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Regulations governing cosmetic products

editorial

In contrast to medicinal products, cosmetics do not require a marketing authorization. They should also not be confused with medical devices, for which a CE mark is obligatory. Cosmetics are nevertheless well-defined consumer products that are extensively tested by their manufacturer prior to being marketed. They are then subjected to rigorous post-marketing surveillance by the authorities. The manufacturer of a cosmetic product, or its legal representative, must take responsibility for the safety of the product by conforming to various regulations. The specific regulations governing cosmetic products may be consulted on the website of the French Medicines Agency (Agence Française de Sécurité Sanitaire des Produits de Santé - AFSSAPS).

As we are sometimes confronted with the regulations concerning cosmetic products in the course of our Regulatory Affairs activities, we thought it would be useful to provide a brief overview of these regulations, with specific reference to France, in issue no. 24 of the Letter of MediBridge.

As always, this document should be considered as a personal review and we urge you to refer to the published official texts and guidelines in all cases.

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Introduction

For over 30 years, cosmetic products marketed in Europe have been controlled by strict regulations specified in an EU directive transposed into the French Public Health Code (Code de la Santé Publique). The ingredients that can be used in these products, the rules for their labelling, their evaluation, etc. are circumscribed by a precise legal framework designed to ensure consumer safety. The stringent rules applicable to the marketing and post-marketing surveillance of cosmetic products, intended primarily to avoid the occurrence of any adverse effects, are justified by the extensive use of cosmetic products and the wide variety of consumers.

This European directive was amended over 50 times and was transposed into the national regulations of several countries. In 2008, the European Commission proposed to simplify the European legislation governing cosmetic products by transforming these various texts into a single European Regulation applicable throughout the European Union. Publication of this regulation is expected this year.

Definition

According to Article L5131-1 of the French Public Health Code:

"A cosmetic product shall mean any substance or preparation intended to be placed in contact with various external parts of the human body, notably the epidermis, hair and capillary systems, nails, lips and external genital organs, or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, modifying their appearance, protecting them, keeping them in good condition, or correcting body odours."

The order dated June 30th 2000 specifies the categories of cosmetic product (creams, emulsions, lotions, etc.).

The following preparations are not considered as cosmetic products:

- rinses for the eyes, ears and nose, considered as medical devices;
- lubricants, considered as either medicinal products or medical devices;
- food complements designed to achieve an aesthetic objective, considered as food products;
- products used for tattooing, considered as consumer goods.

Regulations

The regulations governing cosmetics are based on the European Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, repeatedly amended and transposed into French law in the Public Health Code.

These regulations are described in the following articles of the Public Health Code:

1. Declaration of manufacturing facilities
   - Declaration (Article R5131-1)
   - Contents of the dossier (Article R5131-2)
2. Composition of cosmetic products (Article R5131-3)
3. Labelling of cosmetic products
   - General provisions (Articles R5131-4 to R5131-6)
   - Derogation for reasons of commercial confidentiality (Articles R5131-7 to R5131-12)
4. Information for the public (Articles R5131-13 to R5131-14)
5. Penal provisions (Articles R5431-1 to R5431-4)

The legal aspects are described in the following articles: L5131-1 to 11, L5431-1 to 4 and L5514-5.

A synthesis of the legislation and regulations in France relating to cosmetic products is provided in the brochure entitled "Cosmetic products" (reference no. 1544), available from the "Direction des Journaux Officiels".

Composition

The composition of cosmetic products is governed by the European Council directive 76/768/CEE providing the following lists in its annexes:

Annex II: List of substances which must not form part of the composition of cosmetic products	Prohibited substances (more than 1000)
Annex III: List of substances which cosmetic products must not contain except subject to the conditions and restrictions laid down	Maximum concentration authorized for certain substances *OR* Restrictions concerning the skin zones on which the product may be applied *OR* Restrictions or prohibition of use for children under 3 years of age *OR* Limitations concerning the mode of use *OR* Perfume substances carrying a risk of allergy
Annex IV: list of colouring agents, Annex VI: list of preservatives, Annex VII: list of ultraviolet filters, allowed for use in cosmetic products	Permitted substances: Colouring agents, preservatives and UV filters

In France, these lists are published in the form of a ministerial order in the "Journal Officiel", and are regularly updated to take into account scientific advances.

Marketing of cosmetic products

Before marketing a cosmetic product, the company must submit the two declarations below and ensure that the cosmetic dossier of the product is available for consultation if required.

➡ **Declaration of the qualitative and quantitative composition of the cosmetic product to the French antipoison centres**

➡ **Declaration of the manufacturing, packaging or importing establishment - Qualified Person (Articles R5131-1 and L5131-2 of the Public Health Code)**

The opening of the establishment assuring the manufacture, packaging or import of the cosmetic product must be declared to the AFSSAPS (a template for this declaration is available on the AFSSAPS website). The exact nature of the activity envisaged and the product categories concerned must be specified. Any modification of these necessitates a new declaration.

One or more Qualified Persons responsible for the manufacture, packaging, import, quality controls, evaluation of safety for human health, and the storage and supervision of raw material and finished product stocks, must be designated. These persons must have the professional qualifications stipulated in the order dated August 25th 1999.

However, according to article L5131-3, the declaration of opening is not required for etablishments importing cosmetic products exclusively from Member States of the European Union (EU) or countries within the European Economic Area (EEA).

➡ **Availability of the cosmetic dossier**

In accordance with article L5131-6 of the Public Health Code, a dossier must be held available for consultation by the authorities, at the address indicated on the product, and must be continuously updated (each of the elements listed below, and each modification of these elements, must be dated).

This cosmetic dossier includes the following elements (article R5131-2):

- qualitative and quantitative composition of the product (for perfumes: the name and code number of the supplier must be specified),
- physicochemical and microbiological specifications of the raw materials and the finished cosmetic product,
- description of the manufacturing and control conditions (methods to be provided) conforming to the Good Manufacturing Practices specified in article L5131-5, notably concerning the shelf-life of the product and the corresponding control method (for products with a shelf-life exceeding 30 months, an optimal duration of use after opening should be established),
- evaluation of the safety of the product with regard to human health, taking into account the toxicological profile of its ingredients, the extent of exposure to these, the population concerned, the shelf-life and any adverse effects identified,
- name, address and professional qualifications of the Qualified Person(s) responsible for evaluating the safety of the product with respect to human health,
- evidence of the effect claimed, if appropriate,
- available data concerning any undesirable effects resulting from use of the product (cosmetovigilance),
- proof of declaration of the composition to the antipoison centres of Paris, Lyon and Marseille,
- data relating to experiments on animals (performed by the manufacturer or by its agents or suppliers).

Ban on animal testing

The 7th amendment of the Cosmetics Directive put an end to the testing of finished cosmetic products and their ingredients on animals. This ban has been in force since September 11th 2004 with respect to finished cosmetic products and since March 11th 2009 for ingredients. However, for products having certain specific effects on health, the deadline is March 11th 2013.

Labelling

The labelling of cosmetics is controlled in France by article L5131-4 and R5131-4 and must indicate:

- the name (or tradename), and registered address(es) of the manufacturer (or the establishment responsible for marketing the product). The address of the site holding the cosmetic dossier is specified (by underlining this address, if several addresses appear on the packaging),
- the country of origin for products manufactured outside the EU or the EEA,
- the nominal content expressed as weight or volume (except for packs containing less than 5 g or 5 mL of the product, free samples or single-application packs),
- the expiry date or "date of minimum durability",

  For products with a minimum durability exceeding 30 months, it is not compulsory to indicate the date of minimum durability. However, the labelling must include the authorized duration of use of the product after opening, or "Period After Opening" (PAO), specified as a number of months indicated within the following symbol (decree no. 2004-1219 of 17/11/2004 + order dated 16/11/2004):

  e.g. 12 months after opening:

- the storage conditions, if appropriate,
- particular precautions for use (article R5131-3) and particular precautions to be respected for cosmetic products intended for professional use,
- the batch number of manufacture (this may be indicated solely on the packaging if the cosmetic product itself is too small),
- the function of the product (unless this is clear from its presentation),
- the list of ingredients in decreasing order of quantity, preceded by the heading "ingredients:".

  Ingredients representing less than 1% of the total composition are indicated in any order, after those present at a concentration above 1%.

  Perfume and aromatic compositions are referred to simply as "perfume" or "aroma". However, any allergenic substances must be indicated (the 26 allergens concerned are listed in the ministerial order dated 17/11/2004).

  Colouring agents are indicated at the end, in any order.

  Each ingredient must be declared using the name established by the International Nomenclature of Cosmetic Ingredients (INCI) Committee of the European Commission, or otherwise its chemical name, its name according to the Cosmetic, Toiletry and Fragrance Association (CTFA) or the European Pharmacopoeia, its INN as defined by the WHO, its EINECS, IUPAC or CAS number, and its colour index.

  If it is impossible to list the ingredients on the packaging, they may be listed on a separate information sheet. The consumer is referred to this list either by an abbreviated indication or by the following symbol:

The AFSSAPS recommends labelling sunscreens according to the explanatory note published by the European Commission on September 22nd 2006. This recommendation, based on French studies, is designed to encourage companies to improve the quality of marketed products on the market by ensuring protection against both UVA and UVB rays and modify the labelling to simplify the comparison of different products and facilitate consumer choice. The various recommendations can be consulted on the AFSSAPS website.

Regulations for biomedical research

Biomedical research on cosmetic products, like that conducted on any health care product, is subject to a specific regulation. This was modified by new legislation, legally binding since August 27th 2006, the date when decree no. 2006-477 of April 26th 2006 on biomedical research came into force. All the legal and regulatory provisions applicable may be found on the AFSSAPS website. However, these provisions do not apply to non-interventional research. This comprises studies conducted in healthy volunteers, using investigative methods involving negligible risk and testing cosmetic products demonstrated to be safe and applied under the normal conditions of use (R1121-2).

Good Manufacturing Practices (GMP)

Guidelines on GMP have been published in the compendium "Cosmetic Good Manufacturing Practices" (CGMP; 1995) and also in the EN ISO 22716 standard, which is not legally binding.

The ISO 22716 standard, published in November 2007, contains guidelines for the production, control, storage and transport of cosmetic products.

These guidelines address the quality of the product, but as a whole, address neither the safety of factory personnel nor environmental protection. Safety and environmental concerns are the responsibility of the company concerned and may be governed by local regulations and legislation.

The guidelines do not apply to research and development activities or to the distribution of finished products.

In principle, this ISO standard will be adopted as an official text by the European Commission and transposed into French law.

French authorities responsible for cosmetic products: Monitoring - Inspection

In France, three bodies share responsibility for the cosmetic sector:

- the Ministry of Health, in particular the Department of Health (Direction Générale de la Santé - DGS),
- the Ministry of Finance, in particular the Department of Competition, Consumption and Repression of Fraud (Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes - DGCCRF) and the Department of Industry (Direction générale des Entreprises - DGE),
- the AFSSAPS.

With regard to cosmetic products, the activities of the AFSSAPS include keeping abreast of new information, evaluation, safety monitoring, inspections (with the right to intervene on site), sampling, consignment, authorization of clinical trial centres, laboratory controls, and regulatory activities.

The interministerial orders concerning transposition of the annexes of directive 76/768/CEE are issued by the ministry departments cited above, on the basis of proposals by the Director of the AFSSAPS, taking into account the opinion of the Cosmetology Commission created by the order dated June 23rd 2000.

The control of cosmetic products by the AFSSAPS is generally accomplished in cooperation with the DGCCRF and the DRASS (Directions Régionales des Affaires Sanitaires et Sociales).

Reinforcement of controls on cosmetic products intended for use on young children.

In 2008, the AFSSAPS set up a working group charged with determining the strategies currently implemented by the manufacturers of cosmetic products to conform with the obligation to specifically evaluate products intended for use on **children under 3 years of age**. The Agency will also lay particular emphasis on this issue in its inspection program for cosmetic products in 2009.

Cosmetovigilance

According to Article L5131-9 of the French Public Health Code:

Cosmetovigilance comprises all measures implemented to monitor the adverse effects associated with the use of marketed cosmetic products.

It consists in:

- the declaration of all adverse effects and the collection of information concerning these,
- the recording, evaluation and use of this information,
- the performance of studies investigating the safety of use of cosmetic products,
- the implementation and follow-up of corrective measures, if necessary.

Health care professionals must declare any serious adverse effect reported, as well as any adverse effect that appears to meet one of the criteria defining a serious adverse effect.

Companies must declare to the DGCCRF any effect that is inconsistent with the mandatory safety of cosmetic products (article L221-1-3 of the Consumer Code [Code de la Consommation]). They must also keep on file, available to the AFSSAPS on request, details of all adverse effects listed for each of their products.

If serious doubts arise concerning the innocuity of a particular substance, the AFSSAPS may ask manufacturers or importers to provide a list of their cosmetic products that include this substance (article L5131-10 of the Public Health Code).

A form for declaring an adverse effect is available on the AFSSAPS website. This form is primarily intended for health care professionals, but may be completed by anyone who witnesses an adverse effect.

A working group set up at the European level drafted a resolution concerning the organization of a cosmetovigilance system which was adopted on November 8th 2006.

Borderline products

Cosmetic products and medicinal products are governed by two distinct EU directives in which their definition is clearly specified. However, the legislation applicable to certain cosmetics that may resemble medicinal products is sometimes unclear. Besides cosmetics, these so-called "borderline" products may include food complements, biocides, etc.

The transposition of directive no. 2004/27/CE into French legislation by law no. 2007-248, dated February 26th 2007, modified the definition of a medicinal product in the Public Health Code and completed this by the addition of provisions relating to borderline products. In particular, the Public Health Code now specifies that if a product "apparently meets both the definition of a medicinal product, specified in the first paragraph, and that of a product category covered by other EU or national legislation, it should be considered, in case of doubt, as a medicinal product."

At the European level, the "Manual on the scope of application of the Cosmetics Directive 76/768/EEC (art.1(1))" should be used as the basis for deliberation. This document presents the various criteria permitting judgement of whether or not a product is a cosmetic:

- type of product: preparation or substance,
- site of application,
- site of desired effect,
- purpose of the product,
- absence of pharmacological, immunological or metabolic action.

What about the creation of a third category of products intermediate between medicinal products and cosmetic products?

There is now a considerable body of jurisprudence on borderline products and it is worth noting that the decision on how a product should be classified, when there is a doubt as to which set of regulations are applicable, is now made in court.

For example: the AFSSAPS recently issued an opinion stipulating withdrawal from the market of a product against hair loss product, marketed in the form of patch, which was sold as a cosmetic product without a marketing authorization. It was ruled that this product corresponded to the definition of a medicinal product in terms of both its presentation and its function: by its presentation in the form of a patch, and by the claimed pharmacological mode of action.

"Visa Publicité Produit", the so-called Visa PP A specifically French concept

Advertising of products presented as being beneficial to health

The visa PP is a control procedure applicable prior to market launch for products presented as "beneficial to health". According to article L5122-14 of the Public Health Code, these are products other than medicinal products claimed to favour the diagnosis, prevention or treatment of diseases, pathological conditions associated with surgery and physiological disorders, the diagnosis or modification of a physical or physiological state, or the restoration, correction or modification of organic functions.

In practice, this procedure principally concerns the advertising of certain cosmetic products presented as being beneficial to health and that of *in vitro* diagnostic tests intended for consumer use.

The Visa PP is granted by the AFSSAPS on the basis of a dossier providing evidence of the effects claimed on all types of advertisement concerning the product and targeting the general public.

Although still in force, the Visa PP has been challenged in the context of EU legislation, as it may be regarded as being inconsistent with the principle of free circulation of goods in the European Union.

Useful links

France

http://www.afssaps.fr/Produits-de-sante/Produits-cosmetiques
http://www.parlonscosmetiques.com/
http://www.febea.fr/

Europe

http://ec.europa.eu/enterprise/cosmetics/index_en.htm
http://ec.europa.eu/enterprise/cosmetics/inci/inci_2006.pdf
http://www.colipa.eu
http://ec.europa.eu/health/ph_risk/committees/04_sccp/04_sccp_en.htm

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