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EU legislations affecting safety data availability of cosmetic ingredients

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Abstract

With the introduction of the 6th and 7th Amendments (OJ L151, 32–37, 23 June 1993; OJ L066, 26–35, 11 March 2003) to the Cosmetic Products Directive (OJ L262, 169–200, 27 September 1976), imposing a testing and marketing ban on cosmetic products tested on animals, the retrieval of toxicological data on individual ingredients became of greater need.

Since the majority of cosmetic ingredients are used for many other purposes than their cosmetic function, they fall under the scope of more than one EU Directive. An overview is given of EU legislation that could potentially affect the availability and interpretation of cosmetic safety data. It will become clear that, although cosmetics are regulated by a specific so-called ''vertical'' legislation, ''horizontal'' influences from other products' legislations play a role since they determine the type and amount of data that theoretically could be found on the specific substances they regulate. This knowledge is necessary while performing extended searches in databases and becomes indispensable when initiating negotiations with manufacturers or suppliers for obtaining the safety data required.

Keywords: Cosmetics; Toxicological data; Risk assessment; Hazard (identification); Dangerous substances; Safety evaluation; Regulatory toxicology; EU legislation

1. Introduction

The safety assessment procedure for cosmetics in the European Union (EU) is regulated by the provisions of Directive 76/768/EEC (EU, 1976), including its important 6th and 7th Amendments. It is a so-called ''vertical'' legislation, specific for cosmetic finished products and their ingredients. Although cosmetics are exempted from other legislations such as the Dangerous Substances (EU, 1967) and the Dangerous Preparations Directive (EU, 1999), several substances used in cosmetics equally fall under the scope of other legislations. Therefore, ''horizontal'' influences of all types of product-specific legislations need to be considered when collecting safety data for a particular cosmetic ingredient. It is therefore important to provide a structured overview of the relevant EU legislations generating data that can increase our knowledge on cosmetic ingredients.

It must, however, be emphasized that the accessible parts of available toxicological data, not necessarily consist of full study reports. In general, summaries and study results will be described (e.g. in reports of official instances), while the details and raw data of the studies remain property of the company involved.

2. Data requirements under the cosmetic products directive

According to Article 1 of Directive 76/768/EEC (EU, 1976), a ''cosmetic product'' is defined as *any substance or preparation intended to be placed in contact with the various external 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 odors and/or protecting them or keeping them in good condition*.

The Cosmetic Products Directive (EU, 1976) ensures free movement of cosmetics in the European Union. One of its specific starting points is that cosmetic products must

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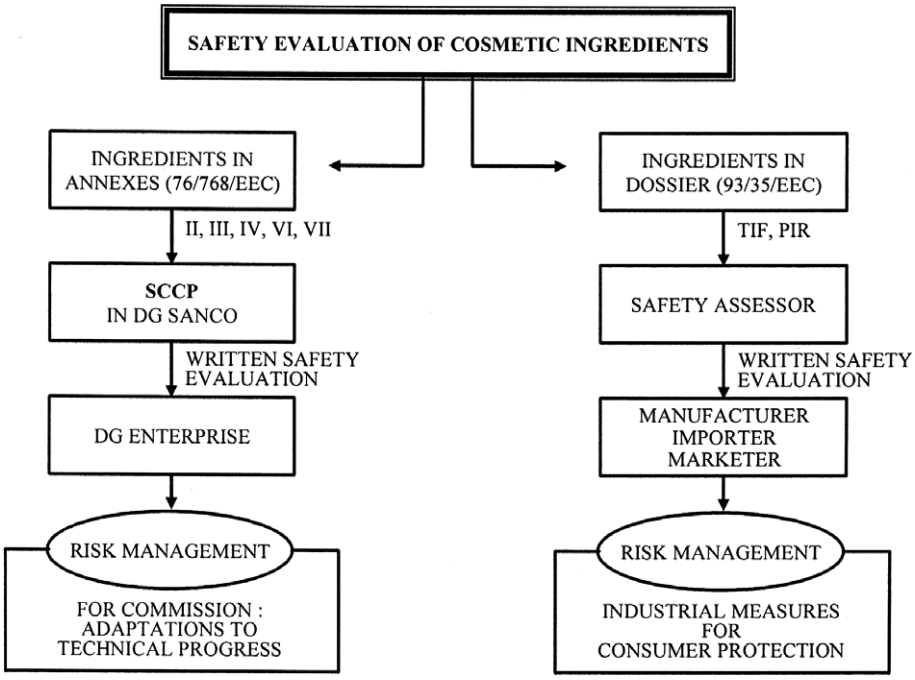

Fig. 1. Two different channels are operative in the EU for the safety assessment of cosmetic ingredients (SCCP, 2006).

be safe and this is the responsibility of the manufacturer/marketer. In 1993, the 6th Amendment (EU, 1993a) to Directive 76/768/EEC (EU, 1976) imposed the existence of a compilation of toxicological data for every finished cosmetic product placed on the EU market. The purpose is to support the human safety claim without testing the finished product on animals. Directive 93/35/EEC clearly states that the safety of a cosmetic product must be assessed *by taking into consideration the general toxicological profile of the ingredients, their chemical structure and their level of exposure* (EU, 1993a).

According to the actual cosmetic legislation in the EU, two distinct channels are operative for the safety evaluation of cosmetic ingredients (see Fig. 1), namely:

(i) The safety evaluation of **cosmetic ingredients of direct relevance to Council Directive 76/768/EEC**, thus substances to be taken up in the Directive's Annexes IV, VI, VII or III, being colourants, preservatives, UV-filters, or substances for which restrictions in application and/or concentration apply, respectively. For these compounds, concern for human health has been expressed (Pauwels and Rogiers, 2004). They are subject to an evaluation by the Scientific Committee on Consumer Products (SCCP), previously called Scientific Committee on Cosmetic products and Non-Food Products intended for consumers (SCCNFP). When the outcome is favourable, a substance can be taken up in its corresponding Annex to the Directive (EU, 1976). In case the opinion is unfavourable, industry usually is asked to provide additional information and/or argumentation. The final decision on the inclusion lies with the European Directorate General (DG) Enterprise. Full reports of SCC(NF)P evaluations, including data with respect to the performed physico-chemical and toxicological studies with their flaws and strengths, are publicly available through the Internet.[1]

(ii) The safety evaluation of **all ingredients present in finished cosmetic products**. The latter constitutes relevant information for the toxicological data compilation or the so-called Technical Information File (TIF) or Product Information Requirement (PIR) of the cosmetic product under consideration. According to Art. 7.a.1.(e) of the 6th Amendment to the cosmetic legislation (EU, 1993a), the safety evaluation needs to be carried out by a qualified safety assessor, whereas the ultimate responsibility for the finished product lies with the manufacturer, importer or marketer. For substances not taken up in one of the Annexes to Dir. 76/768/EEC (EU, 1976), no specific additional data requirements apply. This means that, besides the results of the safety tests that are carried out on a voluntary basis for certain cosmetic ingredients, the availability of data depends on data requirements and data accessibility measures laid down in the other legislation(s) with which these substances have to comply.

[1] http://ec.europa.eu/health/ph_risk/committees/04_sccp/sccp_opinions_en.htm and http://ec.europa.eu/health/ph_risk/committees/sccp/sccp_opinions_en.htm (consulted July 2007).