CBI
Ministry of Foreign Affairs

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

Which requirements you need to comply with depends on whether you produce ingredients for herbal medicinal products or for food supplements. Your route to the European market also depends on whether your ingredient already has a place and is established on the market.

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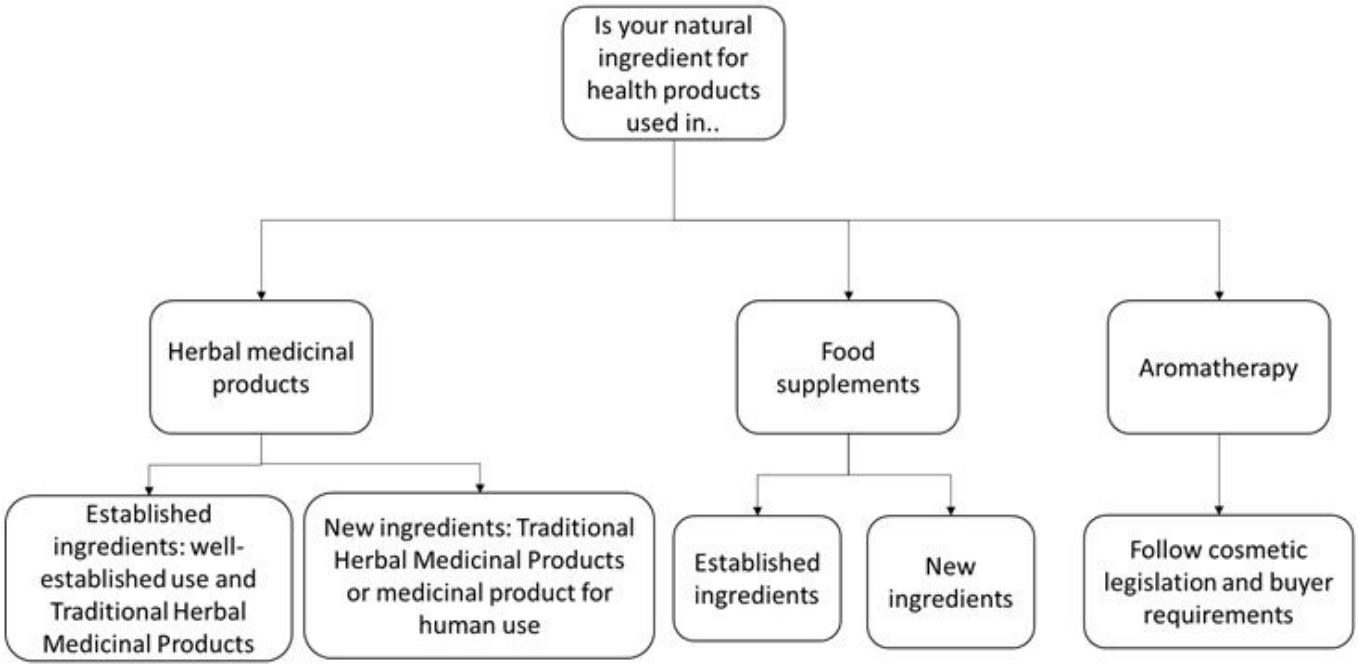
Food supplements offer the greatest opportunities for innovation. However, if you can become a trusted supplier of an established herbal medicinal product ingredient, you can develop stable, longer-term trade.

1 . Introduction: Herbal medicine and food supplements

Figure 1: Route to market for natural ingredients for health products



This module covers requirements for two segments on the European health segments: herbal medicinal products and food supplements. These two segments use the largest share of natural

ingredients.

In addition, high-value essential oils have potential in aromatherapy products. Most of these products are marketed as cosmetic products, and thus need to comply with cosmetic legislation. Compared to the market segments covered in this module, access to the cosmetic market is simpler. Moreover, cosmetic products have the lowest regulations regarding product claims.

In addition, some products containing medicinal plants or extracts are marketed as food for special medical purposes (FSMP), in particular in the German market. This segment is considered easier and less costly to enter for manufacturers. However, European Union legislation for this category is undergoing a revision, effective February 2019. This revision will effectively stop manufacturers from marketing most herbal products in this segment.

In order to know with which requirements you need to comply, you need to know in which segment your ingredient is used. Herbal medicinal products and food supplements have different requirements. Of the two, the herbal medicinal products segment is generally more difficult to enter. Requirements for this segment are more extensive than for food supplements ingredients. Value chains are strictly managed by manufacturers in Europe and as such more difficult to enter.

Furthermore, you need to find out whether you are producing an established or a new ingredient. Established ingredients are allowed and used on the market. For these ingredients you will need to compete with existing suppliers. If you produce a new ingredient, you need to find out if and how you can get your ingredient registered and accepted on the market. See more info below.

Tips:

- See our studies on market channels and segments and trends for natural ingredients for health products for more information on the herbal medicinal products and food supplements market segments.
- See our study on aromatherapy products for more information on the requirements for this segment.

2 . With which general requirements do I need to comply?

You can only export natural ingredients to Europe if you comply with requirements on sustainable sourcing and international treaties on using and trading plant resources. The European Union has translated these treaties into European law. Your own country is probably also signatory to these treaties, meaning that you also need to comply with them to meet national laws.

Sustainable sourcing

You need to be a sustainable supplier and communicate that to European buyers.

You need to demonstrate sustainable sourcing by implementing Good Agricultural and Collection Practices (GACP). This is a requirement for herbal medicinal products, and for both cultivated and wild resources.

Demonstrating sustainable sourcing practices by implementing GACP is especially crucial for wild-collected ingredients, also if your wild-collected ingredients are used in food supplements.

Tips:

- Check the conservation status of your species to determine their availability and sustainability threats. For example, see the red list of the International Union for

Conservation of Nature (IUCN).

- If you produce wildcollected ingredients, avoid overharvesting to ensure future availability of the species. Provide a living wage to collectors to make wild collecting a viable income source in rural areas.
- Conduct a resource assessment and implement a resource management system, for example as prescribed by FairWild certification. Detailed information on availability is crucial for buyers.
- Show that you practice sustainable wild collection through the implementation of GACP. Show how your company impacts biodiversity and provide documentation of sustainable collection practices.
- Try to establish domestication trajectories for wildcollected ingredients that are insufficiently available in Europe. Always conduct a feasibility study first to determine the economic viability of domestication efforts. Show sustainable wild collection through FairWild certification, by collecting according to BioTrade Principles and Criteria or by documenting sustainable collection practices.
- Some European buyers also train their supplier(s) in GACP, knowledge of fair labour practices, Standard Operating Procedures (SOPs), and providing technical and marketing support.

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 may not be exported and/or imported or where export and/or import is restricted. If your product is listed in Annex A and Annex B of Regulation (EC) No 338/97, you will need an export permit from your country's CITES authority. You will also need an import permit from the country you're exporting to.

Tips:

- Check in the Annexes if import and export permits are required for your product.
- If you are not sure if an import or export permit is needed, contact your local CITES authority.
- When you start working with a new species, check its conservation status with the Cites Checklist.

Convention on Biological Diversity (CBD) / Access and Benefit Sharing (ABS)

The goal of the Nagoya Protocol of the Convention on Biological Diversity (CBD) is to make sure the benefits of genetic resources and traditional knowledge are shared in a fair way. This is called Access and Benefit Sharing (ABS).

ABS is especially important for ingredients from native/endemic species, as well as those where there is a local tradition of use.

The Nagoya Protocol provides guidelines for accessing and utilising genetic resources and

traditional knowledge. Many countries have signed this protocol and adopted it into national law. If your home country did as well, you need to comply with these national laws. European companies are now legally required by the European Commission to follow those laws that are in force in your country regarding access and benefit sharing.

You will need to find out if the use of the genetic resources falls within the scope of the ABS legislation in the country of origin. If it does, European companies will need evidence that the entire upstream supply chain in the country of origin complies with those national laws.

You need to comply with requirements on ABS in the utilisation of genetic resources. The national legislation of the country of origin defines the specific meaning of this “utilisation” of genetic resources. If your botanical falls under the scope of ABS, any usage is covered by protection and profit sharing.

You need to find out how your country defines this utilisation. Does the definition include all use of plant materials or only the use of genetic resources for research and development (R&D) purposes? An example of using genetic resources is if you research the genes of an ingredient or their biochemical composition. Anyone who carries out R&D, including the buyer downstream in your supply chain, has ABS obligations under the Nagoya Protocol. They are responsible for compliance with ABS. However, they might ask you for help.

Tips:

- Find out the status of your ingredients in the context of ABS legislation in your country. Find out what your responsibilities are when using traditional knowledge.
- Demonstrate that you comply with CBD principles and offer security to your partners/buyers. Contact local officials for more information.
- Develop a procedure to check if ABS applies to every new genetic resource or traditional knowledge you want to develop. This includes knowing the local context and officials. Have a look at the CBD website for more information. This website also includes country profiles and national contacts.

3 . Buyer requirements for herbal medicinal products

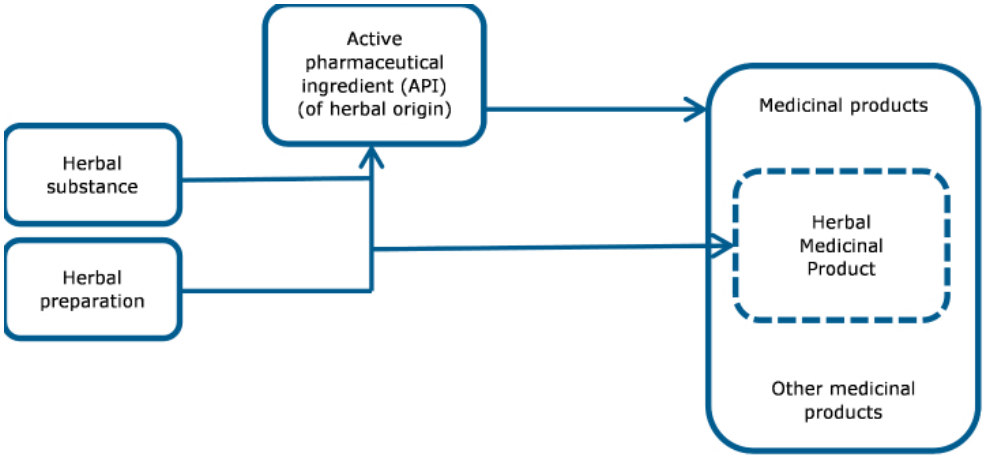
You can only export natural ingredients for herbal medicinal products if you comply with relevant European legislation (Directive 2004/24/EC). This procedure provides a specific, simplified regime for traditional herbal medicine products if they can meet certain requirements.

You also need to comply with detailed quality, documentation, labelling, packaging, certification and traceability standards established in the rules governing medicinal products in the European Union. These rules also specify marketing authorisation of medicinal products and their ingredients that are sold in Europe.

Tips:

- See the Trade Helpdesk for a list of requirements regarding medicinal products for human use and medicinal active substances.
- Contact Open Trade Gate Sweden if you have specific questions regarding rules and requirements in Sweden and the European Union.
- Read more about the simplified procedure for homeopathic and herbal products at the website of the European Commission.

Figure 2: Classification of ingredients according to pharmaceutical legislation



European legislation uses the following classifications:

- Active pharmaceutical ingredient (API): Active substances and components in medicinal products.
- Herbal substance: These are mostly whole, fragmented or cut plants and plant parts, also including algae, fungi and some exudates. Herbal substances are usually dried but can also be fresh. They are defined by botanical name and plant part used.
- Herbal preparation: Preparations are obtained by extraction, distillation, expression, fractionation, purification, concentration or fermentation of herbal substances. These include powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

If your ingredients are used in medicinal products for human use, they need to follow Good Agriculture and Collection Practices (GACP) and Good Manufacturing Practices (GMP) for natural ingredients. These are mostly important for further processing in your clients' facilities, without these your buyers will not be allowed to use the products.

GACP and GMP ensure that medicinal products meet all identity, quality, efficacy and safety requirements. They are established specifically for the industry to determine pharmaceutical grade ingredients. These practices go beyond standards for the food and food supplements industry.

Tips:

- Find out which GACP or GMP guidelines you need to comply with, which depends on your ingredient.
- If you produce raw plant materials you need to follow the Guideline on GACP for Starting Materials of Herbal Origin (GACP). These are based on the WHO GACP Guidelines.
- If you produce starting materials for medicinal products you need to comply with Part II – Basic Requirements for Active Substances used as Starting Materials. Although your buyer is responsible for GMP, they need you to comply with requirements for starting materials and will check for this in their audit.
- If you produce extracts, your GACP/GMP requirements depend on the stage in the extraction process your product is at and how the manufacturer intends to use your extract. If you produce extracts, you need to comply with requirements on page 3 of the European Guidelines to GMP Medicinal Products for Human and Veterinary Use, Annex 7: Manufacture of Herbal Medicinal Products.
- If your ingredient is defined as an Active Pharmaceutical Ingredients (API), you need to

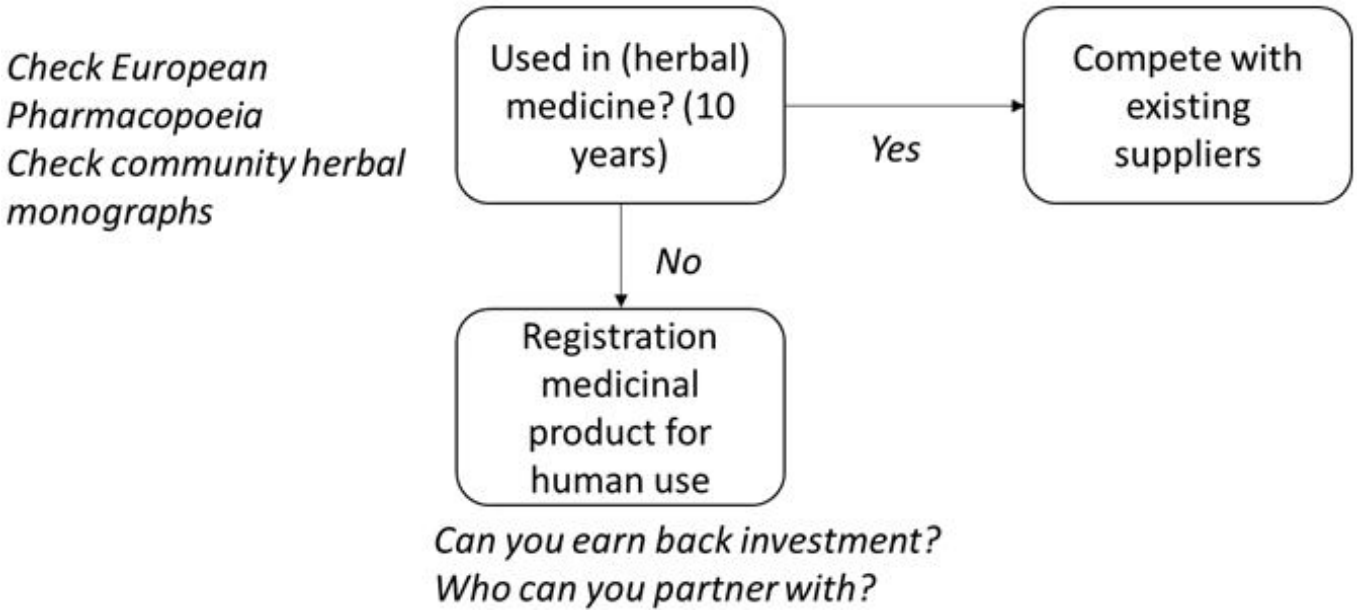
follow requirements on page 7 of Part II – Basic Requirements for Active Substances used as Starting Materials.

- Make sure that your suppliers also comply with GACP and GMP.

Find out if you produce an established or new ingredient for herbal medicinal products

Once you have determined that your ingredient is used in the European herbal medicinal product market, you need to find out whether you producing an established or new ingredient. There are two types of herbal medicinal products on the European market, well-established use herbal medicinal products and traditional use herbal medicinal products (THMP).

Figure 3: Checklist for well-established use herbal medicinal products

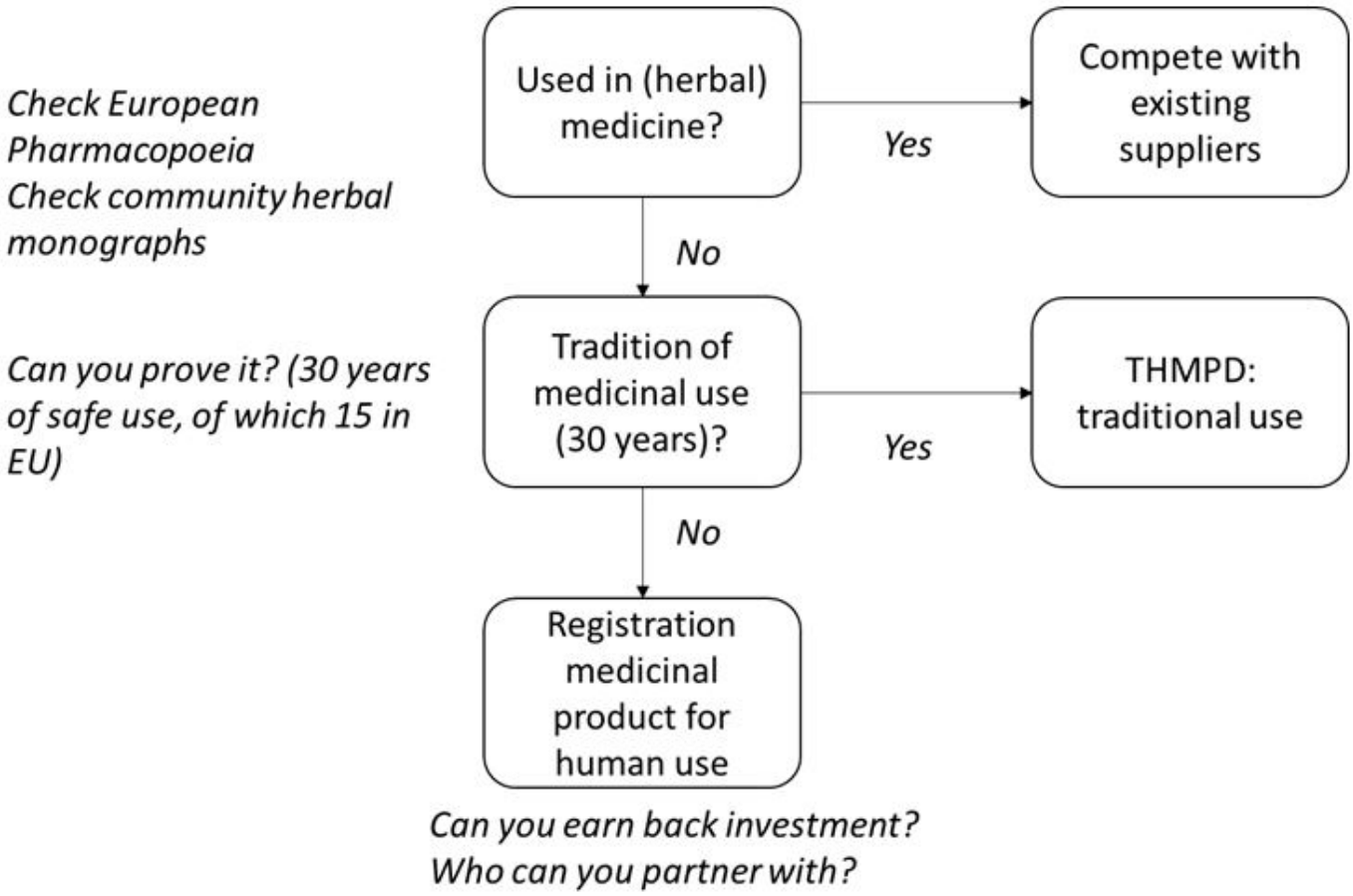


Well-established use herbal medicinal products have a recognised efficacy and levels of safety. These products need to have a minimum of 10 years of usage as a herbal medicinal product in at least one Member State of the European Union. Therefore, it is not possible to register new well-established use herbal medicinal products.

If you produce a new ingredient for herbal medicinal products, you need to determine if you can register it as a traditional use herbal medicinal product (THMP). For this use, you need to prove 30 years of safe use, of which at least 15 years in the European Union. You can only register for an indication that it is traditionally used for.

If you cannot prove well-established use for your ingredient or traditional usage according to the THMP directive (see section 3b. below), your only option is to register it as a new medicinal product. Costs for this can be up to €5–15 million. You will need to find a sponsor for this process and it will be very difficult to recoup that money.

Figure 4: Checklist for traditional herbal medicinal products, new and established ingredients



Tips:

- Check if you produce an established ingredient. Visit the website of the European Medicines Agency (EMA) to check community herbal monographs and European Union list entries. Also check the European Pharmacopoeia.
- Or check if the ingredient is used in wellestablished use herbal medicinal products. This requires 10 years of safe use in herbal drugs in Europe.

3a Established ingredients for herbal medicinal products

The European Medicines Agency (EMA) has developed standards for the most commonly used, established ingredients for herbal medicinal products. These are called community herbal monographs. If you produce an established ingredient, you need to comply with these monographs. Monographs include information on

- what the herbal product is used for
- who the herbal product is intended for
- safety information, such as undesirable effects and interactions with other medicines.

These also specify the claims that manufacturers can make for the herbal medicinal products including these ingredients. You need to use the words of these claims in your own communications as well. In advertisements you can explain the usage and advantages better, depending on national legislation.

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

preferred suppliers or assert control over the value chain themselves.

Even when your ingredient complies with these monographs, you may need to comply with additional requirements from European manufacturers of herbal medicinal products. These requirements can make it very difficult to enter established value chains. The supplier of extracts and raw materials are listed in drug registration files that manufacturers submit to Health Authorities. To change suppliers, manufacturers need a very good reason. Additional buyer requirements include:

- price
- service delivery (delivery schedules, quantities and times, clear documentation, certification)
- professionalism
- communication.

As it is expensive to amend these CTDs, manufacturers rarely switch suppliers. This also means that once you are an established supplier to your buyer, and deliver a consistent quality and quantity, they are less likely to replace you with another supplier.

Aside from competing with existing suppliers, you may find additional opportunities in species that are not well known in Europe, but that are allowed for use in medicinal products. These markets are (much) smaller and they are also less competitive. Species include those that are registered for use in pharmaceuticals in the European (or national) pharmacopoeia, but might not currently be used in herbal medicinal products.

Tips:

- Check if the European Medicines Agency provides a community herbal monograph for your ingredient or a European Union Community list entry. If these exist, comply with these standards.
- See the website of the European Medicines Agency for more information on European Union monographs and list entries.
- Demonstrate traceability of your ingredient throughout value chain.
- Guarantee supply security via documentation. This can be an especially important sales argument for ingredients that experience supply difficulties.
- For more information on established species, see our studies on promising markets, such as cognition, vascular system and joint health.
- See this overview of herbal medicinal products for paediatric use by the EMA to determine for which indications your ingredient is permitted.
- You can buy monographs of less established ingredients at the European Directorate for the Quality of Medicines. If you offer these ingredients you can approach European distributors to determine their interest in introducing or reintroducing these products on the market. You can also approach herbal medicine manufacturers to determine their interest in including the ingredient in their products.
- If you want to market permitted, but lessestablished ingredients on the European market, find a European partner to do this. This can be a time-consuming process.

3b. New ingredients for traditional herbal medicinal products

If your ingredient is new on the European market, it needs to be registered for use as traditional herbal medicinal product (THMP). You cannot sell ingredients for herbal medicinal products if they

are not registered.

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

This procedure allows you to register herbal medicinal products without own data on safety and efficacy, but with expert statements on safety and efficacy. In addition, you will need to provide a full quality documentation for drugs, including analytics, standardisation and stability. You will need detailed references to scientific literature that show that the product's constituents have a traditional use, based on sufficient safety data and plausible efficacy.

For most species from developing countries, there will be insufficient documents of product usage or import and literature references to prove traditional or well-established use. In those cases, the product would need to be registered as a medicinal product for human use. This process is extremely demanding in both time and costs.

Tips:

- For new ingredients, check if there is a history of medicinal use of at least 30 years, of which 15 years in the European Union.
- If you cannot find a history of safe use, focus your efforts to the food supplement segment. See the information below to find out if your ingredient is established or new in the food supplement market.
- Once you have determined sufficient potential, consider asking the European Scientific Cooperative on Phytotherapy (ESCOP) to draw up a herbal monograph. Be aware that this is a lengthy and difficult process. Examine the traditional use and clinical data in your own country. Having such a monograph can provide a basis for partnering with a European company to register your product as a traditional herbal medicinal product.

4 . Buyer requirements for food supplements

If your ingredients are used in food supplements, you need to comply with both European food supplement legislation and the European General Food Law.

Tips:

- See the European Commission website for more information on the European legislation on food supplements and General Food Law.
- Comply with maximum residue levels (MRLs), which are a major concern for buyers. Ensure a strict control of your pesticide use and residues in your production system.
- Apply GACP/GAP and GMP to minimise Contaminants in food and Microbiological contamination of food.
- Train your collectors to collect the right plants without contamination with other plants. This will help to reduce contamination levels in your ingredients. Improving the drying process you use can greatly improve quality as well, for both wild and cultivated plant materials.

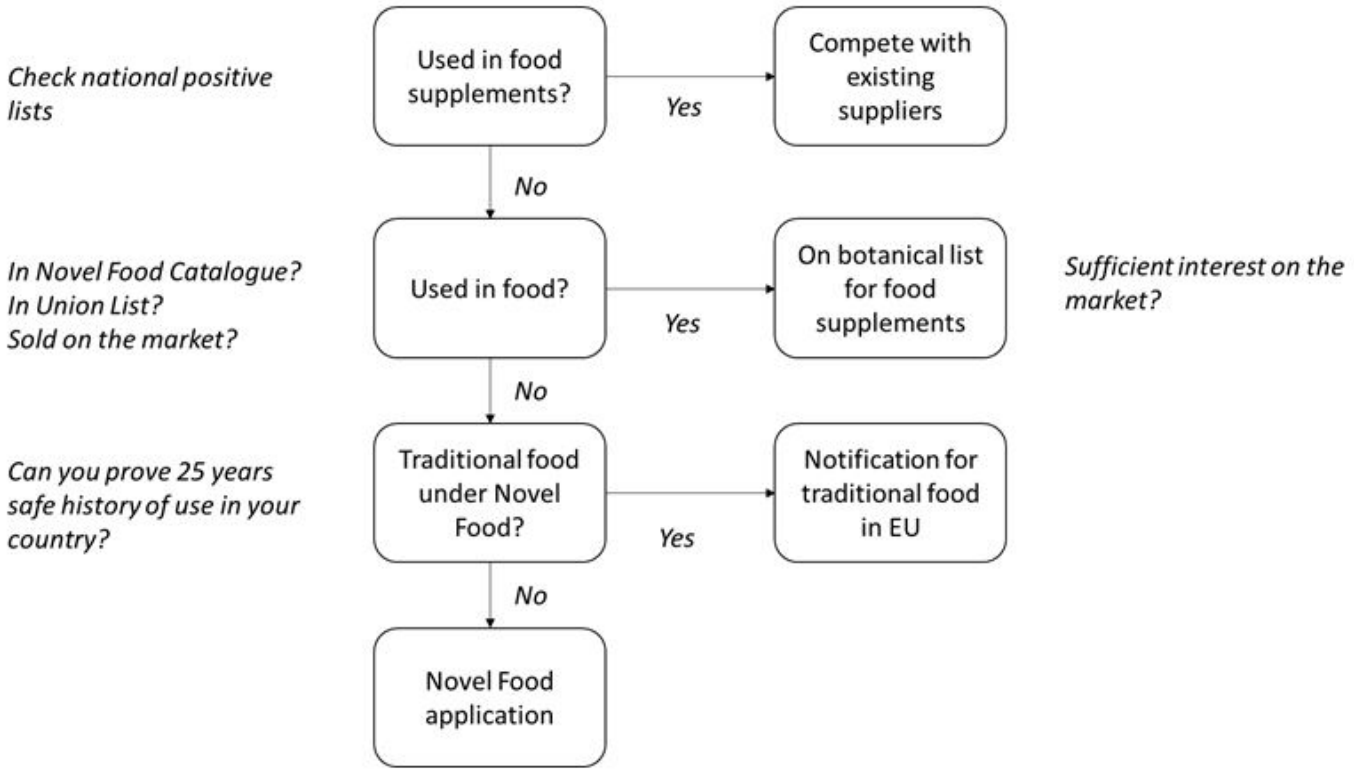
- Check the new legislation on the maximum levels of PAHs (polycyclic aromatic hydrocarbons) which entered into force on 1 April 2016.
- Stay up to date with changes in legislation for contaminants, which is becoming increasingly strict. Laboratory technology used to detect contaminants improves continuously. Check information from associations, such as the European Federation of Health Products Manufacturers Associations. Ask your buyer for changes in their specifications or ask national Food Safety Authorities for advice. You can also hire consultancy firms to advise you on legislation and compliance.
- Comply with Hygiene of food principles, according to Hazard Analysis and Critical Control Points (HACCP). These principles are legally binding for food processors and recommended for farmers (primary production).
- Find out which extraction solvents for food you are allowed to use and under which conditions.
- Find out when irradiation of food is allowed. This is not generally permitted, only in specific cases for spices and herbs.
- Comply with traceability requirements to trace ingredients through the value chain. Legal requirements are based on a “one step back, one step forward” principle. For all your products, you need at least to be able to identify your immediate supplier and immediate buyer.
- Have a look at common causes for border rejection and product withdrawals on the Rapid Alert System for Food and Feed (RASFF).
- If you supply herbs for food supplements, follow the guidelines for herbs according to Codex Alimentarius. Buyers often demand you follow these guidelines.

Find out if you produce an established or new ingredient for food supplements

Depending on whether you produce an established or new ingredient for food supplements, you need to take a different route to the market. You can find established ingredients for food supplements by checking the positive lists that are mentioned in the paragraph below. In addition, many other countries have their own lists as well.

Species that are not listed on these positive lists are new ingredients in terms of European legislation. However, if ingredients are allowed for use in food, they can also be used in food supplements.

Figure 5: Checklist new and established ingredients for food supplements



4a. Established ingredients for food supplements

Established botanicals are those that are permitted (or prohibited/restricted) as food supplements. These are often specified at a national level in so-called “positive lists”, such as in Belgium, Germany and France.

In addition, Belgium, France and Italy have developed a harmonised list (BELFRIT), which has been adopted in these three countries. Italy has adopted the BELFIRT list into its legislation. The country has created a consolidated list, combining both the BELFRIT list and the Italian positive list.

Some countries do not have a positive list themselves, but follow the lists mentioned above. There are some inter-state agreements. For example, Spain automatically recognises botanicals that are authorised in Italy and industry sources indicate that the United Kingdom accepts references to the BELFRIT list by companies.

These positive lists only specify the plants (and parts thereof) that are allowed and not the claims that can be made based on them. Nor do they specify how the product can be placed on the market, for example whether a market authorisation is required or not.

The food supplement sector is driven by claims. Such claims are vital for manufacturers to distinguish themselves on the market. Companies require elaborate scientific data regarding efficacy before they will make an individual product-specific efficacy claim. Although some do make claims without data, this is a dangerous route to take since this is not allowed by European and national legislation. This practice can lead to penalisation, such as recalling products from the market and fines.

The claims made for ingredients such as vitamins and minerals are harmonised under the European Food Safety Authority in Annex II of Directive 2002/46/EC. Claims on herbal ingredients are not yet harmonised. Manufacturers often base product claims on vitamin and mineral content to avoid objections from national supervisors, or issues with competitors and legal battles.

If you enter the market for established ingredients for food supplements, you will find strong competition from existing suppliers. The market for the most used ingredients, especially those derived from plants growing in temperate regions, is highly competitive based on cultivation/forestry for raw material procurement.

Tips:

- Make sure you determine the exact botanical identity of natural ingredients to check whether your species are included on national positive lists.
- Check the positive lists of European countries to determine whether your ingredient is already allowed in those markets or whether there are species that you could potentially produce in your country.
- If you sell ingredients that are allowed on the European market, but not well known or used, you need to entice manufacturers to start using them. It is easiest to do so together with European partners.
- On the market for established ingredients, you will be competing with existing suppliers on identity, quality, price, a better service package (such as delivery schedules and quantities, delivery times, clear documentation), professionalism and communication.
- You will also need to demonstrate sustainable resource management or plans for this and traceability throughout your value chain through documentation.
- For scarce ingredients, you need to demonstrate a sustainable (ecological, economic, social) supply. This is an important part of your sales pitch to potential buyers.
- For more information on established species, see our studies on promising export products, such as anti-obesity, digestive health, joint health and stress and anxiety.

4b. New ingredients for food supplements

If your ingredient is new to the food and food supplements market segment, you need to first get it approved for food use.

Ingredients that were not present on the European market before 1997 fall under Novel Food legislation. This means that you need to obtain documentation and approval (safe and labelled) before you can sell it for use as food supplements. You need to provide data on toxicological, microbiological and allergenic properties. This process can be quite extensive and costly.

A revised Novel Food Regulation entered into force on 1 January 2018. This new regulation sets up a centralised authorisation process, meaning that decision making is faster and more consistent. The new regulation also increases transparency, with a European Union list of novel food ingredients that are permitted on the market.

In addition, this revision introduced an exception for food products that classify as traditional food from a third country. For these foods there is a simplified notification process. This applies to:

- products from plants, animals and microorganisms
- products from primary production
- unprocessed products or products with simple processing; if it is processed, it needs to be close to the original food.

You need to prove history of safe use: documented continual use of at least 25 years in the customary diet of a significant number of people in at least a single third country.

It is not yet absolutely clear what specific evidence you will need to give for a safe history of use, but you will likely need to provide elaborate documentation. The European Food Safety Authority (EFSA) published guidance documents for the authorisation for traditional foods.

Actual use in food supplements is verified on a case-by-case basis to see if they comply with legal

provisions. This is important as ingredients might be used in high concentrations in food supplements. This is left to individual Member States. European Food Safety Authority (EFSA) provides a compendium of botanicals of concern for human health. This compendium refers to relevant national listings, and offers guidance on safety assessment of botanicals for food supplements.

Scientific data that will be needed to carry out a safety assessment of a botanical (preparation) includes:

- technical data (e.g. product identification, composition, specifications, stability, proposed level of use)
- exposure data
- toxicological data.

Tips:

- Check the website of the European Commission for an overview of authorised Novel Foods and a summary of ongoing Novel Food applications.
- If your ingredient is new, find out if you can find a history of use in Europe. Consult experts and do some Internet research. Also check the (nonexhaustive) Novel Food Catalogue for plants subject to the Novel Food Regulation and their current status.
- If you cannot find a history of safe use for your product in Europe, determine if your product classifies as a traditional food. Can you prove 25 years of safe history of use in your country?
- Check the website of the European Commission for more information on the Novel Food Regulation, changes compared to the old Novel Food regulation and authorisation procedures for traditional food and Novel Foods. Stay up to date on developments in Novel Food legislation by checking this website or online news pages such as NutraIngredients.com.
- Look for partnerships with European marketing partners to make market entry feasible. To entice European partners and to determine the market potential of your product, research is needed regarding safety and efficacy beyond traditional use. Local universities and research organisations can help build such portfolios.
- Look into the opportunities of emarketing for your product. This could be a (niche) opportunity, especially to supply traditional products to immigrant populations or people interested in non-Western nutritional solutions. For example, in the United Kingdom with its large South Asian population. Be aware that when you're selling your products online, you still need to comply with the national legislation of the country you're selling to. You cannot sell botanicals online that are not legal in Europe.
- Be careful in making marketing claims for your product that are stronger than the claim that is made on the product label, for example in articles, testimonials or on websites and social media. Although these marketing claims are beyond the regulator's reach, regulators are increasingly vigilant in this respect.
- For more information on new species for food supplements, see our studies on promising export products, such as superfoods, immune system and energy products.

5 . What additional requirements do buyers often have?

Many European buyers have additional quality requirements. These can go beyond legislation and standards. They are outlined in buyer specifications. Examples are requirements related to:

- active ingredient content
- moisture content
- contaminants
- residues
- certification, (e.g. on quality management; see below).

To show that you meet the specifications of buyers, you need to develop well-structured company and product information, including detailed technical data sheets.

Tips:

- Show in your product documentation that you comply with additional requirements of your buyer and their specifications.
- If you produce extracts, follow your buyer's specifications, for example in terms of extraction methods, solvent use and preservatives. Validate and document the extraction conditions, including processing aids, temperature, pressure/vacuum and flow rate.
- In your product specifications, include plant and product identification. You can use a national herbarium and/or a company herbarium as a reference.
- If you use preservatives, make sure you have the human resource capacity to tailor their use to buyer specifications and ensure proper documentation. You also need specialist staff to monitor process quality and microbiology.
- See our tips on doing business with European buyers for more information.

6 . Documentation

Buyers need well-structured company and product information, including detailed technical data sheets. These show that you meet their product specifications.

Tips:

- Make sure your documentation and labelling comply with legislative and buyer requirements.
- Provide all information on possible dangerous characteristics of chemical substances in your Material Safety Data Sheets.
- Implement and document standard operating procedures (SOPs). This can provide a lot of trust with buyers that you will keep up quality standards. It is very likely that your buyers require test reports.
- You will need to receive third party auditors. Provide them with wellprepared documentation. You will need this for various certifications. If you have evidence of checks your buyer performed of your processes and products, give this to auditors as well. Make sure that the appropriate staff is available during the audit.

Traceability and transparency

One of the main aspects for European buyers in selecting product suppliers is a traceable and transparent supply chain. They want guarantees that a product they are buying matches product specifications and can be traced back to the source.

Such information is increasingly digitised. Larger buyers integrate this information in online sourcing systems. This provides improved transparency, increases access to information and statistics, and allows for more efficient purchase and payment processes.

Tips:

- Document your value chain. This has many advantages, for example, it helps you to review and revise your costing and pricing.
- Certifying your ingredients may help you to prove the traceability of your products, as this is verified and documented by an independent thirdparty auditor. See the main standards below.

Social and environmental sustainability

If you want to enter niche markets, you will need to meet standards and requirements for social and environmental sustainability.

- Organic production: If you want to market organic ingredients in Europe, you need to comply with European requirements on production and labelling of organic products. 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.
- Verification and/or certification of sustainable production: This can add value to your product. These include UNCTAD BioTrade Initiative BioTrade Principles and Criteria and the FairWild Standard (environmental sustainability), as well as fairtrade certification such as FLO Fairtrade or FairForLife.
- Codes of conduct and social responsibility standards: Some European buyers may expect you to comply with their supplier codes of conduct regarding social responsibility. These can be based on the United Nations Global Compact, or the labour standards of the International Labour Organization.

Tips:

- Before you certify your products according to one of the standards listed above, find out whether there is a market for your product. Can you recoup your investment? Discuss with (potential) buyers if they would be interested in certified sustainable natural ingredients and in which standards.
- Find out more about organic farming and organic legislation on the website of the European Commission. Compliance can entail a major shift in your company's processes. You need to move to permitted pesticides and fertilisers, control weeds naturally, implement a full traceability and internal control system and switch to only using permitted solvents during extraction (water, steam or organic alcohol).
- For more information on responsible business practices, use the SEDEX online database as an example. In this database, members can share information on ethical and responsible practices. You can also use SEDEX to prepare for possible audits/questions from your

buyers.

- For a full overview of certification schemes in the sector, consult the ITC Standards Map database. In the Standards Map you can identify standards or codes of conduct relevant to your product. You can also review the main features of the selected standards and codes and compare standards requirements side by side.
- Check the Standards Map videos on YouTube to see how Standards Map can help you to determine which initiatives may be useful for your company.

Quality and food safety standards

You can also improve your quality and food safety management to stand out on the market.

- Quality safety management: You can distinguish yourself by installing a quality and safety management system. This is especially relevant if you want to supply the herbal medicine market. ISO 9001:2015 from the International Organization for Standardization is an industry management standard that sets out the criteria for a quality management system. This standard includes principles on customer focus, leadership, engagement of people, process approach, improvement, evidencebased decision-making and relationship management.
- Food safety standards: In addition to the mandatory HACCP standard, European food industries increasingly demand compliance with more comprehensive food safety standards or food safety management systems. This mostly concerns large retailers (such as drugstores) and (private label) manufacturers and is most common for food supplements. Examples include International Food Standard (IFS), ISO 22000 (food safety management) and ISO 31000 (risk management).

Tips:

- Consider carefully whether you want to comply with standards and certifications for food and quality safety management. Verify whether your buyer truly demands compliance. Find out if compliance will facilitate market access or offer you a better price, or whether compliance will benefit your company's supply security or internal processes.
- In the case of food safety standards, determine whether you can gain your buyer's trust in another way.

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