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EDUCATION FOR SAFETY ASSESSORS

THE DGK/IKW EDUCATION PROGRAMME FOR SAFETY ASSESSORS – WHAT'S NEW?

Jens Burfeindt, IKW

DGK/IKW/CTFA Safety Assessment Seminar | 31 August 2023

Scope of EU Cosmetics Legislation

Any substance or mixture intended to be placed in contact with the 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 …

COSMETIC PRODUCT

CLEANING THEM

KEEPING THEM IN **GOOD CONDITION**

PERFUMING THEM

CHANGING THEIR **APPEARANCE**

CORRECTING BODY ODOURS

PROTECTING **THEM**

Basic Safety Requirement

The EU Cosmetic Products Regulation (CPR) sets a legal obligation that all cosmetic products placed on the market **must be safe under normal/reasonably foreseeable conditions of use**.



Safety Requirement in the EU CPR

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Article 3: *"A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use, taking account, in particular, of the following:*

(a) *Presentation ...;*

(b) *labelling;*

(c) *instructions for use and disposal; …"*

Who is responsible for the safety and legal compliance?

‘Responsible Person’ who places the product on the market



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Safety Report (Part of PIF)

PIF: Product Information File

Product Information File

Article 11 par. 1

„When a cosmetic product is placed on the market,
the responsible person shall keep a product information file for it.”

All cited legal texts in this presentation are referring to the EU Cosmetic Products Regulation [Regulation (EC) No. 1223/2009].

Product Information File

- Contains the full documentation for each cosmetic product on composition and safety in use
- A separate documentation for each product is necessary
- Belongs to the responsible person and must be accessible for the competent authority on the address on the packaging



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Cosmetic Product Safety Report (CPSR)

Safety Requirement in the EU CPR

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Article 10.1: *"In order to demonstrate that a cosmetic product complies with Article 3, the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone* ***a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up*** *in accordance with Annex I."*

The Safety Report

→ Central part of the Product Information File

→ Contents are specified in Annex I EC CPR:

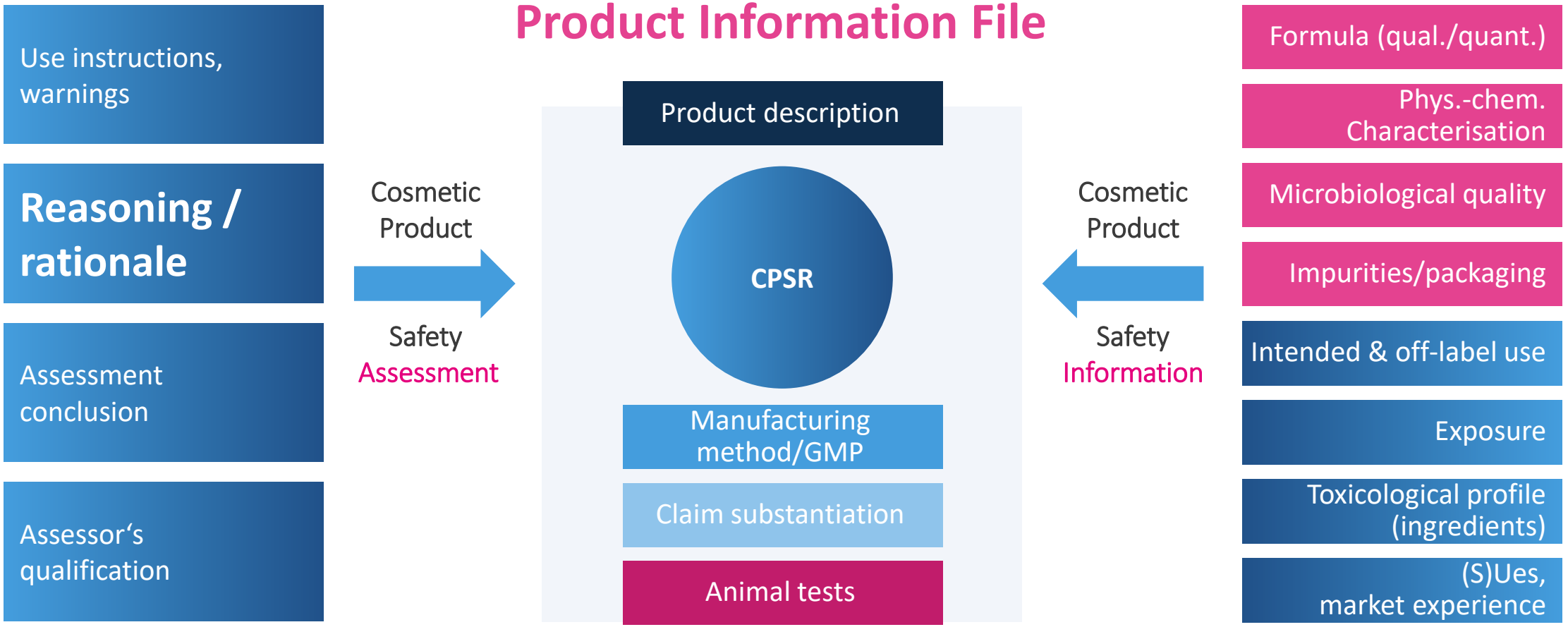
The Safety Report for cosmetic products is composed of:

Part A – Safety information

Part B – Safety assessment (reasoning and conclusion)



Cosmetic Product Safety Report – Building Blocks



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The Safety Assessor

…is responsible for the compilation of the safety report

Status/Appointment of the Safety Assessor

The responsible safety assessor signs the safety report.

Assessor's credentials and approval of part B

Name and address of the safety assessor.

Proof of qualification of safety assessor.

Date and signature of safety assessor.

Of course he/she can delegate tasks/share the practical work to/with colleagues or experts.

The management may also hire an external safety assessor (consultant).

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Tasks and Qualifications of Safety Assessors

Tasks of Safety Assessors

Preparation of the safety assessment in accordance with legal requirements	Examination of the raw material data	Exposure assessment
Examination of health-related claims	Microbiological assessment	Observation of possible restrictions of concentration for individual substances
Possible introduction of warnings	Observation of the market and resulting measures if necessary	Adaption of the safety assessment to formulation changes

Tasks of Safety Assessors

Observation of scientific evaluations (SCCS, CIR, BfR, ...); recommendations (e. g. Cosmetics Europe, European Commission, IKW, BfR, ...); as well as the SCCS‘ Notes of Guidance

Adaption of the safety assessment to new scientific evidence

Basic Qualification

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Article 10.2:

"The cosmetic product safety assessment ... 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."

Advanced Qualifications

The legally agreed definition for a basic qualification is a prerequisite to be able to prepare safety assessments.

However,
this does not suffice to fulfil the actual requirements.

On a case-by-case basis, further specific knowledge has to be taken into account, e. g. experimental and clinical toxicology, dermatology, cosmetics chemistry (including production processes) and cosmetic products legislation.

Need for advanced and continous training to be kept informed about the state of the art of scientific research and technology.

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The DGK/IKW Safety Assessor Trainings

DGK/IKW Training Courses



DGK/IKW Training Courses

Course system developed in 1998

Co-operation with the German Society of Scientific and Applied Cosmetics (DGK)

7 (8) individual trainings in English and German lasting two days each

35 attendees max

No specific qualification required for participation in courses

Costs: 800 €/course

Since 2018: Also available as web trainings



DGK/IKW Training Courses

Examinations on the knowledge acquired at the end of each training.

18 out of 24 questions must be answered correctly.

Participants receive a certificate for the respective training.

Participants successfully completing all seven trainings receive a certificate for the whole series.

Speakers: Members from the Advisory Committee on Cosmetic Products of the Federal Institute for Risk Assessment (BfR), SCCS, University, Industry, DGK, …



DGK/IKW Training Courses

Experts from the competent authorities are also participating in the DGK/IKW trainings

They obviously need the same qualification as a safety assessor

Most of them have passed the 7 (8) trainings

This enables an efficient scientific dialogue between companies (safety assessors) and authorities

The Trainings

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EDUCATION FOR SAFETY ASSESSORS

1. Exposure to Cosmetic Products/Percutaneous Penetration
2. Skin Compatibility and Sensitization
3. General and Systemic Toxicology
4. Essentials of Metabolism Informing Human Health Risk Assessment
5. Carcinogenesis and Mutagenesis
6. Reproduction Toxicology
7. Microbiological Safety of Cosmetic Products
8. **NEW:** NGRA/NAMs (as of autumn 2023)



(Regular exchange of persons responsible for courses once per year)

Exposure to Cosmetic Products/Percutaneous Penetration

- Legal requirements
- Anatomy and physiology of the skin
- Guidelines of the SCCS
- Principles of safety evaluation of ingredients
- Basic information on exposure, e.g. TTC
- Principles of safety evaluation of finished products



Skin Compatibility and Sensitization

- Skin irritation – toxicological considerations
- Toxic-irritative side-effects of cosmetics
- Allergic skin conditions and common allergens in cosmetics
- Regulatory skin sensitization testing – an over-view of currently used methods and approaches
- Dermatological tests
- Cosmetic side-effects in dermatological practice
- Claims and advertisement related to safety assessment



General and Systemic Toxicology

- Introduction to toxicology
- Toxicological mechanisms and principles
- Toxicological test methods
- Repeated dose toxicity – principles and test methods
- Introduction to toxicological risk assessment
- SCCS guidelines/sources of toxicological information
- Safety assessment of cosmetic ingredients
- Adverse effects of cosmetic ingredients



Essentials of Metabolism Informing Human Health Risk Assessment

- Metabolism: Basic information on the biotransformation of exogenous substances
- In-vivo/in-vitro models/biomonitoring
- Mechanisms of structure-activity relationships
- Evaluation of ingredients



Carcinogenesis and Mutagenesis

- General principles of mutagenesis and carcinogenesis
- Test systems
- Test strategies



Reproduction Toxicology

- Basics: Anatomy of the genital organs
- Hormonal control mechanisms of human procreation
- Basics of developmental biology of humans
- Overview on reproductive toxicology, e.g. test methods
- In-vitro methods for the determination of damaging mechanisms
- Endocrine disruptors
- Structure-activity relationship
- Evaluation of cosmetic ingredients



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Microbiological Safety of Cosmetic Products

- Basic requirements for microbiological tests
- Development aspects to reach micro-biologically safe cosmetic products
- Challenge Testing of cosmetic products: Test performance and evaluation
- Limit values for cosmetics and their maintenance through a QA-system
- Control of scale-up phase
- Microorganisms as health hazard
- Contamination cases and following decisions
- Microbiological safety assessment: procedures and documentation



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NEW
Integrating Non-Animal Methods into Risk Assessment (NGRA)

- Course (web training) will be available as of autumn 2023
- Participation in this eighth course module is mandatory for new issuances and renewals of certificates “DGK Safety Assessor” – starting from 1 January 2024



NEW

Integrating Non-Animal Methods into Risk Assessment (NGRA)

- In-vitro test methods – state of science
- Next generation tools
- QSAR, read-across
- Integrated approaches for testing and assessment
- Validation and gaining confidence for decision-making
- Data integration and risk assessment for human health safety assessment without animals



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EDUCATION FOR SAFETY ASSESSORS

NEW
Environmental Safety
(Optional course)

- Background aspects and strategies for environmental assessments of cosmetic ingredients
- Identifying environmental hazard, exposure and fate to calculate environmental risk
- Including environmental NAM approaches
- Current and upcoming environmental concerns



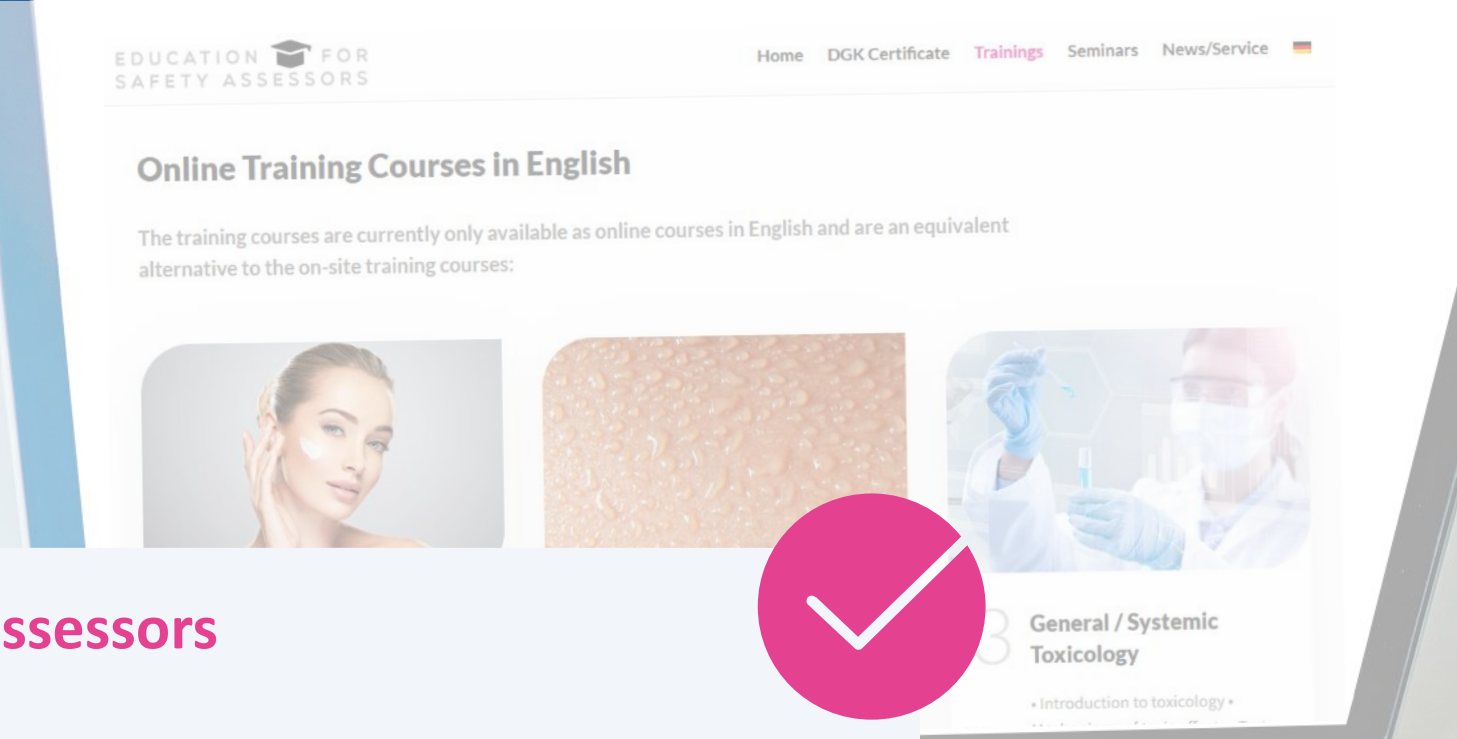
Goal of the Trainings

The trainings deliver the tools for the safety assessor to demonstrate the safety of a cosmetic product and its ingredients based on the relevant toxicological endpoints including evalution and interpretation of relevant studies.




EDUCATION FOR SAFETY ASSESSORS
Home
DGK Certificate
Trainings
Seminars
News/Service
Online Training Courses in English
The training courses are currently only available as online courses in English and are an equivalent alternative to the on-site training courses:
1 Exposure / Percutaneous Penetration
• Principles of the safety assessment
2 Skin Compatibility and Sensitization
• Skin irritation • Toxic-irritative
3 General / Systemic Toxicology
• Introduction to toxicology •
safetyassessor.info

Web Trainings



Web Trainings for safety assessors

All 7 (8) training courses (in English) can be completed ONLINE

- Course videos available for 10 days
- Presentations also available as pdf for download
- Online exam

For registration, more information and a preview video please visit

- https://safetyassessor.info/training-courses/

The Safety Assessor Certificates



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CERTIFICATE OF ATTENDANCE

successfully participated in the education and training course of the German Society for Scientific and Applied Cosmetics (DGK) in

Basic Principles of Safety Assessment of Cosmetics
- Exposure to Cosmetic Products / Percutaneous Penetration -

on January 30 - 31, 2020 in Frankfurt.

In this training course, knowledge on the following topics was imparted in lectures and practical excercises:

- Legal framework
- Basic principles of skin anatomy and physiology
- Dermal bioavailability of substances
- Guidelines of the SCCS
- Principles of safety assessment of cosmetic raw materials
- General considerations on exposure of cosmetic ingredients
- Principles of safety assessment of finished products, incl. spray products

A final examination on the knowledge acquired was successfully passed.
Frankfurt, January 31, 2020

Dr. Andrea Weber
DGK-Training safety assessment

Birgit Huber
Course leader

President:
Dr. Hartmut Schmidt-Lewerkühne

Secretary:
Dr. Volker Wendel

Professional groups:
Britta Klebon

Certificate for one course

DGK
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CERTIFICATE OF PARTICIPATION

successfully participated in the continuing education series of the German Society for Scientific and Applied Cosmetics (DGK e.V.)

BASIC PRINCIPLES OF THE SAFETY ASSESSMENT OF COSMETIC PRODUCTS
according to the requirements of Article 10 and Annex I of Regulation (EC) No 1223/2009

The individual courses covered the following topics:

Exposure to Cosmetic Products / Percutaneous Penetration
Course Leader B. Huber, Frankfurt

Topical Safety, Immunology and Sensitization
Course Leader Prof. Dr. U. Heinrich, Witten

Metabolism, Kinetics and Structure-Activity Relationships
Course Leader Prof. Dr. G. Eisenbrand, Kaiserslautern

Carcinogenesis and Mutagenesis
Course Leader Dr. R. Fautz, Darmstadt

General and Systemic Toxicology – Including Risk Assessment
Course Leader Dr. E. Schrader, Düsseldorf

Reproduction Toxicology
Course Leader Dr. W. Schuh, Düsseldorf

Microbiological Safety of Cosmetic Products
Course Leader Dr. U. Eigener, Hamburg

The knowledge acquired in each course was demonstrated through a final examination and certified.

Köln / Kaiserslautern, 31 January 2020

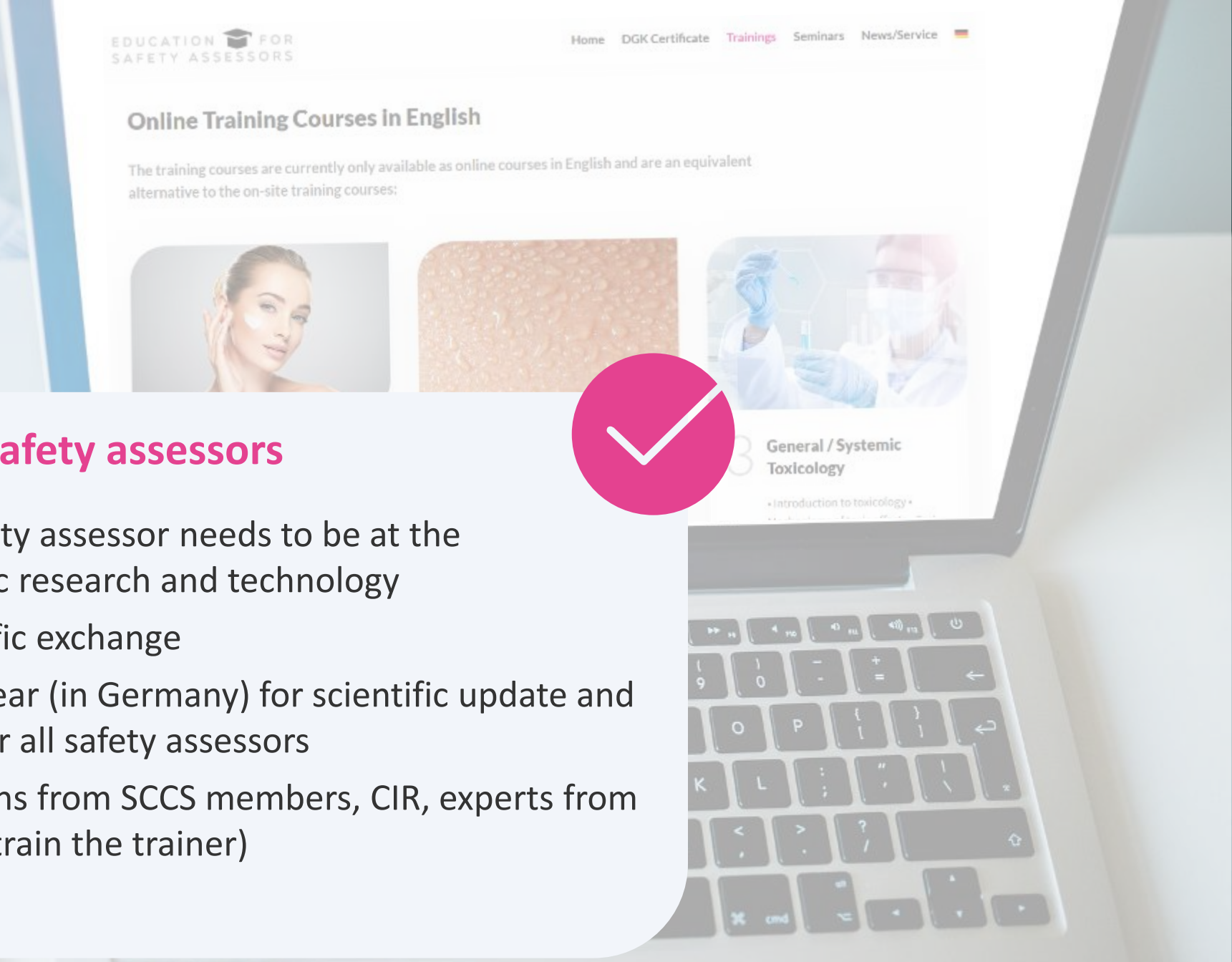
Dr. Andrea Weber

Prof. Dr. G. Eisenbrand
...he Committee on
...ation for Safety Assessors

...Schatzmeister: Dr. Sven Munke

Certificate for all courses

Additional Offer



DGK/IKW Seminars for safety assessors

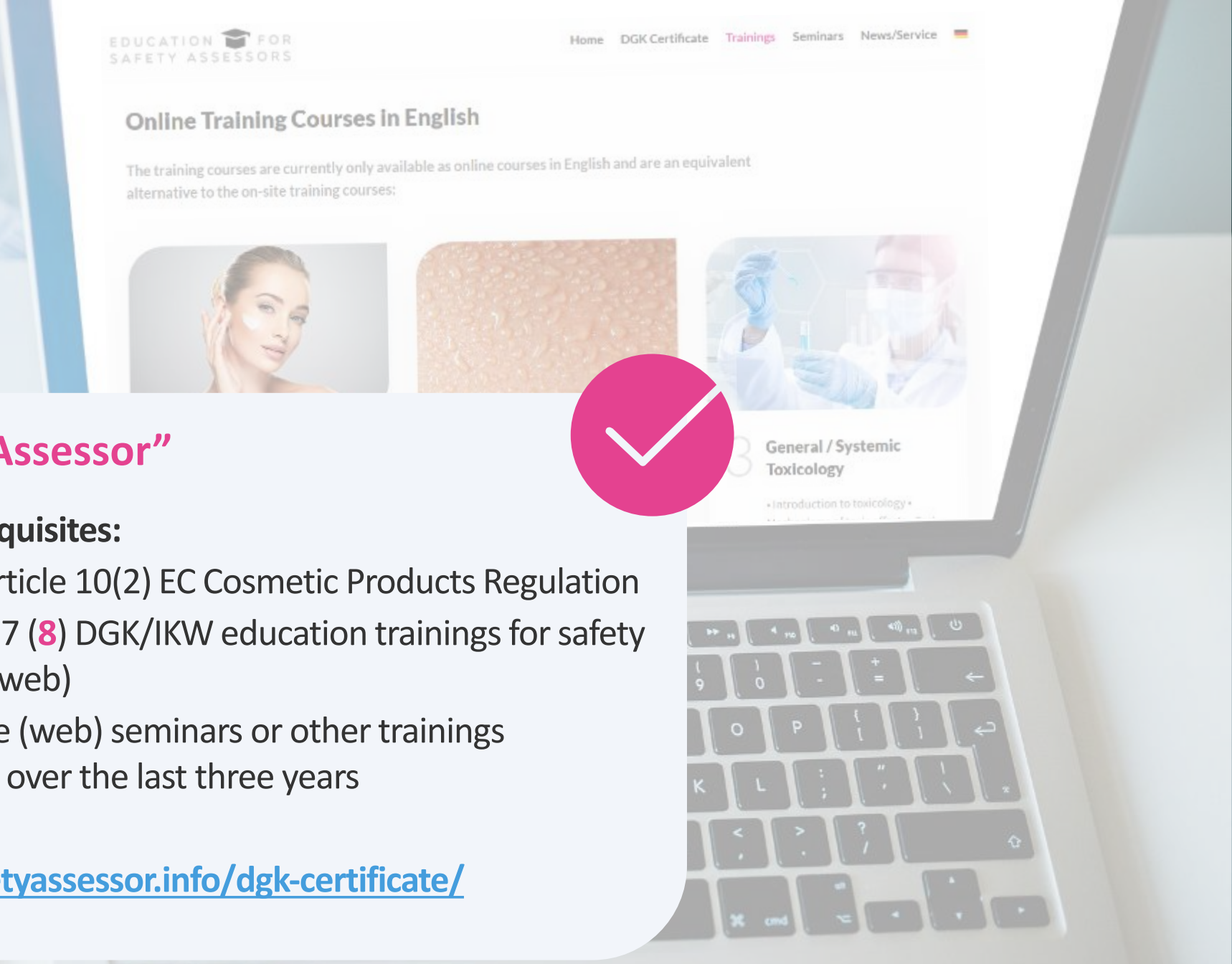
- The knowledge of the safety assessor needs to be at the state of the art of scientific research and technology
- There is a need for scientific exchange
- Two one-day events per year (in Germany) for scientific update and exchange of experience for all safety assessors
- Lectures, e. g. presentations from SCCS members, CIR, experts from international companies (train the trainer)
- Practical exercises

Additional Offer

DGK/IKW Seminars for safety assessors

- Additional seminars on international level in cooperation with local associations/organisations
- Since 2020: Web seminars (in English)
- Seminars available: See https://safetyassessor.info/seminars/

Additional Offer



Certificate “DGK Safety Assessor”

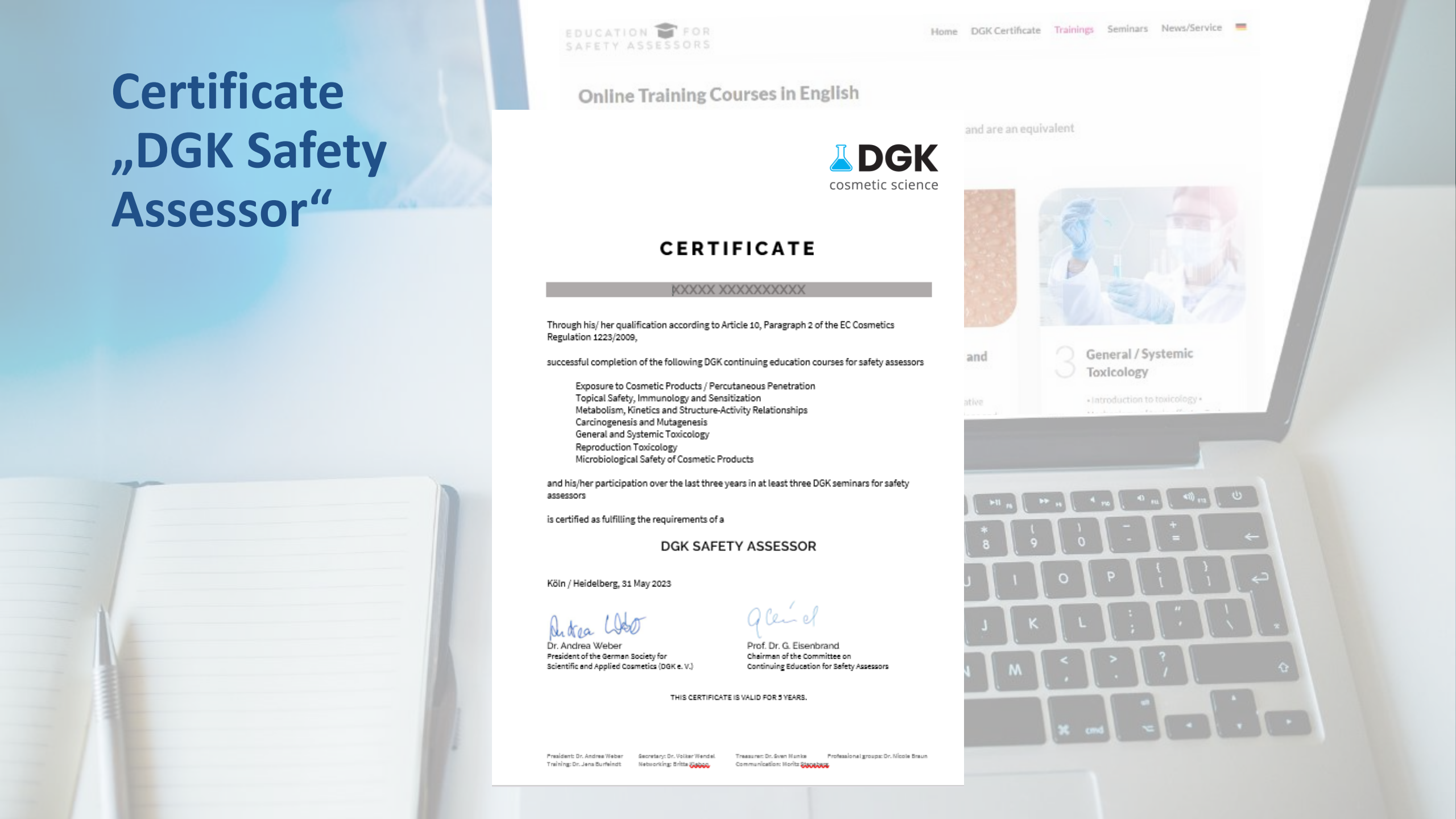
Available upon request – prerequisites:

- Qualification according to Article 10(2) EC Cosmetic Products Regulation
- Successful completion of all 7 (8) DGK/IKW education trainings for safety assessors (in person and/or web)
- Participation in at least three (web) seminars or other trainings relevant for safety assessors over the last three years

Certificate is valid for 5 years

More information: https://safetyassessor.info/dgk-certificate/

Certificate „DGK Safety Assessor“



A Success Story

- The DGK/IKW education programme for safety assessors is an additional tool to obtain the detailed knowledge and specific qualifications which are necessary to be able to perform a scientific sound safety assessment
- It is a unique education scheme worldwide
- There’s no official recognition of this education scheme in the EU,
  nor is there any official requirement to pass these courses
- The courses, however, are highly esteemed by the EU authorities



SINCE 1998

DGK cosmetic science

IKW

EDUCATION FOR SAFETY ASSESSORS

Contact

Jens Burfeindt: jburfeindt@ikw.org



www.ikw.org

Birgit Huber: bhuber@ikw.org



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Thank you for your attention