

Insight: International Trade

July 2013

New EU Cosmetics Regulation becomes fully applicable

On July 11, 2013, the new EU Cosmetics Regulation 1223/2009 became fully applicable. The Regulation, already adopted on November 30, 2009, provides a unified and consolidated framework for the marketing and distribution of cosmetic products on the EU market. It enters into force following a period of transition allowing industry to adapt to the new rules.

Some of the key features of the new Regulation include:

- The introduction of the central concept of “responsible person”: for every cosmetic product placed on the market in the EU (whether imported or manufactured in the EU), a legal or natural person will have to be designated as “responsible person”. The responsible person will bear the responsibility of ensuring compliance with most of the obligations set out in the Regulation, including making available the product information file when requested by competent authorities. The Regulation also includes definitions allowing the identification of the responsible person;
- A requirement to notify all cosmetic products placed on the EU market via a centralized notification system. The Cosmetic Products Notification Portal (CPNP) had started to be operational in January 2012 to allow business operators to begin product notifications in advance;
- Additional requirements applicable to the production of cosmetic products, in the form of a “cosmetic product safety report”, which is part of a product information file to be kept by the responsible person;
- New labeling requirements regarding, in particular, the identification of the responsible person, the date of minimum durability and the presence of nanomaterials;
- Specific requirements concerning the notification and safety assessment of nanomaterials used in cosmetics. Ingredients present in the form of nanomaterials also now need to be labelled in the list of ingredients;
- Strengthened reporting requirements of serious undesirable effects in the context of cosmetics market surveillance: a responsible person will have to notify serious undesirable effects without delay to the competent national authorities of the Member State where the serious undesirable effect occurred.



For further information, please contact:

Erwan Berthelot
Counsel, Geneva/Brussels

+ 41 22 906 98 07

erwan.berthelot@whitecase.com

White & Case LLP
82 Rue de Lausanne
CH-1202 Geneva
Switzerland
Tel: + 41 22 906 9800
Fax: + 41 22 906 9810

White & Case LLP
Avocats-Advocaten
62 rue de la Loi/Wetstraat 62
1040 Brussels
Belgium
Tel: + 32 2 219 16 20
Fax: + 32 2 219 16 26

In addition, the Commission published on the same day Regulation 655/2013 which lays down “common criteria” for claims used in cosmetics. The Regulation provides for a general set of requirements in the areas of legal compliance, truthfulness, evidential support, honesty, fairness, and informed decision-making, that all claims made in relation to cosmetic products will have to comply with. The common criteria are also applicable as of July 11, 2013.

Earlier this year, the final stages of an animal testing and marketing ban for cosmetic products placed on the EU market entered into force on 11 March 2013.

As a result of the new Regulation becoming fully applicable, the old cosmetics directive 76/768/EEC is also repealed.