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A COMMON INTERNATIONAL APPROACH TOWARDS THE REGULATION OF COSMETICS

MARCH 2013

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AGENDA

1 INTRODUCTION

2 PRINCIPLES FOR REGULATORY CONVERGENCE

3 INTERNATIONAL STANDARD (ISO)

4 ICCR AND AUTHORITY/INDUSTRY GUIDELINES

INTRODUCTION

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GENERAL REASONS FOR REGULATING COSMETICS

PROTECTION OF CONSUMER HEALTH

FAIR COMPERTITION

MARKET ACCESS

Key Stakeholders : Authorities, Consumers, Industry

CONVERGENCE – A POSSIBLE APPROACH

> More pragmatic approach to bring regulations more closely together

> Based on 2 complementary ideas

> Results through a variety of means which will be dependent on the cirscumstances

> Industry could play a key role to help achieve workable solutions

SOME GENERAL PRINCIPLES FOR REGULATORY CONVERGENCE

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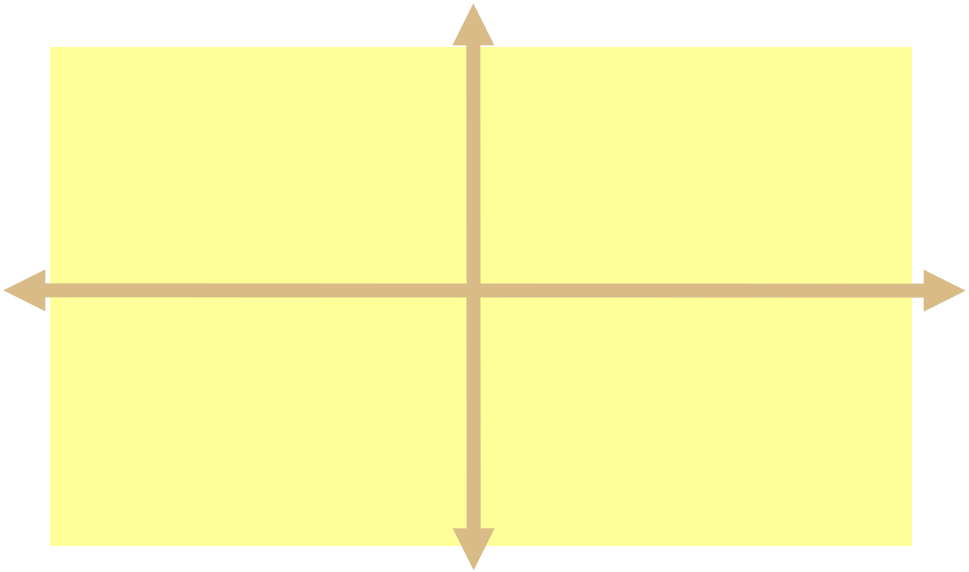
WHERE SHOULD COSMETICS LEGISLATION BE SITUATED?

Manufacturers responsible
Placing product on market



Manufacturers
Secretive
Towards
Regulators

Manufacturers
Transparent
Towards
Regulators

Regulators responsible
Placing product on market

COMMON WORLDWIDE PRINCIPLES FOR COSMETICS LEGISLATION

IT SHOULD ENSHRINE THE FOLLOWING BASIC PRINCIPLES:

>No pre-market approval system (but positive to notification when required by authorities)

>Harmonization of the regulation on ingredients and labelling

>List of regulated ingredients based on scientific evidence

>The company's responsibility for safety and compliance with the regulation

>The national competent authority's responsibility for cosmetics in the market

>Transparency of safety information in the context of in-market control:
- Safety Evaluation
- Risk Management Strategies
- Post Market Surveillance

>Reference to some International Standards ,Authority/Industry and Industry Guidelines

COMMON WORLDWIDE PRINCIPLES FOR COSMETICS LEGISLATION

notification

Harmonization **Ingredients** **Labelling**

Transparency **Safety information**

International Standards **Regulators/Industry Guidelines**

NOTIFICATION

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NOTIFICATION

>Notification is not contradictory to responsibility of person placing cosmetic product on the market

>Legitimate for competent authorities to trace products on their markets and manufacturers on their territory

>Manufacturing information should be generic on production sites and not linked to specific products

HARMONISATION OF INGREDIENTS

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HARMONISATION OF INGREDIENTS

As a general rule, the use of substances in cosmetics should be subject to appropriate risk assessments

Inclusion/ exclusion on lists should follow the following principles:

> It should be scientifically founded
> Assessments should be risk based and not hazard based
> Application of the precautionary principle should not be unduly restrictive
> List of regulated ingredients

HARMONISATION OF LABELLING

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HARMONISATION OF LABELLING

ISO Standard 22715 (Cosmetics – Packaging and Labelling) is a good basis for international harmonisation

Full Ingredient Labelling is important information to the consumer as it enables individual consumers to make an informed choice (i.e. personal risk management):

> It should be based on INCI (trivial names in Latin) and be totally international

TRANSPARENCY OF SAFETY INFORMATION

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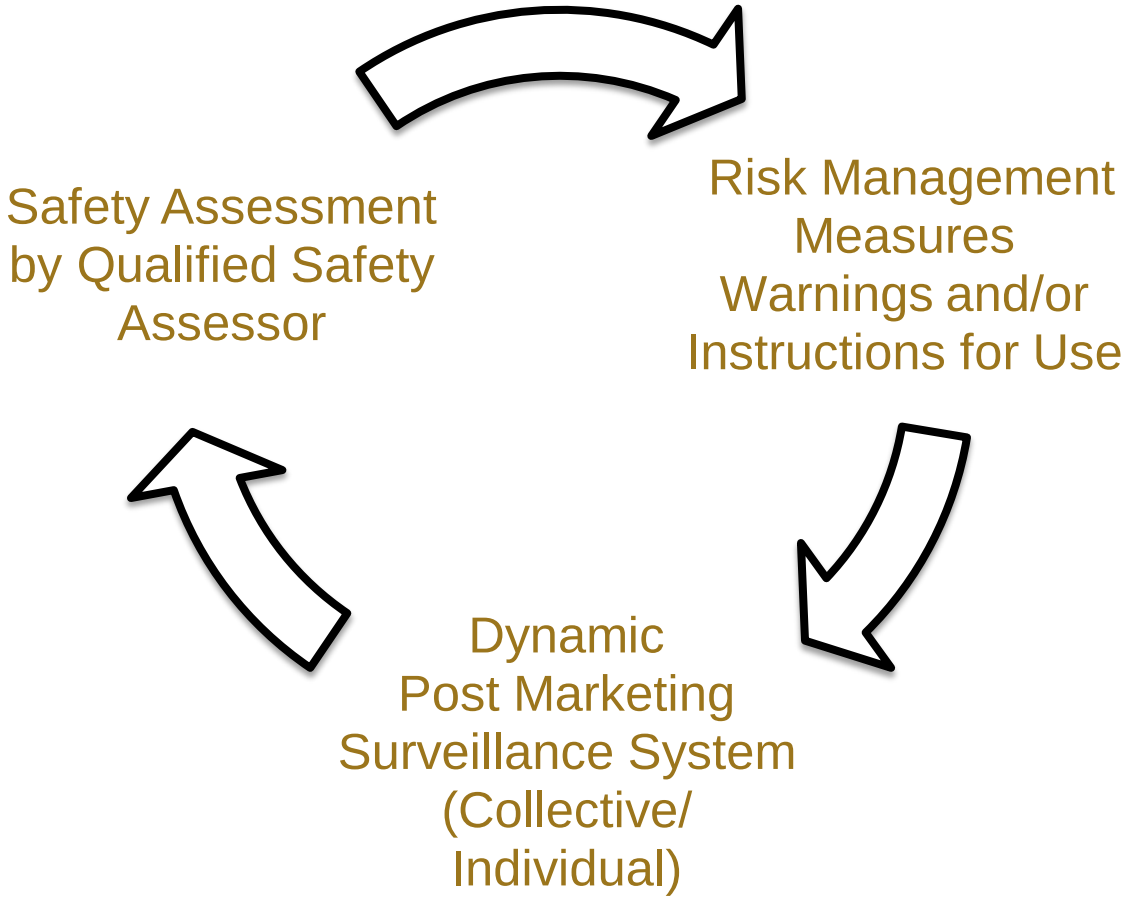
A VIRTUOUS CIRCLE FOR CONSUMER PROTECTION ENSURED VIA A COMPLETE SAFETY EVALUATION AND MANAGEMENT APPROACH



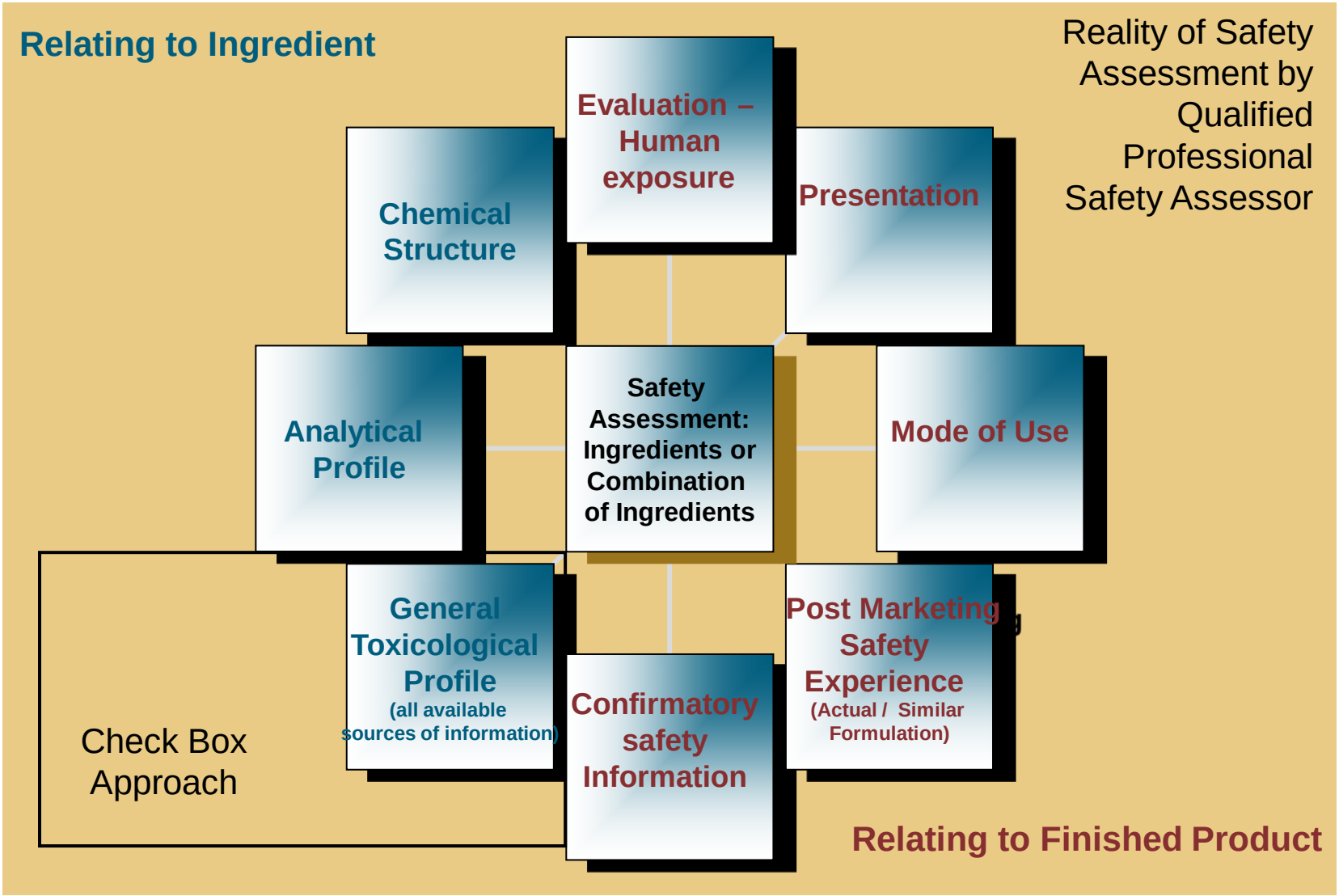
SAFETY ASSESSMENT

>Safety assessment ➔Expertise conducted by competent professional safety assessor

>More complex than compilation of predefined list of toxicological data on ingredients

Important note: Safety evaluations conducted by suitably qualified and experienced persons should be recognised at an international level

SAFETY ASSESSMENT



RISK MANAGEMENT

>These should be under the responsibility of the safety assessor and will generally take the form of warnings and/ or instructions for use

>Together with Full Ingredient Labelling, this enables individual consumers to make an informed choice (i.e. personal risk management)

POST MARKETING SURVEILLANCE

Any system should be harmonised internationally with balanced roles & responsibilities
(cosmetics industrialists, health professionals, national health authorities)

Requires a flow of high quality data produced using a set of common definitions and tools amongst all stakeholders
> Definition of serious undesirable effect
> Harmonised case assessment

TWO ADDITIONAL PILLARS

EFFICACY

GOOD MANUFACTURING PRACTICES

INTERNATIONAL STANDARDS ICCR AND INDUSTRY GUIDELINES

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INTERNATIONAL CONVERGENCE

Cosmetics regulations worldwide diverse reflecting the local context and culture

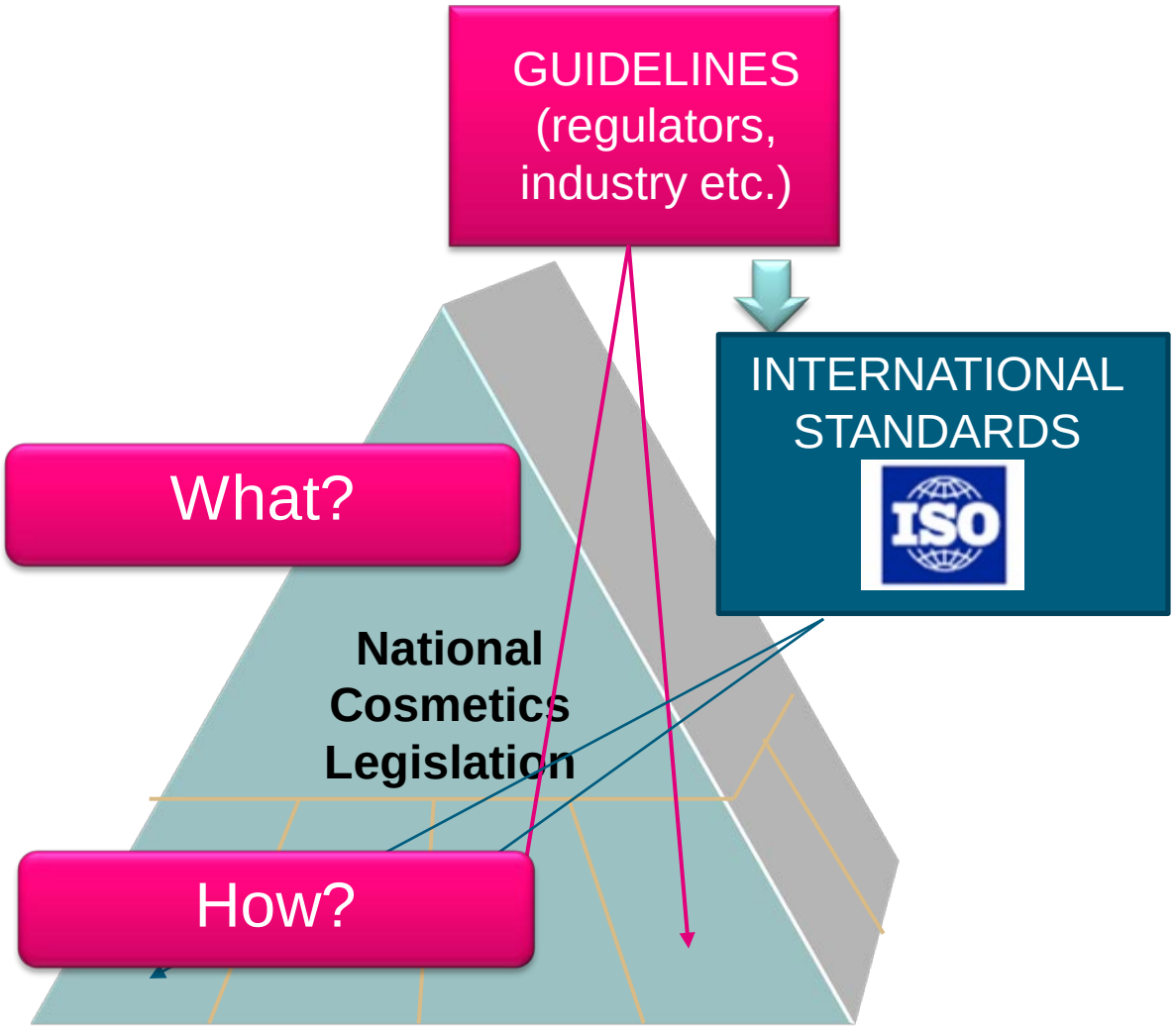
Nevertheless, we should move towards inclusion of some common requirements

Regulations generally state « what to do » but do not give guidance on « how do do it »

Beneficial to create a range of international reference points:
> 'best practices'
> 'promote international convergence

Emerging subjects

WORK AREA OF ISO TC 217



> These outline practical aspects relating to application of a regulation

> They may often apply to numerous national regulations – thus offering a basis for international convergence

ISO (INTERNATIONAL ORGANIZATION FOR STANDARDIZATION)

>World's largest developer and publisher of International Standards.
>Network of the national standards institutes of 163 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system.
>ISO is a non-governmental organization that forms a bridge between the public and private sectors.
>Enables a consensus to be reached on solutions that meet both the requirements of business and the broader needs of society.

Key principles in ISO standard development:

1. Respond to a need in the market
2. Based on global expert opinion
3. Developed through a multi-stakeholder process
4. Based on a consensus

ISO standards as such are voluntary in nature

ISO STANDARD - ISO

Stage name	Product name	Acronym
Preliminary stage	Preliminary work item (project)	PWI
Proposal stage	New proposal for a work item	NP
Preparatory stage	Working draft(s)	WD
Committee stage	Committee draft(s)	CD
Enquiry stage	Draft International Standard	DIS
Approval stage	Final draft International Standard	FDIS
Publication stage	International Standard	IS

DEFINITION: Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

NORMATIVE DOCUMENT

OTHER ISO DELIVERABLES:

> Technical Specification (ISO/TS)
> Technical Report (ISO/TR)
> Publicly Available Specifications (PAS)
> Internal Workshop Agreements (IWA)

ISO TC 217 TIMELINE

Secretary

M. R. Tabari (Iran)

Chair

R.Van Buuren (Netherlands)

WG1	MICROBIOLOGY
WG2	PACKAGING, LABELLING & MARKING
WG3	ANALYTICAL CHEMISTRY
WG4	TERMINOLOGY
WG6	GOOD MANUFACTURING PRACTICE
WG7	SUN PROTECTION
WG8	NANOMATERIALS

Chair

J. James (UK)

3 Registered Projects (+6 un-registered)

1998 2005 2008 2010 2012

Standard development 3-5 years

Creation | R. Van Buuren | J. James

P-members

Liaison members

Published documents

12 p members
- France
- Switzerland
- South Korea
- Thailand
- India

16 p members
- USA
- Japan
- South Africa
- UK

- Cosmetics Eu
- CASIC

6 ISO Docs
- Labelling
- Microbiology (x5)

28 p members
- Spain
- Australia
- China

13 ISO Docs
- GMP
- NDELA (x2)
- Microbiology

40 p members
- Germany
- Brazil
- Singapore

- ACA
- NaTrue
- COSMOS
- IFRA

20 ISO Docs
- Sun protect(x3)
- Micro low risk
- Micro protection
- Chromotography

IFRA

Europe

Austria, Belgium, Croatia, Czech Rep, Denmark, France, Germany, Ireland, Italy, Lithuania, Netherlands, Norway, Poland, Spain, Sweden, Switzerland, U.K.

Cosmetics Europe, NaTrue, COSMOS

North America

U.S.A.

Latin America

Brazil, Colombia, Argentina

CASIC [Lat.America]

Liaison Members

Asia - Pacific

Australia, China, India, Indonesia, Japan, S. Korea, New Zealand, Singapore, Sri Lanka, Thailand

ACA [ASEAN]

Africa & Middle East

Algeria, Egypt, Ghana, Iran, Jordan, Kenya, Nigeria, South Africa, U.A.E.

ISO TC 217, COSMETICS

Chair: Mr J. James (United Kingdom); Secretariat Ms M. R. Tabari (Iran)

	SUBJECT	CONVENER	COMMENTS
WG1	MICROBIOLOGY	Ms M. R. Tabari (Iran)	
WG2	PACKAGING, LABELLING & MARKING	Ms F.Ahmed (USA)	On hold
WG3	ANALYTICAL CHEMISTRY	Mr P.A. Bonnet (France)	
WG4	TERMINOLOGY	Mr H. Ohshima (Japan)	
WG6	GOOD MANUFACTURING PRACTICE	Mr J. James (United Kingdom)	On hold
WG7	SUN PROTECTION	Mr P. Masson (France)	
WG8	NANOMATERIALS		On hold

On hold = no live projects

WORK PLAN OF ISO TC 217

REFERENCE METHODS for chemical analysis, microbiology and sun protection

GUIDELINES for Good Manufacturing Practices and labelling

COMMON TERMINOLOGY in the area of natural and organic cosmetic products

BENEFITS OF ISO COSMETIC STANDARDS

WHEN ADOPTED BY REGULATORY AGENCIES:

> They provide guidelines allowing for conformity to a regulatory reguirement (e.g. GMP)

> They provide reference methods which could be used for in-market control (e.g. analytical chemistry, microbiology, sun protection)

TO PROVIDE POINTS OF REFERENCE for other key stakeholders (industry, consumers etc.)

TO PROVIDE A SET OF 'BUILDING BLOCKS', the widespread adoption of which would contribute to international convergence in the cosmetics sector

ISO TC 217 AS A MEANS OF ACHIEVING INTERNATIONAL HARMONISATION – INDUSTRY PERSPECTIVE

Some general principles towards the creation of ISO projects:

>Projects should have a recognised international interest

>Projects should relate to the « protection of consumer health »

>« Fair competition » subjects should not generally form the basis for ISO – Self regulation within industry is more appropriate

>Standards should not create boundaries which would stifle future innovation (product conception, industrialisation, commercialisation, …)

ICCR

AN INTERNATIONAL TOOL FOR HARMONISATION

INTERNATIONAL COOPERATION ON COSMETIC REGULATION (ICCR)

INTERNATIONAL GROUP OF COSMETIC REGULATORY AUTHORITIES SET UP IN 2007:

> United States (Food & Drug Administration)
> Japan (Ministry of Health, Labour and Welfare)
> European Union (Commission, DG Enterprise)
> Canada (Health Canada)

“Highest level of global consumer protection”

“Minimising barriers to international trade”

DIALOGUE with cosmetics industry trade associations from each region
(PCPC, JCIA, Cosmetic Europe, CCTFA)

ICCR SUBJECTS

Alternative to Animal Testing
Nanotechnology
Trace Impurities
Safety Assessment Approach
Endocrine Disuptors
In silico Prediction Model for Safety Assement
Allergens

INTERNATIONAL STANDARDS AND INDUSTRY/AUTHORITIES (EG ICCR)GUIDELINES

INDUSTRY/ GUIDELINES allow for a common approach between members
- often on subjects of international concern

AUTHORITIES/INDUSTRY GUIDANCE eg ICCR (International Cooperation on Cosmetics) documents on Traces and Principles of Safety Evalaution

INTERNATIONAL STANDARDS (ISO) and the harmonisation of these guidelines at international level are a key tool towards the international convergence

COMMON AGREED PRINCIPLES

should be in line with the industry commitment to increase the manufacturer's responsibility to market safe products for consumers.