

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

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The European Union's (EU) 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.

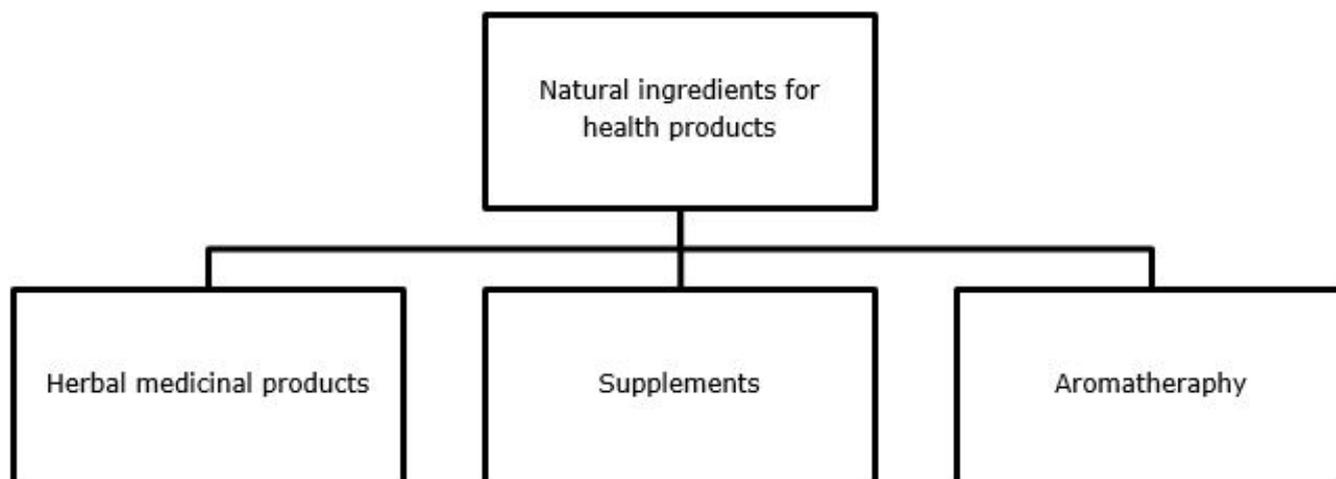
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1. What are the mandatory requirements?

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



Source: Ecovia Intelligence

Mandatory legal 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:

European buyers of your natural ingredients for herbal medicinal products may also have additional buyer requirements. Do not enter into an agreement with buyers if you are unable to meet their 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, visit the [European Commission's herbal medicines product page](#).

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 legal 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 data on toxicological, microbiological and allergenic properties. The [new Novel Food Regulation](#) came into force in January 2018. It is important that you follow this regulation. Ensuring food safety for consumers is extremely important to the EU, with EU regulation concerning food safety expected to become stricter in the coming years.

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:

Visit the [CITES website](#) to learn more about CITES. 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' Appendices](#).

Contact the relevant CITES authority in your country if you require an export permit. Note that you might need an import permit from the country you are importing to. In such cases, contact [local CITES authorities](#) for further assistance.

Regularly check for updates to EU Regulation No 338/97 because regulation is always subject to update and change. 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.

Visit [the Species+ website](#) which is designed to help implement CITES and use its features. Doing so will help you comply with a mandatory requirement that (if applicable) you must comply with to enter the European market.

Non-mandatory legal requirements

Documentation

European buyers of natural ingredients require exporters to provide them with well-structured and organised product and company documentation. They use it to verify whether or not you meet their requirements. Doing this will give you an advantage when trying to establish yourself in the European market from which you can develop long-lasting trading relationships with buyers. Additionally, it gives your business credibility as it makes you look organised and business ready.

European buyers of natural ingredients for health products usually want exporters to provide them with Safety Data Sheets (SDS). Safety Data Sheets must contain the following:

- product description;
- classification;
- hazard identification; and
- information on safety measures.

European buyers also want to be provided with Technical Data Sheets (TDS) which must contain:

- a product description;
- product classification;
- 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.

Thus, you need to prepare an SDS, TDS and CoA for your natural ingredients and have them ready for European buyers. In addition, if you already have relevant documentation for your European buyers, be sure to let them know. Documentation is expected to remain important for European buyers in the coming years, especially when EU regulation is getting stricter.

Tips:

Meet European buyer demands for documentation concerning your natural ingredients for health products.

Ensure that any samples that you send buyers match your documentation. This is because samples are assessed against documentation. For example, do not send samples of lower quality than what you have stated in your documentation.

Review the example [Safety Data Sheet](#), [Technical Data Sheet](#) and [Certificate of Analysis](#) for organic baobab powder.

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. 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 enter and trade on the European market, which is becoming increasingly competitive.

Ensuring quality

If you are an exporter of natural ingredients for food supplements, one 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. Thus, consider aiming for compliance with HACCP as it will give you an advantage when you are 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. You should therefore consider obtaining certification, with the most relevant being:

- International Organization for Standardization (ISO) [22000](#) food safety management system certification and [ISO 9001:2015](#) and quality management systems certification;

Food Safety System Certification ([FSSC 22000](#)) which is based on ISO 22000 and is aimed specifically at food manufacturers. In addition, European buyers often require natural ingredients for natural health products to meet:

- British Retail Consortium Global Standard for Food Safety ([BRCGS](#)) standards which provide technical standards for food safety;
- International Featured Standards ([IFS](#)) which provide several standards concerning food safety.

As such, you should try to determine whether you could benefit from compliance with meeting 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.

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

Tips:

Review the [FAO Guidelines for the implementation for HACCP](#) as it provides useful guidance about implementing HACCP.

Inform prospective European buyers about your compliance with standards and certification you hold demonstrating quality as it will make you more appealing to them.

Ensure you clearly highlight your compliance with standards and certification you hold in your sales and marketing materials. For example, by displaying the certification logos on your company website, marketing materials and product catalogue.

Meeting social and environmental standards

European consumers and retailers are putting increasing pressure on companies to ensure their products are

made according to social and environmental standards. European buyers of natural ingredients are therefore requesting 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:

- [UNCTAD BioTrade Initiative BioTrade Principles and Criteria](#) which provides a framework for the conservation and sustainable use of biodiversity in business and trade;
- [FairWild Standard](#) which is for the sustainable collection, social responsibility and fair-trade principles for wild collected plants.

To prove you meet social standards acquire:

- [Fairtrade International](#) standards which requires producers and traders to meet a range of economic, environmental and social criteria;
- [Ecocert Fair Trade](#) which concerns adequate and safe working conditions, fair pricing and the empowerment and independence of producers along with good environmental practices;
- [Fair for Life](#) standards which concerns certification programmes for fair trade, responsible supply chains and Corporate Social Responsibility.

Across Europe, there is [growing consumer demand for ethically produced products](#). Food products in particular, as these showed the highest growth of sustainable product sales with 18.3 percent in the last five years. This trend is expected to continue. AS such, there is greater demand for natural ingredients for health products that meet social and environmental 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 as it will give you a competitive advantage in your journey to enter the European market.

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 on the website of the [Union for Ethical BioTrade](#)

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:

Acquire detailed information about the sources of your natural ingredients, particularly from growers and farmers. Know the exact sources of your natural ingredients and the people involved in handling them. European buyers want to know about the origins of natural ingredients and the processes and working practices involved in their production, along with information about growers and farmers involved.

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.

Use the transparency and traceability of your natural ingredients to create a marketing story for your products. For example, you could create a section on your website that gives European buyers an overview of your natural ingredients supply chain from farmer to European export destination. Indian

exporter of turmeric [Suminter India Organics](#) is an example of a company doing this.

3. What are the requirements for niche markets?

Organic Ingredients

Across Europe, there is increasing consumer demand for organic products. In order to meet that growing demand, many European buyers are demanding organic ingredients for their natural health products. Furthermore, organic certification is also perceived as a sign of quality. 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. To market your natural ingredients as organic on the European market, you must meet European Union regulations. You can find information about [EU organic certification](#) on the website of the European Commission.

In January 2021 the new EU organic regulation ([EU 2018/848](#)) will enter into force. This new regulation adds new checks for imported organic products. As a producer from a third country you must comply with this new regulation if you are supplying organic ingredients.

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). If you do not have a COI, your natural ingredients cannot be traded as organic. The demand for certified ingredients for health products in the European market is likely continue to grow in the future. Indeed, [sales of organic products in Europe have increased](#) during the COVID-19 pandemic. Exporters of natural ingredients from developing countries should consider organic certification when targeting the European market. European buyers increasingly demand high-quality ingredients.

Tips:

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

Ensure you are compliant with the new EU organic regulation that comes into force in January 2021.

A Certificate of Inspection (COI) which proves your natural ingredients are organic is mandatory if you want to trade them on the European market.

Ensure your COI is up to date with the [latest changes made by the EU](#) that came into force on 3 February.

Let prospective European buyers know if your natural ingredients already have a COI, as it makes you more appealing to them.

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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