



CBI
Ministry of Foreign Affairs

CBI Product Factsheet:

Natural Ingredients for Digestive Health products in Europe

Introduction

In Europe, there is growing demand for natural ingredients aimed at digestive health, due to increasing consumer awareness of the link between health & wellbeing and the digestive system. A wide range of herbal medicinal products and food supplements is marketed to prevent or relieve digestive problems. Aromatherapy also offers solutions for this indication.

Indication & product definition

Digestive Health

Digestion is the process of breaking down food into nutrients, such as vitamins, proteins and fats, so that they are more easily absorbed. The digestive system involves organs (mouth, gullet, stomach, intestines) and glands (salivary glands, liver, gall bladder and pancreas). Digestive problems, e.g. changed or abnormal digestion, encompass a wide range of conditions; they vary in their severity and cause, and may depend on the part of the digestive system involved. Most conditions occur in the intestines. These are often caused by bacteria or are related to food intake (e.g. allergies). Common symptoms include abdominal pain, changes in bowel habits, indigestion and heartburn. Severe conditions include Irritable Bowel Syndrome (IBS), Inflammatory Bowel Syndromes (e.g. Crohn's disease and ulcerative colitis), gastroesophageal reflux disease (GERD), peptic ulcers and Celiac disease.

Digestive Health and natural health options

Different health options can be chosen depending on the severity of the condition. Severe conditions are commonly treated with synthetic medication, as herbal medicinal products are unable to offer effective treatment.

Box 1: How to use this Factsheet

- Learn how European consumers use herbal medicinal products and food supplements for digestive health.
- Learn about the developing country species that are most commonplace and of greatest interest.
- Learn about requirements you need to meet for established and non-established species.
- Learn more about digestive health market segments and receive key insights into how to enter them.

For mild digestive problems, and to improve digestive health, consumers tend to consider natural health solutions. In line with changing lifestyles or diet, many consumers are opting for over-the-counter (OTC) medicines and food supplements. The type of product chosen depends on whether a consumer aims to improve overall digestive health (preventative function) or to relieve specific symptoms.

Natural food supplements are particularly popular as they are seen as a safer and healthier option than synthetic alternatives. To improve digestive health, supplements (or functional foods) containing pre- or probiotics remain the best-selling products. For mild digestive discomfort, consumers are also keen on herbal teas to relieve symptoms and provide a feeling of wellbeing. In addition, various food supplements based on botanicals are used as laxatives.

Herbal medicinal products exist for digestive problems, but they are less commonly used and fewer products are available to consumers in most EU countries. Moreover, innovation and product development is much more limited than in food supplements.

Natural ingredients for digestive health products

According to industry sources, various botanicals are used for digestive health products in Europe. These are used internally. The most commonly used plants include:

peppermint (<i>Mentha piperita</i>)	Roman chamomile (<i>Chamaemelum nobile</i>)
green tea (<i>Camellia sinensis</i>)	turmeric (<i>Curcuma longa</i>)
ginger (<i>Zingiber officinale</i>)	boldo leaf (<i>Peumus boldus</i>)
fennel (<i>Foeniculum vulgare</i>)	black psyllium (<i>Plantago psyllium</i> , syn. <i>P. psyllium</i> , <i>P. ovata</i> , <i>P. indica</i>)
senna (<i>Senna alexandrina</i>)	psyllium (<i>Plantago ovata</i>)
aloe vera/ferox (<i>Aloe vera</i> , <i>A. ferox</i>)	rosemary (<i>Rosmarinus officinalis</i>)
artichoke (<i>Cynaria scolymus</i>)	fumitory (<i>Fumaria officinalis</i>)

Other natural ingredients allowed for digestive health can be found in this [overview of herbal medicinal products for paediatric use](#) by EMA (the European Medicines Agency).

As both green tea extract and turmeric are covered in the Market Intelligence Report on Natural Ingredients for Immune System Products, these species will not be discussed in this factsheet.

In addition, aromatherapy oils are used to help relieve digestive health problems. These include chamomile and peppermint. Among species of interest to developing country producers are Calophyllum (*Calophyllum inophyllum*), Cajeput (*Melaleuca cajuput*), ginger (*Zingiber officinale*), and wintergreen (*Gaultheria fragrantissima*). These essential oils can be regulated as cosmetic products, unless a specific medicinal claim is made on the label. More than 30 essential oils are included in the European Pharmacopoeia for medicinal use. For more information on aromatherapy, refer to the CBI's Market Intelligence on [Natural Ingredients for Cosmetics](#) on several essential oils and also refer to relevant European and International literature available under [Forum Essenzia](#).

Exemplary species for developing country producers

Not all species are equally relevant to developing country producers. This is the case for mint and Roman chamomile, which have highly competitive markets with very limited market-entry possibilities. Industry sources indicate that ginger, boldo leaf, fennel, black psyllium and senna have good potential for developing country producers in areas with the right growing conditions. These species, as well as other species used for digestive health, can be divided into those aiding digestion and those used as laxatives.

The table below provides information on the use of these exemplary species in digestive products, including available documentation and references, claims, origins, as well as data on traditional use, clinical trials and filed patents¹, to determine possible product development activity for specific species. The products which are based on these ingredients are mostly offered as herbal tea or infusions, and as pills in dosage form, but they can also be used as tonics, for example.

Tips:

- Check final Community herbal monographs as provided by the [European Medicines Agency](#) (EMA) to assess product standards and possible claims. If you produce ginger, green tea or turmeric, also check the Market Intelligence Report on Natural Ingredients for Immune System products.
- Link up with local universities or laboratories to conduct thorough research and product development. This can help in terms of claim substantiation.
- If you want to enter the European market with new or established ingredients, please refer to the [CBI Module Buyer Requirements](#) for information and tips. Many other plants are used in digestive health products worldwide. Some of these can be used/are already used in Europe. In order to enter the market with new species, you need clinical evidence on their efficacy in relieving digestive health problems.
- Check databases such as [Herbmed](#) to identify research on traditional use, clinical trials (safety and efficacy evaluation of herbal formulations on people) and patents. In Europe, you can contact relevant universities such as the [University of Vienna](#), the [University of Veterinary Medicine Vienna](#) and the [University of Graz](#). Access scientific resources, for example through [Elsevier Science Direct](#) (not for free). Also consider becoming a member of the [Society for Medicinal Plant and Natural Product Research \(GA\)](#) to access their research.

¹ Information on traditional use, clinical trials and filed patents should be used as an indication only. Additional research for your specific species will be required.

Table 1: Selected key species for digestive health

Definition	Monographs ²	Permitted usage in supplements ³	Origin	R&D
<p>Zingiber officinale (Ginger)</p> <p>Ginger is found in various supplements for oral use, e.g. in the form of tablets or herbal teas. Herbal monographs are available which permit claims made for herbal medicinal products for digestive health, but fewer products are on the market.</p> <p>There are various species and subspecies of ginger, with the potential for marketing stories based on origin and traditional use.</p>	<p>WHO Monograph ESCOP Monographs 2nd Edition Suppl. (Zingiberis officinale rhizoma) European Pharmacopoeia Monograph # 1522 (Zingiberis officinale rhizoma) Draft Community Herbal Monograph</p> <p>As a herbal medicinal product, claims made for ginger may include "to prevent nausea and vomiting in motion sickness".</p> <p>As a traditional herbal medicinal product, claims may include "symptomatic treatment of mild gastrointestinal complaints (bloating, flatulence)".</p>	<ul style="list-style-type: none"> Belgium: allows the use of the root with a warning that maximum daily intake should not exceed 5 g. France: root. Italy: roots and oil. Germany: roots, with maximum level recommended for food. <p>Food supplements cannot make a medicinal claim. As an example, the following claims were found on products containing ginger in the UK: "Ginger is known for its warming properties and as an aid to digestion" "Well-known 'stomach settler'" "... provides digestive support for when you travel"</p>	<p>Cultivated in South Asia, East Africa, Caribbean</p>	<p>Much research has been conducted on ginger: Herbmed registered 47 articles on traditional use, 43 clinical trials and 32 registered patents.</p> 
<p>Peumus boldus (Boldo leaf)</p> <p>Boldo leaf is an upcoming product for digestive health.</p> <p>Boldo is found in herbal medicinal product for oral use, e.g. in the form of tablets. Herbal monographs are available, as are claims for digestive health. The species is also used in food supplements, but not yet very widely.</p>	<p>No WHO monographs available. ESCOP monograph 2nd Edition (Boldi Folium) European Pharmacopoeia monographs: # 1396 Boldo leaf # 1816 Boldo leaf dry extract Final Community herbal monographs</p> <p>No well-established use of boldo leaf in herbal medicinal products has been documented. As a traditional herbal medicinal product, claims may include use for "symptomatic relief of dyspepsia and mild spasmodic disorders of the gastrointestinal tract".</p>	<ul style="list-style-type: none"> Belgium, France and Italy: allow use of leaf. Italy: also allows use of cortex. Germany: restriction is recommended for use in food Restricted and/or limited for use in food in Austria and Switzerland. <p>Food supplements cannot make a medicinal claim, some UK examples of claims that are made for supplements containing boldo leaf are: "Support healthy liver function." "Promotes friendly bacteria and a healthy intestinal flora balance." "Supports healthy digestive system."</p>	<p>Introduced to Europe and North Africa, extensive cultivation in South America</p>	<p>Herbmed has not registered research on Boldo leaf.</p> 
<p>Foeniculum vulgare (Fennel)</p> <p>Fennel is a well-known product for digestive health. As it is also used by the food and tea industry, it is widely cultivated and markets are competitive.</p>	<p>WHO monograph ESCOP monographs 2nd Edition (Foeniculi Fructus) European Pharmacopoeia monographs: # 824 Fennel, bitter # 825 Fennel, sweet # 1629 Fennel oil, sweet # 2808 Sweet-fennel fruit oil # 1826 Bitter-fennel fruit oil # 2380 Bitter-fennel herb oil Final Community herbal monographs, Foeniculum</p>	<ul style="list-style-type: none"> Belgium and France: allow use of aerial parts, with max. daily use added on label for estragole (0.05 mg/kg of bodyweight for children under 12). Italy: allows use of fruit and oil. Germany: allows use of fruit with maximum level recommended for food. 	<p>Temperate regions, Africa, Australasia, Europe, North America Widely cultivated</p>	<p>Herbmed registered 18 articles on traditional use, 9 clinical trials and 1 registered patent.</p>

² Only European Pharmacopoeia monographs (legally binding), Community Monographs (non-binding) and entries (binding) are valid in the EU. WHO monographs provide information on what herbs are used for in medicine systems outside of Europe, including information on growing conditions, purity tests, chemical constituents and an overview of the botanical's specific action. ESCOP monographs provide a basis for EMA dossiers on herbal medicinal products. They are a reference standard (not legally binding).

³ Indication only. For many countries this information is not available but is expected to be comparable.

<p>It finds substantial application in food supplements, where it is used in the form of capsules, oil or as herbal tea.</p> <p>For herbal medicinal products, fennel finds uses both in digestive health products as well as in products supporting normal menstruation.</p>	<p>vulgare Miller subsp. vulgare var.: dulce, fructus vulgare, fructus vulgare, aetheroleum</p> <p>No well-established use of fennel in herbal medicinal products has been documented. As a traditional herbal medicinal product, claims can include use for "symptomatic treatment of mild, spasmodic gastro-intestinal complaints (bloating and flatulence)" "minor spasm associated with menstrual periods"</p>	<p>Food supplements cannot make a medicinal claim, examples from the UK of claims made for supplements containing fennel are: <i>"Fennel seeds ... are offered at the end of a meal in Asia and South America to sweeten breath and aid digestion"</i> For fennel oil: <i>"Excellent for digestion and wind problems"</i></p>		
<p>Plantago afra, syn. P. psyllium, P. ovata, P. indica (Black psyllium)</p> <p>Both the seeds and the seed husks of the above subspecies of Plantago are commonly used in Europe as laxatives.</p> <p>Use of the species Plantago afra, P. ovata and P. indica in herbal medicinal products has been documented. It is used more in herbal medicinal products than in food supplements. Psyllium is for internal use and is most commonly sold in the form of capsules.</p>	<p>WHO monograph ESCOPE monographs 2nd Edition (Psyllii semen) European Pharmacopoeia monograph # 858 Psyllium seed Final Community herbal monographs Plantago afra and Plantago indica, semen Plantago ovata Forssk., semen Plantago ovata Forssk., seminis tegumentum</p> <p>As a herbal medicinal product, psyllium claims may include use for "treatment of habitual constipation" "conditions in which easy defecation with soft stool is desirable (after rectal or anal surgery, anal fissures and haemorrhoids)"</p>	<ul style="list-style-type: none"> Belgium, France: allow use of seed. Italy: seed and husk. Germany: allows use of seed, with max. level recommended for food. <p>Food supplements cannot make a medicinal claim, examples from Germany of claims that are made for supplements containing black psyllium are: <i>"Psyllium husks for a healthy digestive system"</i> <i>"Psyllium cleans your intestines and supports your digestive system"</i> <i>"...psyllium regulates your bowel movements"</i></p>	<p>Temperate regions; Africa, temperate Asia, Europe, cultivated in Pakistan and India.</p>	<p>Many patents have been registered for black psyllium: Herbmed registered 6 articles on traditional use, 30 clinical trials and 28 registered patents.</p> 
<p>Senna alexandrina, syn. Cassia angustifolia, C. acutifolia (Senna)</p> <p>Senna is an established product in the market for laxatives. There is significant production. New entrants could encounter strong competition. This product is often regulated as herbal medicinal products and not allowed to be sold as a food supplement. Most potential for developing country exporters lies in markets where the product is mostly sold as a food supplement</p>	<p>WHO monograph Folium Sennae Fructus Sennae ESCOPE monographs 2nd Edition Sennae Folium Sennae Fructus Acutifoliae Sennae Fructus Angustifoliae European Pharmacopoeia monograph # 206 Senna leaf # 207 Senna pods, Alexandrian # 208 Senna pods, Tinnevely # 1261 Senna leaf dry extract, standardised Final Community herbal monographs for Cassia Senna and Cassia angustifolia: folium fructus</p> <p>As a herbal medicinal product, claims for senna (leaves and fruit) may</p>	<ul style="list-style-type: none"> Belgium: allows use of fruit (pod) and leaf, with various cautionary notes included on the label. France, Germany: not allowed. Italy: allows use of fruit and leaf. Restricted in food in Austria and the Czech Republic. <p>Food supplements cannot make a medicinal claim, a UK example of a claim that is made for supplements containing senna is: <i>"... which may help maintain a healthy digestive system."</i> An example from the Netherlands: <i>"Supports bowel function"</i></p>	<p>Native to Africa, Middle East, India, Pakistan, Egypt Wild-collected.</p>	<p>Herbmed registered 27 articles on traditional use, 81 clinical trials and 1 registered patent</p> 

(e.g. Belgium, the Netherlands or Italy). Senna is used internally, most commonly in the form of tablets or capsules.	include "short-term use in cases of occasional constipation".			
--	---	--	--	--

Source: *Herbmed*, 2012.

What is the demand for digestive health products in Europe?

- Demand for food supplements and herbal medicinal products is strongest in Germany, France, Italy and the UK. The strongest growth in these segments stems from Eastern European countries, such as Poland, Romania and Slovakia.

Digestive Health

In order to estimate the need for digestive health products, statistics have been included on the main digestive health conditions in Europe and related conditions.

- A study from the UK has shown that digestive symptoms are very commonplace; around 40% of people have suffered at least one digestive symptom at some point. However, it is important to note the difficulty of estimating the prevalence of these symptoms, as digestive symptoms are not recorded in statistics, and consumers do not always visit a doctor.
- United European Gastroenterology has published a [survey on digestive health in Europe](#). This survey indicates that prevalence rates of gastrointestinal (GI) disorders vary considerably across European countries. The highest rates are reported in Eastern Europe and less affluent parts of Western Europe.
- Morbidity and mortality as a result of GI conditions are growing. Mortality is lowest in north-west Scandinavia and Mediterranean countries. Annually, over 200,000 Europeans die as a result of these diseases.
- Estimates of prevalence are available for some of these conditions. One very common condition is Irritable Bowel Syndrome (IBS). The prevalence of IBS varies between 5-25% in European countries, with most patients reporting abdominal pain (close to 90%) and nearly half defining their pain as severe. High prevalence has been reported in studies in Greece and some countries in Eastern Europe (>20%), Spain and the UK (10-15%), followed by Italy and Germany (5-10%) ([Clinical Gastroenterology and Hepatology, 2012](#)). IBS is often treated with alternative therapies, including botanicals.
- Two other highly prevalent digestive diseases are GERD and functional constipation, which affect 1 out of every 6 people worldwide.
- In 2013, EFSA positively evaluated a [health claim](#) relating to the alleviation of short-term constipation and improved bowel movement through the use of a herbal blend (*hydroxyanthracene root* and *rhizome*). This might encourage future health claims in this segment and the sector at large regarding products which are well documented.

Tips:

- If you produce ingredients for digestive food supplements, consider targeting the Italian market as the largest market for these health products. Be aware that it may be difficult to enter this market with non-dairy digestive products.
- Consider targeting Eastern European countries, as these countries have a high prevalence of digestive health issues and because they are growing markets for health products.
- Please refer to [CBI Trade Statistics for Natural Ingredients for Health Products](#) for statistics on European markets for herbal medicinal products and food supplements.
- For more information on sector associations in various European countries, please refer to the sources and promising countries (France, Germany, Italy and the UK) on the [CBI Natural Ingredients for Health Products website](#).

What trends offer opportunities on the European market for digestive health products?

Need in society: growing food intolerance and increasing numbers of people suffering from digestive diseases signal a need in society for products that offer relief from digestive problems and improve digestive health.

Ageing population: An ageing population will increase the demand for natural health options and their ingredients. Maintaining a healthy digestive system is a high priority for 87% of consumers aged 65 and above. It is estimated that 30% of the European population will be 65 or above by 2050, compared with 17% in 2013. This consumer group uses herbal medicinal products and supplements more extensively than younger populations. Note that the elderly are especially keen on well-established, traditional products. Many such products are already on the market in Europe.

From curing to preventing illness: the demand for products that maintain or improve digestive health has increased. Consumers believe that maintaining good digestive health supports the immune system and prevents illness. Healthy lifestyles, including daily dietary supplements, are increasingly important. This is a particular cause of the rise in demand for supplements.

Supplement manufacturers spearheading innovation: Many more innovative supplement manufacturers are seeking new ingredients for digestive health conditions. These new ingredients will permit them to give their products a distinct profile within a competitive market place. This is not easy, as many well-established products are already on the market for this indication. These products enjoy consumer trust and can depend on healthy marketing budgets from key manufacturers in both segments, as well as in the herbal teas sector.

Tips:

- Do not make medicinal claims for your ingredient in your product documentation or marketing materials if you are targeting the food supplements market. Claims in food supplements can relate only to function (e.g. relating to development and functions of the body, slimming or weight control) and risk reduction. For example, you may not claim that your ingredient prevents/cures specific digestive issues, but you may stress that a certain species can help maintain good digestive health. Also ensure you have the research results to back up your claim with any potential buyer.
- If you are targeting producers of herbal medicinal products, make sure the claims you mention in your documentation are mentioned in the European Pharmacopoeia, monographs or list entries.
- Look for a partner in Europe to help build the marketing story and product dossier. Find a company which is interested and sees potential for the (new) ingredient. Please refer to the CBI Module Finding Buyers for more information and tips to find companies.

Long-term use: consumers are looking for digestive health products which are safe, or safer, to take on a regular basis. Many people believe products deriving from botanicals have fewer side effects and are thus safer to use over extended periods. This is particularly the case for products that support digestive health, with consumers viewing natural products as safer. Please note that natural solutions are not necessarily safer to use than chemical alternatives; in general, this relates to a public perception that natural products are safer.

Research: scientific research and clinical trials that back efficacy and safety are essential for the long-term success of supplements and traditional herbal medicinal products for digestive health. Research partnerships are needed in order to develop this research. Most importantly, consumers want products that provide measurable benefits. For example, the effectiveness of ginger extracts has been demonstrated in various studies, which has driven their use in the sector beyond traditional use.

Tips:

- Communicate that long-term use of your species does not have negative health effects; this is an important marketing argument. However, you need to be able to substantiate product safety based on scientific research.
- Have a look at traditional use as a starting point for new ingredients for digestive health. Such species may form a foundation on which to build substantiation. Refer to [Market channels and segments](#) for more tips and information.
- Focus on the potential of your botanical product in terms of mild digestive problems or relieving the symptoms of chronic conditions such as IBS, rather than serious digestive diseases which are beyond the scope of botanicals. Botanicals possess greater potential for mild conditions, as consumers are looking for health products they can use regularly. Your data should also indicate whether the product is safe for continued use. Although European manufacturers are responsible for product safety, providing such information supports your marketing effort.
- Please refer to [CBI Trends](#) for more market trends.

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

This factsheet considers two industries: herbal medicinal products and food supplements. Both have a distinct legislative framework and route to market, which are elaborately explained in the [Module Buyer Requirements](#).

What requirements do I need to comply with to export natural ingredients?

- You need to comply with the **Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)**. CITES regulates the trade in (for example) wild-collected endangered plants and provides guidance on the species for which trade is prohibited or restricted.
- Your ingredient might require you to establish **Access and Benefit Sharing (ABS)** agreements. These 'mutually agreed terms' detail the terms and conditions of access and use of genetic resources and/or traditional knowledge and supply of raw materials.
- You need to ensure **sustainable sourcing** of your ingredients. This is important to buyers, as they are facing supply shortages for an ever-increasing number of cultivated, but especially wild-collected species. You do not always have to certify sustainable sourcing; have a look at these value-addition opportunities in the section [Competition](#).

Tips:

- Conduct a resource assessment and implement a resource management system.
- If you are an exporter of wild-collected botanicals or their derivatives, take into account the provisions of [CITES](#) in order to guarantee the EU entry of your products. Check [Annex A and B of Regulation \(EC\) No 338/97](#) to ascertain whether import and export permits are required for your product. You can also contact the [local CITES authority](#).
- Read more about [CITES](#) in the EU Export Helpdesk.
- Put a procedure in place to check whether ABS applies. Contact the competent authorities in your country as a starting point. [UEBT](#) and [FairWild](#) provide thorough information on the practical implications of ABS, as established by the [Convention on Biological Diversity](#).

What requirements do I need to comply with to enter the EU market for herbal medicinal products?

If you want to enter the European herbal medicinal products market, you need to comply with the relevant [EU legislation](#) (Directive 2004/24/EC). This procedure provides a specific, simplified regime for traditional herbal medicinal products which can meet certain requirements. Compliance is still required with the detailed quality, documentation, labelling, packaging, certification and traceability standards as established in [the rules governing medicinal products in the European Union](#). This set of rules also governs [marketing authorisation](#) of medicinal products to be sold in the EU market.

Tips:

- Read more about [marketing authorisation for pharmaceutical products](#) in the EU Export Helpdesk.
- Read more about the simplified procedure for homeopathic and herbal products on the [website of the European Commission](#).
- Consult the [EU Export Helpdesk](#) and the [CBI Module Buyer requirements: natural ingredients for health products](#) for a full list of requirements for natural ingredients in health products.

GACP and GMP for natural ingredients: If your ingredients are used in medicinal products for human use, you need to follow Good Agricultural and Collection Practices (GACP) and Good Manufacturing Practices (GMP), established specifically for the industry to ensure your product meets all identity, quality, efficacy and safety requirements. You can support the implementation of these Good Practices by developing Standard Operating Procedures (SOP) and work instructions (WIN). SOPs should be developed for your specific processes and products, but some institutions are developing SOPs, such as Europam, the European Herb Growers Association.

Tips:

- Which guidelines you need to comply with depends on your product:
 - Raw plant materials: [Guideline on Good Agricultural and Collection Practice for Starting Materials of Herbal Origin](#) (GACP). GMP starting material needs to comply with [Part II - Basic Requirements for Active Substances used as Starting Materials](#).
 - Extracts: GACP or GMP requirements depend on stage of product (in extraction process) and intended use. For extracts, comply with requirements on page 3 of the [EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use, Annex 7: Manufacture of Herbal Medicinal Products and for Active Pharmaceutical Ingredients \(API\)](#), follow requirements on page 7 of [Part II - Basic Requirements for Active Substances used as Starting Materials](#).
 - [Develop company specific SOPs and WINs to implement the Good Practices](#)

What requirements do I need to comply with to enter the EU market for food supplements?

EU Legislation specific to food supplements: In addition to general requirements for food, as established under General Food law, food supplements are subject to specific legislation. This legislation lays down compositional and labelling requirements, but still leaves composition beyond minerals and vitamins (e.g. essential fatty acids, fibre, and various plants and herbal extracts) at the discretion of national authorities.

Tips:

- Familiarise yourself with the legislation on food supplements, which is listed on the [website of the European Commission](#).
- Make sure that your ingredients comply with [general requirements for food](#) and food labelling. Buyers usually demand compliance with guidelines for herbs according to [Codex Alimentarius](#). Standards have not been established for extracts.
- 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. You can find such lists at:
 - [German Federal Ministry of Food and Agriculture](#)
 - [Italian Ministry of Health](#) (BELFRIT list for Belgium, France and Italy).

Food safety: Ingredients for food supplements need to comply with requirements for food safety. You can read more about food safety and Novel Food requirements on the websites of the [EU Export Helpdesk](#) and the [European Commission](#).

Tips:

- [Novel Food Regulation](#): Consumer safety of ingredients that were not consumed within the EU before 15 May 1997 needs to be assured to comply with this regulation. Consult experts and internet research for insights into whether there is historical use in Europe. The (non-exhaustive) [Novel Food Catalogue](#) lists plants subject to the Novel Food Regulation and provides their current status.
- [Maximum Residue Levels \(MRLs\)](#): strict control of pesticide use must be a focal point in your production system. These controls are increasingly strict, as improving laboratories can detect more residues.
- Criteria and maximum levels of [contaminants in food](#) and [microbiological contamination of food](#): Apply GACP/GAP and GMP to minimise and document contamination.
- [Hygiene of food \(HACCP\)](#): legally binding for food processors (including ingredients) and recommended for farmers (primary production).
- Find out which [extraction solvents for food](#) you can use and under which conditions.
- [Irradiation of food](#) is only permitted in specific cases for spices and herbs, including supplements.
- [Traceability is based on the](#) "one step back-one step forward" principle; you need to trace food that is used for consumption through the value chain.
- Be ready to demonstrate traceability by documenting your value chain. If you want to have your product certified (e.g. FairWild, Fairtrade or organic), traceability will be important as well.
- Moreover, have a look at common causes for border rejection and product withdrawals on the [Rapid Alert System for Food and Feed \(RASFF\)](#). Examples include contaminants and unauthorised food ingredients.
- Check and adhere to the food safety legislation in your country.

What additional requirements do buyers often have?

Buyer specifications and requirements: Many buyers have additional quality requirements which can go beyond legislation and standards (active ingredient content, moisture content, contaminants, residues, etc.). These are established in buyer specifications. To show that you meet their specifications, they also require well-structured company and product information, including detailed technical data sheets.

Tips:

- Make sure you meet international product standards and buyer specifications.
- Include plant identification through a national and/or a company herbarium in your product specifications, this is important as a reference.
- Prevent (un-)intended adulteration and contamination by other foreign materials by keeping facilities and equipment clean, and by ensuring full documentation and traceability.
- If you produce extracts, you need to meet buyer requirements in terms of extraction methods, solvent use, preservatives, etc. Validate and document extraction conditions: processing aids, temperature, pressure/vacuum, flow rate, etc.
- If you use preservatives, make sure you have the HR capacity to tailor their use to buyer specifications and for their proper documentation. You also need specialist staff to monitor process quality and microbiology.
- Make sure your documentation and labelling comply with respective legislation and buyer requirements. Information on possible dangerous characteristics of chemical substances must be provided on Material Safety Data Sheets. Furthermore, it is likely that your buyer requires test reports.
- Implementing and documenting Standard Operating Procedures can provide a lot of trust on the part of buyers that you will keep up quality standards.

What are the standards and requirements for niche markets?

Social and environmental sustainability:

- If you want to market **organic ingredients** in the EU, you need to comply with EU requirements on the production and labelling of organic products of agricultural origin. Herbal medicinal products cannot be labelled as organic or fair trade.
- Verifying and/or certifying **sustainable production** represents a niche market, but can add value to your product. For more information on such value addition, please refer to value-addition opportunities in the section [Competition](#). Better-known sustainability standards include:
- The [UNCTAD BioTrade Initiative BioTrade Principles and Criteria](#) or [FairWild](#) Principles and Criteria
- Social: Fair Trade certification, such as [FLO Fairtrade](#) or [FairForLife](#).
- Some EU buyers may expect you to comply with their supplier **codes of conduct** regarding **social responsibility**, which are often based on ILO labour standards or on UN Global Compact reporting.

Tips:

- Discuss with (potential) buyers whether they would be interested in certified sustainable natural ingredients of the above standards.
- If you choose to obtain a certificate for organic production, find out more about [Organic production and labelling](#).
- Dedicate the processing plant to the exclusive production of organic ingredients. If this is not possible, ensure thorough cleansing of machinery and equipment at all times.
- Consult the [Standards Map database](#) for different sustainability and organic standards.
- For more information on responsible business practices, refer to the [UN Global Compact](#) and ISO 26000 as guidance, and use the [SEDEX](#) online database, where members can share information on ethical and responsible practices. You can also use SEDEX to prepare for possible audits/questions from your buyers.

Quality and food safety management: In addition to the mandatory HACCP standard, EU food industries increasingly demand compliance with more comprehensive food safety standards (food safety management systems), as well as quality safety management as specified in [ISO 9001:2008](#) (required for health ingredients). This mostly concerns large retailers and (private label) manufacturers, most notably for food supplements. Examples include the [International Food Standard \(IFS\)](#), [ISO 22000](#) (food safety) and [ISO 31.000](#) (risk management).

Tips:

- Consider carefully whether to comply with the above standards and certifications. Verify whether your buyer truly demands compliance, whether 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, it is also important to ascertain whether you can gain your buyer's trust in another way.
- Stay up to date with information on food safety standards by checking news items published on the [Codex Alimentarius](#) and [HACCEUROPA websites](#).

What competition do I face on the European market for digestive health products?

Synthetic alternatives

Certain digestive diseases are treated with *conventional medicine*. For example, inflammatory bowel diseases are often treated with non-steroidal anti-inflammatory drugs (NSAIDs). Bacterial infections are mostly treated with antibiotics. With reference to replacing antibiotics, opportunities for natural ingredients are improving because of increasing bacterial resistance. Moreover, there is strong demand for natural antibiotic options in veterinary medicine/supplements.

In terms of *food supplements*, synthetic alternatives encompass both synthetic vitamins and digestive enzymes. Digestive enzymes are a particularly popular product for improving digestive health and preventing indigestion.

Tips:

- Consider whether your ingredient offers anti-inflammatory or anti-bacterial properties which might be of interest to this segment. Also consider whether your ingredient is already used in this segment. Online resources to assist with this include herbal medicinal product manufacturers' websites, [EMA monographs](#), [Pharmacopoeia](#) and websites such as the [European Medicines Agency](#), [MedlinePlus](#) or [Herbmed](#).
- Please refer to [CBI Competition](#) and CBI Top 10 Tips for doing business for more information.

Existing natural alternatives

There is a wide range of natural alternatives aimed at digestive health:

- Dietary fibres are the most common alternative, either sold as food supplements or used in functional food. Alongside botanical sources (e.g. algae), a variety of fruits are also popular. Examples include plums, figs, dates and apricots. Additionally, health claims have been authorised for several grain fibres (e.g. rye, oat grain, barley and wheat bran fibres), which producers can include in their marketing.
- Probiotics and prebiotics are marketed as supporting digestive health. Probiotics introduce/support "good" intestinal bacteria, while prebiotics stimulate growth and activity of bacteria. A strong competitive advantage of probiotics is that they are commonly consumed as an element of fermented drinks (yoghurt) with added, active live cultures instead of being taken as tablets. Europe represents the largest market for pre and probiotics in the form of yoghurts, with sales of around € 4.5 billion in 2012.
- Natural alternatives for digestive enzymes can be obtained from fruits such as papaya or pineapple.

Several alternatives are also marketed for weight control. An example is flaxseed oil, which contributes to the healthy functioning of the digestive system and benefits from its marketing appeal as a high-omega oil.

Tips:

- Create a strong marketing story, backed up by solid, independent research. This is important to generate interest in products in this indication. It is also important to have a story to support the marketing effort because, although digestive health is a large vibrant market, the wide range of existing alternatives make the marketing of new ingredients difficult. You could also link products to weight control.
- Carefully consider whether you would be able to meet the high legislative and buyer requirements for herbal medicinal products, and whether your offer would improve to such an extent on offers made by current suppliers (in terms of price, delivery and services) that it would enable you to entice buyers to work with you.
- Traceability is not available for many ingredients of herbal medicinal products. Your offer will be of greater interest to buyers if you can show traceability and sustainable future access to raw materials, particularly with regard to scarce ingredients.

Value-adding opportunities when competing in the market

Adding value can be a way to create a distinct profile in the market and make your product more attractive to buyers. You can add value with further processing (e.g. from raw material to extract to final product):

- Opportunities to **add value to raw materials** are often not fully exploited; proper post-harvest processing (sorting, grading) and proper documentation can lead to you obtaining a higher price.
- Developing country producers are moving **beyond raw material** towards the export of extracts. Processing raw materials into essential oils is guided by the existence of standards, and buyer demands are well understood. In contrast, it is more difficult to come to a common understanding on quality in the case of many herbal extracts. With that in mind, many EU buyers prefer to import raw materials, even if their suppliers would prefer to export extracts (to other markets).
- **Finished products** in the EU market aimed at relieving digestive problems are beyond the scope of most companies in developing countries, taking into consideration product development, market authorisation and marketing costs.

Tips:

- Help manufacturers build their story by, for example, documenting and visualising your product and company's unique value proposition. This will also contribute enormously towards your own marketing effort. Final manufacturers can use this information to market the end-product in Europe.
- Align quality improvements to your product with buyer requirements (specifications) and their willingness to pay for them. Quality improvements can be costly, and you need to ensure that the potential exists for getting an adequate return on investment.
- Determine your option to market simple finished products such as herbal teas. Herbal teas are commonly used for minor digestive problems, e.g. teas containing ginger, fennel, mint, aniseed, camomile or cinnamon, or a combination thereof.

You can also add value by certifying your company according to social and environmental sustainability principles:

- Producers with a company image focused on sustainability (ethical/ environmental) place more value on certification of the ingredients in their food supplements.
- 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.
- Even though certifications cannot be used on labels for **herbal medicinal products**, sustainable certification will add value when approaching manufacturers adhering to a philosophy that calls for such certification.

Tip:

- Verify your buyers' interest in certified ingredients:
 - Organic certification also acts as a quality control system and can help to improve your quality image.
 - Fair Trade and FairWild certification can help indicate to your buyer that the production of ingredients is generating rural income and does not harm local communities (this could jeopardise the buyer's image).
 - Certification demonstrating sustainable sourcing (e.g. FairWild) can help show potential buyers that you could be a reliable future partner.

What do the trade channels and interesting market segments look like in Europe for digestive health products?

Market segments

Both herbal medicinal products and food supplements to relieve digestive health symptoms are based on traditional recipes and well-known, established species. **Herbal medicinal products** offer several products to relieve digestive symptoms; most producers of herbal medicinal products will have some products for this indication in their portfolio.

Although their use as medicinal products is well documented, fewer products are marketed as herbal medicinal products when compared with food supplements. One reason for this is that legislative hurdles limit product innovation and introductions to Europe. In Europe, the only exception is Germany, where *Aloe ferox* is not allowed as a food supplement. Moreover, the laxative senna is restricted in supplements in most countries.

Botanical-based **food supplements** are commonplace and are marketed as either preventing or relieving digestive issues. Consumers tend to use food supplements for minor digestive problems, rather than herbal medicinal products. Digestive health supplements are mainly single-herb products.

Manufacturers are interested in product development (with new species) in order to create a distinct profile for their companies in the highly competitive digestive health market and to improve their margins. In general, the UK and France are more vibrant in terms of product introductions than Germany or Italy.

Market channels

With regard to established species for food supplements, trade relations focus on maximising supply security and reducing costs. By contrast, new ingredients call more strongly for collaboration. Concerning herbal medicinal products, trade relations offer more room for collaboration owing to the paramount importance of supply security.

Tips:

- Look at local practice: what do local people use to improve digestive health? Build up files on traditional use, and support this with clinical tests. Such information can be used to approach European traders, ingredient processors and manufacturers.
- If you supply senna or *Aloe ferox* (as laxatives), focus on countries where it can be sold as a food supplement, as market entry is easier in this segment.
- Consider whether you would be able to become a preferred supplier for larger players (larger volumes, very high expectations in terms of service delivery).
- For tips on finding buyers, have a look at the CBI Module Finding Buyers. Use your knowledge of product development activity and potential for marketing your product more specifically to the right buyer.
- Please refer to [CBI Market Channels and Segments](#), where the various players at the various levels of the value chain are discussed in more depth. You are also provided with an overview of the key market characteristics and trends for both segments: herbal medicinal products and food supplements.

Useful sources

Visiting and, above all, participating in trade fairs are highly recommended as among the most efficient methods of testing market receptiveness, obtaining market information and finding prospective business partners. The European trade fairs of greatest relevance to exporters of natural health ingredients are:

- [SANA](#) in Bologna, Italy
- [Hi/Ni](#) (Health ingredients/Natural ingredients): Travelling trade fair
- [Fi/Ni](#): Food ingredients/Natural ingredients travelling trade fair
- [Biofach](#) in Nuremberg, Germany (for organic producers)
- [Vitafoods](#) in Geneva, Switzerland
- [CPHI](#) is more focused on pharmaceuticals, but larger natural extract companies also exhibit at this fair in a dedicated natural extracts zone.
- [Anuga](#) in Cologne, Germany, is a food and beverages fair with a dedicated "Wellfood" department (supplements, functional food and medicine).

Trade press/news

- [Nutra Ingredients](#): News on supplements and nutrition in Europe.
- [Foodnavigator](#): Science and nutrition research, product news, newsletter, health and nutritional ingredients.
- [Nutraceuticals World](#): News, buyers' guide on various herbs and botanicals, knowledge centre and market, peer-reviewed and supplier research.
- [Nutraceuticals Now \(spring issue 2015\)](#): technical review on functional products and ingredients which are defined as disease preventing and/or health promoting in addition to nutritional value.

More information

CBI market information: Promising EU export markets.

EU Expanding Exports Helpdesk - <http://exporthelp.europa.eu>.

Eurostat - <http://epp.eurostat.ec.europa.eu/newxtweb> - statistical database of the EU. Several queries are possible. For trade, choose 'EU27 Trade Since 1995 By CN8'.

International Trade Statistics - <http://www.trademap.org> - you have to register.



CBI Market Intelligence

P.O. Box 93144
2509 AC The Hague
The Netherlands

www.cbi.eu/market-information

marketintel@cbi.eu

This survey was compiled for CBI by ProFound Advisers In Development
in collaboration with CBI sector expert Klaus Duerbeck

Disclaimer CBI market information tools: <http://www.cbi.eu/disclaimer>

November 2015