HOW TO PLACE A COSMETIC PRODUCT ON THE EU MARKET?

REGULATION (EC) NO 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 30 NOVEMBER 2009 ON COSMETIC PRODUCTS

The Regulation (EC) Nº 1223/2009 on cosmetic products

- was passed in December 2009 and replaced the Cosmetic Directive 76/768/EC.
- is implemented in full from July 2013.
- is establishing standards for cosmetic products that are available on the EU market and providing a high-level of protection for the safety and health of EU citizens.

What you need to do prior placing a cosmetic product on the EU market?

1) It is necessary to prepare supporting documentation for cosmetic product – PIF (***P****roduct* ***I****nformation* ***F****ile*).

2) Prepared documentation (PIF) is necessary for registration of cosmetic product on the European central electronic system for cosmetic products – EU CPNP portal (***C****osmetic* ***P****roduct* ***N****otification* ***P****ortal*).

What documentation should the PIF contain?

The PIF is compiled documentation with information about the cosmetic product and according to the EU Cosmetics Regulation (EC) N° 1223/2009, Article 11, the PIF consists of the following sections:

1. A detailed description of the cosmetic product (the necessary information for connecting cosmetic products with documentation)
2. **C**osmetic **P**roduct **S**afety **R**eport – CPSR
3. A detailed description of the production process (method of manufacturing)
4. Evidence (a signed statement) on compliance with **G**ood **M**anufacturing **P**ractices - GMP
5. A proof of the effects claimed for the cosmetic product (where justified)
6. A statement on testing cosmetic products on animals (or data on animal testing, if conducted, for the purpose of placing on the market outside the European Union)
7. Product labelling, which includes primary and secondary packaging

Who should prepare the cosmetic PIF?

- Cosmetic product manufacturer – file coordinator
- Safety Assessor
- Responsible Person

Who should prepare the cosmetic PIF?

Cosmetic Product Manufacturer

- The cosmetic product manufacturer should ensure the preparation of PIF.

- Most often the manufacturer appoints a person (some employee) to be file coordinator and he/she is responsible for assembling the PIF and for keeping it up to date.

Who should prepare the cosmetic PIF?

Safety Assessor

- **BUT**, the most important part of PIF, Cosmetic Product Safety Report (CPSR), **MUST** be prepared by a qualified 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 recognized as equivalent by a Member State**" (**EC 1223/2009, Art. 10**).

- The Safety Assessor must be a professional who possesses the necessary experience in analysis, evaluation and interpretation of toxicological data.

What are responsibilities of a safety assessor?

- The Safety Assessor performs safety assessment based on a knowledge of cosmetic product ingredients and their properties.
- The Safety Assessor has access to the toxicological and analytical information relevant to the assessment.
- The Safety Assessor should carry out the safety assessment of each cosmetic product, *i.e.*, risk assessment based on a thorough analysis of all available data, conditions of exposure and appropriate consideration of weight of evidence.
- The Safety Assessor is responsible **ONLY** for safety assessment, *i.e.*, CPSR and is not responsible for other parts of the PIF.
- The Safety Assessor is independent and signs the CPSR.

Who should prepare the cosmetic PIF?

Responsible Person

- Finally, the cosmetic product manufacturer out of the EU have to designate a legal or natural person within the community as “Responsible Person”.

- The Responsible Person is responsible for the placing cosmetic products on the EU market and should ensure that each cosmetic product marketed in the EU countries complies with the Cosmetics Regulation (EC) N° 1223/2009.

Who may be a responsible person?

The Responsible Person may be

- Manufacturer (established within the EU)
- Importer
- Distributor
- Any person established in the European Union which is designated by written mandate by the manufacturer (from EU or non-EU countries) or the importer.

What are duties of a responsible person?

The Responsible Person should ensure that each cosmetic product fulfil requirements regarding:

- Product Safety Report - CPSR
- Product Information File - PIF
- Nanomaterials
- Animal testing
- Good Manufacturing Practice – GMP
- Cosmetovigilance, adverse effects
- Claims
- Information to general public
- Compliant formulation
- Labelling
- Samples and analysis
- CPNP Notification

What are duties of a responsible person?

The Responsible Person

- must keep the PIF readily accessible to the competent authorities for a period of 10 years after placing the last batch on the market.
- must ensure that the competent and national authority of the Member State in which the file is kept can access that file easily in electronic or other format (paper), at the location indicated on the label.
- insure that all data is updated when necessary.
- ensure immediate information to competent authorities of the Member State in case of risk to protection of human health (serious undesirable effect that occurred).
- ensure immediate corrective measures, withdrawal/recall if appropriate in case of non-conformities.

For additional information visit www.cosmeticspif.com or contact info@cosmeticspif.com

THANK YOU