The New EU Cosmetics Regulation EC No 1223/2009 – Changes and Impacts on Safety Assessment in the EU

Author: C .I. Betton B.Sc., FSB, C Biol, FIEMA, CEnv, FRSC, EUROTOX Registered Toxicologist, Delphic HSE Solutions Limited, Deepcut, Surrey, United Kingdom

Introduction

The new EU Cosmetics Regulation EC 1223/2009, replaces the existing EU Cosmetics Directive (76/768/EEC) and the various National Laws based on the Directive and introduces a number of changes that will affect all manufacturers and importers of cosmetic products within the EU. The new Regulation will remove the differences of implementation and interpretation that exist between the ways in which Member States have implemented the Cosmetics Directives and which make life awkward for companies that sell products across the EU but also has resulted in different levels of requirement in a number of parameters. The changes affect safety assessments and tighten up procedures and practices in all matters related to human health and product safety. The basic controls of ingredients remain the same but have been expanded significantly.

Manufacturers and importers will of course be concerned about how the proposed changes will affect their business. This summary outlines some of the major changes that will affect the cosmetics industry within the EU and suggests some solutions to companies who will need to comply with the new Regulation in the years ahead. The style and emphasis of the proposed Regulation has much in common with the REACH regulation that came into force in June 2007.

Basic Framework

The new Regulation places greater requirements on the 'Responsible Person' who manufactures or imports a cosmetic product, to demonstrate safety and places more rigorous demands on them to generate, keep and update information than exist at present. The registration of products is radically altered, with notification of sale and compositional information being supplied to the Commission electronically, who will disseminate information to poison centres and Member States. This facility went 'live' on 11th January 2012. The Regulation extends to all countries in the European Economic Area, the EU Member States plus Iceland, Liechtenstein and Norway.

Regulatory Changes

Whilst much of the legislation is unaltered, there are changes in organisation of the Regulation and some significant new additions and changes. These, with reference to their place in the new Regulation are described below.

Article 2: Definitions

These are similar to the existing definitions but do clarify some aspects of cosmetic safety issues. The definition of a preservative is clarified as a substance which is "exclusively or mainly intended to inhibit the development of microorganisms." This should make the assessment of products containing only 'natural' preservatives less contentious, as it defines the concept of a preservative, yet disassociates the presence of a 'preservative' from the microbiological characteristics of the product, as seen below.

Article 4: Responsible Person

The major responsibility for all issues relating to marketing and safety of a cosmetic falls on the 'Responsible Person'. This is either an individual or a company within the EU who:

- manufactures a cosmetic within the EU
- imports a cosmetic into the EU.

A new feature is that a manufacturer or importer may by 'written mandate' designate a person established within the community as the Responsible Person, who will carry out all of their legal obligations in respect of the new Regulation, including safety assessments, maintenance of product files, registration etc.

With the advent of the internet, it is not uncommon for individuals to buy products on-line and to import directly from a manufacturer situated outside of the EU who has no presence within the EU. This type of import is addressed in the new Regulation and it will be necessary for the person placing the product on the market (outside the EU) to designate a person within the EU as the Responsible Person if the goods are to be legally exported to the EU.