



CBI
Ministry of Foreign Affairs

CBI Product Factsheet:

Natural Ingredients for Stress & Anxiety products in Europe

Introduction

The need for products relieving stress and anxiety is growing as stress levels are increasing worldwide. Consumers are more aware of the negative impact of stress on their health and related conditions such as insomnia and depression. Botanical-based health products currently on the market help relieve mild nervous tension and sleep disorders. Food supplements producers are especially keen to source new ingredients for product development. Aromatherapy also offers solutions for this indication and is a segment of interest.

Indication & product definition

Stress & Anxiety

The indication "Stress & Anxiety" encompasses various interconnected conditions related to the sympathetic and parasympathetic nervous systems. These nervous systems stimulate activities associated with fight-or-flight responses (sympathetic) and activities that occur when the body is at rest (parasympathetic). Stress disturbs the functioning of these processes.

Box 1: How to use this Factsheet

- Learn how European consumers use herbal medicinal products and food supplements and aromatherapy for stress & anxiety.
- 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 stress & anxiety market segments and receive key insights into how to enter them.

Stress influences both a person's mental and physical wellbeing. It can be caused by various factors, such as environmental conditions, chemical or biological agents, and external stimuli or events. Anxiety is an unpleasant state of inner turmoil often accompanied by nervous behaviour. Both stress and anxiety can lead to sleep deprivation, insomnia, a state of low mood and mild to severe depression. This factsheet discusses the whole range of conditions, as similar botanicals are used to treat them.

Stress & Anxiety and natural health options

Different health options can be chosen depending on the severity of the condition. Severe cases of depression, insomnia and anxiety disorders are mostly treated in consultation with physicians, using conventional medicine instead of herbal medicinal products or supplements. For mild forms of depression, stress, anxiety, trouble with sleeping and a state of low mood, consumers are more liable to consider herbal solutions. This is also related to the wide availability of non-prescription and over-the-counter (OTC) products. Most products are marketed as aromatherapy and as food supplements with lower concentrations of active ingredients. However, many companies market supplement and medicinal products based on the same active ingredients. The latter are marketed as having greater efficacy, i.e. higher concentration of active, pharmaceutical-grade ingredients (the standard suitable for use as medicine).

In terms of mild stress and anxiety, consumers also show a keen interest in herbal teas and aromatherapy to increase feelings of wellbeing. Key words used in marketing are relieving, calming, relaxing, soothing, refreshing, uplifting and balancing.

Natural ingredients for stress and anxiety products

According to industry sources, various botanicals are used to relieve stress and anxiety in Europe – particularly "mellow" herbs. These are either used internally or as essential oils for aromatherapy. The most commonly used plants include:

St John's wort (<i>Hypericum perforatum</i>)	valerian (<i>Valeriana officinalis</i>)
passionflower (<i>Passiflora incarnata</i>)	lavender (<i>Lavandula angustifolia</i> , L. <i>officinalis</i>)
German chamomile (<i>Matricaria recutita</i>)	lemon balm (<i>Melissa officinalis</i>)
Rhodiola (<i>Rhodiola rosea</i>)	Siberian Ginseng or eleuthero (<i>Eleutherococcus senticosus</i>)

Moreover, aromatherapy oils are also used to help relieve stress and anxiety symptoms. Oils of interest to developing countries include neroli, petitgrain, coriander seed, frankincense, (rose) geranium, palmarosa, patchouli and ylang-ylang. The table in Annex I provides more information on these aromatherapy oils. 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](#) regarding several essential oils and refer to relevant European and International literature available under [Forum Essenzia](#).

Exemplary species for developing country producers

Not all these species are equally relevant to developing country exporters. St John's wort contraindications with conventional medicine and competitive production in Europe make it less relevant to exporters from developing countries. In the case of lavender, production in (Eastern) Europe is highly competitive; in order to compete with other countries, particularly Ukraine, it is essential that you operate on a sufficient scale and with a high level of mechanisation.

Industry sources indicate that valerian root, passionflower and lemon balm have the best potential for developing country producers in areas with the right growing conditions. Regarding German chamomile, industry sources indicate that, although scale is essential for entry into this highly competitive market, shortages on the market offer opportunities to quality exporters in temperate regions of Asia.

The table below provides information on the exemplary species used in stress and anxiety 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 based on these ingredients are mostly offered as pills in dosage forms, but they also find applications in tonics or herbal teas.

Tips:

- Check Community herbal monographs as provided by the [European Medicines Agency](#) to assess product standards and possible claims.
- Link up with local universities or laboratories to conduct thorough research and product development. Investigate existing intellectual property and include this in your product documentation. In terms of market entry with regard to new species, it is important to have clinical evidence of their efficacy in relieving stress and anxiety.
- 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 stress and anxiety products worldwide. Some of these can be/are already being used.
- 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.

Table 1: Selected key species for stress & anxiety

Definition	Monographs ²	Permitted usage in supplements ³	Origin	R&D
<p>Valeriana officinalis (Valerian)</p> <p>Valerian has a large and well-established market, both for herbal medicinal products and for supplements, especially in terms of sleeping aids. Although competition will be strong, both from Europe, as well as from producers in temperate Asia, there have been supply shortages in the past.</p>	<p>WHO monograph</p> <p>ESCOP monographs 2nd Edition Supplement (Valerianae radix)</p> <p>European Pharmacopoeia monographs:</p> <ul style="list-style-type: none"> # 453 Valerian root # 2526 Valerian root, cut # 1898 Valerian dry hydroalcoholic extract # 1899 Valerian tincture # 2400 Valerian dry aqueous extract <p>Final Community herbal monographs:</p> <p>Valerianae radix</p> <p>Valerianae radix/Lupuli flos</p>	<p>Belgium: allows use of root and rhizome (rootstock), with max. daily use shown on the label of 3.6 g dry root. Final products cannot contain valepotriate.</p> <p>France: allows use of subterranean plant parts. Absence of valepotriate needs to be proven, label needs to advise against use by minors under 12.</p> <p>Italy: allows use of root and rhizome.</p>	<p>Cultivated in temperate Asia and Europe.</p>	<p>Much research has been conducted on valerian: Herbmed registered 33 articles on traditional use, 66 clinical trials and 18 patents.</p> 

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.

² Only European Pharmacopoeia monographs (legally binding), Community Monographs (non-binding) and entries (binding) are valid in the EU. WHO monographs provide information on for the uses to which herbs are put 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. This information is unavailable in many countries, but it is expected to be comparable.

<p>In supplements, the species is often used in combination with other herbs.</p>	<p>Draft Entry to list of herbal Substances</p> <p>As a herbal medicinal product, valerian claims can include use for: "the relief of mild nervous tension and sleep disorders". Claims for valerian with hop (<i>Humulus lupulus</i>) can include use for: "the relief of sleep disorders".</p> <p>As a traditional herbal medicinal product, claims can include use for: "relief of mild symptoms of mental stress and to aid sleep".</p>	<p>Germany: allows use of root, but with recommended maximum levels.</p> <p>Food supplements cannot make a medicinal claim, examples from the Netherlands of claims made for supplements containing valerian are: "supports a good night's sleep" "supports relaxation". From the UK: "Valerian supports mental wellbeing in cases of stress from a busy lifestyle, and helps with normal relaxation".</p>		
<p>Melissa officinalis (Lemon balm)</p> <p>Although also used as an essential oil, its main use is as a herb processed into supplements and herbal medicinal products. There is a large market for lemon balm in both segments. It is often used in combination with other species.</p>	<p>WHO monograph ESCOP monographs 2nd Edition (<i>Melissa folium</i>). European Pharmacopoeia monographs: # 1447 Melissa leaf # 2524 Melissa leaf dry extract # 2311 Melissa leaf dry extract, quantified # 2291 Melissa officinalis for homeopathic preparations Final Community herbal monograph</p> <p>No well-established use of lemon balm in herbal medicinal products has been documented. As a traditional medicinal product, lemon balm claims can include use for: "relief of mild symptoms of mental stress and to aid sleep". "symptomatic treatment of mild gastrointestinal complaints (bloating and flatulence)".</p>	<p>Belgium, France and Italy: allow use of leaf. Italy: also allows use of flowering herb and oil. Germany: allows use of leaf, but with recommended maximum levels.</p> <p>Food supplements cannot make a medicinal claim; an example from the UK of claims made for supplements containing lemon balm is: "Lemon balm helps to maintain balanced mood, and also supports relaxation".</p>	<p>Cultivated in Europe, North Africa and North America, native to Southern Europe and Western Asia.</p>	<p>Little research has been conducted on lemon balm: Herbmed registered 11 articles on traditional use, 12 clinical trials and 1 patent.</p> 
<p>Passiflora incarnata (Passionflower)</p> <p>Enjoys growing interest from manufacturers, especially from food supplement manufacturers, in products for relaxation, often in combination with other herbs. It is not used as much in herbal medicinal products.</p>	<p>WHO monograph ESCOP monographs 2nd Edition (<i>Passiflorae herba</i>) European Pharmacopoeia monographs: # 1459 Passion flower # 1882 Passion flower dry extract Final Community herbal monograph</p> <p>No well-established use of passionflower in herbal medicinal products has been documented. As a traditional medicinal product, passionflower claims can include use for: "relief of mild symptoms of mental stress and to aid sleep".</p>	<p>Belgium: allows use of aerial parts of the plant. France: allows use of aerial parts of the plant. Italy: allows use of flowers and flowering herb. Germany: allows use of flower and herb.</p> <p>Food supplements cannot make a medicinal claim; examples from the Netherlands of claims made for supplements containing passionflower are: "helps with inner restlessness and in stressful situations". "Soothing during stress" "...helps with (exam) nerves".</p>	<p>Cultivated in North America and Eastern Europe; moderate climates.</p>	<p>Little research has been conducted on passionflower: Herbmed registered 5 articles on traditional use, 6 clinical trials and 6 patents.</p> 
<p>Matricaria recutita (German chamomile)</p> <p>Chamomile is described in the European Pharmacopoeia and is used extensively in this segment.</p> <p>German chamomile is also an established product in the</p>	<p>WHO monograph ESCOP monographs 2nd Edition (<i>Matricariae flos</i>). European Pharmacopoeia monograph # 2493 Chamomilla for homeopathic preparations Drafts Community herbal monographs under discussion: <i>Matricariae flos</i> <i>Matricariae aetheroleum</i></p>	<p>Belgium: allows use of all plant parts with max. daily use shown on the label of 1.9 mg of α-bisabolol and 5.6 mg of apigenine-7-glucoside. France: allows use of all plant parts. Italy: allows use of flower heads, flowers, herb and oil. Germany: allows use of flower (with recommended</p>	<p>Cultivated in Europe, temperate Asia, North America and Australia.</p>	<p>Little research has been done on German chamomile: Herbmed registered 13 articles on traditional use, 9 clinical trials and</p>

<p>market for supplements and herbal teas.</p> <p>Supply shortages have been repeatedly reported in the past, offering opportunities to producers in temperate Asia able to ensure sufficient availability at a commercially viable price.</p>	<p>No well-established or traditional use of German camomile in herbal medicinal products has yet been established, as there are currently only draft monographs available.</p>	<p>maximum level), herb and seed.</p> <p>Food supplements cannot make a medicinal claim; an example from the UK of claims made for supplements containing German camomile is: "May help to...support normal relaxation". "For good sleep and relaxation".</p>	<p>1 patent.</p> 
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Source: *Herbmed*, 2012

What is the demand for stress & anxiety 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.
- Although antidepressants fall within the category of prescription drugs, their consumption can be a useful indicator for depression rates and the need for stress and anxiety relieving health products. In Europe, Iceland had the highest consumption of antidepressants in 2012, followed by Portugal, Denmark, Sweden, the UK, Belgium and Finland. Data from 2012 show that consumption of antidepressants nearly doubled in EU countries from 2000 to 2012. Researchers see the following causes: a greater intensity and duration of treatments; an increase in the use of antidepressants for milder forms of depression; as well as the insecurity related to the economic crisis.

Stress & Anxiety

In order to estimate the need for stress & anxiety products, statistics have been included on the main conditions in Europe.

- Mental disorders (in their broadest sense) affect 27% of Europe's adult population (aged 18-65). This translates to 83 million people being affected every year. The [WHO](#) estimates that the actual number is even higher, as this figure does not include people over 65 years old. Rates among women are higher than among men: 33.2% vs 21.7% respectively.
- Less than one-third of those affected by mental disorders are receiving some kind of treatment. The most commonly identified disorders are anxiety (14% of the total), insomnia (7%) and depression (6.9%).
- According to the WHO, if anxiety and all forms of depression are included, nearly four out of 15 people are affected in Europe every year.
- According to a report by the European Agency for Safety and Health at Work, a major source of stress is work-related. This is most often reported by workers in the 40-54 age group. It is estimated that more than 1 out of 4 sick days at work is stress-related.
- In Western Europe, 31% of the population have reported difficulty sleeping. Sleep disorders such as insomnia are often under-diagnosed and under-treated. A European survey concluded that 37% of people suffering from insomnia took no action to resolve it, 10% used OTC remedies and 13% adopted non-pharmacological remedies, such as cognitive behaviour therapy or sleep hygiene (establishing a sleep routine and exercise).

Tips:

- Focus on markets with a higher need for stress and anxiety products and high sales of mood/relaxing food supplements, such as France, Belgium, Scandinavian countries, Portugal and the UK.
- 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 stress & anxiety products?

Need in society: There is an increased need for herbal medicinal products and food supplements used to relieve symptoms related to stress, due to rising stress levels. Stress levels in contemporary society have increased as a result of

work, travel, pressure, sensory overload and vast quantities of information. Herbal food supplements that help reduce stress are also expected to benefit from the trend towards preventive health care, according to market research by Global Industry Analysts Inc.

Ageing population: An ageing population is increasing the demand for certain herbal supplements and remedies. The elderly experience sleeping problems more often than other age groups. Moreover, relatively high numbers of consumers in this age group are interested in natural self-medication.

Consumer awareness: Demand is growing for aromatherapy products and for food supplements that can be taken long-term as a result of increasing consumer awareness of general health and wellbeing and the effect that stress has on them. Stress is increasingly seen as affecting the general immune system. Healthy diets and lifestyles are increasingly important, and there is interest in non-European health traditions for relieving stress.

Tradition of use: when it comes to food supplements, traditional usage helps European manufacturers create their own distinct profile in the market by means of a marketing story. It is this story that influences the consumer image of a product's effectiveness. One such example is valerian, which has a very long documented history concerning its sedating medicinal qualities. Traditional usage is of particular importance with regard to aromatherapy oils, particularly given that these oils often lack scientific proof of their effectiveness when used in this form. Therefore, the way in which they are used is mainly based on tradition and their image. For aromatherapy oils, good marketing stories are essential.

Tips:

- Traditional uses can be a good starting point when determining new ingredients for stress or anxiety relief. Find out about local practices in relation to remedies for stress.
- Create marketing stories for ingredients and aromatherapy oils that offer stress or anxiety relief. Focus on the feeling of relaxation. Develop a thematic story, e.g. by highlighting the country of origin as an exotic place where you can wind down. Examples include ylang-ylang from the Comoros or rose geranium oil from Réunion. Country of origin is important in this context and needs to be clearly communicated to end-users. Consumers are less interested in social responsibility issues for stress or anxiety relief. It is best to discuss certification options with your buyers.

Side-effects of conventional medicine: Given that herbal supplements and remedies derive from botanicals, consumers believe that they are mild and thus have fewer side-effects than conventional medicine, making them safer to use long-term. Evidence of side effects from conventional medicine is increasing, e.g. antidepressants have been shown to have several negative side-effects. Additionally, consumers using sleeping pills may become dependent on them. However, certain herbal remedies for depression also have considerable side-effects, e.g. St John's wort and kava-kava (*Piper methysticum*), which is banned in the European Union because it may cause liver damage.

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 growth, development and functions of the body and psychological and behavioural functions) and risk reduction. For example, you may not claim that your ingredient can cure depression, but you may stress that a certain species can help maintain a balanced mood. Ensure you can back up your claims 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.
- Focus on your botanical's potential in terms of managing specific stress and anxiety issues, such as long-term daytime stress relief. To target such a market you need to determine whether your product is suitable for long-term use. Although European manufacturers are responsible for product safety, providing such information supports your marketing effort. The same holds true for mild sleep relief products, such as those containing camomile.

Multiple ingredients: there is a trend towards multiple ingredients in food supplements that target a specific condition. Examples include supplements for stress relief that combine different species which remedy stress or anxiety, such as a sleeping-aid tea that contains valerian root, lavender and camomile.

Tip:

- Emphasise the potential for combining herbs with vitamins or minerals to create food supplements to remedy stress, anxiety or related conditions. Examples include supplements containing passion flower together with camomile for a calming effect, or a combination of valerian, vitamin E and calcium as a sleeping aid.

Research: particularly for food supplements, ingredient companies are conducting research that will enable them to make claims and thus create their own distinct market profile. Research is essential in order to substantiate claims for stress and anxiety ingredients, as a wealth of data and documentation is available for the most important species used in existing herbal medicinal products and food supplements. Any new ingredient would need to compete with products which are very well established commercially and scientifically.

Tips:

- Look for a partner in Europe to help build the marketing story and the business. Find a company which is interested and sees potential for the (new) ingredient. Please refer to the section on market segments and the useful sources section for more information on finding companies.
- Please refer to [CBI Trends](#) for more market trends.

What requirements should natural ingredients for stress & anxiety 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 and fair trade.
- Verifying and 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 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 [HACCPEUROPA websites](#).

What competition do I face on the European market for stress & anxiety products?

Synthetic alternatives

Consumers are predominantly using prescribed non-herbal medicinal products to relieve more severe forms of stress, anxiety and, above all, depression. These *conventional medicines* are based on either chemical or synthesised compounds with proven effectiveness. General practitioners and specialists turn to these products when looking for treatments for their clients. Therefore, beyond a small niche of consumers rejecting synthetic health solutions, herbal solutions cannot compete.

Tips:

- Communicating that long-term use of your species does not have negative health effects is an important marketing argument. However, you need to be able to substantiate product safety based on scientific research.
- Please refer to [CBI Competition](#) and CBI Top 10 Tips for doing business for more information.

Existing natural alternatives

Herbal medicinal products and food supplements have a stronger position in relation to less severe conditions, e.g. relieving minor stress or anxiety, offering sleep aids or increasing relaxation. Herbal products have a strong position, particularly in terms of long-term use.

Most species used for stress and anxiety have *established markets* and can be used interchangeably in different combinations, often with vitamins and/or minerals. Therefore, these are highly competitive markets where margins are comparatively low.

This makes it difficult to introduce new species, as they need to compete with products that the public sees as highly effective. Nevertheless, product innovation is occurring in the food supplements area.

Tips:

- Determine whether you can attain sufficient economies of scale to compete with products such as German chamomile or lemon grass.
- Provide documentation that enables your buyer to market the product in terms of its origin and/or traditional use(s). You will also need to demonstrate efficacy and safety for new ingredients, but this alone is probably insufficient.
- 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.
- 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](#).
- 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 of creating your own distinct market profile and making 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 both get you 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 terms of many herbal extracts. Therefore, many EU buyers prefer to import raw materials, even if their suppliers would prefer to export extracts (to other markets).
- **Finished products** for stress and anxiety relief on the EU market are beyond the scope of most companies in developing countries, taking into consideration product development, market authorisation and marketing costs. One exception could be the marketing of simple products such as herbal teas and aromatherapy products. South-South trade also offers good opportunities for this type of final product, as it is relatively simple and well established.

Tips:

- Help manufacturers build their story, e.g. by documenting and visualising your product and company's unique value proposition. Particularly in the case of stress and anxiety, images linked to traditional uses, wellbeing and a stress-free life can contribute considerably 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 or aromatherapy products.

You can also add value by certifying your company according to social and environmental sustainability principles. However, compared to other indication areas, certification is less important in stress and anxiety health products, as consumers are less interested in sustainability when they are themselves trying to relax.

- 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:

- Before committing to a certification scheme, always 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 stress & anxiety products?

Market segments

Herbal medicinal products on offer in Europe include various products to help relieve stress or anxiety. Most producers will have some products for this indication in their portfolio. Product innovation in and introductions to Europe are very limited, and key products on the market have a long history of use and enjoy consumer trust, e.g. valerian and camomile. Therefore, taking legislative hurdles and existing supplier-buyer relations into account as well, it will be difficult for new species to compete.

Currently, more stress-relieving products are marketed as **food supplements**, especially outside of Germany. These mostly contain lower concentrations of the same active ingredients as those used in herbal medicinal products. Food supplements are marketed for milder stress and anxiety conditions. Almost all supplement manufacturers offer stress & anxiety (relaxing) health products, often based on traditional recipes.

Product development and innovation are difficult, as existing products are highly established. Ingredients are proven to be effective and enjoy consumer trust. It will be difficult for new supplements to compete with them. However, manufacturers want to create their own distinct profile within the highly competitive market and improve their margins. Examples are herbal teas with low concentrations of established species, or products with lavender. Some companies are being (increasingly) innovative in adding new ingredients unfamiliar as supplements in Europe.

Market channels

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

Tips:

- Look at local practice: what is the term for relaxation in your local language? What do local people use to 'relax' or to remain calm in stressful situations? Build up files on traditional use, and support this with clinical tests. Such information can be used when approaching European traders, ingredient processors and manufacturers.
- Consider mild herbs or essential oil species used for aromatherapy, to find new products with good potential for stress and anxiety. One such example is lavender, which is already well-known in aromatherapy and is now increasingly used in supplements.
- Seek a partner in Europe to help research the effectiveness of new ingredients, to build product documentation and to assist with the marketing story. Find a company that shows interest and sees potential for the (new) ingredient.
- 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 most relevant trade fairs in Europe for 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 the pharmaceutical market, 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 but now also has a dedicated "Wellfood" department, including food 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



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