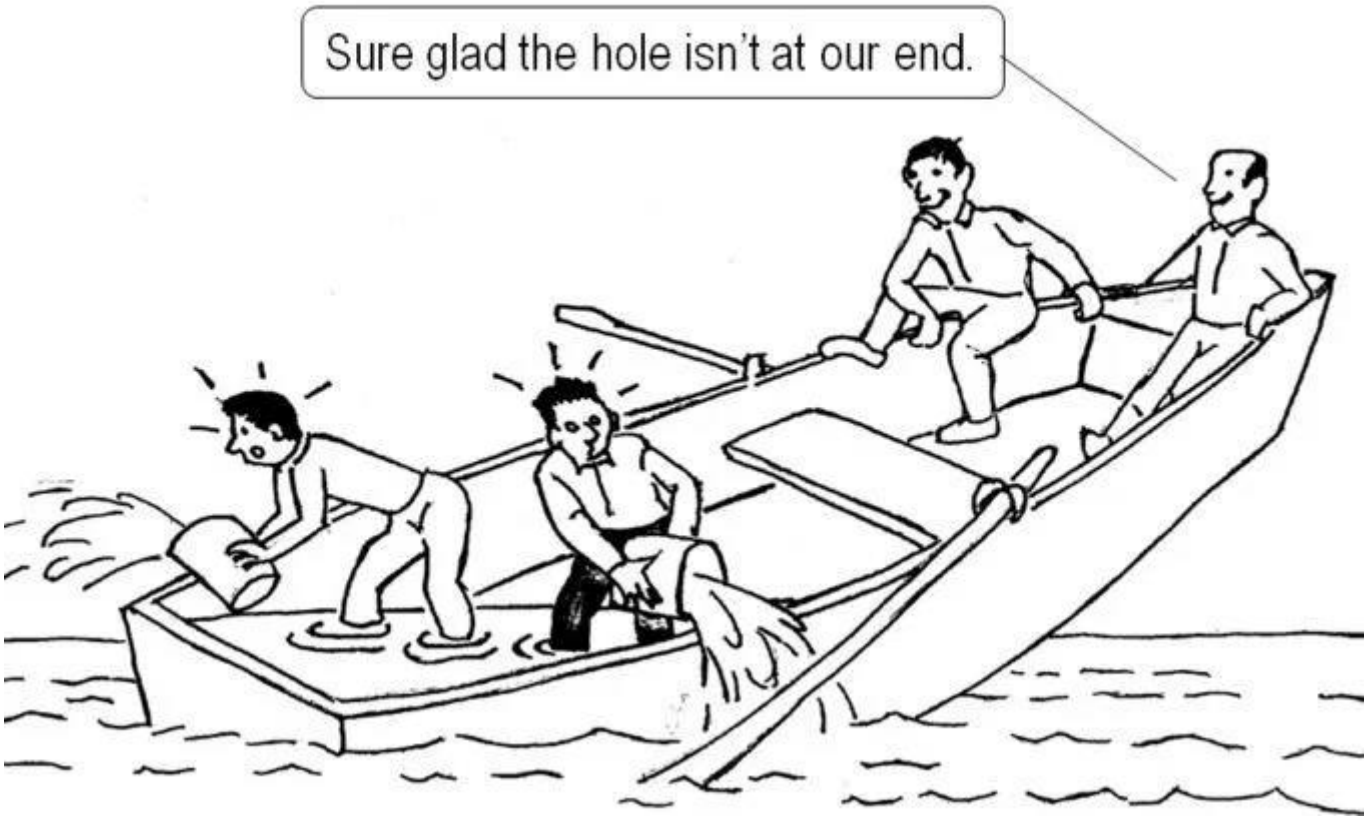
We are all in this Together



MISSION

ICCR provides a multilateral framework to maintain and enable the highest level of global consumer protection by working towards and promoting regulatory convergence, while minimizing barriers to international trade.

- Established in 2007
- ICCR achieves this through by bringing together cosmetics regulatory authorities:
  - Discuss common issues on cosmetics safety and regulation
  - Enter into a constructive dialogue with relevant cosmetics industry trade associations
- Meet in-person annually with regular calls.

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Structure - Members

- Formal ICCR "Members" are the cosmetics regulatory authorities although there are multiple stakeholders
- The five current ICCR members are:
  - ✓ Food and Drug Administration of the United States of America,
  - ✓ Ministry of Health Labour and Welfare of Japan,
  - ✓ European Commission,
  - ✓ Health Canada, and
  - ✓ Brazilian Health Surveillance Agency (ANVISA) (2014)
- Members together make up the ICCR Steering Committee (SC).
- A member serves as Secretariat for 1 year term on a rotating basis.

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Structure - Industry

- While each member holds the ultimate responsibility for implementation, successful implementation requires a constructive dialogue with the cosmetics' industry
- ICCR looks to the Industry Trade Associations to represent the affected industry sector and potentially other stakeholders
- The list of cosmetic industry trade associations is not limited, and can be extended to other relevant associations at the discretion of each member, and when the specific topic warrants the involvement of other interested parties

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Structure - Observers

- ICCR SC can invite other non-Member regulators as Observers.
- The principal regulatory representative(s) of the Observer country are invited to participate in:
  - Quarterly teleconferences
  - Annual meeting of ICCR
  - Work Group(s), as appropriate
- All activities except they do not have voting rights

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Structure - Working Groups (WG)

- Develop guidelines and policy statement that are publicly available may be adopted by members or any other authority
- WG participants are appointed by members undertake specific activities described in a WG Terms of Reference (ToR)
  - Joint Regulator – Industry Experts
- Outside technical experts invited on an as-needed basis
- Participants appoint their Chairs and develop a detailed work plan
- Work will be completed mainly via teleconference -video or email
- WG Chairs provide Secretariat function
- WGs shall be terminated upon completion of their mandate

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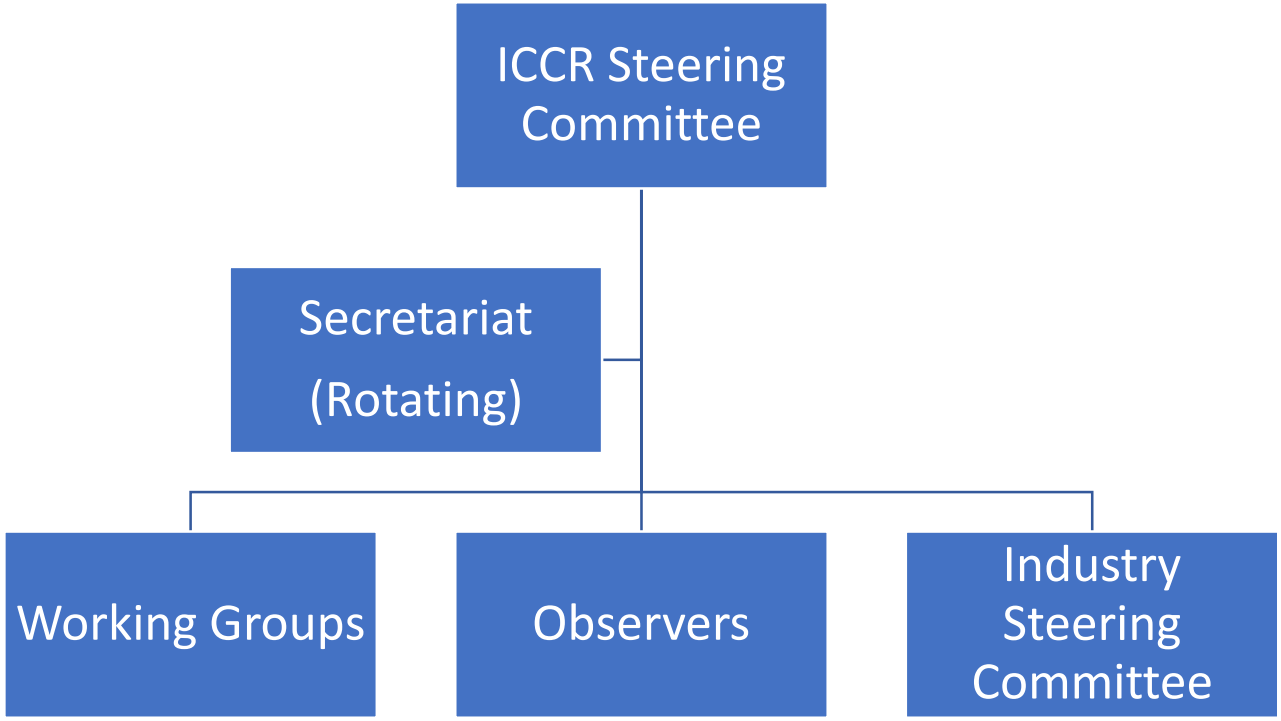
ICCR Structure



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Responsibilities – ICCR Individual Members

- While ICCR is a voluntary international group of cosmetics regulatory authorities representatives of the members agree to:
  - Take appropriate steps to implement the items within the boundaries of their legal and institutional constraints.
  - Promote the documents reflecting the consensus within their own jurisdictions and to seek convergence of regulatory policies and practices

Committed To Action

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Responsibilities – Steering Committee (SC)

- Acting Collectively:
  - Provide overall strategic guidance including subject areas for activities, future topics process, administration, and external communications
  - Oversight of ad-hoc working groups including defining the scope of work, appointment of members and **approval WGs work products**.
- Rotating annually, 1 member serves as "Secretariat"
  - Act as an administrative contact to facilitate and coordinate work such as disseminating information, and coordinating meetings
  - Serves as the primary focal point for all Working Groups
  - Hosting the Annual Meeting
- Be a forum for the exchange information on regulatory, trade and market developments of interest.
- Take on any other initiatives that contribute to achieving ICCR objectives.

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Responsibilities – Industry Steering Committee

- Organize participation in the various Working Groups by subject matter experts
- Gather input from each region in order to represent all affected industry sectors on specific issues at meetings with Regulators
- Prior to ICCR meetings suggest items for priority actions to be consider by ICCR members
- Overall enter in a constructive dialogue with the members, give their opinion and recommendations for future work

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Responsibilities – Working Groups

- Undertake the activities as mandated by the SC, reporting on progress made and committing to completing action items
- Participants are responsible for:
  - Committing to ‘active participation’ in meetings
  - Liaising with their home organization or constituency in order to communicate the efforts and accomplishments of the WG initiative

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Qualifications

- All participants must be:
  - Personally committed to its success
  - Have the qualifications and experience needed to represent their national/regional body
  - Have the authority to devote the time and energy required for success
- SC members should have the ability to participate in the decision-making process during ICCR meetings and teleconferences

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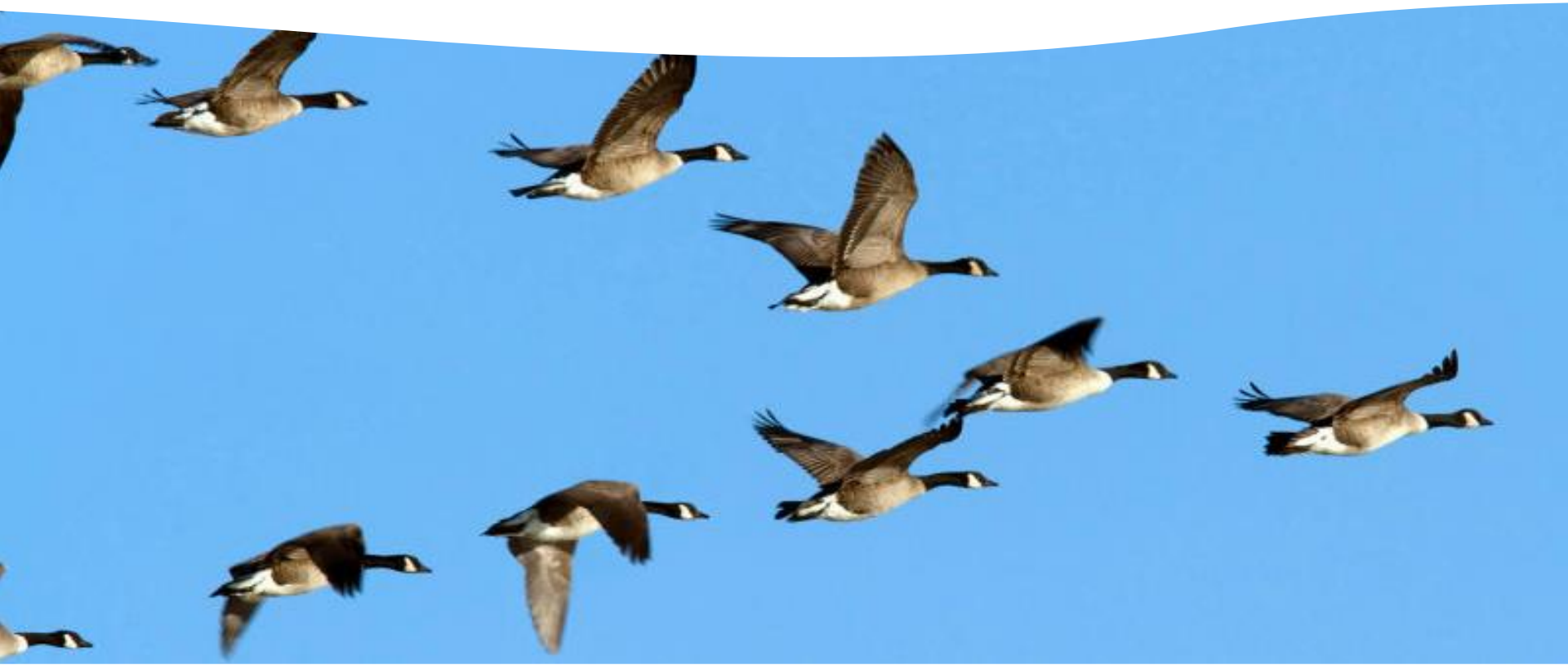
LUNCH

ROLE OF THE ICCR IN INTERNATIONAL ALIGNMENT & BEST PRACTICES

CONT'D

Dr. Jay Ansell, Vice President, Cosmetic Programs, PCPC



Governance

- All decisions of the members and subsequent actions are taken by consensus
- All decisions to be taken should be compatible with the laws, policies, rules, regulations and directives of the respective administrations and governments
  - May require the final approval by senior levels of management at a later date to allow their operational implementation or transposition into practice.
- If required by applicable legal or regulatory policies in each region/country, notice of meetings and draft guidelines to be considered may be publicly notified with adequate time to allow for public comments.

Annual Meeting Format

- The annual meeting will usually be three days
- **First day**: Separate Regulators & Industry Pre-Meetings
- **Second day**: Formal ICCR Annual Meeting
  - Structured dialogue between members' representatives, Industry trade associations, and Observers
- **Third day:** Regulators Post-Meetings with adoption of the meeting's report. Separately Industry holds a post-meeting debrief
- Since 2011 (ICCR-5) Half-Day Stakeholder "Open Session"
- Other associated meetings as appropriate

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Scope of Work

- Nanotechnologies
  - 7 Reports from 2008 – 2013: Safety Approaches, Survey of Ingredients, Characterization
- Allergens
  - Three reports on the Regulation; Compilation of Lists of Allergens; and the Use of OECD Methods
- International Standards
  - Review of ISO International Standards in Analytical; Microbiology Methods and Limits
- Product Preservation
- Safety Assessment
  - Safety Assessment Principles
  - Alternative Test Methods
  - In silico Prediction Models for Safety Assessment
- Microbiome

➢ Integrated Strategies for Safety Assessments of Cosmetic Ingredients

➢ Trace Contaminants

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Allergens

- Allergens in Cosmetics and Personal Care Products: Comparison of Jurisdictional Regulatory Approaches (2014)
- Survey of Approaches Undertaken to Develop Authoritative Lists of Potential Allergens in Cosmetics and Personal Care Products – Allergens II: Part 1 (2017)
  - American Contact Dermatitis Society; Brazilian Contact Dermatitis Research Group; Canadian Dermatology Association; Japanese Society for Dermatoallergology and Contact Dermatitis; EU Scientific Committee on Consumer Safety
- Allergens Working Group (Allergens III) on Alternative Safety Assessment Tools for Identifying Potential Dermal Allergens (2019)
  - OECD validated methods (442C; 442D; & 442E)

ICCR In Practice
ICCR-13 Montreal Canada

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ICCR-13 Agenda

- 3 Days –
  - Joint Meeting July 10;
  - Separate meetings July 9 &11.
- Open stakeholder meeting.
- Montreal Symposium on Self-care products fall into three broad categories: cosmetics; natural health products; and non-prescription drugs organized by Cosmetics Alliance Canada, July 12.
- Invitation-only workshop “NGRA -- Principles underpinning the use of new methodologies in the risk assessment of cosmetic, July 11 & 12.

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Reports: Endorsed

- Cosmetic Product Preservation
  - Establish a common overview of key scientific elements and principles that should be considered in ensuring access to an appropriate palette of preservatives and the maintenance of adequate preservative solutions, across the globe. JWG to consider future work item.
- Allergens III Alternative Safety Assessment Tools for Identifying Potential Dermal Allergens
  - Examine how the combination of non-animal methods recently adopted by OECD, may be used within Integrated Approaches to Testing and Assessment (IATA) to adequately substitute for animal tests in the evaluation of skin sensitization potential. Minor edits
- International Standards WG
  - Review & Update Annex 1 (ISO Standards and Adoption). The Annex, currently revised every 3 years will be revisit every year and to assign this task to the ICCR secretariat. Legend terminology to be reviewed.

Projects: Status Reports

- Microbiome: Survey of Products, Approaches and Terminology in Cosmetics
  - ICCR-12th, in Tokyo agreed that new technologies exploring the relationship between the human microbiome and healthy skin was an area of increasing interest and the safety, quality, regulation and potential development of international guidelines for products arising from these technologies would be a worthwhile topic for ICCR. Work to continue.
- Integrated Strategies for Safety Assessments of Cosmetic Ingredients JWG
  - Report on the July 11 & 12 Workshop will submitted to SC for review.
- Communications JWG
  - Agreed to update ICCR web site. Other topics to be proposed to SC as appropriate.

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Stakeholders

- Rob Stewart Sharkwater Foundation to raise awareness about ingredients sourced from endangered animal species.
- Human Society International presented the work to encourage the use of alternatives to animal testing.

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How to Participate

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ICCR Observers

- Since 2012, other cosmetic regulatory authorities have participated as ICCR Observers.
  - ICCR-13 July 2019 -- Colombia, Israel, South Korea, Taiwan & Thailand participated
  - Previously ICCR meetings Argentina, Australia, Brazil, Chile, People's Republic of China, Saudi Arabia & South Africa, some many times
- *Brazil was accepted as Member following ICCR-8 in July 2014.*

Key Requirements for ICCR Observers

- A cosmetic regulatory authority that would like to attend the annual meeting; participate in quarterly regulator-industry teleconferences or join a Working Group should make a request to the Chair of ICCR.
- The regulator represents the regulatory authority that:
  - Has a structure in place for cosmetics that is aligned with that of the current ICCR Members
  - Has a recognized representation (i.e. trade association) to act as a link with the private sector
- The inclusion is decided by consensus by the ICCR SC
- 2020 Secretariat is the EU.

"Requirements for ICCR Observers" & "Process for ICCR Observer to transition to ICCR Steering Committee Member" are available on the ICCR web page at in the "TOPICS Tab" https://www.iccr-cosmetics.org/topics/

Cosmetics Europe
the personal care association

Indian Beauty & Hygiene Association
IBHA

Personal Care Products Council
Committed to Safety, Quality & Innovation

Value to Harmonization

- Industry
  - Transparency – Compete Fairly Anywhere In The World
- Government
  - Efficiency – Leveraging The Best Practices Developed By International Experts
- Consumers
  - Satisfaction – Delivering The High Quality And Safety They Expect.

ICCR – Helps Deliver on All 3!

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Questions?

Keynote Address

Dr V G Somani,
Drug Controller General (India), CDSCO

Dr. V. G. Somani, Drug Controller General, CDSCO

Ms. Nisha Bura, PCD-19, BIS, Drug Controller

Uttar Pradesh, Drug Controller, Uttarakhand

Dr. A. Sivakumar, IBHA

Mr. John Chave Cosmetics Europe

Dr. Jay Ansell, PCPC

Session Moderator:

Dr. Sonal Shidhore, IBHA

Panel Discussion

Closing remarks

Mr. Chris Priddy, International Relations Specialist, USFDA

Mr John Chave, Director General, Cosmetics Europe

Ms Malathi Narayanan, Secretary General, IBHA