The new EU Regulation 1223/2009 on Cosmetic Products
Everything you need to know!

SCC Ontario - March 25th, 2014
Marie Roussel & Ariane Divetain
INTRODUCTION TO THE REGULATION
European Economic Area

- European Union (28 countries)
- Norway + Iceland + Liechtenstein

= 31 countries concerned with the new Cosmetics Regulation
# List of concerned countries

<table>
<thead>
<tr>
<th>In alphabetical order:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Austria</td>
</tr>
<tr>
<td>2. Belgium</td>
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<tr>
<td>3. Bulgaria</td>
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<td>4. Croatia</td>
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<td>5. Cyprus</td>
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<td>6. Czech Republic</td>
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<td>7. Denmark</td>
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<td>8. Estonia</td>
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<td>9. Finland</td>
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<td>10. France</td>
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<td>11. Germany</td>
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<td>12. Greece</td>
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<td>13. Hungary</td>
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<td>14. Iceland</td>
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<td>15. Ireland</td>
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<tr>
<td>16. Italy</td>
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<tr>
<td>17. Latvia</td>
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<tr>
<td>18. Liechtenstein</td>
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<tr>
<td>19. Lithuania</td>
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<tr>
<td>20. Luxembourg</td>
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<tr>
<td>21. Malta</td>
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<tr>
<td>22. Netherlands</td>
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<tr>
<td>23. Norway</td>
</tr>
<tr>
<td>24. Poland</td>
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<tr>
<td>25. Portugal</td>
</tr>
<tr>
<td>26. Romania</td>
</tr>
<tr>
<td>27. Slovakia</td>
</tr>
<tr>
<td>28. Slovenia</td>
</tr>
<tr>
<td>29. Spain</td>
</tr>
<tr>
<td>30. Sweden</td>
</tr>
<tr>
<td>31. United Kingdom</td>
</tr>
</tbody>
</table>
BEFORE the Regulation

Before

DIRECTIVE 76/768

COMPLEXITY
A different interpretation for each country

July, 11th 2013

After

REGULATION 1223/2009

HARMONIZATION
Common obligations to all 31 countries
Associated regulations...

- Directive « Nominal Quantities »
- Directive « Aerosols »
- Directive « Prepacked Products »
- Directive « Common Criteria »
- Regulation 1223/2009
- Regulation « CITES »
- Etc...
The Regulation = Evolution

The Regulation brings NEW obligations:
- Responsible Person
- Nanomaterials
- CPNP notification portal
- Packaging material
- Undesirable effects to notify
- Etc.

Obligations already published in the Directive
The actors concerned

OUTSIDE EUROPE

- Suppliers
- Manufacturer

EUROPE

- Border Control Authorities
- Responsible Person
- Importers
- Distributors
- Consumers
Definition of a “cosmetic”

Any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity...

...with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.
Borderline products

- Biocides: Mosquito repellent
- Drugs: Hair-growth spray
- Foods: Whitening gum
- Toys: Make-up for a doll
Exporting means complying

Successful compliance = successful exports

MANY OBLIGATIONS TO RESPECT
The Responsible Person

Canadian manufacturer

Who is the RP?

1. EU subsidiary
2. Distributor / Importer
3. Regulatory Expert

Must be based in Europe
Legal or natural person
Choose your RP carefully

Responsible Person

COMPLIANCE
Scientific & Regulatory expertise

AUTHORITIES
Credibility & Network

LABELLING
Long-term & Trust
What the RP does for you

- Data collection
- Safety Assessment
- PIF compilation
- Labelling compliance
- CPNP notification

EU market
Responsibilities of the RP

- Safety Report
- Compliant composition
- Product Information File
- Labelling
- CPNP Notification
- Nanomaterials
- Cosmetovigilance, undesirable effects
- Sampling and analysis
- Claims
- Information for the public...
- Animal testing, Good Manufacturing Practices...
Compliance = PIF

PRODUCT INFORMATION FILE

1. Product description
2. Product Safety Report
3. Good Manufacturing Practices
4. Proof of the effect claimed
5. Animal testing

PIF = must be kept for 10 years by the Responsible Person (paper or electronic)
Product Safety Report

PRODUCT INFORMATION FILE

1. Product description
2. Product Safety Report
3. Good Manufacturing Practices
4. Proof of the effect claimed
5. Animal testing
Content of the Safety Report

Part A - Data to collect

For every raw material:
• Microbiological specifications
• Safety Data Sheets
• Toxicological data
• Presence of impurities

For every packaging material:
• Composition and impurities

For every finished product:
• Composition of the finished product
• Analysis certificate
• Manufacturing and analysis methods
• Shelf-life and stability tests
• Microbiological quality
• Product use and exposure
• Undesirable effects
• Clinical tolerance tests

Part B - Assessment report

Conclusion on the Safety by a Safety Assessor
# Product composition

<table>
<thead>
<tr>
<th>Raw Material Name</th>
<th>CAS Number</th>
<th>INCI Name</th>
<th>Function</th>
<th>Exact % in product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of raw material #1</td>
<td>7732-18-5</td>
<td>AQUA</td>
<td>Solvent</td>
<td>6.93%</td>
</tr>
<tr>
<td></td>
<td>89998-01-6</td>
<td>CUCUMIS SATIVUS FRUIT EXTRACT</td>
<td>Skin conditionning</td>
<td>3.05%</td>
</tr>
<tr>
<td></td>
<td>24634-61-5</td>
<td>POTASSIUM SORBATE</td>
<td>Preservative</td>
<td>0.02%</td>
</tr>
<tr>
<td>Fragrance 1</td>
<td>n/a</td>
<td>Parfum</td>
<td>Perfurming</td>
<td>1.00%</td>
</tr>
<tr>
<td>...</td>
<td>...</td>
<td>...</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100%</td>
</tr>
</tbody>
</table>
Annex II = 1,373 prohibited substances

**PETROLATUM**: except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen.

Annex III = around 280 restricted substances

**LAURETH-9**: Maximum concentrations:
- Leave-on products: 3%
- Rinse-off products: 4%

Annexes are updated over time...
Positive lists of substances

**Annex IV** = 153 colorants
- **CI 77499**: Purity criteria
- **MICA**: opacifying (not a cosmetic colorant)

**Annex V** = 57 preservatives
- **PARABENS**: some are allowed under restrictions

**Annex VI** = 28 UV-filters
- **BENZOPHENONE-3**: max. concentration: 10%

Annexes are updated over time...
### CosIng database

When one CAS number = several INCI names...

<table>
<thead>
<tr>
<th>#</th>
<th>INCI Name/Substance Name</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td><strong>CUCUMIS SATIVUS EXTRACT</strong></td>
<td>89998-01-6</td>
</tr>
<tr>
<td>2.</td>
<td><strong>CUCUMIS SATIVUS FRUIT</strong></td>
<td>89998-01-6</td>
</tr>
<tr>
<td>3.</td>
<td><strong>CUCUMIS SATIVUS FRUIT EXTRACT</strong></td>
<td>89998-01-6</td>
</tr>
<tr>
<td>4.</td>
<td><strong>CUCUMIS SATIVUS FRUIT WATER</strong></td>
<td>89998-01-6</td>
</tr>
<tr>
<td>5.</td>
<td><strong>CUCUMIS SATIVUS JUICE</strong></td>
<td>89998-01-6 / 8024-36-0</td>
</tr>
<tr>
<td>6.</td>
<td><strong>CUCUMIS SATIVUS OIL</strong></td>
<td>70955-25-8 / 89998-01-6</td>
</tr>
</tbody>
</table>
When formulating...

CosIng is a great source of regulatory information

<table>
<thead>
<tr>
<th>Ingredient: POTASSIUM SORBATE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INCI Name</strong></td>
</tr>
<tr>
<td><strong>Description</strong></td>
</tr>
<tr>
<td><strong>INN Name</strong></td>
</tr>
<tr>
<td><strong>Ph. Eur. Name</strong></td>
</tr>
<tr>
<td><strong>CAS #</strong></td>
</tr>
<tr>
<td><strong>EC #</strong></td>
</tr>
<tr>
<td><strong>Chemical/IUPAC Name</strong></td>
</tr>
<tr>
<td><strong>Cosmetic Restriction</strong></td>
</tr>
<tr>
<td><strong>Other Restriction(s)</strong></td>
</tr>
<tr>
<td><strong>Functions</strong></td>
</tr>
<tr>
<td><strong>SCCS opinions</strong></td>
</tr>
<tr>
<td><strong>Identified INGREDIENTS or substances e.g.</strong></td>
</tr>
<tr>
<td>Main functions of ingredients</td>
</tr>
<tr>
<td>--------------------------------</td>
</tr>
<tr>
<td>Abrasive</td>
</tr>
<tr>
<td>Absorbent</td>
</tr>
</tbody>
</table>

Main functions of ingredients:

- Abrasive
- Absorbent
- Anticorrosive
- Antidandruff
- Antifoaming
- Antimicrobial
- Antioxidant
- Antiperspirant
- Antiseborrhoeic
- Antistatic
- Astringent
- Binding
- Bleaching
- Buffering
- Bulking
- Chelating
- Cleansing
- Colorant
- Denaturant
- Deodorant
- Depilatory
- Detangling
- Emollient
- Emulsifying
- Emulsion stabilising
- Film forming
- Foam boosting
- Foaming
- Gel forming
- Hair conditioning
- Hair dyeing
- Hair fixing
- Hair waving
- Humectant
- Hydrotrope
- Keratolytic
- Masking
- Moisturising
- Nail conditioning
- Oral care
- Oxidising
- Pearlescent
- Plasticiser
- Preservative
- Propellant
- Reducing
- Refatting
- Refreshing
- Skin conditioning
- Skin protecting
- Smoothing
- Soothing
- Stabilising
- Surfactant
- Tanning
- Tonic
- UV absorber
- UV filter
- Viscosity controlling
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<td>...</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100%</td>
</tr>
</tbody>
</table>
Fragrances & extracts

Vegetal extract

E.g. Cucumis sativus fruit extract

List of allergens

Fragrance

E.g. fragrance, essential oil, etc.

List of allergens

IFRA certificate
Which information is required?

• Name of the fragrance supplier
• Name of the FP manufacturer
• Name of the product/fragrance
• Statement of compliance regarding the last IFRA amendment (47th)
• IFRA Class and maximum concentration level
• Additional information: IFRA restricted and IFRA prohibited materials
<table>
<thead>
<tr>
<th>Allergens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amyl Cinnamal</td>
</tr>
<tr>
<td>Amylcinnamyl Alcohol</td>
</tr>
<tr>
<td>Anise Alcohol</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
</tr>
<tr>
<td>Benzyl Benzoate</td>
</tr>
<tr>
<td>Benzyl Cinnamate</td>
</tr>
<tr>
<td>Benzyl Salicylate</td>
</tr>
<tr>
<td>Butylphenyl Methylpropional</td>
</tr>
<tr>
<td>Cinnamyl Alcohol</td>
</tr>
<tr>
<td>Citral</td>
</tr>
<tr>
<td>Citronellol</td>
</tr>
<tr>
<td>Coumarin</td>
</tr>
<tr>
<td>Eugenol</td>
</tr>
<tr>
<td>Farnesol</td>
</tr>
<tr>
<td>Geraniol</td>
</tr>
<tr>
<td>Hexyl Cinnamal</td>
</tr>
<tr>
<td>Hydroxyisohexyl 3-cyclohexene Carboxaldehyde</td>
</tr>
<tr>
<td>Hydroxycitronellal</td>
</tr>
<tr>
<td>Isoeugenol</td>
</tr>
<tr>
<td>Alpha-isomethyl Ionone</td>
</tr>
<tr>
<td>Limonene</td>
</tr>
<tr>
<td>Linalool</td>
</tr>
<tr>
<td>Methyl 2-Octynoate</td>
</tr>
<tr>
<td>Oak Moss Extract</td>
</tr>
<tr>
<td>TreeMoss Extract</td>
</tr>
<tr>
<td>Cinnamal</td>
</tr>
</tbody>
</table>

Possible updated list of 82 allergens late 2014
Must appear on the label:

All allergens > **0.01%** in the finished product

- Geraniol = **0.003%**
- Limonene = **0.015%**
Must appear on the label:
All allergens > 0,001% in the finished product

- Geraniol = 0,003%
- Limonene = 0,015%
Overview of data collection

Raw Material

- Microbiological specifications
- Toxicological profile of the substances

Finished Product

- Challenge test (Preservative test)
- Stability test in aging accelerated conditions
- Product use and exposure
- Existing UE and/or SUE

Packaging

- Physical / chemical characteristics - Purity

GO / NO GO
Physical-chemical characteristics

- **Origin** of the RM (vegetal, animal, synthetic...)
- Extraction method, synthesis process
- Physical/chemical specifications
- Determination of the **impurities** rate
- MSDS
- **Granulometric distribution** curve for nano

**RM**

**Formula**

Certificate of Analysis (**CoA**)
CoA must include galenic & organoleptic characteristics and some other descriptors

<table>
<thead>
<tr>
<th>Test</th>
<th>Target Result</th>
<th>Specification</th>
<th>Test Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>To Match Standard</td>
<td>To Match Standard</td>
<td>Visual</td>
</tr>
<tr>
<td>Odour</td>
<td>To Match Standard</td>
<td>To Match Standard</td>
<td>Olfactive</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>0.875</td>
<td>...</td>
<td>EU Method A.3</td>
</tr>
<tr>
<td>pH</td>
<td>4.25</td>
<td>...</td>
<td>Calibrated pH meter</td>
</tr>
<tr>
<td>Viscosity</td>
<td>X cPs</td>
<td>...</td>
<td>EPA OPPTS 830.7100</td>
</tr>
<tr>
<td>Microbial quality</td>
<td>Aerobic germs &lt; 100 cfu/g</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yeast &amp; Mould &lt; 100 cfu/g</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Overview of data collection

Raw Material
- Physical / chemical characteristics - Purity
  - Microbiological specifications
- Toxicological profile of the substances

Finished Product
- Challenge test (Preservative test)
- Stability test in aging accelerated conditions
- Product use and exposure
- Existing UE and/or SUE

Packaging

GO / NO GO
Microbiological quality

Microbiologically low-risk products

- single use product
- low water activity $a_w$: anhydrous minerals powders
- pH of formulation ($\text{pH} > 10$ or $\text{pH} < 3.5$)
- products with high alcohol content as perfumes ($\sim > 20\%$)
- RM which creates a hostile environment
- the type of packaging (pump dispenser, airless container)

Challenge test must be performed

- ISO 29621
- ISO 11930
Microbiological quality

Microbiological specifications (germs counting)

- Numerous ISO norms to enumerate and detect yeast and moulds, aerobic mesophilic bacteria
- During characterization of the formula or during stability tests

Category 1 = Products intended for children under 3, to be used in the eye area and on mucous membranes: < 100 cfu/g (ml)
Category 2 = Other products < 1000 cfu/g (ml)

Microbiological specifications & Challenge test

Evaluation of the preservation of a cosmetic product based on an inoculation of the formulation with calibrated µorg inocula
Overview of data collection

Raw Material:
- Physical / chemical characteristics - Purity
- Microbiological specifications
- Toxicological profile of the substances

Finished Product:
- Challenge test (Preservative test)
- Stability test in aging accelerated conditions

Packaging:
- Product use and exposure
- Existing UE and/or SUE

GO / NO GO
Stability test

One goal — DMD determination

1. Under «Accelerated» conditions at 1, 2, 3 and/or 6 months

Methods:
- Temperature variation & constant humidity
- Temperature variation & humidity variation
- Temperature & humidity constant
- Constant temperature & humidity variation

Temperature variation:
- RT: 25 °C
- Sterilizer: 40 °C, 45 °C, 50 °C
- Freezer: -4 °C

Hygrometry variation

Light influence

Microbiological counting

Qualitative & quantitative observations:
odor, color changes due to oxidation phenomenon, pH modification, alcohol evaporation, viscosity change, preservative dosage...

2. Under real conditions of use

Formula
Step 1 = DMD

**Step 1** Define the Date of Minimum Durability (DMD)

If DMD < 30 months  ➔ or “best used before the end of”

If DMD > 30 months The PAO must be labelled
Step 2 = PAO

How to determine PAO?

- Result of the challenge test
- Composition and process: % of water & solvent, nutrients, pH
- Packaging: contact product/packaging, volume/dose/frequency of use
- Function and conditions of use: rinse-off, leave-on
- Type of users: adult, children, infant or elderly
- Aera of application: low, medium, high
- Specific risks: storage products, travelling products, extemporaneous
New requirement of the Regulation is to identify the composition of the material, particularly its purity and stability.
Packaging requirements

- AC process
- REACH status
- Formula content
- Stability test
- Food contact

Risk Analysis

Packaging change

Assessment OK
Overview of data collection

Raw Material

- Physical / chemical characteristics - Purity
- Microbiological specifications
- Toxicological profile of the substances

Finished Product

- Challenge test (Preservative test)
- Stability test in aging accelerated conditions
- Product use and exposure

Packaging

- Existing UE and/or SUE

GO / NO GO
Safety assessment process

Hazard identification

Dose-response characterization

Exposure assessment

Risk characterisation

No benefit/risk concept in cosmetics

Worst case scenario

MoS = \frac{NOAEL}{SED}

SED (Systemic Exposure Dosage)
\rightarrow Oral, dermal, inhalation routes

Subchronic study \rightarrow NOAEL

\text{LOAEL, 28-day, reliability}
\rightarrow \text{Uncertainty Factors}

Toxicological profile
Toxicological data

For each ingredient, toxicological data is necessary:

**Local tolerance**
- Skin irritation / corrosion
- Eye irritation / corrosion
- Skin Sensitization
- Phototoxicity / Photoallergy

**Systemic tolerance**
- Acute toxicity
- Mutagenicity / genotoxicity
- Carcinogenicity
- Subacute, subchronic, or chronic toxicity
- Reprotoxicity
- Dermal absorption
## Tolerance toxicity assessment

<table>
<thead>
<tr>
<th></th>
<th>Bibliographic data</th>
<th><strong>In vitro test</strong></th>
<th><strong>Clinical test</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Skin irritation</strong></td>
<td>OECD 404 (4h)</td>
<td>Episkin® (RhE)</td>
<td>Single patch-test</td>
</tr>
<tr>
<td></td>
<td>Erythema, Oedema scores</td>
<td>HET-CAM</td>
<td>Open test</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Eye irritation</strong></td>
<td>OECD 405</td>
<td>BCOP</td>
<td>Frontal ocular</td>
</tr>
<tr>
<td></td>
<td>Cornea, iris chemosis, conjunctivae, scores</td>
<td>HET-CAM</td>
<td>application</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sensitization</strong></td>
<td>LLNA OECD 429</td>
<td>Not yet available</td>
<td></td>
</tr>
<tr>
<td></td>
<td>GPMT/Buehler tests OECD 406</td>
<td>OECD 432 - 3T3 NRU</td>
<td>HRIPT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Keratinosens, DPRA</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Phototoxicity</strong></td>
<td>UV spectrum</td>
<td>Photo- LLNA</td>
<td>patch-test + UV</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OECD 432 - 3T3 NRU</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>« Photo – HRIPT »</td>
</tr>
<tr>
<td><strong>Photoallergy</strong></td>
<td>Unkovic method</td>
<td>Not yet available</td>
<td></td>
</tr>
</tbody>
</table>
Systemic toxicity assessment

Genetic toxicology

- Mutagenicity: Ames test
- Genotoxicology: clastogenicity and aneugenicity

Carcinogenicity

- Appearance of malignant or benign tumors
- Target organs of carcinogenicity
Systemic toxicity assessment

Acute toxicity: LD50/LC50

Single dose exposure
Oral – Dermal - Inhalation

Reprotoxicity
Parameters of reproduction cycle are observed
Key systemic toxicity endpoints

Repeated dose toxicity

- Subchronic toxicity study: 28d, 90d
- NOAEL, LOAEL
- Treatment related dose-effects
Key systemic toxicity endpoints

Dermal penetration

- By default, percutaneous absorption = 100%
- Molecule with MW > 1,000 Da, negligible
- Estimated percutaneous absorption
- Experimental data OECD 428
Toxicological data

How a safety assessor proceed to conduct a toxicological profile?

Bibliographic data

NO DATA

Read-across approach

Waiving

QSAR prediction

TTC (DST) approach

Weight of evidence approach

Read-across approach

Waiving

QSAR prediction

TTC (DST) approach
Exposure calculation

External exposure \times Absorption = SED

- Estimated daily amount applied (g)
- Use frequency
- Retention factor
- $C^\circ$ of the ingredient into the FP on the application site
- Exposure duration

- Oral route
- Dermal route
- Inhalation route

60 kg

SED
MoS calculation

\[
\text{MoS} = \frac{\text{NOAEL}}{\text{SED}} \geq 100
\]
MoS calculation

$$\text{MoS} = \frac{\text{NOAEL}}{\text{SED}} > 100$$

**Calculation rules**

1. MoS of 100 is from NOAEL derived from a subchronic study (90d)
2. Additional correcting factors can increase the MoS value:
   - LOAEL
   - Subacute study (28 days)
   - Route to route extrapolation
   - Particular effects observed during the repeated dose toxicity
Key definitions

"Undesirable Effects"
Harmful reaction for human health attributable to the normal use of a cosmetic product.

"Serious Undesirable Effects"
SUE that causes (temporary or permanent) functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death.

SUE must be declared to the competent authorities without delay.
Cosmetovigilance is organized as such:

- Distributors
- Responsible Person
- Consumers and health professionals

It is the RP that must notify the known undesirable effects

Other competent authorities of the EU
Good Manufacturing Practices

PRODUCT INFORMATION FILE

1. Product description
2. Product Safety Report
3. Good Manufacturing Practices
4. Proof of the effect claimed
5. Animal testing

This standard gives guidelines for:
• the production,
• control,
• storage,
• shipment of cosmetic products.

A compliance declaration is the minimum requirement and an audit report can also be requested.
Proof of the effect claimed

PRODUCT INFORMATION FILE

1. Product description
2. Product Safety Report
3. Good Manufacturing Practices
4. Proof of the effect claimed
5. Animal testing
Claims

Regulation No 655/2013

Common criteria:

1) Legal compliance
   « skin care product does not contain hydroquinone »

2) Truthfulness
   « This product contains honey » / « honey flavour » in ingredients

3) Evidential support
   « SPF 35 »

4) Honesty
   « one million consumers prefer this product »

5) Fairness
   « This product does not contain dimethicone »

6) Informed decision-making
   “this product inhibes the cyclooxygenase pathway”
1. Product description
2. Product Safety Report
3. Good Manufacturing Practices
4. Proof of the effect claimed
5. Animal testing
Animal testing

Testing and marketing BAN

Sept. 2004: testing ban on finished products

March 2009: - testing ban on ingredients - marketing ban for all human health effects (except of repeated-dose toxicity, reproductive toxicity and toxicokinetics)

March 2013: total marketing ban
What the RP does for you

- Data collection
- Safety Assessment
- PIF compilation
- Labelling compliance
- CPNP notification
- EU market
Mandatory information on the label

- Name and address of the Responsible Person
- Country of origin (outside Europe)
- Nominal content
- Date of minimum durability or Period-After-Opening
- Precautions for use *
- Batch number
- Function of the product *
- List of ingredients

* The TRANSLATION in the language of the export country is MANDATORY
Labelling symbols

**Hourglass**
Date of minimum durability (<30 months)

**Open jar**
Period-After-Opening (>30 months)

**Open-booklet**
Card or leaflet enclosed with the product
What the RP does for you

- Data collection
- Safety Assessment
- PIF compilation
- Labelling compliance
- CPNP notification

Responsible Person

EU market
CPNP notification

Web portal to notify BEFORE the placing on the market:

- Category and name of the product
- Name and address of the RP + contact details of a person
- Country of origin in case of import
- Country concerned with the 1st placing on the market
- Presence of nanomaterials, of CMR substances
- Product composition
- Compliant label + photo of the packaging

⚠️ Each product must be notified by the RP
- Only one notification for all 31 countries
Nanomaterials

Definition

“an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm”

STEPS

1. Notify 6 months before placing on market
2. Authority authorization
3. Mandatory labelling, e.g. Titanium dioxide [nano]
4. Placing on the market
CMR substances

Definition

• Carcinogenic
• Mutagenic
• Reprotoxic

CMR 1A
CMR 1B
CMR 2

CMR are banned, unless all of the following conditions are met:
• compliance with the regulation on food safety
• absence of alternative substances
• particular use (product category and known exposure)
• positive assessment by the SCCS (only condition for cat. 2 CMRs)

Annex VI of the CLP regulation (EC No 1272/2008) lists the CMR substances.

> 1,250 substances*
What the RP does for you

Responsible Person

- Data collection
- Safety Assessment
- PIF compilation
- Labelling compliance
- CPNP notification

EU market
Continued compliance

Compliance is not a DESTINATION but a JOURNEY!

The regulation is always evolving (~ 2/3 months)
• New restricted substances
• New prohibited substances
• New allergens
• Acceptability of claims

Your reality can evolve!
• New formulation
• New supplier
• New packaging, etc.
Steps to full compliance

1. Choose a Responsible Person
2. Gather all your available data
3. Get ready to update your labels
4. Get ready to be patient 😊
5. Draft of the Safety Report and PIF
6. CPNP notification
7. Keep an eye on regulatory updates
8. Place on the market

8 steps
EcoMundo offers COMPLETE compliance without outsourcing

- Responsible Person
- Label verification
- CPNP notification
- Safety Report
- Product Information File

6 months to 1 year
- Number and complexity of products
- Speed of the client to provide the data
PRODUCT INFORMATION FILE AND SAFETY REPORT

To be kept by the RP in case of a control by the authorities

CPNP NOTIFICATION

Routine check: authorities + customs

LABELLING

Possible check: customs + clients + consumers!
Reminder of your key actions

1. List the cosmetic products you are exporting into Europe
   Pay attention to the definition of a cosmetic product (different in the US)

2. List all the ingredients contained in your products
   Pay attention to nanomaterials, CMRs, restricted & prohibited substances

3. Designate a Responsible Person based in Europe
   Consultant, distributor, manufacturer, importer (pay attention to expertise)

4. The RP manages your compliance: safety report, PIF, CPNP, etc.
   The RP fulfils all your legal responsibilities vis-à-vis the Regulation

5. Amend your product labels to be compliant
   Example: the name and address of the RP must appear!
Thank you for your attention!

mroussel@ecomundo.ca
+1 778 231 1607

www.ecomundo.eu