

A position of responsibility

What does the role of the responsible person under the EU's Cosmetics Regulation entail, and how should you approach selecting yours? CONUSBAT's **Dr Annelie Struessmann** gives her insight

With the implementation of the Cosmetics Products Regulation of the European Union (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."

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 previous legislation. New, however, 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 the focal point for a system that ensures the safety of cosmetics 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'.

WHO CAN BE RP?

For cosmetic products manufactured within the EU, the RP role is – by law – automatically assigned to the manufacturer. In the case of imported products, the RP is 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 or she is marketing.

WHAT IS THEIR ROLE?

The RP obligations are directed towards a natural or legal person; one natural person may cover all responsibilities and can succeed, especially when representing cosmetic products with low hazard potential.

However, usually a team of experts and executives is needed to address the regulatory and scientific compliance requirements in all their complexity. Within large companies, these skills may be available in-house; otherwise, for smaller companies or non-EU manufacturers often external experts get involved, who take on the RP role and obligations in total, or address parts of this, for example the safety assessment and compilation of the PIF, notification, etc.

For all experts involved in the RP fulfilment processes, a profound knowledge of their area applies, which requires ongoing training and updating to state-of-the-art science and the regulatory environment. Additionally, an expert is needed who can maintain an overview of the compliance status, and who has the managerial skills to bring the team together; often this

Articles outlining RP obligations

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





A CLOSE RELATIONSHIP NEEDS TO BE ESTABLISHED BETWEEN A COSMETICS COMPANY AND THE EXTERNAL RP

includes communication with other decision makers in the line of bringing a cosmetic product to the market.

COMPLIANCE MADE EASY

The compliance standard is the law and, ultimately, a decision of the European Court of Justice^[2]. Supporting 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, Spanish and others. However, an ongoing exchange on compliance objectives is mandatory for the RP using pertinent tools like secondary literature and online information, as well as exchange with peers in the industry. Thereto, the website of the EU commission

provides comprehensive information^[3].

Furthermore, important sources in this context are industry associations, for example Cosmetics Europe^[4], Cosmetics Consultants Europe^[5] and multiple Europe-wide workshops^[6] and conferences^[7]. When looking for an external RP, the contacts for organisations providing these services may also be found at these mentioned forums.

RELATIONSHIP COUNSELLING

A close relationship needs to be established between a cosmetics company and the external RP. It is important to bear in mind that the service provider taking the role of RP will be held responsible under the law in the event of any issues with or infringements of the regulation, whereas the RP can only know as much about the products as the manufacturer provides in upfront information. Therefore, the relationship is a partnership and needs to be built on good understanding, honesty, trust, time and patience.

While taking – at the beginning of the cooperation – the time to file the cooperation conditions, each side has the opportunity to learn about the other and gain the necessary confidence in skills, ethics and professionalism. The filing of a profound cooperation contract also has the consequence of establishing the working standard between the parties, which can be reviewed at any time during the course of the cooperation, for example when new people join, or in cases of any issues arising.

The good partnership has to be nurtured and to do so professional tools may be used, like regular meetings, on-site presentations and a concise reporting system ●

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References

1. Cosmetics Products Regulation: <http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32009R1223>.
2. Court of Justice of the European Union http://curia.europa.eu/jcms/jcms/j_6/en/.
3. EU Commission: https://ec.europa.eu/growth/sectors/cosmetics_en.
4. Cosmetics Europe (CE): <https://www.cosmeticseurope.eu/>.
5. Cosmetics Consultants Europe (CCE): <http://cosmeticsconsultantseurope.org/>.
6. in-cosmetics Regulatory Workshop, April 5, 2017 – The ever changing regulatory landscape in Europe: <http://www.in-cosmetics.com/education/Workshops-Timetable/>.
7. Cosmetics Business Regulatory Summit: http://www.cosmeticsbusiness.com/company/single_company/Cosmetics_Business_Regulatory_Summit_CBRS.

