

What requirements must natural ingredients for cosmetics comply with to be allowed on the European market?

Cosmetics regulations are becoming more stringent in Europe. Suppliers of natural ingredients from developing countries need to make sure that they comply with European regulations. It is essential for suppliers to keep up to date with regulatory changes in order to ensure they have access to the European market.

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1. Mandatory requirements

Legally mandated requirements

Safety of cosmetics ingredients

Cosmetic Regulation (EC 1223/2009) is the main regulatory framework for cosmetics products on the European market. The regulation affects manufacturers and importers of cosmetics products as well as suppliers of cosmetics ingredients.

Cosmetics ingredients are covered by this regulation from different angles. Cosmetics manufacturers are obliged to provide a Product Information File (PIF), which should include a Cosmetics Product Safety Report. The report should include data on any animal testing performed by the manufacturer, his agents or suppliers relating to the development or safety assessment of the cosmetics product or its ingredients. This also includes animal testing performed to meet the regulations of third countries. Cosmetics manufacturers also need to provide information on the toxicological profile of the ingredients, their chemical structure and their level of exposure.

Suppliers of natural ingredients from developing countries should be prepared to provide data supporting no animal-testing claims. They should also make sure to inform manufacturers of any animal tests relating to development or safety evaluation having been performed. Suppliers of cosmetics ingredients from developing countries need to provide buyers with information on properties and attributes of their ingredients.

Tips:

For more information about the main rules and regulations for cosmetics, see [Regulation \(EC\) No 1223/2009](#) on cosmetics products

Visit the EU Trade Helpdesk for more [information on import rules and taxes in the European Union](#).

Please be aware that Cosmetic Regulation (EC 1223/2009) is subject to constant change and updates. For example, new substances are added to lists of forbidden and restricted substances all the time.

Contact Open Trade Gate Sweden if you have [specific questions regarding rules and requirements in Sweden and the European Union](#).

Look for examples of a [Cosmetics Product Safety Report](#) online.

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is the strictest law to date

regulating chemical substances. Companies headquartered outside of the EU do not have to abide by this protocol. The responsibility lies with the importers established in the EU, or with the sole representative of a non-EU manufacturer established in the EU.

Importers that import more than 1 tonne of natural ingredients are obliged to register them with a REACH central authority. Natural ingredients that are not registered cannot be used in the EU, unless they are exempt. Naturally occurring and chemically unmodified substances, such as vegetables, are exempt from registration.

As a supplier, you can register new cosmetics ingredients yourself by establishing your company as a sole representative in Europe. This would give you more protection as a supplier, as you are not dependent on an importer who is registered. [REACH Registration costs and fees](#) are expensive and may put a lot of pressure on smaller suppliers from developing countries.

With regard to this process, the European Chemicals Agency (ECHA) does provide assistance. You can contact ECHA to find consortia for your product, and you can join such a consortium by signing a letter of access and paying contribution.

Tips:

Even if you supply less than 1 tonne, make sure you comply with the REACH regulation. Buyers may prefer companies that are already registered, as they may look to increase volumes in the future.

Find consortia for your product in Chemical Watch's REACH consortia database.

Setting up a European entity to act on your behalf allows you to 'buy into' these consortia and become registered in their name; however, this involves you contributing to its costs.

If your product is required to be registered, determine whether registering it yourself is worthy of investment. Questions to consider include the value of your ingredient, how much you can supply, and if it will return your substantial investments. You should discuss this with your potential European business partner and determine whether they are prepared to go through the registration process with you. Note that in return, your partner may want exclusivity for the ingredient.

Check how you need to implement REACH for your product in the 'Identify Your Obligations' section on the website of the [European Chemicals Agency](#). This site gives a practical step-by-step guide.

In case of new ingredients, a European importer or a sole representative is responsible for registering new ingredients. Suppliers of natural ingredients from developing countries should look to join a consortium, which could help with reducing costs.

No company is exempt from the requirements for chemical safety, but there could be exemptions from REACH and CLP if other legislation applies. [Check exemptions](#) on the website of the European Chemicals Agency.

Labelling and packaging

The Classification, Labelling and Packaging (CLP) Regulation (CE) 1272/2008 aligns previous EU legislation with the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). It is expected to facilitate global trade and the harmonised communication of hazard information regarding chemicals and to promote regulatory efficiency.

Natural ingredients have to be labelled and packaged in a way that protects workers, consumers, and the environment. It is up to the suppliers to decide the classification of a substance or mixture.

The CLP regulation supplements the REACH regulation. It regulates the notification of classifications, the establishment of a list of harmonised classifications and the creation of a classification and labelling inventory.

According to the CLP regulation, the label should include the following:

- The name, address and telephone number of the supplier
- The nominal quantity of a substance or mixture in packages made available to the general public (unless this quantity is specified elsewhere on the package)
- Product identifiers
- Where applicable, hazard pictograms, signal words, hazard statements, precautionary statements and supplemental information required by other legislation

Suppliers of natural ingredients from developing countries should make sure that their batches are labelled in line with the CLP regulation. Information on potentially dangerous substances must be included on the Safety Data Sheets (SDS), as required by the REACH regulation. If you do not abide by the CLP regulation when exporting to the European market, European buyers will refuse to trade with you.

Tips:

Visit the website of [the European Chemicals Agency](#) for more information on the CLP regulation.

If you do not have enough experience with Safety Data Sheets, use consultants to help you prepare them. One way to do this is by performing basic online searches for consultancies that offer such services. [NEXREG](#) and [Freyr](#) are examples of consultancies offering such services. Another way of finding consultancies is to contact government ministries of trade in the country you are exporting from. This is because they sometimes have experience helping exporters with legal and regulatory issues concerning exports.

Use relevant software applications and databases that contain information that will help you to generate Safety Data Sheets.

If you've made any changes on your existing Safety Data Sheets, communicate this with buyers. You also need to keep a record of the changes you have made.

Efficacy claims

It is common for cosmetics companies to use claims to market their products. However, the EU has robust regulations on cosmetics claims, which protects consumers and helps them make informed decisions. The same rule applies to cosmetics ingredients, especially natural ingredients, as they may have functional and active properties that cosmetics companies may use in their marketing materials.

Commission Regulation (EU) No 655/2013 states that claims for a cosmetics product (explicit or implicit) have to be supported by adequate and verifiable evidence. Commission Regulation (EU) No 655/2013 sets criteria for this evidence, with which companies must comply.

As an ingredient supplier, this can be challenging as you will be required to provide extra documentation to buyers to prove the effectiveness of new ingredients. You can substantiate your claims by using scientific and marketing data that are already published, experimental studies, or consumer perception tests.

Cosmetic Regulation (EC 1223/2009) requires manufacturers to provide a Product Information File (PIF) with technical data necessary for substantiating claims. Suppliers of natural ingredients from developing countries should provide technical and scientific data on the characteristics of their ingredients. There are also specific

requirements related to claims with regard to [sunscreen products](#).

Cosmetics companies are increasingly making claims about natural ingredients in their products. It is expected that this part of EU regulation will become stricter.

Make sure that you comply with Commission Regulation (EU) No 655/2013 when making claims about your ingredients if you want to export your products to the European Union. All your claims must be substantiated by requested materials, such as experimental studies, consumer perception tests or already existing marketing materials.

Tips:

Prepare a dossier for your ingredients to support your claims. There are various ways to support your claims. See the [CBI study on how to prepare a technical dossier for cosmetics ingredients](#) for more information.

Cooperate with universities and scientific organisations when gathering data to back up your claims. Consider approaching these institutions in Europe. This may help you when approaching European buyers.

Evaluate the feasibility of preparing a dossier for your claims. When supplying natural ingredients that are already known to formulators and buyers in Europe, use already existing data.

Biodiversity and species protection

The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), also known as the Washington Convention, is a [multilateral treaty](#). It aims to ensure that international trade in specimens of wild animals and plants do not threaten their survival. The CITES convention became part of the EU law under the Regulation No 338/97. You are therefore required to meet CITES requirements.

CITES has a list of plant species that you cannot export/import or where export/import is restricted. Check if your product is listed in Annex A and Annex B of Regulation (EC) No 338/97. If it is listed, you must obtain an export permit from your country's CITES authority.

Companies in Europe also need to comply with legislation on Access and Benefit-Sharing (ABS). Suppliers of natural ingredients to the cosmetics sector should ensure that they abide by ABS.

Biodiversity regulations such as CITES and ABS are becoming more important in Europe and other regions. This can provide a major challenge to natural ingredient suppliers in developing countries. It can also provide an opportunity if suppliers integrate biodiversity and species protection into their ethical sourcing programmes. This can help them access the European market.

Biodiversity and species protection are likely to become increasingly important for European buyers in the future. Growing awareness among European consumers and increasing demand for more environmentally-friendly products are making cosmetics companies look at ethical sourcing of ingredients.

Tips:

Familiarise yourself with [CITES](#) on its website. Check in the [CITES Annexes](#) whether import and export permits are required for your product.

Contact the relevant CITES authority in your country for an export permit. You may also need an import permit of the country you are importing to in some cases. Contact local authorities for further information.

Keep updated on the [Regulation No 338/97](#) visit eur-lex.europa.eu website.

Check if the sourcing of your natural ingredients falls within the scope of Access and Benefit-Sharing legislation in your country.

Visit the [CBD website](#) for more information. The Convention on Biological Diversity (CBD) provides a range of useful information on CITES and ABS, such as country profiles.

Not legally mandated requirements

Technical documentation

You have to make sure that your technical dossier is organised and well-structured. This is necessary for you to meet mandatory regulations when exporting to the European Union. It is a major source of information with regard to your ingredients and it can be used as evidence of conformity with the relevant legislation.

The technical dossier contains documentation such as Technical Data Sheets (TDS), Safety Data Sheets (SDS) and Certificates of Analysis. Safety Data Sheets contain information on handling, storage, hazards and emergency measures in case of an accident. Based on the information in SDSs, European buyers will be able to make an assessment of potential hazards with regard to sourcing your ingredients. Technical Data Sheets contain information on common applications of your ingredients, industry standard specifications, operating requirements, information on composition and warnings. Certificates of Analysis refer to analytical data that support the product specification.

Having a comprehensive technical dossier is essential for you if you want to export to the European Union. If you do not have one, European buyers may refuse to trade with you and you may lose your reputation as a credible supplier of natural ingredients. It is very important that you invest a substantial amount of time and resources to prepare a well-organised and structured dossier.

2. Additional requirements buyers often have

Sustainable sourcing & CSR

Sustainable sourcing is becoming increasingly important in the cosmetics industry. There is a growing impetus to source raw materials according to ethical practices. Many cosmetics companies and ingredient buyers look at the sustainable sourcing and traceability of natural ingredients.

There are some voluntary standards that cater to this trend. The [Union for Ethical BioTrade](#) (UEBT) certifies natural ingredients that are sourced with respect for biodiversity and the environment. The [Roundtable on Sustainable Palm Oil](#) (RSPO) has a standard for sustainable sourcing of palm oil. The [Initiative for Responsible Carnauba](#) is working to ensure the responsible production of carnauba, which is indigenous to Brazil. The [Responsible Mica Initiative](#) was introduced in February 2017.

Companies are expected to provide greater transparency with regard to the traceability and sustainable production methods of their ingredients. Ethical sourcing is likely to become more important in the cosmetics industry in the coming years. Suppliers of natural ingredients from developing countries should ensure that their ingredients are traceable. Those that do not will find this trend a risk, as they may not meet buyer requirements. For more information on trends related to sustainability and ethical sourcing in the cosmetics sector, see the [CBI study](#) on which trends offer opportunities or risks on the European natural ingredients for

cosmetics market.

Tips:

Register your company on the [Supplier Ethical Data Exchange](#) (SEDEX). This online platform provides a template of the typical information required. It also facilitates sharing this information with potential customers.

Use sustainable sourcing practices, as they can help you make your ingredients competitive on the European market.

Quality management

Quality management standards are becoming increasingly recognised by European buyers of natural ingredients for cosmetics. By adopting specific quality management standards, you show buyers that you are trustworthy and that you consider quality of your ingredients important. Quality standards can help suppliers of natural ingredients from developing countries ensure batch-to-batch consistency.

Examples of quality standards that you can adopt are ISO 22000, FSSC 22000 and ISO 9001:2015. Other common guidelines include [Good Agricultural and Collection Practices](#) and [Hazard Analysis & Critical Control Points](#). If natural ingredients such as essential oils are destined for use in perfumes, you may be required to follow [International Fragrance Association \(IFRA\) standards](#).

The importance of quality standards will increase in the future. European buyers face a lot of pressure from their customers to deliver high-quality raw materials. With more stringent EU regulations and increasing demand for high quality, product buyers look for suppliers of raw materials that can ensure a consistent level of quality.

Tips:

Adopt quality standards that refer to production methods. This shows credibility to European buyers and it can help you when approaching them.

Make sure you communicate the standards and certification that you meet on your marketing materials. An example of an existing exporter of natural ingredients for cosmetics that does this well is [Guru Nanak Oil Mills \(U\) Ltd., Uganda](#).

3. Requirements for niche markets

Natural and organic cosmetics

There is a growing demand for natural and organic cosmetics in Europe. The market was valued at €3.6 billion in 2018. A growing number of cosmetics companies are either developing certified products and/or incorporating certified ingredients into their formulations. Many cosmetics products, as well as raw materials, are becoming certified according to natural and organic standards.

The most common natural and organic standards are [COSMOS](#) and [NaTrue](#). These standards have certification schemes for finished products, as well as raw materials. There are about 25 other natural and organic cosmetics standards in Europe; they include [Nature & Progrès](#), [CCPB](#), [Organic Farmers & Growers](#) and [Demeter](#). Most are

adopted on a national basis, and the adoption rates are relatively low compared to COSMOS and NaTrue.

Natural and organic standards for raw materials will continue to become important in the future. Certifications, such as NaTrue and COSMOS, add credibility to raw materials and are seen as a proof of quality. Ingredient buyers and cosmetics manufacturers often use these labels on their marketing materials and packaging.

Tips:

Look to certify your ingredients natural and/or organic. Make sure you communicate this on your website and your marketing materials.

Review [the COSMOS website](#) and [the NaTrue website](#) for more information. Look at the criteria to have ingredients certified natural/organic.

Target buyers that specialise in natural/organic ingredients. These buyers are well connected with natural and organic cosmetics companies in Europe.

Fair trade

The fair-trade standard was originally an agricultural standard. However, it is increasingly used on cosmetics products. [Fairtrade International](#) has the most popular certification schemes for fair-trade products. Other certification schemes include [Fair for Life/For Life Certification](#), [Ecocert Fair Trade](#), and [FairWild](#). The fair-trade standard is popular with suppliers in developing countries, as it is mainly designed for north-south trade.

Suppliers of natural ingredients from developing countries should consider a fair-trade standard, as it covers the social aspect of sustainable production. These claims are becoming increasingly popular among European consumers.

Suppliers of natural ingredients in developing countries should look to have their products fair-trade certified. The trends of ethical certification will continue to grow in the future. Suppliers are advised to consider FairWild certification for wild harvested ingredients.

Tips:

For a full overview of certification schemes in the sector, consult the [ITC Sustainability Map](#).

Consider [fair-trade certification](#) if it applies to your ingredients. By adopting fair-trade standards, you can increase your credibility and competitiveness on the European market. Producers also enjoy the benefits of fixed minimum prices for their fair-trade ingredients.

Use your fair-trade status to create a marketing story. You can include information about your products and how they are collected and harvested. Examples of existing exporters of natural ingredients for cosmetics that do this well are [FairTale](#) and [The Savannah Fruits Company](#).

This study has been carried out on behalf of CBI by [Ecovia Intelligence](#).

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