

Proposed amendment of Article 4 of Regulations for Cosmetic Product Information
File Management

This Draft has been translated into English according to the original Chinese version. If there is any inconsistency or ambiguity between these two versions, the Chinese version shall prevail.

Article 4 A person who has taken cosmetic safety evaluation training courses which are provided domestic or foreign university which complies with Regulations Governing the Assessment and Recognition of Foreign Academic Records by Institutions of Higher Education (hereinafter referred to as " domestic or foreign university"), or by central competent authority, and complied with the following conditions, the person may serve as a signatory for the safety report of product information file mentioned in Subparagraph 16 of Paragraph 1 of the preceding article:

1. who graduated from department of medicine, department of pharmacy, toxicology, cosmetic and other related departments or graduate schools at the domestic university or the foreign university.
2. Who had at least five years of relevant work experience in cosmetic safety evaluation, and graduated from the department of chemistry or chemical engineering at the domestic or foreign university before 2019.6.30.

The content and hours of cosmetic safety evaluation training courses mentioned in the preceding paragraph shall be:

1. Cosmetic management regulations: including cosmetic hygiene management regulations of R.O.C (Taiwan), international cosmetic hygiene regulations, and the system of cosmetic product information file in R.O.C. (Taiwan); at least 4 hours.
2. Applications and risks of cosmetic ingredients: including the action principles and safety of whitening, sunscreen, antiperspirant, deodorant, hair-dyeing, permanent waving and other ingredients, and common cosmetic adverse effects and violations; at least 8 hours.
3. Methods of cosmetic safety evaluation: including skin anatomy and

physiology, cosmetic percutaneous absorption capacity, skin irritation, the mechanism and symptom of photoaging and photoallergy, the safety evaluation of nanomaterials, the safety evaluation of natural substance cosmetic, the cosmetic risk assessment, toxicological evaluation methods(skin irritation, skin sensitization, skin corrosivity, eye irritation and genetic toxicity and mutagenicity test), systemic toxicity and margin of safety, and alternative methods of animal testing; at least 36 hours.

4. Concluding the product safety evaluation: at least 6 hours.