



Steps to Exporting Cosmetics Products to the European Union

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EU cosmetics rules are changing. On **11 July 2013**, the new Cosmetics Regulation (EC 1223/2009) will fully replace the existing Cosmetics Directive (76/768/EEC). Overall, the legislation is simplified and harmonized, with one single rule applying to all EU Member States. However, the new regulation will impact important issues such safety assessment, product notification and labeling. This report provides an overview of the upcoming changes in the cosmetics regulation and advice on how to comply with the new rules.

Steps to exporting cosmetic products to the European Union:

1. Determine if your product is a cosmetic under EU law:

A cosmetic product is defined in EU law as *"any substance or preparation intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, and/or correcting body odors, and/or protecting them or keeping them in good condition."*

This definition is important for products which are at the borderline between cosmetics and other product types such as pharmaceuticals, biocides, medical devices or foods. Your product's classification as a cosmetic establishes your legal obligations, and different obligations apply to different product types placed on the EU market.

For guidance on the classification of products as cosmetics, please see the "Manual on the Scope of Application of the Cosmetics Directive" at the following link:

http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/manual_borderlines_version50_en.pdf

2. Check if your product ingredients are allowed or banned in the EU:

Some ingredients may be banned outright, while others may carry specific restrictions. The Cosmetics Regulation lays out special restrictions for certain ingredients.

- Annex II: list of substances prohibited in cosmetic products
- Annex III: list of substances which cosmetic products may contain only under the restrictions and conditions laid down.
- Annex IV: list of colorants permitted in cosmetic products
- Annex V: list of preservatives permitted in cosmetic products
- Annex VI: list of UV filters allowed in cosmetic products

You should check your product ingredients against the annexes to the existing cosmetics Directive (in force until 11 July 2013) at the following link to make sure your ingredients are allowed and comply with any applicable use restrictions: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1976L0768:20100301:en:PDF>

3. Prepare a Product Information File (PIF):

A Product Information File (PIF) must be prepared for each cosmetic product and made readily accessible to the Competent Authorities for inspections. The PIF encloses all evidence of conformity.

The UK has issued a guidance document in English on how to compile such a dossier (PIF) and carry out a safety assessment. The UK guidance is illustrative and is not binding for other countries. It serves only as an indication for other markets. See pages 25-31: <http://www.bis.gov.uk/assets/biscore/consumer-issues/docs/guide-to-cpsr.pdf>

New! Cosmetic Product Safety Report: The requirements of the product safety assessment are clarified in the new Cosmetics Regulation which will apply on 11 July 2013. All safety-related information must be combined in a cosmetics safety report (CPSR). A CPSR must be prepared for every product placed on the EU market. The safety report (CPSR) is a mandatory part of the product dossier (PIF). See Annex I, available at page 21 of this linked PDF:

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

The safety assessment must be signed by a **qualified safety assessor**. The safety assessor must be "a 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".

4. New! Appoint a Responsible Person:

Starting on 11 July 2013, only cosmetic products for which a legal or natural person is designated within the EU as 'responsible person' can be placed on the market. The responsible person must ensure compliance of the product. The Responsible Person will serve as the primary contact for the product's compliance, and will have its name and contact information on the label. The Responsible Person must also keep the product information file and safety assessment available and up-to-date, and will do the product notification.

The responsible person would usually be the EU manufacturer or importer, the distributor (under certain conditions) or a third party.

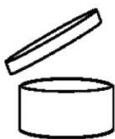
If you are looking for a Responsible Person, please check our website:

http://export.gov/europeanunion/accessingeumarketsinkeyindustrysectors/eg_eu_044318.asp

5. Label your product according to EU rules:

Both the container and packaging must bear, in indelible, easily legible and visible characters, the following information:

- An address in the EU – the name and EU address of the person responsible for the marketing of the cosmetic product in the EU (also where the PIF may be found)
- Nominal content – weight or volume in metric at the time of packaging; dual labeling is allowed.
- Date of durability – the labeling requirements are based on your product's durability.



6 months

First, the open jar symbol is for the "period after opening", which is to be used only on products which have a shelf life of 30 months or more. The number accompanying the open jar indicates the durability of the product after it has been opened.



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New! The hour glass symbol is used for products which have a durability of less than 30 months, and is accompanied by the date of minimum durability. The date must indicate either the month and year, or the day, month and year, in that order.

- Particular precautions for use – warnings and conditions of use
- Batch number - product reference to permit identification
- Product function - unless it is clear from the product presentation
- List of ingredients - Labeling must be listed in descending order of weight at the time added to the product. Product ingredients must be listed according to common ingredient names used in the International Nomenclature of Cosmetics Ingredients (INCI). Please be aware - there are differences between the INCI requirements for the United States and those used in Europe. A list of the European INCI may be found here:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:097:0001:0528:EN:PDF>

- **New!** **Labeling Nanomaterials** – the presence of nanomaterials must be indicated with the term nano in brackets after the ingredient. For example: *Titanium Dioxide [nano]*. Note that products containing nanomaterials must also be notified to the EU with certain safety information.
- **New!** **Country of origin** – the country of origin must be indicated on the label.

Other notes on labeling:

- Language - Label information must be in the national or official language or languages of the respective Member State where the product is marketed. The only exception is the ingredients listing, which must use the INCI ingredient names.

- **Small Packaging** – where it is not practical to print warnings, ingredients, and product use information on the packaging or container itself, a leaflet, label, or card may be provided containing that information. However, the container and packaging must make reference to this leaflet, label, or card, through use of the hand inside an open book symbol. Everything else in the above list must be on the container and packaging.



For more information on how to label products, see pages 13-24 of the UK guidance: <http://www.bis.gov.uk/assets/biscore/consumer-issues/docs/guide-to-cpsr.pdf> The UK guidance is only illustrative for markets other than the UK.

6. Notify your product to authorities:

Notification must be given to the proper authority for every product placed on the EU market. Note that there is no pre-market authorization. Cosmetic products do not require a CE mark. Cosmetics products only have to be notified before you can start selling them on the EU market. There are two ways to notify products:

- **National Notification** - You should notify the national competent authorities and poison centers once the safety assessment has been carried out, and before you place the product on the market. National notification may be done until July 2013. A list of the relevant Competent Authorities is available at this link: http://ec.europa.eu/consumers/sectors/cosmetics/cooperation-trade/eu-level/national-contacts/index_en.htm
- **New! Notification to the EU portal (CPNP)** - The current system of notification of national competent authorities is being replaced by a central electronic notification system at EU level. The procedure is being simplified as one single notification will have to be sent electronically to the EU cosmetic products notification portal (CPNP). The electronic notification system has been in place since January 2012, and EU notification will become mandatory in July 2013. Products already notified at national level must be re-notified to the CPNP. Notification must be done by the EU Responsible Person (see point 4).

7. Check your product's claims:

There are currently no precise guidelines for making claims on products, such as "all-natural" or "organic". The general rule is that *"labeling, marketing, and advertising of cosmetics products, texts, names, trademarks, pictures and figurative or other signs cannot be used to imply that these products have characteristics or functions which they do not have."* If the product claims that its use will produce a certain effect, the PIF must contain information that proves the claim.

The EU Commission is currently developing criteria for common claims. In the meantime, industry associations have stepped in and created their own certifications or collective trademark schemes, but these *industry marks are not legal requirements.*

8. No animal testing allowed:

Animal testing has been banned in the European Union since 2009. An exception has been made until 11 March 2013 for the marketing of products which are tested for repeated-dose toxicity, reproductive toxicity, and toxicokinetics.

9. Rules for specific marketing and sales strategies:

Europe has strict rules for internet marketing, internet sales, and direct sales.

Internet Marketing: The e-commerce Directive (2000/31/EC) imposes specific requirements connected to the direct marketing business. For more information, please see: http://ec.europa.eu/internal_market/e-commerce/index_en.htm

Internet Sales: The EU's Directive on Distance Selling to Consumers (97/7/EC and amendments) sets out a number of obligations for companies selling over the internet. For more information, please see: http://ec.europa.eu/consumers/cons_int/safe_shop/dist_sell/index_en.htm
http://ec.europa.eu/consumers/rights/gen_rights_en.htm

Direct Sales: Where sales are conducted by unsolicited visits to a consumer's home or work, specific rules apply. For more information, please see the Council Directive 85/577/EEC on protection of consumers in contracts negotiated off business premises: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1985:372:0031:0033:EN:PDF>

10. Secure trademark protection:

You may wish to obtain a trademark for your products. The easiest way to register your trademark is to file an application online through the Office for Harmonization in the Internal Market (OHIM). The online application will allow you to get recognition for your trademark throughout Europe. Information on the application process through OHIM may be found at the following link: <http://oami.europa.eu/ows/rw/pages/CTM/regProcess/regProcess.en.do>

For more information:

Link to the Cosmetics Regulation (1223/2009): <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF>

European Commission Website (DG Consumer Affairs): http://ec.europa.eu/consumers/sectors/cosmetics/index_en.htm

More questions? E-mail Office.BrusselsEC@trade.gov

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