



## EU Life Sciences Practice

Sidley's EU Life Sciences practice assists multinational companies and trade associations with food, pharmaceutical, biotechnology, medical device, cosmetics and dietary supplement issues in the European Union and its 27 Member States. Our lawyers offer strategic advice for gaining and maintaining market access. We anticipate government actions, advise on approval and submission strategies, and interface with trade associations, consultants and governmental officials. Clients turn to our group for assistance with compliance issues relating to Good Manufacturing Practice, EU Drug Safety/Pharmacovigilance, and Quality System regulations, as well as EU competition and trade law issues.

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## Sidley Global Life Sciences Practice

On three continents, Sidley's Global Life Sciences Practice team offers coordinated cross-border and national advice on Food, Drug and Medical Device laws, Healthcare, Intellectual Property, Products Liability, International Trade and Arbitration, FCPA Enforcement, Environmental/Nanotechnology, Antitrust/Competition, Corporate M&A, Licensing and Joint Ventures.

Globally rated as one of the top life sciences practices, our team includes former government officials, medical doctors, and leaders in various life sciences fields.

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## New EU Cosmetics Regulation Published

A new EU law on cosmetic products, the Cosmetics Regulation (the Regulation), was published in the EU's Official Journal today.<sup>1</sup> The Regulation, which will be directly applicable in all EU Member States, introduces a number of important changes to the way cosmetic products are regulated in the EU. As such, it will affect all companies that manufacture or import cosmetic products in the EU. The Regulation will enter into force on January 11, 2010. Most of the provisions will apply from July 11, 2013, but some of the provisions will apply as early as December 1, 2010. Companies should consider planning for its application now. This update discusses some of the key elements cosmetics companies should take into account.

### Restrictions on Product Claims

The Regulation may restrict the ability of cosmetics companies to use certain claims on their products, for three main reasons. First, the Regulation provides that the labeling and advertising of cosmetic products "shall not be used to *imply* that products have characteristics or functions which they do not have" (emphasis added). Second, the Regulation requires the European Commission (Commission), in cooperation with the EU Member States, to set up an action plan related to claims and, after consulting the Scientific Committee on Consumer Safety (SCCS) or other relevant authorities, to adopt a list of common criteria for claims – the content of that list may provide restrictions on product claims. Third, by July 11, 2016, the Commission shall report to the European Parliament on the use of claims on the basis of the common criteria and shall take appropriate measures to ensure compliance with those criteria.

### Notification, Evaluation and Labeling Requirements for Nanomaterials

A significant change in the Regulation is the introduction of specific notification, evaluation and labeling requirements for all cosmetic products that contain nanomaterials.

In addition to normal notification procedures that must be undertaken for any cosmetic product, cosmetic products that contain nanomaterials will need to be notified to the Commission six months before the product is placed on the market.

Further safety assessment provisions relating to nanomaterials have also been incorporated into the Regulation. Should the Commission have *any* concerns regarding the safety of a particular nanomaterial, it must request that the SCCS opines on the safety of such nanomaterial for its stated use. Both the Commission's request and the opinion of the SCCS shall be made publicly available.

<sup>1</sup> Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009, p. 59 available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:EN:PDF>

Additional safety assessment provisions relating to nanomaterials have been incorporated into the Regulation. All ingredients present in the form of nanomaterials must be clearly indicated in the list of ingredients with each such ingredient being followed by the word “nano”. This provision was introduced by the European Parliament and approved by a majority of EU Member States – despite the objections of Germany, which argued that the term “nano” might be misunderstood by consumers as a warning.

### **Carcinogenic, Mutagenic or Reprotoxic (CMR) Substances**

The Regulation introduces a risk management regime which allows, subject to rigid conditions, the use of CMR 1 and 2 substances if they have been evaluated and found safe by the SCCS for use in cosmetic products.

By January 11, 2012, we can expect to see appropriate published guidance relating to the establishment of global exposure estimates of CMR substances and their use in individual product safety assessments.

The implementation date for provisions relating to CMRs is December 1, 2010.

### **Introduction of a Responsible Person**

The Regulation also includes the new requirement that only cosmetic products with a designated Responsible Person (RP) can be placed on the market. Who the designated RP should be depends on where the cosmetic product is manufactured and whether it is imported and/or exported. The obligations of RPs are set out in the Regulation and mainly consist of ensuring compliance with a variety of requirements related to, e.g., Good Manufacturing Practices, safety assessment, traces, labeling and nanomaterials.

**If you have any questions regarding this update, please contact the lawyers listed below or the Sidley lawyer with whom you usually work.**

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Other changes made to improve in-market controls include the creation of a single, centralized electronic notification system for cosmetic products (replacing various national procedures), the duty to monitor undesirable effects induced by cosmetic products, and increased market surveillance and enforcement cooperation between competent authorities.

### **Pre-market Safety Assessment**

Prior to placing any cosmetic product on the market, and in order to establish that a cosmetic product made available on the market is safe for human health when used under normal or reasonably foreseeable conditions, the RP of the product must ensure that a safety assessment, containing particular information as specified in the Regulation, is performed on the cosmetic product. The cosmetic product safety report must be set up as prescribed by the Regulation.

### **Labeling**

In addition to existing labeling requirements that were set out by the Cosmetics Directive, new information requirements including regarding the RP and nanomaterials, are found in the Regulation. The possibility to suppress ingredients on labels for trade secrecy reasons has been deleted.

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