

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

Europe's regulations for natural health products are considered strict. At the same time, there are additional buyer requirements for natural ingredients. Suppliers of natural ingredients from developing countries need to ensure they meet regulations and buyer requirements to access the European market.

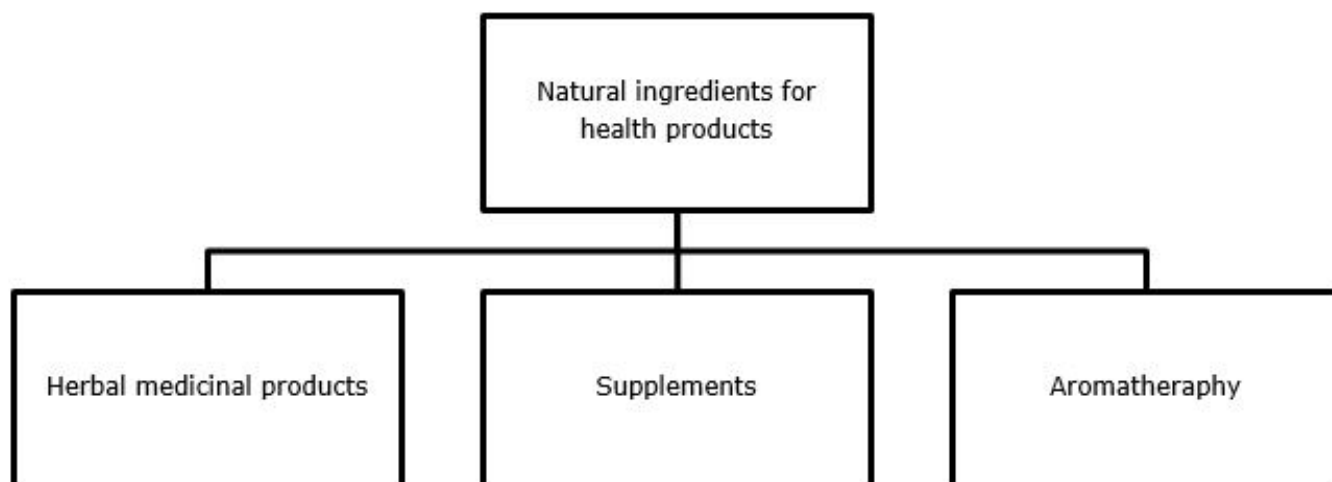
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## 1. What are the mandatory requirements?

This document provides an overview of requirements that exporters of natural ingredients need to comply with when exporting to the European health products sector. The majority of natural ingredients for the health sector are used in supplements and herbal medicinal products. Exporters of natural ingredients from developing countries need to decide what segment they want to target, in order to comply with the right type of regulations. When targeting the aromatherapy sector, you have to follow requirements that apply to the cosmetics sector.

Figure 1: Applications of natural ingredients for health products



## Mandatory requirements for herbal medicinal products

If your natural ingredients are used in herbal medicinal products, you must comply with [EU legislation](#) (Directive 2004/24/EC). Failure to do so will prevent you from entering the European market. You must also comply with 'The rules governing medicinal products in the EU', which state what [marketing claims](#) medicinal products can make.

The [European Medicines Agency](#) (EMA) is the agency responsible for the scientific evaluation, supervision and safety monitoring of medicines in EU Member States. The EMA has a series of standards for the most widely used established ingredients for herbal medicinal products, known as [community herbal monographs](#). If you are a producer of an established ingredient, you must comply with the EMA's monographs.

The EMA's monographs state what claims European manufacturers can make about herbal medicinal products and ingredients used. In your communications, you must therefore use the terminology of the claims made by manufacturers. When marketing your natural ingredients, give details about their use and advantages according

to national legislation. This will help you make a stronger case in marketing your natural ingredients to European buyers.

New natural ingredients in the European market must be registered for use in traditional herbal medicinal products (THMP). If you are a supplier of new ingredients, then you must comply with this procedure. Failure to comply means you cannot enter the European market.

### Tips:

You must comply with [EU legislation](#) (Directive 2004/24/EC) and [rules](#) governing medicinal products in the EU. Failure to do so will prevent you from entering the European market.

You must comply with the rules set by the EMA, for example in community herbal monographs.

European buyers of your natural ingredients for herbal medicinal products may also have additional buyer requirements. Do not enter into an agreement if you are unable to meet these requirements, as this will put your trading relationship at risk.

Check if your natural ingredients for health products are new. If they are, then you must register them. For information on how to do this, click [here](#).

Visit the [EPing](#) website for an overview of country-specific measures that could affect the trade of natural ingredients for health products and that differ from the international standards. You can also find [a list](#) of contact persons per country appointed by the World Trade Organisation (WTO) [here](#).

## Mandatory requirements for food supplements

If your natural ingredients are used in food supplements, you must be compliant with [EU food supplement legislation](#) and the [European General Food Law](#). Compliance is essential; non-compliance will result in your natural ingredients not entering the European market.

Established ingredients for food supplements are listed in the [Novel Food Catalogue](#), the [Union List](#) and the [botanical list](#) for food supplements. If your natural ingredients are not listed here, then you must register them for use. Natural ingredients not sold in Europe before 1997 fall under the EU's Novel Food legislation. If this applies to your natural ingredients, you must have documentation, as well as safety and labelling approval, before they can be used in food supplements.

You must also provide toxicological, microbiological and allergenic-property data. The [new Novel Food Regulation](#) came into force in January 2018. It is important that you follow this regulation.

### Tips:

You must comply with EU food supplement legislation and the European General Food Law at all times.

Determine if your natural ingredients are established for food supplements by checking if they are listed in the Novel Food Catalogue, the Union List or the botanical list for food supplements. If they are not, you must register them.

If your natural ingredients were not sold in the EU before 1997, you must go through the process of registering them, in addition to providing information about them.

You must comply with the new Novel Food Regulation that came into force in January 2018.

Some European countries are signatories to harmonised lists of natural ingredients for food supplements such as [BELFRIT](#); other European countries follow these lists despite not being signatories. Check if your natural ingredients are on these lists and inform prospective European buyers.

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

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

## Protection of Species and Biodiversity

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 plants and animals does not threaten their survival. The CITES convention became part of EU law under [Regulation No 338/97](#).

If your natural ingredient is registered under Annex A and Annex B of EU Regulation (EC) No 338/97, you must obtain an export permit from your country's CITES authority to trade it on the European market.

Companies in Europe also need to comply with legislation on Access and Benefit-Sharing (ABS). Suppliers of natural ingredients to the natural health products 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 be a major challenge for natural ingredients 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.

### Tips:

Learn about CITES by visiting its [website](#). This will give you a better understanding of what legal requirements are expected.

Determine whether your natural ingredients for natural products require import and export permits to enter the European market. Do this by checking if your natural ingredients are listed under CITES' [Annexes](#).

If your natural ingredient requires export permits to enter the European market, then you must obtain these permits. Do this by contacting the relevant CITES authority in your country. Keep in mind that you might need an import permit from the country you are importing to. In such cases, contact local authorities for further assistance.

Regularly check for updates to EU [Regulation No 338/97](#). You can do this by visiting [the eur-lex.europa.eu website](#).

Determine if the sourcing of your natural ingredients requires compliance with Access and Benefit-Sharing legislation in your country. You can do this by visiting the [CBD website](#) for information.

## 2. What additional requirements do buyers often have?

European buyers of natural ingredients for natural health products have additional quality requirements beyond the mandatory requirements set by the EU. In order to successfully establish trade and have a good business relationship with European buyers, you must meet their additional buyer requirements. Failure to do so will only make it difficult for you to trade on the European market.

### Ensuring quality

If you are an exporter of natural ingredients for food supplements, a popular additional buyer requirement is compliance with [Hazard Analysis and Critical Control Points](#) (HACCP). This is because it demonstrates that your natural ingredients are of high quality. You should therefore consider aiming for compliance with HACCP. Doing so will give you an advantage when seeking to enter the European market.

A second common additional buyer requirement from European buyers of natural ingredients is certification of a food management system based on HACCP. This is because having certification suggests high quality of natural ingredients for health products.

The most widely used certification for natural ingredients for health products is Food Safety System Certification ([FSSC 22000](#)). You should therefore consider obtaining FSSC 22000 certification by meeting its quality requirements. Other widely used quality standards are ISO 22000 and ISO 9001:2015. These standards can help you establish trade with European buyers.

In addition to FSSC 22000, buyers often require natural ingredients for natural health products to be in line with British Retail Consortium ([BRC](#)) standards and International Food Safety ([IFS](#)) standards. Determine whether you could benefit from compliance with BRC and IFS standards; note that such compliance will make you more appealing to European buyers.

Consumers are demanding natural health products and the natural ingredients used in them to be of higher quality. In turn, European buyers of natural ingredients require high-quality natural ingredients. Furthermore, EU legislation ensuring the quality of natural ingredients for natural health products is getting stricter. You must therefore meet additional buyer requirements concerning good quality.

The importance of quality management in the health products sector will likely continue to increase in the future. Quality is very important to European consumers and health product manufacturers who want to ensure they meet consumers' needs.

### Tips:

HACCP compliance can be very beneficial. This is an important additional buyer requirement if you wish to enter and establish yourself on the European food supplements market, as it helps to ensure your natural ingredients are of good quality.

Consider obtaining FSSC 22000 certification. This certification is widely used and proves your natural ingredients are of good quality. It will therefore give you an advantage and help you to establish trade with European buyers.

Determine if there is a business case for meeting BRC and IFS standards with your natural ingredients. Note that compliance with these standards will help you in an increasingly competitive market driven by higher buyer demands.

## Meeting social and environmental standards

European consumers and retailers are increasingly putting pressure on companies to ensure that their products are made according to social and environmental standards. European buyers of natural ingredients are therefore requesting that suppliers meet social and environmental standards.

As an exporter, you can do this by gaining verification and certification proving you meet social and environmental standards. One way to demonstrate environmental sustainability is to meet the [UNCTAD BioTrade Initiative BioTrade Principles and Criteria](#), alongside the [FairWild](#) Standard. To prove you meet social standards, acquire [FLO Fairtrade](#) certification or meet [Fair for Life](#) standards.

### Tips:

Acquire verification and certification to demonstrate that your natural ingredients for health products meet social and environmental standards. This will help you find opportunities in the European market.

If your natural ingredients already meet social and environmental standards, inform prospective European buyers of this.

Demand for natural ingredients that meet social and environmental standards is expected to increase over the coming years. You should therefore consider whether there is a business case for investing in such standards.

## Ethical sourcing

Ethical sourcing is becoming important in the export of natural ingredients to the European market, offering an effective way to demonstrate that you are a sustainable supplier of natural ingredients. You can do this by meeting Good Agricultural and Collection Practices (GACP) [guidelines](#).

GACP guidelines are important if your natural ingredients are collected from the wild. This is especially important if your natural ingredients are used in food supplements.

The importance of ethical sourcing is expected to increase in the future. This trend is driven by increasing awareness of European consumers about ingredients in health & natural products. Exporters of natural ingredients from developing countries should ensure that they meet the principles of ethical sourcing.

### Tips:

Meet industry standards for ethical sourcing. You can get details of the Union for Ethical BioTrade charter [here](#).

Meet and implement GACP guidelines. Additionally, ensure you have the relevant documentation proving that you meet GACP guidelines. This will make it easier for you to establish trading relationships with European buyers and enter the European market.

Find out if there is a business case for you to acquire [FairWild](#) certification.

## Transparency and traceability of sourcing

European companies with health & natural products face a lot of pressure to ensure their supply chains are transparent and traceable. Many finished product manufacturers need to disclose information related to ingredient authenticity, raw material origins and social risks in supply chains. Thus, buyers often choose suppliers with transparent supply chains. Buyers need to be able to trace ingredients back to the source.

As an exporter of natural ingredients or health products to Europe, you should have information on production practices, labour practices and environmental issues. Buyers may request that you abide by their code of conduct or sign industry charters. European buyers expect their suppliers to disclose all information necessary.

Increasing demand for transparency and traceability puts additional demands on exporters from developing countries with regard to data collection and information disclosure. However, this can improve business relationships and create a sense of trust between suppliers of natural ingredients from developing countries and European buyers.

The importance of transparency and traceability in supply chains in the health products sector will likely continue to increase in the future. Growing awareness of European consumers is putting pressure on health products companies. Exporters from developing countries should expect this requirement to become even more important in the future.

### Tips:

Use data gathering tools and systems to improve the traceability and reliability of your natural ingredients.

Be prepared to disclose data on raw materials sources, processes and companies involved in the supply chain.

Register your company with 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.

## Documentation

European buyers of natural ingredients request that exporters provide them with well-structured and organised product and company documentation. Doing this will give you an advantage when trying to establish yourself on the European market. On this basis, you can develop long-lasting trading relationships with European buyers. Additionally, it makes you look organised and well prepared to do business with European buyers.

European buyers of natural ingredients for health products usually want exporters to provide them with Safety Data Sheets (SDS). Safety Data Sheets contain a product description, a classification, hazard identification and information on safety measures. European buyers also want to be provided with Technical Data Sheets (TDS). Technical Data Sheets contain a product description, a product classification, a quality analysis, information on applications and certificates.

European buyers also request a Certificate of Analysis (CoA), which contains analytical data on the product delivered. The Certificate of Analysis matches data mentioned in the TDS, the pre-shipment sample that was approved by the buyer and contractual agreements with the buyer.

Consider acquiring SDS, TDS and CoA for your natural ingredients and have them ready for European buyers. Additionally, if you already have them, inform European buyers of this when you approach them.

### Tips:

Consider meeting the demands of European buyers who want documentation concerning your natural ingredients for health products.

If you already have the documentation sought by European buyers, notify them of this.

## 3. What are the requirements for niche markets?

### Organic Ingredients

In Europe, consumer demand for organic products is growing. Many buyers are therefore demanding organic ingredients for their natural health products. Producers in developing countries should therefore consider getting organic certification.

Certified organic ingredients are produced and processed using organic farming techniques, such as crop rotation, biological crop protection and the use of green manure and compost. In order to market your natural ingredients as organic on the European market, you must meet European Union regulations. You can find information on [EU organic certification](#) on the IFOAM website.

Several certification agencies can help you with the conversion to organic production. Once you are certified, many buyers will request a [Certificate of Inspection](#) (COI). The absence of a COI means your natural ingredients cannot be traded as organic.

The demand for certified ingredients for health products on the European market will likely continue to grow in the future. Exporters of natural ingredients from developing countries should consider organic certification when targeting the European market. European buyers will increasingly demand high-quality ingredients.

### Tips:

With increasing demand for organic health products, consider converting to organic production methods and getting certification.

You must have a Certificate of Inspection (COI) which proves your natural ingredients are organic if you want to trade them on the European market.

If your natural ingredients already have a COI, inform prospective European buyers of this.

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

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

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