THE EU COSMETIC REGULATION 1223/2009

For the past three years the cosmetic industry has been preparing itself for the full implementation of Regulation (EC) No 1223/2009. On 11 July 2013 the Cosmetic Directive 76/768 EEC will be history and the cosmetic industry will need to be compliant with 1223/2009. What does this mean for the cosmetic industry?

RESPONSIBLE PERSON

The key person in implementing the cosmetic regulation is the responsible person. This can be the manufacturer, the importer or the distributor. The manufacturer and the importer can mandate this responsibility to a third party. The responsible person can be a person but is more likely to be a company based within the EC.

COSMETIC PRODUCT NOTIFICATION PORTAL

The Cosmetic Product Notification Portal replaces the requirement to inform the poison centres of each country that the product is sold in. All products that are placed on the market or are already on the market must be registered on the cosmetic product notification portal. There are two websites that you will need to use: ECAS – The European Commission Authentication Service to get a login and a password; and SAAS – The SANCO Authentication and Authorisation System which provides access to the cosmetic product notification portal. For more details on the notification process see the Cosmetic Products Notification Portal (CPNP) User Manual.

COSMETIC PRODUCT SAFETY REPORT

The Cosmetic Product Safety report is in two parts: Part A is the Cosmetic Product Safety Information which includes the formulation, product specification, microbiological specification, preservation challenge test, product stability, impurities, packaging, normal and reasonably foreseeable use, exposure to the cosmetic product and toxicological profile of the ingredients and product. Part B is the Cosmetic Product Safety Assessment and is the cosmetic safety assessor's expert opinion as to why the cosmetic product is safe.

Compared to the cosmetic safety assessment carried out under the directive there is a lot more information for the safety assessor to consider. As per our experience, we are finding that the responsible person may not have all this information and this is slowing down the process of issuing the cosmetic product safety report. SGS can help you identify and obtain the data you require for your Cosmetic Product Safety Report.

GOOD MANUFACTURING PRACTICE

This should be to ISO 22716 unless you are able to show that you have good manufacturing practices that exceed these requirements. For raw ingredients the European Federation for Cosmetic Ingredients (EFfCI) guidance on good manufacturing practice may be more appropriate.

PRODUCT INFORMATION FILE (PIF)

A Product Information File should be kept by the responsible person. It should contain a description of the cosmetic product, the cosmetic product safety report, a description of the method of manufacturing, a statement on compliance with good manufacturing practice, proof of any claims made, and data on any animal testing performed on the product or raw ingredients.

NANOMATERIALS

Nanomaterials are commonly found in sunscreens. For products that contain nanomaterials that are on the market before 11 January 2013, the responsible person must inform the Commission by electronic means between 11 January 2013 and 11 July 2013. For products placed on the market after 11 January 2013 the responsible person must notify the Commission six months prior to the product being placed on the market.

ACCESS TO INFORMATION FOR THE PUBLIC

The responsible person shall ensure that the qualitative and quantitative composition of the cosmetic product, the fragrance details, and any data on undesirable and seriously undesirable effects from use of the cosmetic product are made easily accessible to the public and to the authorities in each Member State where the product is sold...

ONE STOP SOLUTIONS

At SGS we manage your compliance to the Cosmetic Regulation by devising a compliance checklist to assist your firm in gaining or maintaining its foothold in the EU. Our experts can assist you every step of the way, including checking and review of the data for the PIF, cosmetic safety assessment, formulation review and testing services as well as GMP audits.

For more information please contact your local SGS representative or our global team: consumer.products@sgs.com.

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