



SCIENTIFIC AND REGULATORY SUPPORT FOR THE NEW EUROPEAN UNION COSMETIC REGULATIONS

The 8th Amendment of the EU Cosmetic Regulations (EC No. 1223-2009), originally published in December 2009, will replace the Cosmetic Directive 76/768/EEC and unify the EU's approach to the regulation of cosmetic products. With this change, many new compliance objectives must be achieved including the appointment of a Responsible Person and enhancement of product information files supporting each product intended for placement on the European market. Following the current transition period, the regulations will be in full effect starting July 2013, thus making the European Union the most highly regulated community for cosmetic products.

Among the most significant outcomes of the revised regulations is the role of Responsible Person. This individual or corporate entity must reside in the European Union and has obligations dictated by the regulations for all aspects of assuring total product compliance. Duties of the Responsible Person include, but are not limited to:

- Compliance with current GMPs;
- Maintenance of up-to-date safety assessments and product information files for each cosmetic product;
- Notification to the European Commission of product placement or removal from the EU marketplace;
- Compliance with labeling requirements including assurance of accurate and not misleading product claims; and
- Communication of undesirable and serious undesirable effects resulting from the use of a cosmetic product to the Member State of the event's occurrence.

In addition to the new role and vastly encompassing duties of Responsible Person, the revised Cosmetic Regulations also require updated product information files containing a robust product safety report to be maintained by the Responsible Person. Product safety reports must include safety information on the cosmetic product including a toxicology profile and anticipated exposure information. These reports must be assessed by a qualified safety assessor who possesses a certified background in toxicology, pharmacology, medicine, or similar discipline.

Coordinating your company's compliance with the revised Cosmetic Regulations will present challenges, including the identification of the Responsible Person, updating product safety reports and information files, conducting label compliance reviews, and assuring upstream compliance when ingredient sourcing; however, these obstacles can be handled with confidence if the right steps are taken early.

toXcel has partnered with a major UK based legal company to provide comprehensive services to the cosmetic and personal care industry. The responsibilities and compliance objectives of your company's Responsible Person can be fulfilled through this complementary legal service. **toXcel** specializes in providing expert scientific support, and through its U.S. and European offices, can augment your company's product stewardship efforts in creating, updating, and submitting product safety reports as well as performing labeling and ingredient compliance reviews. Through the combined efforts of **toXcel** and our recommended expert legal associates, your company can better navigate the European marketplace in a cost-effective manner and achieve success in its marketing goals.

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