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

Last updated:
26 June 2024

The requirements you need to meet depends on whether you produce ingredients for herbal medicinal products or food supplements and whether you supply raw materials or value-added extracts. Your way onto the European market also depends on whether your ingredient is known and accepted on the market or not. Food supplements provide the most opportunities for innovation. However, if you can become a trusted supplier of a known and accepted ingredient of a herbal medicinal product, you can develop stable and long-term trade relationships.

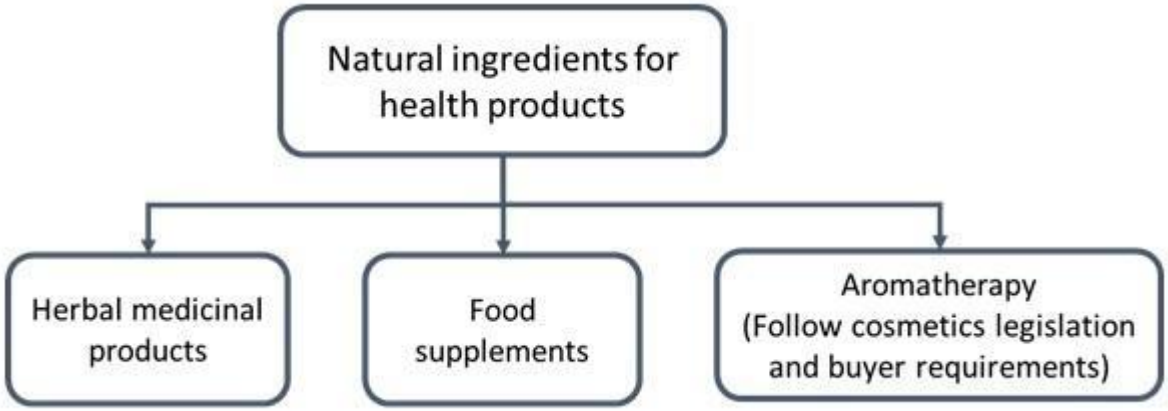
Contents of this page

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

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

High value essential oils can also be used in aromatherapy products. Most of these products are marketed as cosmetics so you need to follow regulations for cosmetics. Compared to the parts of the market covered in this text, it is easier to introduce new natural ingredients to the cosmetics market as the legal requirements involved are less demanding.

Figure 1: The applications of natural ingredients for health products



Source: ProFound

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). You also need to meet the detailed quality, documentation, labelling, packaging, certification and tracking standards set in the rules that govern 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) if you supply active substances that are used as starting materials for medicinal products. GACP and GMP ensure that medicinal products meet all the identity, quality, effectiveness and safety requirements for medicinal-grade ingredients.

You 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. 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:

- The composition and form of the product, including its botanical name;
- What the herbal product is used for and how it should be used;
- Who the herbal product is intended for;
- Safety information and available preclinical safety data, such as side effects and interactions with other medicines; and
- Claims that manufacturers can make for herbal medicinal products that use these ingredients, if they meet requirements described in the monograph.

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

If your ingredient is new on the European market, it should be registered for use as a 'Traditional Herbal Medicinal Product' (THMPD). Under the Directive 2004/24/EC, 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 documentation it needs is still beyond the scope of most small and medium enterprises (SMEs) from developing countries. You need to provide sufficient evidence that shows a medicinal use of at least 30 years; 15 of these need to be in the EU.

Tips:

- Check if the EMA provides an EU herbal monograph for your ingredient by using the organisation's 'Find medicine' search function. If there is one, follow the monograph's standards. Only use the claims specified in the EMA monographs in your own product information and communications (including your email, website, social media and other market communications).
- See the EMA website for more information on the different types of EU monographs and list entries.
- For new ingredients, check if there is a history of medicinal use of at least 30 years. 15 years of these years need to be in the EU. 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 can affect the trade of natural ingredients for health products and that are different from international standards. You can also find the World Trade Organisation's (WTO) list of contact persons per country here.
- See the Export Guide for Medicinal and Aromatic Ingredients and Plants by the International Trade Centre for more information on market access for new ingredients for herbal medicinal products and food supplements.
- Read CBI's study on buyer requirements for natural ingredients for the cosmetics sector for more information on requirements for cosmetics.

Legal requirements for food supplements

If your ingredients are used in food supplements, you need to follow EU food supplement laws. These laws 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 for consumption. Food safety involves requirements on maximum residue levels (MRLs), contaminants in food, the microbiological contamination of food and food hygiene as outlined in the EU's Hazard Analysis and Critical Control Points (HACCP). The General Food Law also includes traceability requirements (PDF), which means you should trace ingredients throughout the value chain. The legal requirements are based on a 'one step back, one step forward' principle.

Depending on whether you produce a known and accepted or a new ingredient for food supplements, you need to take a different path into the market. Known and accepted botanicals for food supplements are often specified at a national level and are on so-called 'positive lists', such as Germany's plant lists, which is divided into botanical plant names that start with A–K and those that start with L–Z. These lists can also specify which parts of the plant are allowed and if certain plants are not allowed. Belgium, France and Italy have also developed a coordinated list (BELFRIT), which has been adopted in these three countries. Some countries that do not have a national list follow these lists as well.

These positive lists are only specific about the species and plant parts that are allowed. They do not say what claims manufacturers can make for these ingredients or in what form plants can be sold on the market. The claims made for ingredients like vitamins and minerals are organised under the European Food Safety Authority (EFSA) in Annex II of Directive 2002/46/EC.

There are no authorised health claims for botanicals and herbal ingredients. These have either been rejected or

classified as 'pending' by EFSA. This means that these claims have not been evaluated. Instead, manufacturers often make product claims using authorised vitamin and mineral claims to avoid complaints from national supervisors, conflicts with competitors and legal battles.

If your ingredient is new to the food and food supplement market, you first need to get it approved for use in food. Ingredients that were not consumed 'to a significant degree' in the EU before 15 May 1997 fall under Novel Food law. This means that, for these novel ingredients, you need to get approval before you can sell them 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. There is a simplified notification process for these foods. 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 one country outside the EU.

The actual use in food supplements is verified on a case-by-case basis to see if it meets legal requirements. This is important because ingredients can be used in high concentrations in food supplements. Actual use is a topic left to individual Member States. The EFSA provides information about botanicals and their possible negative effects on human health. This list is regularly updated and aims to help food supplement manufacturers by highlighting potential safety issues.

Tips:

- Train your wild plant collectors to pick the right plants without the plants being contaminated. This will help reduce contamination levels in your ingredients. Improving the drying process can also greatly improve the quality of both wild and cultivated plant materials.
- Search the EU's Rapid Alert System for Food and Feed (RASFF) database for examples of withdrawals from the market and the reasons for these withdrawals.
- Check if your natural ingredient is on any 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 EFSA for more information.
- Check the Novel Food Catalogue, the Union List (a list of all authorised Novel Foods to date) 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.
- Check the CBI's study on buyer requirements for natural food additives for more information on European food regulation and food safety requirements.

Requirements to export natural ingredients

If you want to export natural ingredients for health products, you need to follow international agreements.

These international rules are particularly 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 an overview of plant and animal species that you cannot export or import (Appendix I), and where exports and imports are restricted (Appendix II).

If your product is listed in Annex B or Annex C 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 you will be exporting to. If your product is listed in Annex A, international trade is prohibited.

You also need to determine whether the Nagoya Protocol of the Convention on Biological Diversity (CBD) applies and, if so, how. This protocol aims to make sure the benefits of genetic resources and traditional knowledge are shared fairly. 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 has done so as well, you need to follow these laws. European companies are legally required to follow the laws that are in force in your country regarding ABS. Regulation EU 511/2014 sets the rules for the implementation of the Nagoya Protocol at the EU level. Your buyers will expect you to know and follow the rules in your country on this topic.

Figure 2: Video – The Nagoya Protocol and ABS, simply explained

Source: Naturvårdsverket, 2018

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 B and C 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 whether 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.

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

Visit the CBD website, which 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 should communicate this to European buyers. Sustainable sourcing is important to buyers as they face shortages for ever-more species, especially species collected in the wild.

You need to show sustainable sourcing, for example by using Good Agricultural and Collection Practices (GACP) for medicinal plants (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 good quality.

Tips:

Check the conservation status of your species to determine its availability and threats to sustainability. For example, check the Red List compiled by the International Union for Conservation of Nature (IUCN).

If you produce wild-collected ingredients, avoid overharvesting to ensure the future availability of the species. Provide a living wage to collectors to make wild collection a viable income source in rural areas.

Show that you use sustainable wild collection practices through FairWild certification by collecting according to the UNCTAD BioTrade Principles and Criteria (PDF), following GACP or documenting sustainable collection practices.

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

Increasing requirements on traceability and transparency

One of the main aspects for European buyers when choosing product suppliers is having a transparent supply chain to ensure traceability. Traceability refers to being able to identify, track and trace elements of a product as it moves along the supply chain, from its raw material to the finished product on the market. Buyers want guarantees that the products they buy match the product specifications and can be traced back to the source. They also face increasing pressure to make sure their supply chains are transparent under new sustainability

legislation.

The EU is committed to environmental sustainability and sustainable growth, something it has made clear in the European Green Deal. As part of this framework, new laws have been proposed to increase European manufacturers' responsibilities so they should be able to explain where and how products are produced and what impacts these have on people and the environment.

One example of a legislative change is the proposal for a directive on corporate sustainability due diligence, which was adopted by the European Commission in February 2022. The new rules will ensure that businesses address adverse human rights and environmental impacts that result from their actions, including their value chains within and beyond Europe. This directive proposal is in line with the Farm to Fork strategy, part of the European Green Deal. The Farm to Fork strategy aims to create fair, healthy and environmentally friendly food systems across Europe.

The EU has also approved the Directive on Empowering Consumers for the Green Transition to prevent companies making unproven 'green' claims to consumers about the environmental sustainability of their finished products. This legislation will be written into national laws in the next two years. Although this will not directly affect you as a supplier of natural ingredients, your buyers may ask for more evidence on the sustainability of your ingredients.

A transparent supply chain is key to deal with sustainability concerns and upcoming legislation. This may mean that you need to put more intense traceability systems in place to deliver information that your buyers want from you.

You should have information on production and labour practices, and 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 digital. 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 importance of transparency and traceability in supply chains in the health products sector is expected to grow in the future. This may put additional demands on your company to collect and disclose data. At the same time, increasing your transparency and improving traceability can also help you build trust with your buyer.

Tips:

- Start collecting supply chain information and consider sharing this with your buyers so you can identify and fill potential gaps together. You can refer to this Proforest briefing (PDF) for more information on how to trace the flow of your supplies and what type of information your buyers are looking for.
- Register your company with the Supplier Ethical Data Exchange (SEDEX). This website provides a template for the standard required information. It also makes it easier to share this information with potential customers.
- Read 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 traceability of your products, as this is verified and documented by an independent third party inspector. Read 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 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 SDS, TDS and 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. If this is relevant, your SDS must also include risk and safety information, depending on the hazard classification of your ingredient. The risk information outlines the main risks and hazards, while the safety information indicates the safety measures that need to be taken because of them.

Tips:

- Make sure that any samples you send to buyers match your documentation, as they will use it to review your samples.
- 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. Your buyer will likely require test reports.
- Review examples of technical documentation of raw materials and extracts that you use. For example, take a look at 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 about the hazard classification for specific ingredients.

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

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

Many buyers have additional requirements that can go beyond laws. These can include requirements regarding active ingredient content, moisture content, contaminants and MRLs. These are included in buyers' specifications, which buyers will ask you to meet.

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 these standards gives your company credibility and shows your commitment to delivering high-quality ingredients. Improving your quality and food safety management, and seeking certification can help you stand out in the market.

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

In addition to the required HACCP standards on hygiene, 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. Examples of these standards or systems include:

- 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, containing 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 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 provide better prices, or whether compliance will benefit your company's supply security or internal processes. Also determine whether you can gain your buyers' trust in other ways.

Show potential buyers that you follow standards and certifications. Clearly highlight this in your sales and marketing materials. For example, you can show 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 on getting certification.
Fairtrade International	Social sustainability	Use the cost calculator of FLOCERT to find out how much it 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

Labelling requirements

To export your natural ingredients for health products to the European market, you have to comply with the following labelling requirements:

- Name, address and phone number of exporter
- Product name and identification, including Chemical Abstracts Service (CAS) number
- Batch code
- Place of origin
- Date of manufacture
- Best-before date
- Net weight
- Recommended storage conditions
- Relevant hazardous symbol if you export extracts that are classified as such (see the section on documentation above)

If you supply organic ingredients, your label needs to include the name/code of the inspection body and certification number. Label your products in English unless your buyer wants you to use a different language.

Packaging requirements

Packaging requirements can differ from buyer to buyer, so they should always be agreed with your buyer. In general, European buyers demand high-quality ingredients. To meet these high requirements, you should preserve the quality of your products by always:

- Using packaging materials that do not react with your product.
- Storing your product in a dry, cool and odour-free environment.

Tips:

Always ask your buyer for their specific packaging requirements.

Consider using recycled and/or recyclable packaging materials, as sustainability is important for

European buyers. Read this guide on packaging to reduce environmental impacts for information and guidance on ways to do this.

Read our factsheets on Ayurvedic Ingredients, Essential Oils, Chlorella and Spirulina and Immune-Boosting Botanicals to learn more about specific packaging requirements for these products.

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 over the last ten years. Although the market decreased 2.2% from 2021 to 2022, Europe's organic market was still worth 53.1 billion EUR in 2022. The European organic market is projected to maintain its significant size and importance. However, its growth is anticipated to slow down compared to previous years, primarily due to economic challenges such as high inflation and constrained consumer spending.

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 to adhere to their company philosophy.

In food supplements, the value of certification depends on the positioning of the producer and 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 like moringa and baobab, which are sold mainly as powders 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 came into force. This regulation adds new checks for imported organic products. Following these regulations can involve major changes in your company's processes. You need to move to allowed pesticides and fertilisers, control weeds naturally, set up 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 your investment back? 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 pressure on companies to ensure that their products are made according to social and environmental standards. Some European health product manufacturers have made meeting 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 only makes up 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 like 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, but Fair for Life can also be used for cultivated ingredients. See the figure below 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: Namibian Naturals, 2024

Tips:

- Before applying for these certifications, talk with (potential) buyers about whether they are interested in certified sustainable natural ingredients that meet the standards described above.
- Consult the ITC Standards Map for a full overview of the certification plans used in this sector.
- Read 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.

ProFound – Advisers In Development carried out this study on behalf of CBI.

Please review our market information disclaimer.