

# A Training Concept for Safety Assessors of Cosmetic Products

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For the first time, the principle of safety assessment of cosmetic products was anchored in the European Cosmetics legislation through Directive 93/35/EEC (6<sup>th</sup> Amendment to the EC Cosmetics Directive 76/768/EEC). Prior to its placing on the market, manufacturers and distributors of cosmetic products were required to subject every product to a comprehensive assessment of its safety for human health. In the meantime – after the entry into force of the EC Cosmetics Regulation [Regulation (EC) No 1223/2009] in January 2010 – the requirements concerning the safety assessment have been specified in more detail and concretised (in Annex I of the Regulation).

This legal requirement of the EU now serves as a model for many other regions, and there, too, the safety assessment is required by law. But even in countries where safety assessment is not legally required, manufacturers want to make sure to bring safe products to market for the consumers. These manufacturers are often also guided by the requirements of the EU, although the comprehensive documentation does not necessarily have to be carried out.

In the EU, the law requires that a safety assessor who is personally responsible for the safety of a cosmetic product has to be appointed. This means that the product must meet all requirements of the EC Cosmetics Regulation in terms of its effects on human health in the event of normal or reasonably foreseeable use of a cosmetic product. When preparing a safety assessment, first of all, the expert must review all existing basic requirements of cosmetic legislation (substance regulations, labelling provisions etc.). The more extensive assessment must be in conformity with Article 10 and Annex I of the EC Cosmetics Regulation. In this connection, the toxicological profiles of all ingredients and the exposure conditions to be expected must be taken into due account.

For the elaboration of the safety assessment, the legislator has specified a certain group of individuals. Article 10 of the EC Cosmetics Regulation stipulates in Section 2:

*“The cosmetic product safety assessment, as set out in Part B of Annex I, shall be carried out by a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognised as equivalent by a member state.”*

Such an education is, however, not sufficient as a rule. For the competent assessment of the safety of cosmetic products, interdisciplinary knowledge is required, in particular in the fields of chemistry, toxicology, dermatology and (cosmetics) law so that the corresponding person must engage in specific continuing education in these fields. Together with IKW and university experts, DGK developed continuing education courses for safety assessors for the first time in 1998. The structure and the content of the courses were extensively revised and updated in 2006. More emphasis was placed on their orientation towards practice. The lecturers for these courses are highly qualified experts from the respective disciplines from universities, public authorities and industry, including, for instance, several members of the Cosmetics Commission of the Federal Institute for Risk Assessment (BfR) or the SCCS (Scientific Committee on Consumer Safety).

The cycle of courses regularly offered consists of **seven individual courses of two days in each case**. At the end of each course, the learning contents are checked by a written test (participation on a voluntary basis). In this connection 18 of 24 questions must be answered correctly. A corresponding certificate for the attended course is then issued. After successful participation in all 7 individual courses, overall participation is confirmed.

The series is divided into the following courses which can be attended in any order

- Exposure of Cosmetic Products/Percutaneous Penetration
- Topical Safety, Immunology and Sensitisation
- Metabolism, kinetics and structure-activity relationships
- Carcinogenesis and Mutagenesis
- General and Systemic Toxicology
- Reproduction Toxicology
- Microbiological Safety of Cosmetic Products

In addition, DGK and IKW offer two to three seminars for safety assessors per year. The morning session features lectures on latest developments or specific topics in the area of safety assessment. In the afternoon session, participants have the opportunity to work together in small groups on practical exercises which have been provided ahead of the meeting. Meanwhile, such seminars are also offered in other countries like Poland, India, South Africa etc..



In the beginning, courses and seminars have been provided in German language only. For some years now, they have also been available **in English**. From spring 2019, the courses will also be available as **webinars**. It is, of course, possible to mix any number of face-to-face trainings and webinars to get the certificate of successful participation in the full 7-course cycle. Trainings and webinars will be fully equivalent in this respect.

Safety assessors who fulfil the minimum education requirements in Article 10 of the EC Cosmetics Regulation, who have successfully completed the 7-course series of trainings, and who have participated in at least three seminars for safety assessors in the past three years, may apply for the optional certificate "DGK Safety Assessor".

This concept is unique in this form worldwide. So far, almost 200 people have completed all 7 courses, and the **certificate "DGK safety assessor"** has already been awarded more than 100 times.

**For upcoming courses and seminars please consult**

**[www.safetyassessor.info](http://www.safetyassessor.info):**

<https://www.safetyassessor.info/trainings.html>

<https://www.safetyassessor.info/seminars.html>

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