

# A Road Map to Beauty: Exploring the Differences Between the EU Cosmetic Directive (76/768/EEC) and Regulation (EC 1223/2009)

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The cosmetic industry is complex. More than ever, manufacturers and distributors are facing new legislation. As innovative cosmetics as well as the technology behind them emerges and advances through new studies and research, so too does the demand for governance. But deciphering the demands of legislation can be challenging. This particular article will explore the differences between both the EU Cosmetic Directive (76/768/EEC) as well as the EU Cosmetic Regulation (EC 1223/2009).

In order to do so, we have to start with each concept at its most basic form.

A Directive, by definition, is a legislative act that serves to direct, indicate or guide. A directive in the EU represents a guide that every member country has to transpose into its national legislation. However, because some countries are stricter than others about adoption of laws, sometimes rules are not equally applied everywhere as intended, resulting in the need to draft multiple versions of the directive specific to each country.

A Regulation is a legislative act that imposes clear and detailed rules. A regulation is not required to be incorporated into the national laws, but is immediately enforceable in all member states. Keep in mind as well the fact that a regulation only needs to be translated into the national language of the 27 EU member states.

But why do both a regulation and directive exist for cosmetics in the EU?

Well, the EU Cosmetic Directive (76/768/EEC) was originally issued on July 27, 1976 as an initial means of ensuring the safe sale and distribution of cosmetic products within the EU Community market. With a primary goal of protecting overall consumer health, the Directive included rules on the composition, labeling and packaging of cosmetic products.

But as the cosmetic industry advanced utilizing new, ground-breaking technologies and innovations, the legislation supporting it needed to change / evolve too.

The **Cosmetic Regulation 1223/2009** was adopted on the 30<sup>th</sup> of November 2009 to essentially replace the EU Cosmetic Directive. The regulation was created to implement a more robust approach at enforcing product safety and is immediately enforceable because there is no transposition into the laws of individual countries, and only translation into the languages of the EU member countries is required.

Now that you have a general understanding between the difference of a directive and regulation, as well as why one superseded the other in the cosmetic industry, let us explore further differences between both forms of legislation dependent on the country in question.

Several differences regarding notification procedures, the level of standards addressed, as well as labeling protocols exist for implementation of the 76/768/EEC Cosmetic Directive. Allow me to address each separately below:

### 1. Notification

Before placing an imported cosmetic product on the EU market, the responsible person – the manufacturer, the importer or the distributor, depending on the situation – is required to notify all EU member countries in which the product is intended for sale. A manufacturer is considered any natural or legal person who manufactures a cosmetic product or has such a product designed or manufactured, and markets that cosmetic product under his / her name or trademark. A distributor is any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available in the EU Community. An importer is any natural or legal person established within the EU, who places a product from a third country into the EU Community market.

BUT the act of notification can also be subcontracted. The manufacturer, the importer and the distributor may, by written mandate, designate a person established within the EU Community as the “responsible person.”

The notification requirement is different within each specific country the product is sold. For instance, in France, it is required to notify three anti-poison centers (Paris, Lyon and Marseille) in writing. There are specific, required documents to complete with the name of the product (commercial name and brand), name and address of the manufacturer, conditioner or importer, phone and fax numbers, category of the product, date and frame formulation.

The difficulty for importers is that they have to declare in each country in which the cosmetic product is sold. This can be difficult because the notification is not harmonized and must be done in the local language. Currently there are 23 official languages in the EU, and this number is only increasing as the community grows.

Concerning the EC 1223/2009 Regulation, there is only one “e-notification” required via an electronic system for all countries in which the product is sold.

### 2. Level of Standards

The level of market supervision is not the same from country to country, resulting in manufacturing inconsistencies from country to country. These gaps mean the Product Information File (PIF or cosmetic dossier) can differ from country to country. For instance, France has a reputation of strict enforcement as the authorities are very watchful of the cosmetic industry.

### 3. Labelling Differences

Country of origin is not obligatory for some member states under 76/768/EEC. In addition, the claims supervision is different, resulting in a gap between how cosmetic products are marketed in different countries. For example in some countries it is not permissible to use certain claims or words like “slimming,” whereas it may be

permissible in another country. Also, the level of detail required to be included in the presentation of proof for claims differs from country to country.

With all the differences evident, one might start to ponder if there are any areas of harmonization amongst all 27 countries. The needs and requirements for the following below are actually the same in all countries:

- A clear definition of the cosmetic product.
- Ingredients list in annex: there are positive and negative lists of ingredients. Negative lists include ingredients that are prohibited (more than 1,000 exist in the EU). Positive ingredients are permitted ingredients like colorants, preservatives and solar filters. For instance, there are 58 preservatives allowed by the Directive, representing the only ingredients that can be used as preservatives. There is also restriction on the maximum allowable percentage of some ingredients.
- A ban on animal testing: finished cosmetics products are not allowed to be tested on animals. ECVAM (European Centre for the Validation of Alternative Methods) that include “in vitro” methods are in current development for some testing done only on raw materials.
- The rules of labelling are the same except for the country of origin and claims. A translation in the national language is required most of the time.

So in a nutshell, what do we expect the future will look like for manufacturers, responsible parties and end consumers alike?

The global objectives of both the 76/768/EEC Directive and the EC 1223 / 2009 Regulation are to:

- Remove differences and inconsistencies (due to more than 50 different adaptations)
- Avoid divergences in national adoption (Directive vs. Regulation)
- Improve the of products in the EU market

For Manufacturers in particular, the major change is the implementation of Good Manufacturing Practices (GMP) according to the ISO 22716 standard.

Cosmetic products sold in the EU must be manufactured by using GMP. Even if cosmetics are manufactured in the US, if they are intended for sale in the EU, GMP must be applied.

Another major point which may impact a cosmetic company is linked to nanomaterials. A nanomaterial is an insoluble material that is intentionally

manufactured on an atomic and molecular scale. A variety of consumer products such as cosmetics are being made with nanostructured materials to increase their performance. For instance in cosmetics, nanoparticles are used to minimize the appearance of wrinkles or block the absorption of ultra-violet rays. For nanomaterials, a notification must be made to the European Commission six months prior to use in a new product. Labelling, definition and safety assessments are also required.

The new safety report format provides more detail on required safety assessments and information required for consideration. Specific guidelines regarding this point are expected to be published by the European Commission in the beginning of 2011.

For Responsible Persons, Clarification has been made regarding increased manufacturer responsibility and in-market control processes. New responsibilities have been implemented for distributors of cosmetic products.

For Consumers, no major changes have been implemented as of yet, however products should be even safer in the near future as a result of this directive and regulation. Furthermore, information on the exact country of origin, claims, etc will become more apparent to the end consumer.

### **Complementary Information:**

Cosmetic regulation : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:EN:PDF>

### Application - deadlines

