



European Regulation & Cosmetics :

“The key issues and responsibilities for Beauty Institutes & Spas”

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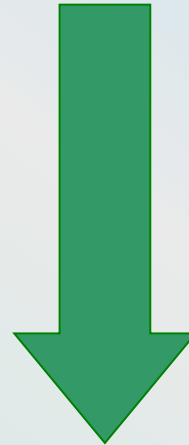
I. PREAMBLE



- **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

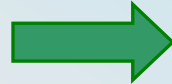


III. KEY RESPONSIBILITIES

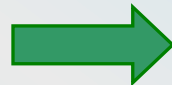


KEY RESPONSIBILITIES

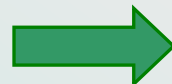
Responsible Person
(RP)



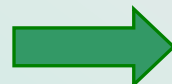
**natural or legal person
chosen inside of EU**



**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”



REQUIREMENTS FOR THE “**RP**”

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



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



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**)



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**



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



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



Thank you for your attention

Any question ? ! ...



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