



CBI
Ministry of Foreign Affairs

CBI Product Factsheet:

Natural Ingredients for Cognition products in Europe

Introduction

Cognition products have a wide range of uses, with opportunities at either end of the spectrum. On the one hand, European consumers use cognition-enhancing natural products to cope with the fast pace of contemporary society. On the other hand, they look at natural alternatives to prevent cognitive impairments such as dementia for which conventional medicine does not offer an effective treatment.

Indication & product definition

Cognition

Cognition is the set of mental abilities and processes that are related to knowledge, including awareness, perception, reasoning and judgement. Functions of cognition mainly include memory, attention, creativity and intelligence. Cognitive impairment comprises any characteristic that acts as a barrier to the cognition process and covers many conditions. The main cognitive dysfunctions covered in this factsheet are mild cognitive impairments and dementia. Mild cognitive impairment is a syndrome in which cognitive decline is greater than expected for a person's age and education, and does not interfere with daily life. By contrast, dementia is characterised by a global and irreversible cognitive decline which severely undermines daily functioning.

Box 1: How to use this Factsheet

Learn how European consumers use herbal medicinal products and food supplements for cognition.

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 cognition market segments and gain key insights into how to enter them.

Dementia occurs more often in elderly people and is most commonly associated with Alzheimer's disease. Other forms of dementia include neuro-generative, infectious, metabolic, traumatic, toxic and cerebro-vascular diseases. Causes of other forms of dementia include: stroke, brain injury, other diseases (e.g. Parkinson's and Huntington's), brain tumour, vitamin B deficiency, and drug or alcohol abuse. This factsheet also includes products used to enhance cognition in healthy people.

Cognition and natural health options

Different health options can be chosen depending on the severity of the condition. Given that there is no cure for Alzheimer's disease or vascular dementia, medications are used instead to help slow the progression of the disease, as well as to lessen its symptoms.

Treatment may also include a combination of drugs and psychiatric or behavioural therapies. Other options include lifestyle changes, including change of diet and exercise. Industry sources indicate that, in the absence of any cure for dementia, there has been a transition from the use of synthetic drugs to the use of herbal medicinal products. Consequently, patients are looking for any alternatives that may help them.

Natural food supplements are particularly popular, as they are seen as a safer and healthier option than synthetic alternatives – not least because it is common practice to add food supplements to a diet. These supplements are used to help reduce the risk of developing Alzheimer's, as well as to enhance cognition in healthy people. Examples of the latter include increasing alertness in intellectual activities or sports.

Herbal medicinal products exist for cognition and are in common use. However, the range of botanical species available to herbal medicinal products is limited. Moreover, innovation and product development in herbal medicinal products is much more limited than it is in food supplements.

Natural ingredients for cognition products

According to industry sources, various botanicals are used to support or improve cognition in Europe. These are used internally. The most commonly used plants include:

Ginkgo biloba (<i>Ginkgo biloba</i>)	Lemon balm (<i>Melissa officinalis</i>)
Bacopa (<i>Bacopa monnieri</i>)	Spanish sage (<i>Salvia lavandulifolia</i>)
Gotu kola (<i>Centella asiatica</i>)	Huperzine A (<i>Huperzia serrata</i>)

Ashwagandha (<i>Withania somnifera</i>)	Rosemary (<i>Rosmarinus officinalis</i>)
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(Given that lemon balm is covered in the Market Intelligence Report on Natural Ingredients for Stress & Anxiety, this species is discussed in that factsheet.)

In addition, aromatherapy oils can also be used to help improve cognition, concentration or alertness. These include lemon balm, Spanish sage and rosemary (most commonly chemotype 1.8 cineol). The latter is more commonly used in aromatherapy for this indication area than it is as a herbal medicinal product or food supplement. Although not registered to improve cognition specifically, these three species are registered in the European Pharmacopoeia and may be used as medical products. In aromatherapy, they are used to help the recipient feel focussed.

Among species that may also be of interest to developing country producers are cardamom (*Elettaria cardamomum*), lemongrass (*Cymbopogon citratus*) and citronella (*Cymbopogon nardus*). 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 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 Huperzine A. and sage. The market for sage is highly competitive, and there are very limited market-entry opportunities. In addition, Huperzine A is an alkaloid that is extensively produced in Europe. Industry sources indicate that Ginkgo biloba, bacopa, gotu kola and ashwagandha have good potential for developing country producers in areas with the right growing conditions.

The table below provides information on these exemplary species used in cognition products, including available documentation, references, claims and 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 infusions and pills in dosage form, but they can also be used, for example, as herbal teas or tonics.

Tips:

- Check final Community herbal monographs as provided by the [European Medicines Agency](#) (EMA) to assess product standards and possible claims for the most established species.
- If you produce lemon balm, also check the Market Intelligence Report on Natural Ingredients for Stress & Anxiety products.
- If you want to enter the European market with ingredients that are new or not as well established, please refer to the [CBI Module Buyer Requirements](#) for information and tips. You can also use this module for tips on how to find established species. Many other plants are used in cognitive products worldwide and documentation is available for existing ingredients. Some of these can be used in Europe or else are already in use there.
- Link up with local universities or laboratories to conduct thorough research and product development. This can help in terms of claim substantiation.
- 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 will be required for your specific species.

Table 1: Selected key species for cognition

Definition	Monographs ²	Permitted usage in supplements ³	Origin	R&D
<p>Ginkgo biloba (Ginkgo biloba)</p> <p>Ginkgo biloba is the most common botanical species for cognition, and it is used both as a herbal medicinal product and as a food supplement. Scientific evidence demonstrates that ginkgo leaves and their extract improve cognitive impairment in mild dementia.</p> <p>Originally from China, the trees are widely cultivated in various regions, including Europe. Developing country producers have opportunities to enter the market because the species enjoys great popularity in the treatment of cognitive impairment.</p>	<p>WHO monograph ESCOP monograph 2nd edition (Ginkgo folium) European Pharmacopoeia monographs: # 1828 Ginkgonis folium # 1827 Ginkgonis extractum siccum raffinatum et quantificatum # 2381 Ginkgonis extractum siccum normatum Draft Community herbal monograph</p> <p>As a herbal medicinal product, claims for Ginkgo biloba can include "improvement of (age-associated) cognitive impairment and of quality of life in mild dementia"</p> <p>As a traditional herbal medicinal product, claims can include "relief of heaviness of legs and the sensation of cold hands and feet associated with minor circulatory disorder"</p>	<p>Italy, Belgium and France allow use of the leaves, with a warning not to use them during pregnancy and breastfeeding and to alert your doctor if you use anti-coagulants or platelets. Germany: the safety of Ginkgo biloba cannot be judged owing to insufficient data Restricted and/or limited for use in food in Sweden and Austria</p> <p>Food supplements cannot make a medicinal claim; examples from the Netherlands of claims made for supplements containing Ginkgo biloba are: "Ginkgo biloba contributes to the functioning of the memory" "Ginkgo biloba improves your memory and cognitive functions"</p>	<p>Native to China, widely cultivated in Europe and other continents.</p>	<p>Much research has been conducted on Ginkgo biloba: Herbmed registered 80 articles on traditional use, 298 clinical trials and 7 patents.</p> 
<p>Centella asiatica (Gotu Kola)</p> <p>Gotu kola is a well-known herb in Ayurvedic and Chinese medicine, with a wide variety of health benefits. According to the EMA assessment, the herb has been used in Europe for a long time.</p> <p>Extracts of the entire plant are used in both herbal medicinal products and food supplements. For both, the products are for internal use in the form of capsules.</p>	<p>WHO Monograph ESCOP monograph 2nd edition suppl. (Centellae asiaticae) European Pharmacopoeia monograph # 1498 (Centellae asiaticae herba) Final assessment report</p>	<p>Italy, Belgium and France allow use of aerial plant parts. Germany: allows use of herb with maximum level recommended for food. Restricted and/or limited for use in food in Austria.</p> <p>Food supplements cannot make a medicinal claim; some examples of claims made for supplements containing gotu kola in France are: "Boosts brain function" "Gotu kola helps improve alertness" "Improves concentration during stress"</p>	<p>Native to Africa, Asia, Australasia, and South America, cultivated in India</p>	<p>Herbmed registered 9 articles on traditional use, 39 clinical trials and 2 patents.</p> 
<p>Withania somnifera (Ashwagandha)</p> <p>Ashwagandha is used in Ayurvedic medicine to improve brain function and learning.</p>	<p>WHO Monograph No ESCOP monograph available. European Pharmacopoeia Monograph # 2746 (Withaniae somniferae radix)</p>	<p>Italy, Belgium and France allow use of entire plant Germany: not listed, thus permitted usage in Germany is unclear.</p> <p>Food supplements cannot make a medicinal claim;</p>	<p>Cultivated in India, native to Africa, Asia, temperate and southern Europe,</p>	<p>Herbmed registered 15 articles on traditional use, 20 clinical trials and 1 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 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 a 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. Italy, France and Belgium have created a common positive list for the plants and derivatives permitted in food supplements, and updates may be made to this. Italy is the first country to adopt this list; individual country lists still apply to France and Belgium.

<p>In Europe, herbal monographs are available, but the species is more commonly used as a food supplement in the form of tablets or capsules. Food supplements containing ashwagandha are also marketed to improve concentration in healthy people.</p>	<p>No Community herbal monograph (public statement).</p> <p>No well-established use or traditional use of ashwagandha in herbal medicinal products has been documented.</p>	<p>the following claims were found on products containing ashwagandha in the Netherlands:</p> <p>"Withania somnifera is an adaptogen and supports mental and physical energy"</p> <p>"Improves concentration"</p>	<p>naturalised elsewhere.</p>	
<p>Bacopa monnieri (bacopa/brahmi)</p> <p>Bacopa is another herb used in Ayurvedic medicine, where it also called brahmi. Although permitted for use in herbal medicinal products, most opportunities lie in food supplements.</p> <p>As a food supplement, bacopa is available for internal use in the form of tablets or capsules. The herb is marketed as improving concentration and memory in healthy people.</p>	<p>No WHO Monograph available.</p> <p>No ESCOP monograph available.</p> <p>European Pharmacopoeia monograph # 2850 (Bacopa monnieri)</p> <p>No Community herbal monograph.</p> <p>No well-established use or traditional use of bacopa has been documented.</p>	<p>Italy, Belgium and France allow use of entire plant. Germany: not listed, thus permitted usage in Germany is unclear.</p> <p>Food supplements cannot make a medicinal claim, examples from the UK of claims made for supplements containing bacopa are:</p> <p>"Memory support for a healthy mind"</p> <p>"Improve focus and enhance your memory"</p> <p>"Bacopa promotes intelligence, particularly the power of retention"</p>	<p>Wetlands of southern India, Australia, Africa, Asia, Europe, North and South America.</p>	<p>Herbmed registered 7 articles on traditional use, 25 clinical trials and 17 patents.</p> 

Source: *Herbmed*, 2014

What is the demand for cognition 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.
- Ginkgo biloba, which is mainly used to improve or prevent cognitive impairment, is one of the strongest-growing products in the global market for herbal medicinal products. In terms of food supplements, memory health is a strong category in Germany, with a market share of 13% ([Federsalus, 2014](#)).

Cognition and cognitive impairment

In order to estimate the prevalence of cognitive impairment in Europe, statistics have been included on rates of dementia and mild cognitive impairment, which are some of the most common types of condition affecting cognition.

- Various studies have been conducted on the prevalence of dementia in different parts of the world. According to the WHO, Western Europe has the highest number of people with dementia (7 million) of the 35.6 million who have the disease worldwide in 2010 ([WHO, 2012](#)). In Europe, the largest countries also have the highest incidence of dementia: Germany (1.5 million), France (1.1 million) and Italy (1.1 million). Globally, the total number of people with dementia is estimated to reach 65.7 million in 2030 and 115.4 million in 2050.
- As dementia is associated with old age, prevalence of dementia increases in older population groups. A systematic review of research on dementia by Alzheimer Europe ([2013](#)) indicates that although the prevalence of dementia is 0.6% in the 60-64 age group, this increases to 7.4% (75-79), 15.7% (80-84) and even to 41% in the 90-94 age group.
- Various studies have been conducted into mild cognitive impairment, which can be an intermediate stage between normal cognitive ageing and dementia. These have resulted in different prevalence ratios, ranging from 3% to 42% for adults over 65.
- An online survey by the science journal [Nature](#) indicates that synthetic cognitive enhancing drugs are used by healthy people as well.⁴ Of the 1,400 respondents, one in five said that they had used drugs for non-medical reasons. Reasons given were to stimulate focus, concentration or memory. Use did not vary much among the various age groups.

Tips:

- 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 cognition products?

Need in society: Dementia is most commonly associated with the elderly, a social grouping that is growing in size throughout Europe. It is estimated that 30% of the European population will be 65 or above by 2050 as opposed to 17% in 2013. Simultaneously, the prevalence of dementia is also growing.

Side-by-side with their increased risk of dementia, older consumers are also using herbal medicinal products and supplements more extensively than younger populations. This being the case, an ageing population will mean an increase in demand for natural health options and their associated ingredients. Note that the elderly are especially keen on well-established, traditional products such as *Ginkgo biloba*. According to market research by Global Industry Analysts Inc., herbal supplements that help enhance cognitive functioning are expected to benefit from the increasing popularity of preventive herbal medicinal products.

At the same time, the greater demands and faster pace of today's society is increasing the need to enhance cognition among consumers in other age categories. This includes a need for improved alertness and concentration, e.g. in work or study situations.

Tip:

- For more information on natural health products for energy, please refer to the [CBI Product Factsheet Natural Ingredients for Energy products](#). Species used in this indication area may be used to enhance cognition as well.

Delaying dementia with herbs: Given that dementia cannot be cured, the focus has always been on delaying the condition. There has been an increasing use of natural health options for this purpose. Recent studies have underlined the effect of a healthy diet in lowering the risk of dementia, and this makes a case for food supplements as well.

⁴ The survey was an online, informal poll on the use of ritalin, provigil and beta blockers. The journal conducted the poll at the beginning of 2008 and 1,400 people from 60 countries responded to it.

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 memory or alertness) and risk reduction. For example, you may not claim that your product/ingredient prevents/cures dementia or Alzheimer's disease, but you may stress how a certain species can help support cognitive function. Also ensure you have research results to back up your claim with any potential buyers.
- If you are targeting producers of herbal medicinal products, make sure the claims you use in your documentation are mentioned in the European Pharmacopoeia, monographs or list entries.

Long-term use: Cognitive enhancers for the prevention of dementia are often used for a long time. Therefore, consumers are looking for products that are safe (safer) to take on a regular basis. Many people believe products deriving from botanicals have fewer side effects and thus are safer to use over extended periods. Please note that the use of natural solutions is not necessarily safer 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 relating to cognition. Research partnerships are needed in order to develop this research. Most importantly, consumers want products that provide measurable benefits. For example, the effectiveness of Ginkgo biloba extracts has been demonstrated in various studies, which has driven their use in the sector beyond traditional use.

Tips:

- Look for traditional usage of ingredients, this may be a good starting point when determining new ingredients for cognition and provides the basis to build substantiation. Screen local people in your region to understand how they use herbs to support cognition.
- Focus on the potential of your botanical product in terms of mild cognitive impairment or in terms of delaying the onset of chronic conditions such as Alzheimer's disease.
- Indicate in your data whether the product is safe for continued use and back this up with scientific research. 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 cognition 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.

Tip:

- 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 comply with international product standards and meet 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 [HACCPEUROPA](#) websites.

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

Synthetic alternatives

At the moment, there are no preventative or curative treatments for Alzheimer's disease and other forms of dementia. As such, *conventional medicine* is used only to delay the onset of dementia or to treat its symptoms. Examples include cholinesterase inhibitors and memantine (the only drug approved for treatment of moderate to severe Alzheimer's disease). Medications that are used to ease the symptoms of Alzheimer's disease include antidepressants, stimulants and anti-seizure drugs. Stimulants, which are used to treat conditions such as ADHD, may also be used to enhance cognition in healthy people.

In terms of *food supplements*, synthetic alternatives for cognition encompass synthetic vitamins, minerals and antioxidants. Consumers may take these to reduce risk of cognitive impairment, but most often to improve overall health or enhance cognition in healthy people. Examples include vitamin B complexes (folate), multivitamins, zinc and the antioxidants vitamin E and coenzyme Q10.

Tips:

- Consider whether your ingredient offers cognitive enhancing properties which might be of interest to this segment. Also consider whether your ingredient is already used in this segment. Online resources to help with this include the websites of herbal manufacturers, [EMA monographs](#), [Pharmacopoeia](#) and websites such as [Herbmed](#).
- Please refer to [CBI Competition](#) and CBI Top 10 Tips for doing business for more information.

Existing natural alternatives

Currently, there is a wide range of natural alternatives which are commonly marketed as enhancing cognition, specifically regarding memory and concentration:

- Omega-3 oils or supplements are frequently used natural alternatives. As the most common source for these supplements is fish waste, they can be offered at low prices. Botanical examples include evening primrose oil and borage oil.
- Natural antioxidants may also be marketed as supporting or enhancing cognition. Examples of sources include green tea, a variety of fruits (e.g. blueberries and cherries) and vegetables.
- Botanical sources are also used in food supplements that are marketed as enhancing cognition. These are from European and Asian sources, such as rosemary, Spanish sage, lemon balm and ginseng. These sources are produced on a large scale and may be fierce competitors.
- Food products are most commonly used to enhance cognition in healthy people, especially in relation to increasing their alertness and concentration. The most common example for this is coffee or caffeine. Research indicates that food products such as dark chocolate may improve memory and brain functions as well.

Several of these alternatives are also marketed for other indication areas, such as overall health, immune support and vascular health. An example is evening primrose oil, which contributes to the healthy functioning of the vascular system and benefits from its marketing appeal as a high-omega oil. Antioxidants are used for a wide range of health benefits, including general health and wellbeing.

Tips:

- Create a strong marketing story, backed up by independent research, for products aimed at enhancing cognition in healthy consumers to generate interest. This is important as large numbers of existing alternatives are available on the market. Linking products to overall health or other indications (e.g. vascular health) may be of interest.
- 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 for 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 exporting 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** on the EU market for the relief of cognitive problems are beyond the scope of most developing country companies when taking into consideration product development, market authorisation and marketing costs.

Tips:

- Help manufacturers build their story, e.g. by 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. While not commonly placed in this indication area, herbal teas can be used to improve cognitive function, e.g. those containing lemon balm.

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.

Tips:

- 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 cognition products?

Market segments

Both herbal medicinal products and food supplements to improve cognition are based on traditional recipes and well-known, established species. **Herbal medicinal products** offer some products to prevent cognitive impairment or to relieve its symptoms, but products are more commonly marketed as food supplements. One reason for this is that legislative hurdles limit product innovation and product introductions to Europe in relation to herbal medicinal products.

Botanical-based **food supplements** are commonplace and are marketed as improving cognition (in cognitive impairment or in healthy people) or preventing cognitive impairment. Cognition supplements are mainly single-herb products.

Some companies are (increasingly) innovative in adding new ingredients which are unfamiliar in Europe for use as supplements. In general, the UK and France are more vibrant in terms of product introductions than Germany or Italy.

Market channels

Regarding established species for food supplements, trade relations focus on maximising supply security and reducing costs. By contrast, new ingredients call more strongly for collaboration in terms of product development and registration in Europe. 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 is the term for cognition in your local language? What do local people use to improve cognition? 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.
- 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 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



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