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

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Which requirements you need to meet depends on whether you produce ingredients for herbal medicinal products or food supplements. Your way to the European market also depends on whether your ingredient is known and accepted on the market or not.

Food supplements offer the most opportunities for innovation. However, if you can become a trusted supplier of a known and accepted herbal medicinal product ingredient, you can develop a stable and more long-term trade relationship.

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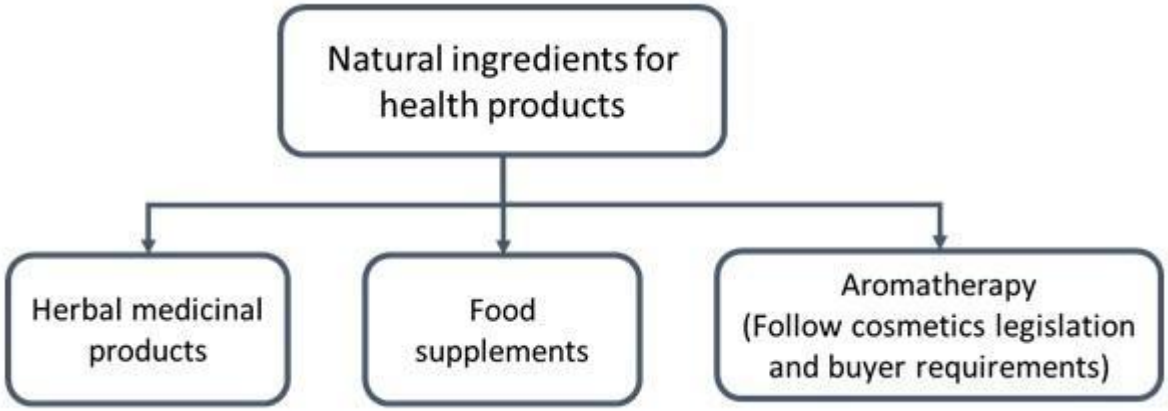
1. What are the requirements for natural ingredients for health products?

This learning section provides an overview of what is required in order to enter the European market for natural ingredients for health products. It covers the requirements for the 2 main parts of this market: herbal medicinal products and food supplements. The requirements for the herbal medicinal product sector are greater than those for food supplements. To understand which requirements you need to meet, you need to know in which part of the market your ingredient is used.

In addition, high-value essential oils can be a successful part of aromatherapy products. Most of these products are marketed as cosmetic products and therefore need to follow cosmetic regulations. Compared to the parts of the market covered in this text, access to the cosmetics market is easier. Also, cosmetic products have less strict regulations about product claims.

Figure 1: Applications of natural ingredients for health products



Source: Ecovia Intelligence

Legal requirements for herbal medicinal products

You can only export natural ingredients for herbal medicinal products if you follow European Union (EU) laws (Directive 2004/24/EC). Doing so provides a specific and simplified set of rules for traditional herbal medicine products if they can meet certain requirements. You also need to meet detailed quality, documentation, labelling, packaging, certification and tracking standards set in the rules governing medicinal products in the EU.

Your ingredients also need to follow Good Agriculture and Collection Practices (GACP) for raw plant materials and Good Manufacturing Practices (GMP) for active substances used as starting material. GACP and GMP ensure that medicinal products meet all the identity, quality, effectiveness and safety requirements for medicinal-grade ingredients.

You also need to understand whether your ingredient is allowed on the market, as you cannot sell ingredients for herbal medicinal products if they are not officially accepted. The European Medicines Agency (EMA) is the agency responsible for the scientific testing, supervision and safety monitoring of medicines in EU Member States. The EMA has developed standards for the most commonly used and accepted ingredients for herbal medicinal products, and these standards are known as EU herbal monographs. If you produce an accepted ingredient, you need to follow these monographs. Monographs include the following information:

- What the herbal product is used for;
- Whom the herbal product is intended for;
- Safety information, such as side effects and interactions with other medicines; and
- Claims that manufacturers can make for herbal medicinal products that include these ingredients.

If there are EMA monographs, herbal medicinal products manufacturers will use them in their Common Technical Document (CTD). They use these documents to control and document the quality of all active substances throughout their supply chain.

If your ingredient is new on the European market, it must be registered for use as Traditional Herbal Medicinal Products (THMPD). The EU offers a simplified registration procedure for herbal substances and preparations with a long tradition of safe medicinal use in Europe. However, this process and the required documentation is still beyond the scope of most small and medium enterprises (SMEs) from developing countries. You need to provide sufficient evidence showing a medicinal use of at least 30 years, 15 of which need to be in the European Union.

Tips:

Check if the EMA provides an EU herbal monograph for your ingredient. If it exists, follow the monograph's standards. Use the words of the claims specified in the EMA monographs in your own communications as well.

See the website of the European Medicines Agency for more information on European Union monographs and list entries.

For new ingredients, check if there is a history of medicinal use of at least 30 years, 15 of which need to be in the European Union. If you cannot find a history of safe use, find out if you can access the food supplement part of the market with your ingredient.

Visit the European Commission's herbal medicines product page for information on how to register new ingredients as traditional herbal medicinal products.

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

See CBI's study on buyer requirements for natural ingredients for the cosmetics sector for more information on cosmetics requirements.

Legal requirements for food supplements

If your ingredients are used in food supplements, you need to follow EU food supplement laws which set requirements on the composition and labelling of supplements.

You also need to follow the European General Food Law, which requires that all foods marketed in the EU be safe. Food safety includes requirements on maximum residue levels (MRLs), contaminants in food, microbiological contamination of food and food hygiene as outlined in the EU's Hazard Analysis and Critical Control Points (HACCP). Also, the General Food Law includes tracking requirements (PDF) to trace ingredients through the value chain. The legal requirements are based on a '1 step back-1 step forward' principle.

Depending on whether you produce a known and accepted or new ingredient for food supplements, you need to take a different path into the market. Known and accepted botanicals are those that are allowed (or not) as food supplements. These are often specified at a national level on so-called 'positive lists', such as Germany's plant list. In addition, Belgium, France and Italy have developed a coordinated list (BELFRIT), which is adopted in these 3 countries. Some countries that do not have a national list follow these lists as well.

These positive lists are only specific about the plants (and the parts of those plants) that are allowed. They do not say which claims manufacturers can make for these ingredients or in what form a plant can be sold on the market. The claims made for ingredients such as vitamins and minerals are organised under the European Food Safety Authority in Annex II of Directive 2002/46/EC. Not all claims about herbal ingredients are fully accepted yet. Manufacturers often make product claims using this vitamin and mineral information in order to avoid complaints from national supervisors, conflicts with competitors or legal battles.

If your ingredient is new to the food and food supplement market, you first need to get it approved for food use. Ingredients that were not consumed in the European market before 1997 fall under Novel Food law. This means that you need to get documentation and approval before you can sell something for use in food supplements. You need to provide data on toxicological, microbiological and allergenic properties. This process can be complicated and costly.

The laws include exceptions for traditional food products from third countries. For these foods, there is a simplified notification process. This applies to products from plants, animals and microorganisms from primary production that are not processed or are made with simple processing. You need to show a documented continued use of at least 25 years in the normal diet of a significant number of people in at least 1 country outside the EU.

The actual use in food supplements is verified on a case-by-case basis to see if it meets legal provisions. This is important because ingredients can be used in high concentrations in food supplements. Actual use is a topic left

to the individual member states. The European Food Safety Authority (EFSA) provides a collection of information about botanicals and their effects on human health. This list is regularly updated and aims to help food supplement manufacturers by highlighting possible safety issues.

Tips:

Train your wild plant collectors to pick the right plants without the plants being contaminated by other plants. This will help reduce contamination levels in your ingredients. Improving the drying process you use can also greatly improve the quality of both wild and cultivated plant materials.

Take a look at common causes for border rejection and product withdrawals on the Rapid Alert System for Food and Feed (RASFF).

Check if your natural ingredient is included on national positive lists to determine if it is a known and accepted ingredient. If your ingredient is considered new, check the authorisation process for novel and traditional foods. Check the guidance documents for the authorisation for traditional foods developed by the European Food Safety Authority (EFSA) for more information.

Check the Novel Food Catalogue, the Union List and consult with experts to determine if there is historical use of your ingredient in the EU.

Determine if there are any safety issues for your specific ingredient by checking the EFSA compendium of botanicals.

Visit EU Access2Markets for more information on import rules and taxes in the EU.

Contact Open Trade Gate Sweden if you have specific questions about the rules and requirements in Sweden and the EU.

Requirements to export natural ingredients

If you want to export natural ingredients for health products, you also need to follow international agreements. These international rules are especially important if you produce ingredients collected in the wild.

You need to follow the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). CITES aims to protect endangered plants and plant products by regulating their trade. CITES provides a list of plant species that you cannot export/import, or where export/import is restricted.

If your product is listed in Annex A and Annex B of Regulation (EC) No 338/97, you need to get an export permit from your country's CITES authority. You will also need an import permit from the country to which you are exporting.

You also need to determine whether and how the Nagoya Protocol of the Convention on Biological Diversity (CBD) applies. This protocol aims to make sure the benefits of genetic resources and traditional knowledge are shared in a fair way. It provides guidelines for accessing and using genetic resources and traditional knowledge in Access and Benefit Sharing (ABS) agreements.

Many countries have signed this protocol and adopted it into national law. If your home country did as well, you need to follow these national laws. European companies are legally required to follow the laws that are in force in your country about ABS. Your buyers will expect you to know and to follow the rules in your country on this topic.

Tips:

If you export wild-collected plants or their derivatives, consider the provisions of CITES to guarantee the EU entry of your products. Check Annex A and B of Regulation (EC) No 338/97 to understand whether import and export permits are required for your product. You can also use the more regularly updated Species+

website to check if your species is listed in CITES.

If you need an export permit or are not sure whether you need one for your ingredient, contact your local CITES authority.

When you start working with a new species, check its conservation status at the CITES Checklist.

Visit the CBD website, as it provides useful information on ABS, including country profiles.

Put a procedure in place to check whether ABS applies. Contact the authorities in your country as a starting point.

Sustainable sourcing

You need to be a sustainable supplier, and you must communicate that to European buyers. Sustainable sourcing is important to buyers, as they face shortages for an ever-increasing number of species, especially species collected in the wild.

You need to show sustainable sourcing, for example by using Good Agricultural and Collection Practices (GACP)(PDF). Although only required for herbal medicinal products, these practices are also crucial for wild-collected ingredients used in food supplements. These guidelines provide technical guidance on growing, picking and handling of plants to ensure a good quality.

Tips:

Check the conservation status of your species to determine its availability and threats to sustainability. For example, see the red list of the International Union for Conservation of Nature (IUCN).

If you produce wild-collected ingredients, avoid overplanting to ensure future availability of the species. Provide a living wage to collectors to make wild collection a viable income source in rural areas. You can show sustainable wild collection through FairWild certification, by collecting according to the UNCTAD BioTrade Principles and Criteria (PDF) or documenting sustainable collection practices.

Perform a resource assessment and put into place a resource management system, for example as prescribed by FairWild certification. Detailed information on species availability is crucial for buyers.

Show that you practice sustainable wild collection through the use of GACP. Show how your company impacts biodiversity and provide documentation of sustainable collection practices.

Increasing requirements on tracking and transparency

1 of the main aspects for European buyers when choosing product suppliers is a transparent supply chain that is easily tracked. They want guarantees that the product they buy matches the product specifications and can be traced back to the source. Also, they face increasing pressure to make sure their supply chains are transparent and easily tracked.

You should have information on production and labour practices, as well as environmental issues. European buyers may also request that you meet the standards of their code of conduct or sign industry charters. Buyers expect their suppliers to provide them with all the necessary information.

This type of information is increasingly digitalised. Larger buyers integrate this information into online purchasing systems. This provides improved transparency, increases access to information and statistics and allows for more efficient purchase and payment processes.

The EU is committed to environmental sustainability and sustainable growth, something it has made clear in the European Green Deal. Laws are being discussed that would increase the responsibility of European manufacturers to explain where and how products are produced and what impacts they have on people and the

environment. This might mean that you need to put more intense tracking systems in place to be able to deliver the information that your buyers want from you.

The importance of transparency and tracking in supply chains in the health products sector is expected to increase in the future. Increasing the demand for transparency and tracking puts additional demands on your company to collect and disclose data. At the same time, increasing your transparency and improving tracking can also help you build trust with your buyer.

Tips:

Start collecting supply chain tracking information and consider sharing this information with your buyers so that together you can identify and fill potential gaps. You can refer to this Proforest briefing (PDF) for more information on how to track the flow of your supplies and what types of information your buyers are looking for.

Register your company with the Supplier Ethical Data Exchange (SEDEX). This online site provides a template for the typical information required. It also makes it easier to share this information with potential customers.

See the CBI study 'The EU Green Deal – How will it impact my business?' for more information on the EU Green Deal and its implications.

Certifying your ingredients can help you prove the tracking of your products, as this is verified and documented by an independent third-party inspector. See the main standards in Table 2 under 'What additional requirements and certifications do buyers ask for in the natural ingredients for health products sector?'

Documentation to meet legal requirements

European buyers of natural ingredients require exporters to provide well-structured and organised product and company documentation. Buyers use it to make sure that you meet requirements and specifications.

European buyers of natural ingredients for health products usually expect exporters to provide them with a Safety Data Sheet (SDS), Technical Data Sheet (TDS) and Certificate of Analysis (CoA). Table 1 shows what information you need to include in these documents.

Table 1: Contents of the Safety Data Sheet (SDS), Technical Data Sheet (TDS) and Certificate of Analysis (CoA)

Safety Data Sheet (SDS)	Technical Data Sheet (TDS)	Certificate of Analysis (CoA) that matches
Product name, description and classification	Product name, description and classification	Specifications mentioned in the TDS
Hazard identification	Quality that you guarantee to supply	Pre-shipment samples approved by buyer
Information on safety measures	Information on applications	Contractual agreements with buyer

	Certificates	

Source: ProFound

If your natural ingredient is classified as hazardous, you need to follow specific laws on classification, labelling and packaging (CLP) of your ingredient. In that case, your SDS must also include risk and safety information, depending on the hazard classification of your ingredient. The risk information indicates the main risks and hazards, while the safety information indicates the safety measures that need to be taken because of those risks and hazards.

Tips:

Make sure that any samples you send to buyers match your documentation, as samples are reviewed according to documentation.

Acquire an SDS, TDS and CoA for your natural ingredients and have them ready for European buyers. Additionally, when approaching buyers, tell them about any documentation you have. Also, it is likely that your buyer will require test reports.

Review examples of technical documentation of raw materials or extracts that you use. For example, see this Safety Data Sheet for ginseng extract (PDF), this Technical Data Sheet for organic maca powder (PDF) and this Certificate of Analysis for Echinacea herb extract (PDF).

Check the database of the European Chemicals Agency for more information on the hazard classification for specific ingredients.

Check the website Your Europe for more information on CLP laws and your obligations.

See the CBI Workbook for preparing a technical dossier and technical documents for a cosmetic ingredient for more information. Several documentation requirements, such as Technical and Safety Data Sheets, will be similar for health ingredients.

2. What additional requirements and certifications do buyers ask for in the natural ingredients for health products sector?

Many buyers have additional (quality) requirements which can go beyond laws. These can include active ingredient content, moisture content, contaminants and MRLs. These are known and accepted in buyer specifications.

Quality and food safety management

Quality is very important in the European market for health products. As such, European buyers increasingly want quality and food safety management rules to be followed. Adopting such standards gives your company credibility and shows your commitment to deliver high-quality ingredients. Improving your quality and food safety management, as well as certification, can help you stand out in the market.

You can make yourself stand out by putting into place a quality and safety management system. This is especially important if you want to supply the herbal medicine market. International Organization for Standardization (ISO) 9001:2015 is an industry (management) standard that sets out the expectations for a quality management system. This standard is required for herbal medicinal products. It includes expectations on customer focus, leadership, people participation, process approach, improvement, evidence-based decision-making and relationship management.

In addition to the required HACCP standard, European food industries increasingly want suppliers to follow more

complete food safety standards or food safety management systems. This is most common for food supplements and if you supply large retailers and manufacturers directly, for example:

- International Organization for Standardization (ISO) 22000 food safety management system certification;
- Food Safety System Certification (FSSC) 22000, based on ISO 22000 and aimed specifically at food manufacturers;
- International Featured Standards (IFS) Food 7, with several standards concerning food safety; and
- British Retail Consortium Global Standard for Food Safety (BRCGS) standards which provides technical standards for food safety.

Tips:

Consider carefully whether you need to follow the above standards and certifications, or others. Verify whether your buyer truly requires certification, whether it will facilitate market access or offer you a better price, or whether compliance will benefit your company's supply security or internal processes. Also, determine whether you can gain the trust of your buyer in other ways.

Show potential buyers that you follow standards and certifications. Clearly highlight this in your sales and marketing materials. For example, by showing certification logos on your company website, marketing materials and product catalogue.

Table 2: Most important certifications requested by European buyers of natural ingredients for health products

Certification name	Type of certification	Cost for companies	How do you get certified?
ISO 9001: 2015	Quality management	Certification costs depend on factors such as company profile, sectors, annual turnover, number of sites and staff.	You can buy the standard through the ISO website, which lists the requirements for essential features of a quality management system. If you want to certify your quality management system, look for an accredited certification body in your country that offers ISO certification.

ISO 22000:2018 FSSC 22000	Food safety management systems	Certification costs depend on factors such as your company's business activities and location.	You can buy the ISO standard from the ISO website. Look for an accredited certification body in your country that offers these ISO and FSSC certifications or check the FSSC 22000 website on how to become certified.
EU Organic	Organic	Costs vary and depend on set-up, scale, location and to what extent your product is different from the set standards.	Refer to Regulation (EU) 2018/848 to learn more about the legal requirements. Access the list of recognised control bodies and control authorities (PDF) for EU Organic, issued by the EU.
FairWild	Social and environmental sustainability (wild-harvested species)	Calculations of the cost of the certification review are made individually. They depend on the location, size and complexity of operations and include inspection, testing, certification and office costs.	See the approved control bodies and accreditation section on the FairWild website for more information about getting certification.

Fairtrade International	Social sustainability	Access the cost calculator of FLOCERT to get an estimate about your costs to become Fairtrade-certified.	Consult this link to learn how to become a Fairtrade producer. Operators usually go through a full recertification review process every 1-2 years.
Fair For Life	Social sustainability for both wild and cultivated species	Certification costs vary depending on the size and complexity of operation, location of your operation and of producers.	View the Fair for Life certification process to learn the steps that must be followed to become certified. Operators usually go through a full recertification review process every year.
UEBT certification programmes	Ethical sourcing and biodiversity	Certification fees depend on the type of certification plan: Ethical Sourcing system certification, ingredient certification and UEBT and Rainforest Alliance Herbs & Spices programme.	See the UEBT certification bodies section on the UEBT website for more information about getting certification.

Source: ProFound

3. What are the requirements and certifications for natural ingredients for health products in niche markets?

Verifying or certifying sustainable production is part of a small, specific market in the health industry. However, it can add value to your product. Organic certification is the most common standard in the EU market for natural ingredients for health products. Other social and environmental sustainability standards and requirements include fair trade standards.

Organic ingredients

Organic product sales in Europe have increased at a faster rate than in the overall food market. During the COVID-19 outbreak, the demand for organic products increased again. In 2020, the EU organic market reached record high sales of €44.8 billion. This was an increase of 15% compared to the year before.

Organic certification is more common for food supplements than for herbal medicinal products, which cannot be labelled as organic. However, some European herbal medicine companies use organic ingredients (exclusively) to adhere to their company philosophy.

In food supplements, the value of certification depends on the positioning of the producer and the product. Opportunities for certification increase if the product is positioned more as a food-type product, rather than as a medicinal-type product. For example, organic certification is very common for botanicals such as moringa and baobab that are sold mainly as powder to be added to recipes. Organic certification also acts as a quality control system and can help improve your quality image.

If you want to market organic ingredients to Europe, you need to meet the European requirements on the production and labelling of organic products. In January 2022, the new EU organic regulation (EU) 2018/848 entered into force. This regulation adds new checks for imported organic products. Following these regulations can involve a major change in your company's processes. You need to move to allowed pesticides and fertilisers, control weeds naturally, put into place a full tracking and internal control system and switch to only using allowed solvents (water, steam, or organic alcohol).

Tips:

Before you certify your products as organic, find out if there is a market for your product. Can you earn back your investment? Talk with (potential) buyers about whether they are interested in organic-certified natural ingredients.

Tell prospective buyers about the certification you have that shows that you meet environmental and social standards and show this on your company website and marketing materials.

You can find information about EU organic certification on the website of the European Commission.

Meeting social and environmental standards

European consumers and retailers are putting more and more pressure on companies to ensure that their products are made according to social and environmental standards. Some European health product manufacturers have made the meeting of environmental and social standards part of their policy and strategy.

Whether European buyers of natural ingredients for health products are interested in certified ingredients depends on the type of health product they produce and how they communicate their sustainability to their customers. If an ingredient makes up only a small part of a product, it is difficult to communicate its sustainability to consumers.

Product certification with social standards such as Fairtrade is most used in commodity food value chains. Standards such as Fair for Life and FairWild can be adapted to a much larger variety of products and ingredients. Both have separate criteria for sustainable wild picking of plants, while Fair for Life can also be used for cultivated ingredients. See Figure 2 for examples of companies that use these certification plans and how labels are presented on consumer products.

You can also apply the UNCTAD BioTrade Initiative BioTrade Principles and Criteria, which provide a framework for the conservation and sustainable use of biodiversity in business and trade.

Figure 2: Examples of health products with certified ingredients

Source: Aduna, Namibian Naturals (2022)

Tips:

Before applying for these certifications, talk with (potential) buyers about whether they are interested in certified sustainable natural ingredients that meet the above standards.

Consult the ITC Standards Map for a full overview of the certification plans used in this sector.

See the CBI study 'What is the current offer in social certifications and how will it develop?' for more information and tips on social sustainability standards.

This study was carried out on behalf of CBI by ProFound – Advisers In Development.