

## Considerations in the Safety Assessment of Cosmetics

a report by

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### Introduction

Cosmetic products are used all over the world and, although aiming at the same high level of consumer protection, their regulations and requirements are quite different from one part of the globe to another.

Since the authors' field of competence mainly covers the European cosmetic legislation, the European situation will be discussed in detail. Nevertheless, some clear references will be made to the US system for evaluating the safety of cosmetics, as regulated by the US Food and Drug Administration (FDA). It will immediately become clear that there are some striking similarities between these two systems, as well as some clear disparities. The latter particularly intensify the challenge of producing worldwide cosmetic products that comply with all the necessary legal requirements.

### Legal Background

Within Europe, cosmetics must fulfil the requirements described by Directive 76/768/EEC, relating to cosmetic products. First published in September 1976, the Cosmetics Directive has been subject to seven amendments and 30 adaptations to technical progress. When advice on scientific issues is required, this is generally directed to officially established scientific committees assisting the appropriate Directorate Generals of the European Commission. The committee most often consulted in the field of cosmetics is the Scientific Committee on Cosmetic Products and Non-Food Products (SCCNFP), which owns the official mandate to answer scientific and technical questions concerning consumer health, relating to cosmetic products and non-food products intended for consumers, especially substances used in the preparation of these products, their composition and their use, as well as their types of packaging and labelling.

In the US, cosmetic products are principally regulated through the US Federal Food, Drug and Cosmetic (FD&C) Act and the Federal Fair Packaging and Labeling (FP&L) Act, both administered by the FDA. The latter shares its responsibility for regulating cosmetics with a number

of official instances, such as the US Federal Trade Commission, The US Consumer Product Safety Commission and the US Environmental Protection Agency. Since it is not intended for this article to unravel the complex web of US jurisdictions on cosmetic products, it will mainly focus on the provisions enforced by the FDA when referring to the US regulation of cosmetics.

### Definition of a Cosmetic Product

According to the European Commission Directive 93/35/EEC, Article 1:

*“A cosmetic product is any substance or preparation intended to be placed in contact with the various parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.”*

According to the US Federal Food, Drug, and Cosmetic Act:

*“Cosmetics are defined as (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance and (2) articles intended for use as a component of any such articles, except that such term shall not include soap.”*

Included in both definitions are products such as skin creams, lotions, perfumes, lipsticks, fingernail polishes, eye and facial make-up preparations, shampoos, permanent waves, hair colours, toothpastes and deodorants. Soap products, however, are not considered cosmetics under the US law.

Products that are cosmetics but are also intended to treat or prevent disease, or otherwise affect the structure or functions of the human body do fall under the US definition of a cosmetic and must comply with both the drug and cosmetic provisions of the law. They

are sometimes referred to as ‘cosmeceuticals’ and the majority of them belong to the category of ‘over-the-counter drug-cosmetics’. Examples of products that are drugs as well as cosmetics are: anti-caries toothpastes (e.g. ‘fluoride’ toothpastes); hormone creams; suntanning preparations intended to protect against sunburn; antiperspirants that are also deodorants; and anti-dandruff shampoos.

The European legislation does not recognise this US category of ‘cosmetics that are also drugs’. It classifies suntanning preparations, antiperspirants and anti-dandruff shampoos as cosmetics, while any product that has the ability to treat or prevent diseases, or any product that is presented with a view to restoring, correcting or modifying physiological functions is considered a medicinal product.

### The Safety Prerequisites and Responsibilities

The current EU legislation on cosmetics literally states the following:

*“A cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product’s presentation, its labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorised agent or by any other person responsible for placing the product on the Community market.”*

The responsibility to ensure cosmetic products are safe for consumer use is placed upon the manufacturer or his/her authorised agent or by any other person responsible for placing the product on the European Community (EC) market. In the US, the manufacturers bear this responsibility and cosmetic products that have not been adequately tested for safety must have a warning statement on the front label that reads “Warning – the safety of this product has not been determined”. It is clear that both legislations place the responsibility on the side of industry and maintain the protection of human health as a primary goal. They share the worldwide view that cosmetic products are not expected to have unacceptable adverse effects for the consumer.

### Safety Evaluation of Cosmetic Products and their Ingredients

#### Safety Evaluation of Finished Cosmetic Products

As stated in Article 7a of the European Cosmetic Products Directive, a specific data package should be

kept readily accessible to the EU Member States’ competent authorities. This data package, also called a Technical Information File (TIF) or a Product Information Requirement, must not only contain information on the identity of the responsible person(s), physico-chemical and microbiological specifications, manufacturing method, existing data on undesirable effects, claim substantiation and data on animal testing, but also a qualified safety assessor’s evaluation of the safety for human health of the finished product. The latter has to be based on the general toxicological profile of the ingredients and their chemical structure and level of exposure.

In real terms, the qualified safety assessor will use the data stated in the TIF, together with all available information relevant to human exposure, in order to indicate in a motivated and undersigned document whether a cosmetic product can be brought onto the EU market without risks to human health when applied under normal and reasonably foreseeable conditions of use. Since animal testing on finished products is prohibited from September 2004 onwards, only *in vitro* toxicity studies and/or human volunteer studies can be envisaged in order to confirm the finished product’s safety. It is self-evident that the safety assessor must have approved all the ingredients for intended use in the specific cosmetic product under consideration, before moving to volunteer studies. As with any study in man, ethical concerns should be considered and it should be emphasised that human studies are not to be preferred to animal tests and cannot be considered as an alternative to the use of animals. The SCCNFP has issued a number of reports on human volunteer testing in the cosmetic field.

In the US, the legally binding provisions related to the safety assessment of finished cosmetic products are mainly restricted to the FD&C Act, in which no practical and/or scientific guidance can be found. Moreover, there is no Federal pre-market approval authority established for cosmetic products and even the registration of cosmetics is not obligatory. This ambiguous legal situation has driven the cosmetic industry trade associations, together with consumer advocacy groups and the government itself, into a program of ‘self-regulation’. This program includes, besides the elaboration of the FDA Voluntary Cosmetic Regulation Program, the initiation of the Cosmetic Ingredient Review (CIR) and the Research Institute for Fragrance Materials (RIFM)/International Fragrance Association (IFRA) programs, each evaluating the safe use of specific cosmetic ingredients in view of their intended use. ■

*This article is continued, with graphics and full references, on the BBL website supporting this business briefing ([www.bbriefings.com/cdps/cditem.cfm?NID=846](http://www.bbriefings.com/cdps/cditem.cfm?NID=846)).*