federal public service
HEALTH, FOOD CHAIN SAFETY
AND ENVIRONMENT

Directorate-General for
Animals, Plants and Foodstuffs

Inspection Service Consumption Products, Animal Welfare
and CITES
COSMETICS

YOUR LETTER OF

YOUR REF

OUR REF

DATE

ENCL(S)

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SUBJECT Legal requirements for placing a cosmetic product on the Belgian or European market

Legal requirements for placing a cosmetic product on the Belgian or European market

The European cosmetics regulation EC 1223/2009 specifies the legal requirements for cosmetics on the European market. There can still be specific requirements per country (e.g. notification of the activity of manufacture), but the basic requirements are the same for cosmetics in all member states.

In Belgium, the relevant legal texts are the European cosmetics regulation and the Royal Order of July 17, 2012 concerning cosmetics (*Arrêté royal (AR) de 17/07/2013 relatif aux produits cosmétiques*).
A consolidated version of the cosmetics regulation can be found on Internet website http://ec.europa.eu/consumers/sectors/cosmetics/index_en.htm , see menu 'regulatory framework'.
A coordinated version of the Belgian law on cosmetics can be found on the website: www.health.belgium.be, menu: 'my health', 'healthy life', 'cosmetics' (available only in French and Dutch).

The following conditions must be met **before** a cosmetic may be placed on the European market:

- Only cosmetic products for which a legal or natural person is designated **within the Community** as '**responsible person**' shall be placed on the market. (note: Switzerland is not part of the EU / Community). The responsible person guarantees the conformity of the cosmetic product to the cosmetics regulation.
- A complete **product information file** as detailed in articles 10 and 11 and annex of the cosmetics regulation must be held available by the responsible person. Part of this file is the safety assessment of the product. Only safe products may be placed on the market. The method of manufacture and proof of the effect claimed for the cosmetic product must also be available in the product information file.
- The **composition** must be conform to the regulation articles 14 and 15. This means the use of colorants, preservatives and UV-filters is limited to the lists in the annexes (annex IV, VI and VII). Moreover, certain substances are prohibited as cosmetic ingredients (annex II), and certain substances may only be used within certain limits (annex III).
- A **notification per product** must be submitted to the authorities, via the portal site CPNP https://webgate.ec.europa.eu/cpnp/ (articles 13 and 16 of the regulation). The notification entails submitting information on the product, responsible person, labelling, and where applicable, nano materials in the product. A frame formulation must be submitted so that Poison Centres can give adequate response to medical urgencies.
- **Labelling** must be conforming to article 19 of the directive. Labelling must be in an appropriate language. For distribution on the Belgian market, **Dutch and French** are necessary (according to article 8 of the Belgian Law of January 24, 1977 concerning the protection of health of consumers with respect to food stuffs and other products).

Requirements for the Product information file (PIF)

The purpose of this file is to have information readily accessible to the competent authorities of a EU member state.
The PIF contains:

(a) a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product;
(b) the cosmetic product safety report referred to in Article 10(1);
(c) a description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 8;
(d) where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product;
(e) data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries.

A guide was published on the contents of the safety assessment
(see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:315:0082:0105:EN:PDF).
The requirements and methods for the safety assessment are described in the SCCP'S Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (see http://ec.europa.eu/consumers/sectors/cosmetics/scientific-assessment/testing-guidance/index_en.htm).

Labelling

The following information must be on the product container and/or packaging:

- the name and address of the responsible person, and the country of origin for goods manufactured outside the Community;
- the nominal content at the time of packaging;
- the date of minimum durability ('best used before the end of'), OR, for cosmetic products with a minimum durability of more than 30 months: the period of time after opening for which the product can be used without any harm to the consumer (note: some products do not require an indication of minimum durability);
- particular precautions to be observed in use, especially those relate to the use of certain ingredients;
- the batch number of manufacture or the reference for identifying the goods;
- the function of the product, unless it is clear from the presentation of the product;
- a list of ingredients in descending order of weight at the time they are added, preceded by the word 'ingredients'.

If you have any further questions about the cosmetics regulation in Belgium, you can contact our service via e-mail address apf.inspec@health.belgium.be or tel +32 (0)2 524.74.70.