Cosmetics

Exporting to the EU

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1 Introduction

The cosmetics sector is particularly attractive to general exporters due to the low import tariffs imposed by the EU. For example, there is a zero-tariff charged on hair products, manicure and pedicure products, perfumes, many essential oils and lip and eye makeup. Information about these tariffs can be found on the TARIC Database, a website maintained by the European Commission (EC).

Section 1 of this report provides information on the categories of products covered by the Cosmetics Regulation. Section 2 outlines the regulatory process required to place a cosmetic product on the EU market. Section 3 explains how exporters can identify regulatory requirements for the use of specific ingredients. Section 4 discusses the prohibition of selling products that contain ingredients that have been tested on animals. Section 5 addresses enforcement. Section 6 explains requirements concerning nanomaterials, and Section 7 provides links to websites containing more specialized information.

2 Definition of "Cosmetic Products"

2.1 Cosmetic Product Definition

The EU Cosmetics Regulation applies to:
"any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, 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, changing their appearance, protecting them, keeping them in good condition or correcting body odors"

In other words, the regulation applies to a range of products. Products covered by the regulation include not only traditional cosmetic products such as perfumes, fragrances and make-up, but also personal care products (i.e. lotions, skin products, soaps, facemasks, toiletries, bath products, deodorants, hair care products and sunscreen). An extensive, but illustrative, list of products is contained in Annex I of the now obsolete EU Cosmetics Directive.

2.2 Borderline Products

For some products, it may be difficult to determine if the most appropriate classification is a cosmetic, medicine or biocide. These products are often referred to as “borderline products”. For example, anti-cavity toothpaste is classified as “cosmetic” in the EU. Sunscreen containing mosquito repellant is an example of a product that could be regulated in the EU as either a cosmetic or a biocide.

Exporters are responsible for the correct classification of their product and are subject to legal challenge by the national authorities of the EU Member States. In borderline cases, exporters should consider the following when classifying their product(s):

- the purpose and use of the product;
- the marketing/presentation of the product; and,
- the properties of all the ingredients used to manufacture the product.

The EC has published a website to help businesses make an informed decision on the correct classification of their products.

3 Required Measures for Placing a Cosmetic Product on the EU Market

All cosmetic and personal care products may be marketed freely within the EU market provided they:

- are subject to the oversight of a Responsible Person;
- are supported by a Product Information File (PIF);
- have been notified on the Cosmetic Products Notification Portal (CPNP); and
- have the correct labeling.

The following sub-sections discuss each of these elements.

3.1 Responsible Person

The Cosmetics Regulation requires that non-EU based exporters of cosmetic products retain a Responsible Person. The primary role of the Responsible Person is to certify that the exported

products are safe, meet all the legal requirements for being placed on the EU market and maintain a copy of the PIF should any questions arise about the safety of a product or compliance. Additionally, only the Responsible Person can submit the notification dossier on the CPNP.

By default, the Cosmetics Regulation designates the importer as the Responsible Person in the event the non-EU based manufacturer fails to appoint one. Many exporters choose to retain a specialized consultant or law firm rather than rely on their importer(s) for commercial reasons. Exporters should note that some Responsible Persons consider it necessary to have a separate agreement with the importer formally acknowledging their status as the Responsible Person.

3.2 Product Information File

Article 11 of the Cosmetics Regulation requires that the Responsible Person retain a PIF for each product their client places on the EU market. The PIF consists of the following elements:

A description of the cosmetic product;

- A cosmetic product safety report (Note: Annex I of the Cosmetics Regulation sets out the requirements of the product safety report.);
- A description of the method of manufacturing and a statement on compliance with
- good manufacturing practice;
- Where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product; and,
- Data on any animal testing performed relating to the development, safety evaluation of the product, or its ingredients regardless of where such tests occurred.

The Responsible Person is required to make the PIF available to the national authorities of the EU Member States in “a language which can be easily understood” by those authorities. The Responsible Person must retain a copy of the PIF for 10 years following the date in which the last shipment of the relevant product was placed on the EU market.

3.3 Notification

As mentioned above, cosmetic and personal care products placed on the EU market must be notified to the EC using the CPNP. The CPNP enables companies to inform the EC about:

- the type of product(s) that the company is placing on the EU market;
- the identity and contact information of the Responsible Person;
- the country of origin;
- the Member State where the product will be placed on the market;
- information about the presence of any substances contained in a nano form;
- the name and the CAS or EC number of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1A or 1B, under part 3 of Annex VI
- to Regulation (EC) No 1272/2008; and,
- the frame formulation of the product.

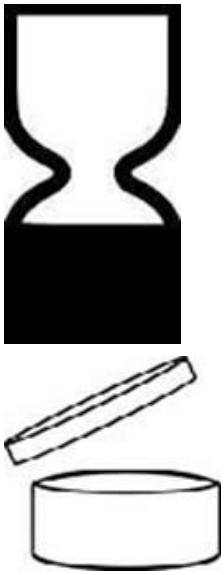
The EC forwards this information to the EU Member State authorities which use it for market surveillance, market analysis, consumer information, and medical treatment.

Although notifying through the CPNP is mandatory, it is distinct from a pre-market approval system as once the product is notified, the exporter can begin shipping the product.

3.4 General Labeling Requirements

The EU Cosmetics Regulation contains special labeling rules applicable to cosmetic and personal care products; however, it does not require the affixation of a CE mark. Rather, the Regulation requires the following be “indelible, easily legible and visible” on the container and packaging:

- the name and address of the Responsible Person;
- the nominal content at the time of packaging (by weight or by volume) expressed in metric units (Dual labeling is permitted.);
- the date of durability (This information is indicated either by the hourglass or open
- cream jar symbol each depicted below. The hourglass is used to show how long a particular product will perform the desired function. The date must indicate the month and year, or the day, month and year, in that order. The open cream jar is used to show how long a product may perform the desired function after opening.);



- use instructions including any relevant precautions;
- batch number or other reference for identifying the goods;
- a statement of the function of the product (unless it is clear from the presentation of the product); and,
- a complete list of ingredients contained in the cosmetic product must be given, preceded by the word" ingredients".

Member States may require the above information to be labeled in their national or official languages.

Also, exporters should note that if it is not practical to print the warnings, ingredients, and product use information on the packaging or container, a leaflet, label, tape, or card must be provided to the consumer. In such cases, the packaging must make a reference by either abbreviated information or with a graphic symbol of a hand inside an open book.

Cosmetics Europe, the association representing the European cosmetics industry, has made available to the public guidelines for product labeling on their website.

3.5 Special Considerations for Labeling of Ingredients

Ingredients must be labeled according to the International Nomenclature for Cosmetic Ingredients, known by the acronym “INCI” corresponding to EU.

Companies seeking to avoid re-labeling their products when exporting to other countries may want to include both the U.S. and the EU INCI name on the label, enclosing one of the two in parentheses.

Perfume and aromatic compositions can simply be referred to by the words 'perfume' or 'aroma', except where these have been identified as a potential cause of contact-allergy reactions in fragrance-sensitive consumers.
All ingredients must be listed in descending order of weight at the time added to the product. In addition, special rules apply to the labeling of products containing nanomaterials and sunscreens.

Nanomaterials must be identified by the word [nano] in brackets (as shown).

3.6 “Not tested on animals” Labeling

The EU Cosmetics Regulation (more specifically, Article 20 (3) allows manufacturers to identify their products as not having been subject to animal testing. In addition, the EC has published specific guidelines to companies desiring to make such claims. Although these guidelines refer to the obsolete EU Cosmetics Directive, they remain valid.

4 Use of Ingredients

Annexes II, III, IV, V and VI of the EU Cosmetics Regulation identify substances that are either banned from products destined for sale within in the EU, subject to restrictions or, in the case of colorants, preservatives and UV filters, are expressly permitted. These Annexes are often updated; therefore, exporters should take care to monitor them so as to ensure that their products will not be caught by a recent regulatory change.

4.1 Use of Ingredients Classified as Carcinogenic, Mutagenic or Toxic for Reproduction (CMR)

In general, the EU Cosmetics Regulation prohibits companies from using CMRs in cosmetic and personal care products. However, CMRs contained in categories 1A and 1B may be permitted provided that the following risk management criteria as set-out in Article 15(2) of the Cosmetics Regulation are fulfilled:

- the substance must comply with the food safety requirements of Regulation No.178/2002;
- no suitable alternatives are available;
- the application specifies a particular use of the product category within a known exposure; and,
- they have been evaluated and found to be safe by the SCCS.

A Category 2 CMR substance may be used if evaluated and approved for cosmetic use by the SCCS.
1 The EC amends these Annexes based on opinions adopted by the Scientific Committee for Consumer Safety (SCCS). The SCCS consists of scientific experts appointed to advise the EC and Member States on safety of cosmetic ingredients.

5 Ban on animal testing

EU Cosmetics Regulation prohibits the:

- testing of finished cosmetic products and ingredients on animals (test ban); and,
- marketing of finished cosmetic products and ingredients which were tested on animals (marketing ban).

This ban went into full effect on March 11, 2013. Ingredients used in cosmetic products before this date are exempt from the ban.

The European Court of Justice clarified the scope of the ban in a judgement adopted on September 16, 2016. The court concluded that the placing on the EU market of cosmetic products containing some ingredients that have been tested on animals outside the EU in order to market those products in third countries may be prohibited if the data resulting from that testing is used to prove the safety of the products concerned for the purposes of placing them

on the EU market.

For more information on cosmetics and animal testing, see the EC website.

6 Enforcement

The Cosmetics Regulation establishes both public and private mechanisms of enforcement.

a. Public Enforcement: In-market Product Surveillance
In-market control is ensured by the competent authorities of EU Member States. National authorities, usually Government Ministries, will check products by randomly selecting samples from retail outlets, by reviewing the PIF or in response to consumer complaints. The following link contains a list of the Member State National Authorities.

b. Private Enforcement: Public Access to Information
The Cosmetics Regulation grants consumers the right to ask cosmetic companies to supply information on the composition and any undesirable effect a cosmetic may have. Cosmetics Europe, the European Cosmetic, Toiletry and Perfumery Association, set up a website to provide the public with easy access to cosmetic companies' contact details: http://www.cosmeticseurope.eu.

In addition, U.S. exporters should bear in mind that, in the event a non-compliant cosmetic product is inadvertently placed on the EU market, the Cosmetics Regulation obliges the Responsible Person to take corrective action to bring the non-compliant product(s) into conformity with EU requirements or have the product(s) withdrawn from the market.

7 Nano Materials

The EU Cosmetics Regulation contains specific requirements and procedures for nanomaterials. It defines nanomaterials as "an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to

100 nm".

From 2013, in addition to all other notification requirements, new products containing nanomaterials must be notified to the Commission six months prior to being placed on the market. Notification of products containing nanomaterials already on the market began in 2012.

Certain nanomaterials are exempt from the notification requirement. These are: colorants, UV-filters and preservatives already regulated under Article 11 and nanomaterials that conform to the conditional usage requirements set out in Annex III of the Regulation.

The Nanomaterial information dossier must include the following:

- identification of the nanomaterial including its chemical name (IUPAC) and other descriptors specified in paragraph 2 of the Preamble to Annexes II – VI;
- specification of nanomaterials including size of particles, physical and chemical properties;
- an estimate of the quantity intended to be placed on the market per year;
- the toxicological profile of the nanomaterial;
- safety data related to the category of cosmetic product it is used in; and,
- reasonably foreseeable exposure conditions.

8 Additional Resources

Exporters should check the extent to which their products are affected by other EU legislation including the Directive on Packaging Waste and the Regulation on the registration, evaluation and authorization of chemicals (REACH). For more information on REACH, see our REACH website.

Useful Links:
REACH http://export.gov/europeanunion/reachclp/index.asp

- European Commission

- EU Cosmetics Regulation http://ec.europa.eu/consumers/sectors/cosmetics/documents/revision/index_en.htm
- Scientific Committee for Consumer Safety http://ec.europa.eu/health/scientific_committees/consumer_safety/index_en.htm
- Communication on the animal testing and marketing ban http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/animal_testing/com_at_2013_en.pdf
- Industry Associations Cosmetics Europe https://www.cosmeticseurope.eu
- Independent Cosmetic Manufacturers and Distributors (ICMAD) http://www.icmad.org
- Personal Care Products Council (PCPC) http://www.personalcarecouncil.org
- http://export.gov

ADDENDUM I

EU Export Guide Rules of Origin Glossary