SRC Consulting
Science & Regulatory Compliance

European Regulation & Cosmetics :

"The key issues and responsibilities for Beauty Institutes & Spas"

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International Beauty Office

www.ibeautyoffice.com

Les matinales de la Cosmétique™

www.lesmatinalesdelacosmetique

I. PREAMBLE

- **July 1976 : The first cosmetic Regulation in EU**

  (EU Cosmetic Directive 76/768/EEC)

- **July 2011 : The new cosmetic Regulation in EU**

  (EU Cosmetic Regulation 1223/2009)

European Directive

European Regulation

European Regulation

- **71 Whereas**
- **40 Articles**
- **10 Appendix**
- **About 280 pages**

II. DEFINITIONS

DEFINITIONS

- **Manufacturer** → who makes, makes make, conceive
- **Distributor** → who put the product on the market (other than Manufacturer/Importer)
- **Importer** → based in EU and release on the market a product from another country outside the EU
- **Subcontractor** → in charge to manufacture the product to an outsourcer

III. KEY RESPONSIBILITIES

KEY RESPONSIBILITIES

Responsible Person (RP)

- **natural or legal person chosen inside of EU**
- **warrants products compliance to the Regulation**
- **manufacturer, importer, distributor**
- **possible delegation, in EU by a written agreement with consulting company**

KEY RESPONSIBILITIES

Distributor

- **compliance control of labeling and text translations**
- **compliance control of sustainability date / expiration**
- **if non-compliance: inform RP and Authorities, take corrective actions and if necessary withdrawal or recall the product**

KEY RESPONSIBILITIES

Distributor → **keep traceability of batch supplying received during 3 years**

→ **notification to the Commission of labeling translations compliance, if that is his own initiative**

→ **notification of serious adverse effect**

IV. REQUIREMENTS FOR THE "RP"

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Has to insure that the cosmetic product put on the market is safe for the final consumer

KEY REQUIREMENTS FOR THE "RP"

1) Product Information File

2) European Notification

3) Recall & Withdrawal Processes

4) Cosmetovigilance

1) PRODUCT INFORMATION FILE

- **Keep 10 years after the last batch put on the market (≠ manufactured batch)**
- **Electronic form accepted**
- **Key technical data : Formula, raw materials specifications, safety evaluation, efficacy tests, …**

2) EUROPEAN NOTIFICATION

- **Product declaration to the European Commission before the launch on the market by electronic form**

- **Supply : name(s) of the product, category, name and address of RP, info. nanomaterial, names of CMR 1A & 1B substances, contact name details, "formulation-cadre"**

- **Concern not only the new products but also the current products already on the market**

3) RECALL & WITHDRAWAL PROCESSES

- **Withdrawal** : every step intended to prevent launch on the market of a product in the supply chain

- **Recall** : every step intended to get back a product which is already available for the final user

4) COSMETOVIGILANCE

- **Definition :** study and management of adverse effects of cosmetic products after placed on the market

- **Serious adverse effect** : temporary or permanent functional incapacity, disability, hospitalization, vital risk or death

4) COSMETOVIGILANCE

In case of serious adverse effect

- Notification by **RP** to the concerned Member State (MS) in EU
- Notification by the **Distributor** to the concerned MS in EU
- Information **from MS** to **RP** about **adverse effect** (from users and professionals)

V. CASE STUDIES

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As Beauty Institute or SPA
=
You are or could be a Distributor

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As Distributor :

- **Prepare and test the recall and the withdrawal process with the supplier**

- **Labeling:**

  - Check the translation of legal information products in the national language

  - Check the Period After Opening (PAO)

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As Distributor :

- **Keep traceability of each batch of the products received, during 3 years**
- **Notification to the Commission of labeling translations compliance, if that is his own initiative**
- **Notification in case of serious adverse effect to the MS and the RP**

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In case of Inspection in your Beauty Institute :

The authorities can inspect :

- The **recall** and **withdrawal** processes
- The **labeling products compliance**
- The **traceability** of each **stored** and **sold** products to the consumers
- The **Product Information File** (if you are RP)

VI. CONCLUSION

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CONCLUSION

- **Read the European law on cosmetics !**
- **As RP and/or Distributor arrange to implement the law with a view to apply the requirements of the European Cosmetic Regulation**
- **To exchange with your supplier on Recall and Withdrawal processes**
- **To train your staff**

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Thank you for your attention

Any question ? ! ...

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