

Safety Assessor Qualifications

ERPA POSITION PAPER

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A. Current legislation-References

1. Regulation 1223/2009/EC

- Article 11 - Product information file
 - *“2. The product information file shall contain the following information and data which shall be updated as necessary:*
 - ...
 - *(b) the cosmetic product safety report referred to in Article 10(1);;”*
- Article 10 - Safety assessment
 - *“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.*
...
 - *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.**”*

B. Issues arising from the above articles

Since the above requirements for the Safety Assessor are relatively vague it is up to each Responsible Person (RP) and the National Authorities of each EU Member State to either accept or reject a Safety Assessment/Safety Assessor. As the RP needs for more specific qualifications for a Safety Assessor the purpose of this position paper is to provide recommendations on the qualifications of the Safety Assessor.

C. Proposal for safety assessor qualifications

A Safety Assessor should meet the below criteria:

1. To hold a post graduate degree (MSc or PhD) of a European Union university course of theoretical and practical study in Chemistry, Pharmaceutical Sciences, Toxicology, Medicine, Biology, Biochemistry, Pharmacology or similar life sciences discipline or a course recognized as equivalent by a Member State and at least 3 years of proven knowledge on production, research and development and/or safety evaluation of cosmetic products.

Any person that does not meet the above shall not be considered Safety Assessor and shall not sign Safety Assessments.

Qualifications of a Safety Assessor shall be clear in his/her CV.

It is responsibility of the RP to evaluate the qualifications of the Safety Assessor.

The Safety Assessor shall be educated continuously when it comes to scientific papers, symposiums, conferences, exhibitions etc. regarding cosmetic products, raw materials and safety references.

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