

Security of cosmetics in the EU market – regulations

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Abstract

The main regulations guaranteeing safety of the cosmetic products are regulation No 1223/2009, No 1907/2006 and No 1272/2008. The regulation (EC) No 1223/2009 on cosmetic products harmonizes the rules in the Community in order to achieve an internal market for cosmetic products while ensuring a high level of protection of human health. Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishes procedures for collecting and assessing information on the properties and hazards of substances - including ingredients of cosmetic products. The purpose of Regulation (EC) No 1272/2008 is harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures also cosmetics products for professional use.

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Europe is the global flagship producer of cosmetic products. In 2017, the European cosmetics market was valued at €77.6 billion, making Europe the largest market for cosmetic products in the world. Trade is a critical component of the industry, with trade in cosmetic products and ingredients exceeding €35 billion. Over €20 billion worth of cosmetic products were exported from Europe in 2017 [1]. Among the European countries, Germany has the largest market for cosmetic products, valued at €13.6 billion in 2017, followed by France (€11.3 billion), the UK (€11.1 billion), Italy (€10.1 billion) and Spain (€6.8 billion) [1].

Cosmetic products may include creams, emulsions, lotions, gels and oils for the skin, face masks, tinted bases (liquids, pastes, powders), make-up powders, after-bath powders, hygienic powders, toilet soaps, deodorant soaps, perfumes, toilet waters and eau de Cologne, bath and shower preparations (salts, foams, oils, gels), depilatories, deodorants and anti-perspirants, hair colorants, products for waving, straightening and fixing hair, hair-setting products, hair cleansing products (lotions, powders, shampoos), hair conditioning products (lotions, creams, oils), hairdressing products (lotions, lacquers,

brilliantines), shaving products (creams, foams, lotions), make-up and products removing make-up, products intended for application to the lips, products for care of the teeth and the mouth, products for nail care and make-up, products for external intimate hygiene, sunbathing products, products for tanning without sun, skin-whitening products and anti-wrinkle products [2]. A substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product. Medicinal products, medical devices or biocidal products also not to be cosmetic products [2].

The European cosmetics sector is one of the areas of industrial activity where there is a falsification of products, which may increase the risk to human health. There is a two-level cosmetics safety assessment system in the European Union:

- the first level of security assessment, is safety components of cosmetics product approved by the Scientific Committee on Consumer Safety
- the second level is product evaluation before placing the product on the market.

Cosmetic products should be safe under normal or reasonably foreseeable conditions of use, and should be produced according to good manufacturing practice [2].

The safety of cosmetics ingredients is controlled by:

- The European Commission
- The Scientific Committee on Consumer Safety (SCCS)
- The European Chemicals Agency

SCCS is the Committee, who provides Opinions on health and safety risks (chemical, biological, mechanical and other physical risks) of non-food consumer products (e.g. cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products) and services (e.g. tattooing, artificial sun tanning). At the end of the risk assessment process, the Committee adopts Opinions. The Committee can also, at its own initiative, publish statements on specific topics for example: final opinion on water-soluble zinc salts used in oral hygiene products – SCCS considers that the use of zinc in toothpaste per se is safe for children aged 0.5–5 years [3]. Given

the hazardous properties of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A, 1B and 2, pursuant to Regulation (EC) No 1272/2008 their use in cosmetic products should be prohibited. However, as a hazardous property of a substance does not necessarily always entail a risk, there should be a possibility to allow the use of substances classified as CMR 2 substances where, in view of exposure and concentration, they have been found safe for use in cosmetic products by the SCCS and are regulated by the Commission in the Annexes to the Regulation No. 1223/2009. A safety assessment of substances, particularly those classified as CMR 1A or 1B substances, should consider the overall exposure to such substances stemming from all sources and should also take into account the exposure to those substances of vulnerable population groups, such as children under three years of age, elderly people, pregnant and breast-feeding women and persons with compromised immune responses [2,3]. A number of substances have been identified by the SCCS as likely to cause allergic reactions and it will be necessary to restrict their use and/or impose certain conditions concerning them. In order to ensure that consumers are adequately informed, the presence of these substances should be mentioned in the list of ingredients and consumers' attention should be drawn to the presence of these ingredients. This information should improve the diagnosis of contact allergies among consumers and should enable them to avoid the use of cosmetic products which they do not tolerate. For substances which are likely to cause allergy to a significant part of the population, other restrictive measures such as a ban or a restriction of concentration should be considered [2].

The SCCS acknowledges the standardisation of the allergy test offered by the proposed Allergy Alert Test (AAT). The AAT is suitable test to provide a signal indicative of an allergic reaction to hair dyes when used by laypersons [4].

Cosmetic products shall not contain any of the following:

- (a) prohibited substances — prohibited substances listed in Annex II of the Regulation No. 1223/2009;
- (b) restricted substances — restricted substances which are not used in accordance with the

restrictions laid down in Annex III Regulation of the No. 1223/2009;

- (c) colorants other than those listed in Annex IV;
- (d) preservatives other than those listed in Annex V;
- (e) UV-filters other than those listed in Annex VI [2].

The use in cosmetic products of substances classified as CMR substances, of category 2 shall be prohibited. However, a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products [2].

A major problem is the presence of nanomaterials in cosmetics because they are not thoroughly tested. Groups of cosmetic products containing nanomaterials are personal hygiene products, cosmetics care, beauty cosmetics, perfumery. For every cosmetic product that contains nanomaterials, a high level of protection of human health shall be ensured. Cosmetic products containing nanomaterials shall be notified to the Commission by the responsible person by electronic means six months prior to being placed on the market. The information notified to the Commission shall contain at least the following: the identification and the specification of the nanomaterial, an estimate of the quantity of nanomaterial, the toxicological profile, the safety data of the nanomaterial and the reasonably foreseeable exposure conditions [2,5].

REACH Regulation (Registration, Evaluation, Authorization and Restriction of Chemicals) follows the norms of the Regulation 1223/2009 and it is applied to every substance, which includes the nanomaterial and others components of cosmetic product. According to REACH, manufacturers, importers should ensure that manufacture, market or use substances that do not affect the environment and human health.

So, manufacturers and importers must submit a registration dossier of substances that go to or are manufactured in the EU, above 1 ton/year. When quantities reach or exceed 10, 100 and 1000 tones/year, a safety report (Chemical Safety Report) and a Safety Assessment must be included in the registry [5,6]. Not only the ingredients of the cosmetic product are subject to testing but also the finished cosmetic product. Only cosmetic products for which

a legal or natural person is designated within the Community as 'responsible person' shall be placed on the market. The responsible person shall ensure that:

- (a) the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation are taken into account in the safety assessment
- (b) an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from all existing sources;
- (c) the cosmetic product safety report is kept up to date in view of additional relevant information generated subsequent to placing the product on the market [2].

Prior to placing the cosmetic product on the market the responsible person shall submit, by electronic means, the following information to the Commission:

- the category of cosmetic product and its name or names
- the name and address of the responsible person where the product information file is made readily accessible;
- the country of origin in the case of import
- the Member State in which the cosmetic product is to be placed on the market;
- the contact details of a physical person to contact in the case of necessity
- the presence of substances in the form of nanomaterials
- the name and the Chemicals Abstracts Service (CAS) or EC number of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), of category 1A or 1B
- the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties [2].

Pursuant to Regulation (EC) No. 1223/2009, a prerequisite for placing a cosmetic product on the market in the European Union is notification via the CPNP central cosmetic interface (Cosmetic Products Notification Portal). Information submitted to the CPNP is then made available through the portal to the relevant Competent Authorities, enabling market surveillance, analysis and evaluation, as well as to safe guard against grey market or counterfeit products. The information is also available to Poison Control

Centres and other similar bodies established in individual member states for medical treatment and consumer safety purposes [2].

After notification of cosmetic product must be preparation of the dossier. The product information file shall contain the following information and data which shall be updated as necessary:

- a description of the cosmetic product
- the cosmetic product safety report
- description of the method of manufacturing and a statement on compliance with good manufacturing practice
- data on any animal testing performed by the manufacturer [2].

The product information file shall be kept for a period of ten years following the date on which the last batch of the cosmetic product was placed on the market [2].

When the cosmetic product is placed on the market, the responsible person shall notify to the Commission the original labelling, and, where reasonably legible, a photograph of the corresponding packaging. Specific labelling in order to avoid misuse of the cosmetic product shall be provided. Cosmetic products shall be made available on the market only where the container and packaging of cosmetic products bear the following information in indelible, easily legible and visible lettering:

- the name or registered name and the address of the responsible person
- the nominal content at the time of packaging, given by weight or by volume,
- 'date of minimum durability,
- particular precautions to be observed in use
- the batch number of manufacture
- the function of the cosmetic product
- a list of ingredients [2].

The list of ingredients shall be established in descending order of weight of the ingredients at the time they are added to the cosmetic product. Ingredients in concentrations of less than 1 % may be listed in any order after those in concentrations. All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients of more than 1% [2].

Without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, the responsible person shall ensure that the qualitative and quantitative composition of the cosmetic product and, in the case of perfume and aromatic compositions, the name and code number of the composition and the identity of the supplier, as well as existing data on undesirable effects and serious undesirable effects resulting from use of the cosmetic product are made easily accessible to the public by any appropriate means. The quantitative information regarding composition of the cosmetic product required to be made publicly accessible shall be limited to hazardous substances [2].

In the event of serious undesirable effects, the responsible person and distributors shall without delay notify the following to the competent authority of the Member State where the serious undesirable effect occurred:

- all serious undesirable effects which are known to him or which may reasonably be expected to be known to him;
- the name of the cosmetic product concerned, enabling its specific identification;
- the corrective measures taken by him, if any

Not only the consumer of the cosmetic product but also the professional user is protected. Under Regulation No. 1272/2008 and REACH professional users of cosmetics receive safety data sheets, or safety information. The supplier of cosmetic raw material is required to provide a safety data sheet if the cosmetic raw material is classified as hazardous or has in its composition, in a specified concentration, components classified as hazardous [6,7].

The safety of cosmetics is protected by many regulation acts that cosmetics do not threaten our health and the environment. We as consumers can feel safe because many people are involved in controlling the safety of the cosmetic product.

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