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The Responsible Person under the EU's Cosmetics Regulation

Introduction: With the implementation of the Cosmetics Products Regulation of the EU (CPR), Regulation (EC) No 1223/2009[1], the role of Responsible Person (RP) was introduced in Article 4: 'Only cosmetic products for which a legal or natural person is designated within the Community as 'responsible person' shall be placed on the market'. With this, the basic approach for a first responsible contact person to be printed on the label of a cosmetic product was not changed in respect to the predecessor legislation; however, newly was the name RP and that all obligations under the law were explicitly outlined in Article 5.

These **obligations** include to ensure compliance with Articles 3, 8, 10, 11, 12, 13, 14, 15, 16, 17, 18, Article 19(1),(2) and (5), as well as Articles 20, 21, 23 and 24. Additionally, the RP is made to the focal point for a system, which ensures that the safety of cosmetic products placed on the EU market is monitored throughout Europe. Although, it is not a term defined in the Cosmetics Regulation this system is known as Cosmetovigilance. Articles outlining RP Obligation:

3: Safety
8: Good Manufacturing Practice
10: Safety Assessment
11: Product Information Files (PIF)
12: Sampling and Analysis
13: Notification
14:Restrictions for Substances listed in Annexes
15: Substances classified as CM
16: Nanomaterials
17: Traces of Prohibited Substances
18: Animal Testing
19(1)(2)(5): Labelling
20: Product Claims
21: Access to Info for the Public
23: Communication of SUEs
24: Information on Substances

By **law**, the RP role is automatically assigned to the manufacturer of cosmetic products in case the products are being manufactured within the EU; or, in case of imported products, to the importer. Both can appoint by written mandate a third party, which is to be a person established within the EU who has to accept this assignment in writing. In certain cases, as laid down in article 4(6), the distributor has to take the role of RP for the products he is marketing.

The **obligations** resulting for an RP from the regulatory framework are directed towards a natural or legal person. One natural person may cover all responsibilities and can succeed, especially, when representing cosmetic products with small hazard potentials. However, usually a team of experts and executives is necessary to address the regulatory and scientific compliance requirements in all its complexity. Within large companies, these skills may be available in-house; otherwise, or for smaller companies or non-EU manufacturers often external experts get involved, which take the RP role and obligations in total or address parts of this, e.g., the safety assessment and compilation of the PIF, notification, etc. For all experts involved into the RP fulfillment processes, a profound knowledge for their area applies which requires ongoing training and updating to state of the art of science and the regulatory environment. Additionally, an expert is necessary who is maintaining the overview of the compliance status and who has the managerial skills of bringing the team together; often this includes communication with other decision makers in the line of bringing a cosmetic product to the market.

The **compliance standard** is exclusively the law; ultimately, a decision of the European Court of

Justice[2]. Supportive for compliance approaches is the fact that the European regulatory framework provides for a comprehensive, well structured legal text with official translations into major languages, which includes English, French and Spanish, etc. However, an ongoing exchange on compliance objectives is mandatory for the RP using pertinent tools like secondary literature, on-line information as well as the exchange with peers in the industry. Thereto, the website of the EU commission provides comprehensive information[3]. Further sources in this context are industry associations, e.g. Cosmetics Europe[4,] Regulatory Workshops[5, 6].

CONUSBAT views its RP relationship with its clients as a 'Marriage'! It is important to have in mind that the service provider taking the role of RP will be held responsible under the law in case of any issues or infringements with the regulation, whereas the RP can only know as much about the products as the manufacturer provides upfront information. Therefore, the relationship is a partnership and needs to be built on a good understanding, honesty, trust, time and patience. The filing of a profound cooperation contract also means in consequence establishing the working standard between the parties, which can be reviewed at any time during the course of the cooperation, e.g. when new people join or in cases of any issues arising. The good partnership has to be nurtured at any time afterwards; professional tools should be used like regular meetings, on-site presentations and a concise reporting system.

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1 CPR: www.eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32009R1223
2 EU Court of Justice: www.curia.europa.eu/jcms/jcms/j_6/en/
3 EU Commission: www.ec.europa.eu/growth/sectors/cosmetics_en
4 Cosmetics Europe: www.cosmeticseurope.eu/
5 In-Cosmetics London Wed., 5, April 2017; CONUSBAT's Regulatory Workshop: www.in-cosmetics.com/en/Sessions/32320/The-ever-changing-regulatory-landscape-in-Europe
6 Cosmetics Business Regulatory Summit: www.cosmeticsbusiness.com/company/single_company/Cosmetics_Business_Regulatory_Summit_CBRS

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