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

SCC California - May 27th, 2014
Marie Roussel
Introduction to EcoMundo

2001

European Research Projects

EcoMundo is launched

2007

Regulatory expertise

Toxicology & Ecotoxicology

Software & Database

Specialist of EU Chemical Regulations

2014

Multidisciplinary team
30+ specialists and PhDs

Recognition
US & Canadian Governments
Export.gov + Canadainternational.gc.ca
International presence

Vancouver office
Contact with North American clients

Brussels office
European Commission contact

Paris office
Headquarters

2012

2009

2007
EU Regulatory landscape

**Substance**
- Raw material
- Finished formula

**Mixture**
- Raw material
- Finished formula

**Article**
- SVHC

**REACH Registration**

**SDS**

**CLP Regulation**

**New Cosmetic Regulation 1223/2009**
European Economic Area

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

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

In alphabetical order:

| 5. Cyprus    | 15. Ireland  | 25. Portugal |
| 7. Denmark   | 17. Latvia   | 27. Slovakia |
|              |              | 31. United Kingdom |
BEFORE the Regulation

**COMPLEXITY**
A different interpretation for each country

**HARMONIZATION**
Common obligations to all 31 countries

Before

DIRECTIVE 76/768

After

REGULATION 1223/2009

July, 11th 2013
Associated regulations...

- Directive « Nominal Quantities »
- Directive « Aerosols »
- Directive « Common Criteria »
- Directive « Prepacked Products »
- Regulation « CITES »
- Regulation 1223/2009
- 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.
The Responsible Person

U.S. manufacturer

Who is the RP?
1. EU branch
2. Distributor / Importer
3. Regulatory Expert

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

Choose your RP carefully

Responsible Person 

- COMPLIANCE
  - Scientific & Regulatory expertise

- AUTHORITIES
  - Credibility & Network

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

Responsible Person

Data collection
Safety Assessment
PIF compilation
Labelling compliance
CPNP notification
EU market
Responsibilities of the RP

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

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)
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
- Certificate of analysis
- 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
<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>
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<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%
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...
When one CAS number = several INCI names...

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

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100%
**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
List of current 26 allergens

- Amyl Cinnamal
- Amylcinnamyl Alcohol
- Anise Alcohol
- Benzyl Alcohol
- Benzyl Benzoate
- Benzyl Cinnamate
- Benzyl Salicylate
- Butylphenyl Methylpropional
- Cinnamyl Alcohol
- Citral
- Citronellol
- Coumarin
- Eugenol
- Farnesol
- Geraniol
- Hexyl Cinnamal
- Hydroxyisohexyl 3-cyclohexene Carboxaldehyde
- Hydroxycitronellal
- Isoeugenol
- Alpha-isomethyl Ionone
- Limonene
- Linalool
- Methyl 2-Octynoate
- Oak Moss Extract
- TreeMoss Extract
- Cinnamal

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%
Allergens & Labelling

Leave-on product → E.g. NIGHT CREAM

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**
- 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**
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
- Incubator: 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
Step 1 = DMD

Define the Date of Minimum Durability (DMD)

If DMD < 30 months  

or "best used before the end of" + date

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.
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.
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
ISO 22716 is the reference for the GMP. It provides guidelines for:
- the production,
- control,
- storage,
- shipment of cosmetic products.

Companies are free to use whatever GMP they wish, they would though be required to demonstrate their own system achieved the same objective as that of the ISO 22716.
Proof of the effect claimed

PRODUCT INFORMATION FILE

1. Product description
2. Product Safety Report
3. Good Manufacturing Practices
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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 »
   ✔️ proofs

4) Honesty
   « one million consumers prefer this product »

5) Fairness
   « This product does not contain dimethicone »

6) Informed decision-making
   “this product restrains the cyclooxygenase pathway”
Animal testing

PRODUCT INFORMATION FILE

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Animal testing

Testing and marketing BAN

Sept. 2004: testing ban on finished products

March 2009: testing ban on ingredients

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

Responsible Person

- 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

Responsible Person

- Data collection
- Safety Assessment
- PIF compilation
- Labelling compliance
- CPNP notification
- 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 biopersistent 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 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.
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!
LinkedIn groups

All you need to know on the new European Cosmetics Regulation (No 1223/2009)

All you need to know on the REACH regulation (No 1907/2006)
Our mobile app’ Comply n’go

Follow the status of substances and evolutions of International regulations!

- User friendly
- Free!
The Pocket Cosmet’

Practical guide for the cosmetic industry
Thank you for your attention!

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