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CONUSBAT

Internationalization Regulatory Services

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for Cosmetics, Personal Care, Fine Chemicals & Borderline Products

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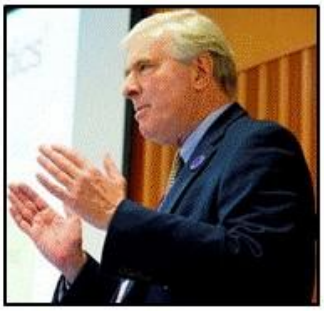

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Regulation (EC) No. 1223/2009
Cosmetic Product Regulation & the Responsible Person

Introduction: With the implementation of Regulation No 1223/2009, 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 RP's name must to be printed on the label of a cosmetic product with all obligations under the law explicitly outlined in Article 5.

The moral imperative includes ensuring 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 duties are the following:

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

Obligations of an RP from the regulatory framework are directed towards a *natural* or *legal* person. One *natural* person may cover all responsibilities, especially, when representing cosmetic products with small hazard potentials. However, usually a team of experts 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 address parts of the safety assessment and compilation of the PIF, notification, etc.

For all experts involved with the RP fulfillment processes, a profound knowledge for their area applies, which requires ongoing updating to state-of-the art of science and the regulatory environment. Additionally, an expert is necessary, who is maintaining the compliance status's overview and has managerial skills to bring the team together.

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, German, 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. The website of the EU Commission provides comprehensive information[3] and further sources in this context are industry associations, e.g. Cosmetics Europe[4], Society of Cosmetic Chemists-USA, 'The CPR Safety Assessment', a workshop organized by CONUSBAT[5].

At CONUSBAT, we consider the 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 should be considered a PARTNERSHIP, which needs to be built on understanding, honesty, trust & 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 partnership has to be nurtured, and professional tools should be used like regular meetings, on-site presentations and a concise reporting system.

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, Brussels, Belgium: www.cosmeticseurope.eu/
5 SCC-USA, Regulatory Workshop by organized CONUSBAT: www.etouches.com/safetyassessment17