

Impact of EU Cosmetics Directive, REACH and CLP on Cosmetics

Cosmetics products (either raw materials or finished products) are impacted by EU cosmetics directive (Regulation EC 76/768/EEC and Regulation (EC) No 1223/2009), REACH Regulation (EC No 1907/2006) and CLP Regulation (EC No 1272/2008). Non-EU exporters/EU importers of cosmetic ingredients or finished cosmetics products have to comply with above regulations before they put cosmetics products on the EU market.

EU cosmetics directive (76/768/EEC) and new cosmetics regulation (EC) No 1223/2009

The EU Cosmetics Directive (76/768/EEC) was revised in January 2003 to ban 1,100 chemicals from cosmetics. Ingredients were reviewed for safety by SCCS (EU Scientific Committee on Consumer Products). The main requirements are listed as below.

- A safety assessment of the finished cosmetic product must be performed before the product can be placed on the EU market;
- A full technical file or product information file (PIF) for a cosmetic product must be kept available for inspection by authorities at a specified EU address. PIF shall include the qualitative and quantitative composition of the product; the physico-chemical and microbiological specifications of the raw materials and the finished product; the method of manufacture complying with GMP; assessment of the safety for human health of the finished product etc.;
- Notification to competent authorities must be done to inform the competent authorities that a cosmetic product will be placed on the EU market.
- In May 2009, Parliament introduced laws regulating cosmetics containing nanomaterials. Additionally, all nanomaterials in the cosmetic must be mentioned on the list of ingredients on the packaging, with the names of such ingredients followed by the word "nano" in brackets.

The new EU Cosmetic Products Regulation, EU Regulation (EC) No 1223/2009, was adopted on November 30, 2009. Most of the provisions of this new regulation will be applicable as from 11 July 2013 and replace the Cosmetics Directive (76/768/EEC) thereafter.

The main changes are listed as below:

- The harmonization of notification provisions in a central digital platform to replace all existing national notification procedures.
- The enhanced coordination of market surveillance activities, reinforcement of responsibilities along the supply chain, and clearer provisions for the content and format of product safety assessments and product information files (PIF).
- All the data on cosmetic products obtained from the notification procedures will be electronically forwarded to the national competent authorities for market surveillance and

consumer information; and provided to poison centers to inform the public of appropriate medical treatments in case of adverse reactions.

- The responsibilities of the actors in the supply chain will be clearly defined and assigned to a *responsible person*.

REACH Regulation (EC) No 1907/2006 and Cosmetics

REACH is the EU regulation (EC) No 1907/2006 concerning **the Registration, Evaluation and Authorization of Chemicals**. It came into force on 1 June 2007. Both chemical raw materials and finished cosmetics products are impacted by REACH.

Most of cosmetic products belong to chemical preparations (mixtures) under REACH regulation and each chemical substance or ingredient shall be (pre)registered with the European Chemical Agency (ECHA) if the annual tonnage of the substance exceeds 1 ton. Non-EU companies may appoint an REACH only representative to submit pre-registration/registrations.

To avoid REACH registrations, EU cosmetics importers/manufacturers have to ensure that all ingredients (either in cosmetics formulations or finished products) have been properly registered by their suppliers as long as the tonnage of the substance is above 1 ton per year.

EU manufacturers and importers of cosmetic products may be required to apply for prior authorization for the use of substances of very high concern in their products.

For more information about REACH registration, please go to:
http://www.cirs-reach.com/EU_REACH/REACH_Registration.html

For more information about Substances of Very High Concern, please go to:
http://www.cirs.ie/EU_REACH/REACH_SVHC_List_SVHC_Testing.html

CLP Regulation (EC) No 1272/2008 and Cosmetics

CLP stands for the Regulation (EC) No 1272/2008 on the **Classification, Labeling and Packaging** of substances and mixtures. CLP entered into force on 20th January 2009.

CLP regulation only impacts chemical raw materials that are used to manufacture cosmetic products. Finished cosmetics products are exempt from CLP regulation.

If you import chemical raw materials to manufacture cosmetics products, you shall **classify, label and package** these substances or mixtures in accordance with CLP.

For more information about CLP regulation, please go to:
http://www.cirs-reach.com/EU_GHS_CLP_Regulation/EU_GHS_CLP_Regulation.html

CIRS provides full range compliance services for the entry of cosmetic products to the EU. If you have any inquiries, please don't hesitate to contact us.



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