



Exporting Cosmetics to the EU

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Are you exporting or planning to export cosmetic products to the European Union? This report from the U.S. Foreign Commercial Service will guide you through the legal requirements for placing cosmetics on the EU market.

Regulation (EC) n.1223/2009 on cosmetic products is the main piece of legislation concerning cosmetic products in Europe. Cosmetics must comply with strict requirements regarding product composition, labeling and safety information. Cosmetics must be notified to a central EU portal and the role of a "Responsible Person" based in the EU is clearly established.

The report identifies 5 key steps for exporting cosmetics to the EU:

- 1. Appoint a Responsible Person in the EU**
- 2. Check that no ingredients are subject to EU bans or restrictions**
- 3. Prepare a Product Safety Report**
- 4. Label your product according to EU rules**
- 5. Notify the product** via the EU Cosmetic Product Notification Portal (CPNP).

After notification, your product is ready to be sold on the EU market.

5 steps to exporting cosmetics to the EU

Step 1. Appoint a Responsible Person:

It is mandatory to appoint a cosmetics Responsible Person in the EU to be able to put the products on the EU market. The EU responsible person must ensure that the product placed on the EU market is safe and complies with the EU cosmetics Regulation (EC 1223/2009). The Responsible Person acts as the primary contact point for authorities, and his name and contact information are placed on the label and product documentation. He must keep the product information file available to competent authorities and notify the product on the EU CPNP portal (see steps 2 to 5). There must be only one Responsible Person per product.

For imported cosmetics, the Regulation designates, by default, the EU importer as the Responsible Person. Many U.S. exporters choose to appoint a specialized consultant or law firm rather than rely on their importer for strategic commercial reasons. U.S. exporters interested in retaining a professional Responsible Person should consult our list of Business Service Providers: <https://2016.export.gov/europeanunion/cosmetics/index.asp>

Step 2. Check that no ingredients are subject to EU bans or restrictions

Cosmetic products' definition:

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. Not all products that are cosmetics in the US would be classified as cosmetics in the EU. Your product's classification as a cosmetic establishes your legal obligations, and different obligations apply to different product types placed on the EU market. The EU manual on the scope of application of the cosmetics directive is useful in making this determination: http://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products_en

Product composition:

Cosmetic ingredients such as preservatives, colorants, hair colors, UV-filters, fragrances and nanomaterials are specifically controlled under the EU cosmetics regulation. Some are banned, while others carry specific restrictions. They are listed in annex to the regulation:

- Annex II: list of prohibited substances (more than 1.000 substances). They include carcinogens (CMRs). When they are CMRs category 2, 1A, 1B, they are prohibited.
- Annex III: list of restricted substances (approximately 300 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

These annexes are regularly updated. US exporters should monitor them to ensure that their products are not subject to EU bans or restrictions:

https://ec.europa.eu/growth/sectors/cosmetics/products_en

Nanomaterials: Nanomaterials are defined as “insoluble or bio-persistent particles on the scale from 1 to 100 nanometer”. In line with the cosmetics regulation, nanomaterials must 1) appear on the product’s label, 2) be notified to the European Commission 6 months before placing the product containing them on the market, 3) undergo a safety assessment if the European Commission has a concern regarding their safety (see steps 4 and 5).

If the Responsible Person and/or the distributor is made aware of a **serious undesirable effects** (SUE) of the product, he has the obligation to inform national authorities and poison centers: <http://ec.europa.eu/growth/sectors/cosmetics/market-surveillance/>

No animal testing allowed:

Since 2013, the Regulation prohibits products where the final formulation has been subject to animal testing and products containing ingredients which have been tested on animals.

Step 3. Prepare a Product Information File (PIF):

Manufacturers need to follow specific safety requirements prior to placing a product on the EU market.

A Product Information File (PIF) must be prepared for each cosmetic product, before placing on the market, and made readily accessible to the Competent Authorities for inspections (for 10 years, electronically and in the language of the country where it is kept) by the Responsible Person at the address shown on the label. The PIF encloses all evidence of conformity:

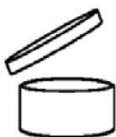
- The product description
- The cosmetics safety report (CPSR), done in compliance with Annex I of the Regulation and done by a certified safety assessor (The safety assessor needs to have an EU degree in toxicology, pharmacy or medicine or an equivalent US qualification). The CPSR has two parts: A) Safety information and B) Safety assessment.
- The method of manufacture and a statement of compliance with Good Manufacturing Practices (GMP). Compliance with standard EN ISO 22716:2007 gives presumption of conformity with GMP for the production, control, storage and shipment of cosmetic products. The compliance declaration must be included in the PIF of each cosmetic product.

- Information on any animal testing performed.
- The proof of the effect claimed: The responsible person must ensure that all **claims** about the product can be supported by evidence, in line with EU regulation 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products. Authorities may verify claims, e.g. if claims says "48h efficacy", it has to be proven scientifically.

Step 4. Label your product according to EU rules:

Cosmetic products cannot be placed on the EU market without fully compliant labels. 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 compliance with the rules.
- 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" (PAO), 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 (Minimum date of durability or period after opening).



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.

- Batch number - product reference to permit identification
- Particular precautions for use – warnings and conditions of use (i.e. 'Do not swallow')
- Product function - unless it is clear from the product presentation (i.e: 'shampoo').
- List of ingredients (which may be indicated on the outer packaging only) - 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 name**). Please be aware - there are differences between the INCI requirements for the United States and those used in Europe. Check CosIng, the EU database for information on cosmetic substances and ingredients: <http://ec.europa.eu/growth/tools-databases/cosing/>

Labeling Nanomaterials – the presence of nanomaterials must be indicated with the term nano in brackets after the ingredient. For example, sunscreens containing titanium dioxide nanoparticles should read: *Titanium Dioxide [nano]*.

- 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 sold. At the moment, full translation is required in Austria, Bulgaria, France, Poland, Portugal and Slovakia. For other EU countries, you only need to translate the product function, composition, the precautions of use and warnings in the local language. For ingredients listing, you must use the INCI ingredient names (see above).



- 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 a practical example, check the European Cosmetics Association's guidance "Understanding the label":

<https://www.cosmeticseurope.eu/cosmetic-products/understanding-label>

Step 5. Notify using the Cosmetic Product Notification Portal:

Cosmetic products do not require a CE mark. There is no pre-market authorization.

However, before placing cosmetic products on the EU market, the responsible person must indicate to the European Commission, via the EU Cosmetic Products Notification Portal (CPNP) the following information:

- Name and product category
- Name and address of the Responsible Person
- Country of origin
- Country of first importation
- Presence of nanomaterials and CMRs
- Product composition.

This European notification replaces the notification to national authorities and national poison centers. One notification is sufficient for the entire EU.

Notification must be done by the Responsible Person.

As described above, cosmetic products containing **nanomaterials** must be notified to the European Commission 6 months prior to their placing on the EU market.

More on the **CPNP portal**: <http://ec.europa.eu/growth/sectors/cosmetics/cpnp/>

Market surveillance: Customs checks and in-market controls, done by the Member States' authorities, ensure that only cosmetic products which conform to EU provisions are placed on the EU market.

Other legislation affecting U.S. exporters of cosmetics:

Online sales: Cosmetics sold over the internet must comply with the Cosmetics Regulation. In addition, they are subject to EU e-Commerce legislation:
https://europa.eu/youreurope/business/sell-abroad/on-line/index_en.htm

Chemicals: Contact the U.S. Commercial Service at the U.S. Mission to the EU for latest developments of EU chemicals legislation (REACH regulation) that may affect cosmetic products: Office.BrusselsEC@trade.gov. Recent EU decisions include the restriction of the silicone compounds D4, D5 in wash-off cosmetic products. The new restriction applies from 1 February 2020 (Regulation 2018/35).

Useful links:

EU Cosmetics Regulation:
<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1223&from=EN>

European Commission: <https://ec.europa.eu/growth/sectors/cosmetics>

Cosmetics Europe: <https://www.cosmeticseurope.eu/>

Personal Care Products Council (PCPC): <https://www.personalcarecouncil.org/>

More questions?

E-mail Office.BrusselsEC@trade.gov

The U.S. Commercial Service at the U.S. Mission to the European Union is located at Boulevard du Regent 27, Brussels 1000, Belgium, and can be contacted at +32 2 811 4817. See also: www.export.gov/europeanunion.

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What Next?

For assistance, find your local Export Assistance Center at: www.export.gov or reach out to the US and Foreign Commercial Service specialists in Europe

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