

Cosmetics
Personal care

Export
Business
Europe

How to...

export your cosmetic and personal care products to Europe?

BIORIUS guide for non European companies:

all mandatory regulatory steps
to follow EU Cosmetics Directive



Company Profile

BIORIUS group was created to answer the ever more complex needs of companies desiring to comply with legal obligations linked to their exporting activities.

Our experts assist our clients by informing them about national and international requirements and help them formalize the legal steps necessary to place products on the market or to ensure their compliance.

Being aware that the regulatory aspect is not our clients' main business, we offer them the tools that will enable them concentrate on the growth of their activities in the respect of applying laws.

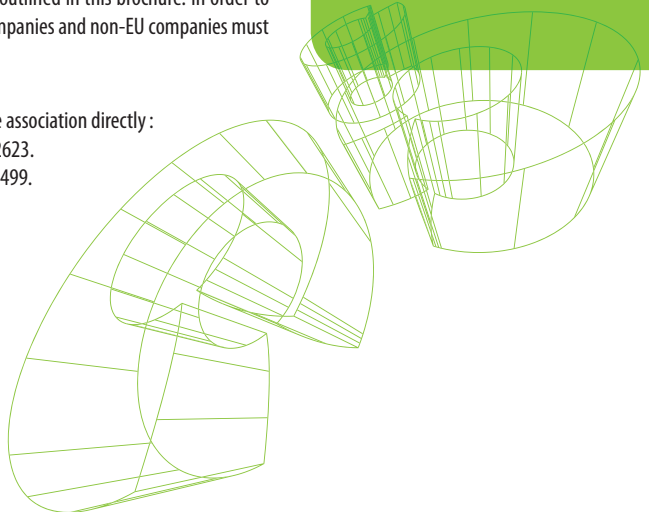
BIORIUS Group offers services in the field of chemicals and has specialized in the cosmetics and dietary supplements sectors. In this brochure, we focused on our specific services. However do not hesitate to contact us to get more details on our other skills!

ICMAD European Legal Representation Program

ICMAD, founded in 1974, is a nonprofit trade association of independent cosmetic manufacturers, distributors and suppliers of services and components to the cosmetic industry. Approximately 90 percent of ICMAD's 650 member companies are small, entrepreneurial businesses in the highly creative and competitive cosmetic, toiletry and fragrance fields.

One of the association's outstanding member benefits is the opportunity to participate in a European legal representation program and use of an address for package labels and notification forms - a requirement for selling products in the 27 countries of the European Union. ICMAD is partnering with BIORIUS in Mons, Belgium, to act as its members' representative and store PIPs on behalf of ICMAD members. BIORIUS also offers additional services for exporting members as outlined in this brochure. In order to participate in this program, U.S. companies and non-EU companies must be ICMAD members.

For more information,
ICMAD members should contact the association directly :
info@icmad.org or call 1-800-334-2623.
If outside the U.S., call 1-847-991-4499.



YOU CANNOT DO WITHOUT...



European Legal Representation

Any non European cosmetics company should designate a legal representative in Europe whose address will be put on the label/packaging of the products. **Biorius assists you with legally authorized representation services in Europe and acts as a legal entity responsible for placing your cosmetic products on the European market in the sense of the European Directive 76/768/EEC.**

The advantage of putting BIORIUS address is that if – for any reason – the distributor changes, the legal representative stays the same and you do not have to re-label your products. The other advantage is that your confidential data (present in the Dossiers) are kept by BIORIUS.

In this regard, we allow our clients to use our contact details in the technical files required when selling products as well as on the product labeling / packaging.

BIORIUS as official legally Authorized Representative offers the following services :

- Use of our contact details on the packaging with an insurance taken out by BIORIUS covering civil responsibility in case of problems
- Secure storage of legal documents in PDF electronic format on our site for immediate availability in case of control by the authorities
- Forwarding of all incoming commercial and informative requests (by e-mail)
- In case of controls, printing of the required legal documents (upon customer formal approval) and reservation of a meeting room

As a well-known regulatory specialist, BIORIUS can support you in case of control and very easily answer the questions of the competent authorities.



Safety Assessments

Each finished cosmetic product is an individual and unique combination of ingredients. The Cosmetics Directive requires that every new product must be assessed for safety to human health **before being launched on the European market.**

The company or person placing a cosmetic product on the market for the first time is responsible for arranging a safety assessment. This must be carried out by a scientist qualified in a relevant discipline with a diploma defined under Article 1 of Directive 89/48/EEC on the recognition of higher education diplomas. The result of the safety assessment must be available for inspection by the competent authorities in EU Member States.

The Cosmetics Directive requires safety assessments to take account of product ingredients, chemical structure and level of exposure. The safety assessment must pay particular attention to where the product will be applied (eyes, mouth, scalp etc) and which population group is expected to use it.

Cosmetic products for children under three years old and products intended for use in external intimate hygiene must undergo specific safety assessments that take account of special needs.

BIORIUS works with several EU certified Safety Assessors who can carry out compliant safety assessments for all your cosmetic products.



Notification to competent authority

The manufacturer or his agent, or the person to whose order a cosmetic product is manufactured, or the person responsible for placing imported cosmetic products on the Community market, shall notify the competent authority of the Member State of the place of manufacture or of the initial importation of the address of the place of manufacture or of initial importation into the Community of the cosmetic products **before the latter are placed** on the Community market.

The notification is a separate document and is not related to the dossier.

A notification does not imply any approval whatsoever. In the EU, cosmetics do not need to be officially approved to be placed on the market.

BIORIUS can notify your cosmetic products to the competent authorities. This notification is valid for all EU countries.

EU COSMETICS DIRECTIVE 76/768/EEC / STEP BY STEP



European Legal Representation

The person responsible for placing an imported cosmetic product on the Community market shall for control purposes keep the information [listed in Art. 7a (a) – (h)] readily accessible to the competent authorities of the Member State concerned at the address specified on the label in accordance with Article 6 (1) (a).“Art. 6 (1)1 (a) requires inter alia the following information labelled on the container and packaging: “[...] the name or style and the address or registered office of the **person responsible for marketing the cosmetic product who is established within the Community**



Safety Assessments

The manufacturer or supplier of the cosmetic product is responsible for ensuring it is safe and each cosmetic must be assessed for safety by a duly qualified safety assessor **before** it is made available to the public.



Notification to competent authority

The manufacturer or his agent, or the person to whose order a cosmetic product is manufactured, or the person responsible for placing imported cosmetic products on the Community market, shall notify the competent authority of the Member State of the place of manufacture or of the initial importation of the address of the place of manufacture or of initial importation into the Community of the cosmetic products **before** the latter are placed on the Community market.



Declaration to Poison Center

Furthermore, a Member State may, for purposes of prompt and appropriate medical treatment in the event of difficulties, require that appropriate and adequate information on substances used in cosmetic products be made available to the competent authority, which shall ensure that that information is used only for the purposes of such treatment. Each Member State shall designate a competent authority and send details thereof to the Commission, which shall publish that information in the Official Journal of the European Communities.



Label review

Member States shall take all measures necessary to ensure that cosmetic products may be marketed only if the container and packaging bear the following information in indelible, easily legible and visible lettering; the information mentioned in point (g) may, however, be indicated on the packaging alone (...)

Member States may require that the particulars provided for in Article 6 (1) (b), (c), (d) and (f) be expressed at least **in their own national or official language or languages**; they may also require that the particulars provided for in Article 6 (1) (g) **be expressed in a language easily understood by the consumer.**



Dossier

The manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market shall for control purposes keep the following information readily accessible to the competent authorities of the Member State concerned at the address specified on the label in accordance with Article 6 (1) (a)

YOU ARE FULLY COMPLIANT WITH...



Declaration to Poison Center

Declaration to Poison Control Centers must be done in each country where the products are sold.

Required for the purpose of prompt and appropriate treatment in the event of difficulties, appropriate and adequate information on substances used in a cosmetic product must be made available (Art. 7(3) Cosmetics Directive).

The Declaration involves a lot of confidential information and very different complicated procedures in several European countries.

BIORIUS specialists declare your products in the required countries while ensuring high level of confidentiality.

This information must be in the national or official language or languages of the respective Member State.

BIORIUS specialists can check your labels in order to make them compliant with EU regulations.



Dossier

Article 7a of the Cosmetics Directive requires any company or person responsible for placing cosmetics on the market in Europe to keep detailed information about all their products. Clearly, the Dossier is neither automatically inspected nor approved. It has to be kept readily available for control purposes.

This information must be made available to national inspection authorities at the address printed on the product's label – inspectors have to be able to track a product on sale in shops to the company or individual responsible for placing it on the market.

The product safety assessment is one of the pieces of information that must be available, along with contact details for the person responsible for completing the assessment.

Other information includes the manufacturing method, physico-chemical and microbiological specifications, and proof of the effect claimed for the product.

A dossier is made of a lot of data and involves a lot of time spent to collect them. It's very important that Dossiers are well done in order to ease as much as possible the data search in case of inspection.

BIORIUS supports you to collect all required data and to create compliant structured Dossiers with all mandatory details.



Label review

In Europe, cosmetic container labels must list all ingredients in the product formulation using identical terms across the whole European Union. These terms are based on the International Nomenclature for Cosmetics Ingredients (INCI) along with descriptions of certain substances specified in the Directive. Containers and/or packaging must bear, in indelible, easily legible and visible characters :

- the name or trade name and address or registered office of the manufacturer or of the **person responsible for marketing the cosmetic product within the Community**;
- the nominal contents at the time of packaging, by weight or by volume;
- for products with a minimum durability of less than 30 months : the date of minimum durability indicated by "Best used before the end of ...";
- for products with a minimum durability of more than 30 months : the period of time after opening for which the product can be used without any harm to the consumer (this information is indicated by a special symbol representing an open cream jar);
- (...)

“A cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product’s presentation, its labeling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the Community market.

Member States shall take all necessary measures to ensure that only cosmetic products which conform to the provisions of this Directive and its Annexes may be put on the market.”

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