



Changes in EU Cosmetic Laws

Proposed New Cosmetics Regulation

A proposed new Regulation, intended to replace the existing EU Cosmetics Directive (76/768/EEC) has been published following a period of consultation. The document, still very much in draft form, can be viewed at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0049:FIN:EN:PDF>

The proposed Regulation introduces a number of changes that will affect manufacturers and importers of Cosmetic Products within the EU. Introduction of Regulation is intended to remove the differences that exist between the ways Member States have implemented the Cosmetics Directives, and which make life awkward for companies that sell products across the EU. Other 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 remains the same.

Manufacturers and Importers will of course be concerned about how the proposed changes will affect their business. The following summary outlines some of the major changes that will affect the Cosmetics industry within the EU and offers some solutions to companies who will need to comply with the new Regulation in the years ahead. We must stress at this stage that the Regulation is not yet agreed, however anyone who has been involved in the Cosmetics Business and in particular EU regulation in general, is unlikely to be surprised by the changes outlined below, nor will they be expecting any significant differences when the final version eventually appears in the Official Journal. 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 responsibility on the “responsible person” who manufactures or imports a cosmetic product to demonstrate safety and places more clearly defined requirements on them to generate, keep and update information. The registration of products is radically altered with notification of sale and compositional information being supplied to the Commission who will disseminate information to Poison Centres and Member states. Details of this process are yet to be determined. It is intended that the Regulation will extend to all countries in the European Economic Area – EU + Iceland, Liechtenstein and Norway.

Regulatory Changes

While much of the legislation remains the same, there are changes in organization of the Regulation and some significant additions and changes. These, with reference to their place in the new Regulation are outlined 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 micro-organisms.*” 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 now 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 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 online 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.

Article 6: Free Trade within the EU

There shall be no restriction or prohibition of a cosmetic product in any member state as long as the requirements of the Regulation are met. This will prevent the situation where a product is considered acceptable in one country but not in others

Article 7: Safety Assessment & Article 8: Product Information File

The proposed Regulation reinforces the link between the product information file (or pack : the PIP), the product safety report (Annex 1) and the cosmetic safety assessment (Annex 1Part B) and sets out clearly the responsibilities of the Responsible Person and the Safety Assessor.

The cosmetic product safety report must be kept up-to-date by the Responsible Person. This shall contain the following information:

- Quantitative and qualitative composition of the product
- Physical/chemical characteristics and stability data
- Microbiological quality including results of preservation challenge test
- Impurities, trace ingredients and information about packaging material
- Normal and readily foreseeable use
- Exposure to the cosmetic product
 - Site of application
 - Surface area of application
 - Amount applied
 - Duration and frequency of use
 - Normal and foreseeable exposure routes
 - People exposed to the product
- Exposure to substances in the product, bearing in mind toxicity and exposure
- Toxicological profile of substances in the product
 - Skin irritation
 - Eye irritation
 - Skin sensitization
 - Photo toxicity
 - Systemic toxicity if dermal absorption is likely
- Note of any unwanted or undesirable effects, including statistical information
- Information on human experience
 - Including human trials and test data if available and / or relevant.

The product safety assessment is similar to the current situation, in that the assessment must be carried out by a suitably qualified individual; however the scope of the assessment is radically increased from that which is currently specified in legislation. All that is required by Law at present is a simple statement saying that the product has been assessed and in the opinion of the assessor it is safe. Once signed and dated by the assessor the requirements the existing legislation are met.

In the new Regulation, a Safety Assessment of a cosmetic product must contain the following as a minimum:

1. Assessment Conclusion
 - A statement on the safety addressing the requirements set out in *Article 3* re:
 - The presentation of the product
 - Labelling
 - Instruction for use and disposal
2. Labelled Warnings and Instructions for use
 - An indication of any specific actions that need be taken in order to ensure safe use of the product
3. Reasoning
 - All decisions of the assessor must be explained and justified. In particular margins of safety shall be considered and indicated where applicable
 - A specific assessment for children under 3 years old must be made
 - A specific assessment of any products intended for external intimate hygiene must be made
 - Possible interactions of ingredients must be considered
 - If the toxicological profile of any ingredient has indicated a particular hazard, then reasons for including or ignoring those effects must be given and justified
 - Any stability changes due to microbial or physical degradation shall be considered as appropriate.
4. Assessors Credentials
 - Name and address
 - Proof of Qualification
 - Date and signature

The Product Information File is kept by the responsible person and must be readily available, in the local language or if acceptable, a language that can be readily understood, for ready access by the authorities if required. The file must contain the following:

- a) Description of product
- b) Product safety report
- c) Method of manufacture and a statement of compliance with good manufacturing practice
- d) If necessary, proof of effect claimed for the product (e.g. anti wrinkle cream)
- e) Data on any animal testing carried out on the product or ingredients in order to meet non-EU regulatory requirements
- f) Although not specifically required, it would make sense to include the product safety assessment

Article 10 : Notification

The current Directive requires that cosmetics are registered with the authorities in each country in which the product is sold, normally within one month of going on sale. These requirements vary markedly in terms of detail required and regulatory controls applied by each different Member State.

Under the proposed new Regulation, the registration will be carried out centrally, once only, with a (yet to be defined) body of the EU Commission. The registration must be made prior to the product being placed on the market and the following information will be required:

- a) Category of product (e.g. Shampoo) and Full commercial name
- b) Name and address of person holding the Product Information File
- c) Country where the product is sold
- d) Contact details of an individual the authorities can contact if necessary
- e) Statement of whether micronized (nano) particles are present and their identity
- f) Statement of whether Category 1 or 2 carcinogens, mutagens or reproductive toxins are present and their identity
- g) Frame formulation detailing
 - Type of ingredient
 - Maximum concentration
 - If the frame formulation does not cover all of the ingredients, a more detailed formulation must be given.

The commission will then be responsible for sending this information electronically to the relevant member states and poison centres. It is the responsibility of the manufacturer / importer to ensure that the information is kept up-to-date.

Article 11: Restrictions

There are, as with the current legislation, extensive lists of chemicals that may not be used or may only be used subject to restriction and/or controls.

- Annex II, lists 1,328 prohibited substances
 - NB many mineral oil derived products are *de facto* prohibited, but can be acceptable if they meet set analytical criteria. Certification must be obtained from the supplier that the following criteria are met as appropriate. If in doubt consult the individual Annex II entry for the substance, or contact Delphic HSE for advice.
 - Butadiene concentration in gases is >0.1%
 - Benzo (α) pyrene concentration is >0.005%
 - The DMSO extract value (IP346) is >3%
 - Full refining history and treatment process is known

- Annex III, lists 158 controlled substances
- Annex IV, lists Colourants that may be used and details any restrictions.
 - NB this list now included products intended to colour hair, these are not included in the current legislation
- Annex V, lists preservatives that may be used and details any restrictions.
- Annex VI, lists UV filter (sunscreen) ingredients that may be used and details any restrictions

Article 12: Carcinogens, Mutagens and Reproductive Toxins (CMRs).

Under existing legislation there is confusion regarding the status of materials that are classified as carcinogenic, mutagenic or toxic to reproduction. The legislation states that substances classed as category 1,2, or 3 should not be used in cosmetics; however there are several examples of common materials e.g. alcohol, that should be prohibited on the basis of the existing law but are clearly in common usage. The proposed regulation states that:

- A category 3 CMR may be used if it has been reviewed by the Scientific Committee for Consumer Products of the EU (SCCP) and been deemed to be safe.
- Category 1 and 2 CMRs may be used if all of the following conditions are met:
 - They have been evaluated by SCCP and been found to be safe in respect of specific exposures
 - They comply with food safety requirements,
 - There are no suitable alternative substances available
- Specific labelling requirements to avoid misuse must be met.

Article 15: Labelling

Labelling requirements are largely unaltered. There is however a new symbol that will need to be included on the packaging indicating “*date of minimum durability*” This symbol (resembling an hourglass) shall be followed by the words as shown:



Best before the end of (Day) Month and Year

This is not mandatory for products where the useful life when stored normally is greater than 30 months. For products where the “shelf life” is less than 30 months, as now, the existing open jar labelling symbol is required.

Article 17: Public Access to Information

In line with current regulation of chemicals as shown in the REACH Regulation, there is an increased emphasis on making information available to the general public and consumers. Commercial confidentiality may be maintained, but considering that all ingredients have to be listed in any case, the only means of achieving this is to show concentrations in bandwidths. Notwithstanding this, the following information shall be made publicly accessible by any means considered suitable:

- Qualitative composition of the product
- Name code number and supplier of any fragrances in the product
- Information on any undesirable effects
- Quantitative information on the content of any ingredients classified as dangerous.

Market Surveillance

There is a new section (Chapter VII and Chapter VIII) introduced with the Regulation that covers Market Surveillance, communication of effects and action to be taken in the event of problems in the marketplace, and non-compliance with the Regulation.

Article 19: Communication of Serious Undesirable Effects

The Responsible Person must keep up-to-date the file of all reported undesirable effects and must notify the Commission of:

- All serious undesirable effects of the product
- The commercial name of the product
- Actions taken to remedy the problem.
- The Commission will then make the information available to the relevant member states

Article 20: Information on Concentration

In the event of a problem being identified with a particular ingredient, the Responsible Person may be asked by the authorities for a **list of all products containing the ingredient and the concentration in each product**. The responsible person should maintain therefore a comprehensive list of ingredients of all products and their concentrations. Bear in mind that if an alert occurs and an ingredient is under suspicion, all uses of that ingredient will need to be identified by the authorities. A responsible person may therefore be asked for information on ingredients even though they have never had an issue with their products.

Article 21: Non Compliance

If a product is found not to be in compliance, a number of actions will be required of the Responsible Person, ranging from corrective actions to attain compliance to product withdrawal. Non compliance with any of the following can trigger the requirement for action, the degree of risk will determine the actions that will be required:

- Incomplete or inadequate product information file
- Not meeting requirements to notify adverse effects
 - It will therefore be important to have a mechanism to collect and assess any adverse effects in place
- Good manufacturing practices
 - How certain are importers of the manufacturing practices of their overseas suppliers and how can those be verified
- Incorrect use of restricted ingredients
- Inadequate labelling
- Unsubstantiated product claims
- Inappropriate animal testing

Product withdrawal may be required if it is considered necessary due to a serious risk to human health or if the Responsible Person does not act within a timeframe set by the commission.

Comment

The Cosmetics Directive of 1976 has been effective in protecting consumers in Europe for over 30 years. It has been subject to constant revision and update during that time and there have been it must be acknowledged, differences in understanding and implementation across the EU. The new proposed Regulation will harmonize the cosmetics legislation across the EU and make updating the laws as technical progress, particularly the new information that will become available because of REACH, more efficient and effective. The responsibility is placed squarely with the Responsible Person, although this does not have to be an in-house individual.

If you require any assistance with new Regulation, you can contact Delphic HSE Solutions Limited for help and advice.

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