



european
botanicalforum

An introduction to the role, safety and benefits of botanical food supplements

factfile



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Introduction

01

Botanicals for health

Man's relationship with botanicals is very long-standing. Throughout history, plants and herbs have formed part of the diet not simply because they provide nutrition, but also because of their health-giving properties. This remains the case today, as can be seen from the exponential growth of botanical food supplement use. And where food supplements are less available, in many rural regions, especially in Southern and Central/Eastern Europe, non-cultivated food plants are still gathered or grown on a small scale and consumed as food for their health effects.¹

In more recent years, advances in research and technology have meant that the health-promoting benefits of plants and herbs can be captured and presented in a convenient form that can be made widely available. The development of botanical food supplements has meant that an ever-growing number of consumers in our increasingly urbanised society can safely and easily use botanicals to both maintain and optimise their health.

The European Botanical Forum

The European Botanical Forum (EBF) was founded in 2004 by the European food supplements sector. Its main goal is to encourage expert debate among industry, governments and the scientific community on issues affecting botanical food supplements.

The EBF works in three main areas:

- To determine the optimum methodology for the safety assessment of botanicals;
- To clarify the borderline between the medicinal use of botanicals and the food use of botanicals;
- To substantiate health claims for botanicals.

The EBF organises workshops and has published a consensus document on the regulatory and safety aspects of botanical food supplements.²



Echinacea (Echinacea purpurea)

The European Botanical Forum Fact File

The Fact File aims to correct some commonly-held misapprehensions about botanical food supplements. Some people think, for example, that botanical food supplements lack a regulatory framework sufficient to ensure their safety and quality; that they are of little benefit to the consumer and therefore of questionable value; that they should be regulated as medicines, or that they make misleading and exaggerated claims that are not scientifically substantiated. In fact:

- Botanical food supplements have a regulatory framework that is fully adequate to ensure their safety and quality;
- Botanical food supplements have a long history of health benefit to the consumer;
- Botanical food supplements are a special group of food products, as confirmed by their regulatory structure;
- Botanical food supplements are subject to regulations which specifically require that claims are not misleading and can be scientifically substantiated.

The European Botanical Forum Fact File offers a comprehensive overview of all aspects related to the use of botanicals in food supplements.

It includes chapters on benefits, safety, and quality. It brings together scientific, regulatory and practical information on their current use, and illustrates the extensive legislation that covers these products in order that consumers can be provided with safe and useful products to supplement their diet.



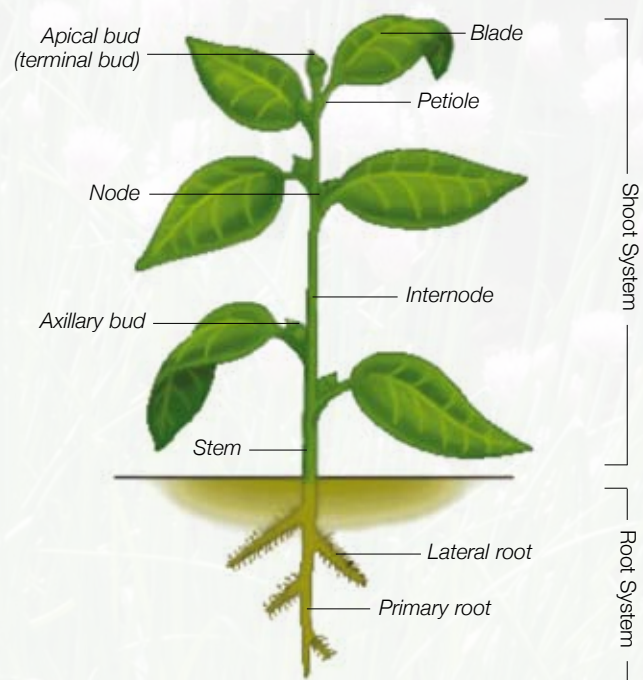


What are 'Botanicals'?

For the purposes of the EBF Fact File, the definition proposed by the Scientific Committee of the European Food Safety Authority (EFSA) is used to define 'botanicals':³

'..all botanical materials (e.g. whole, fragmented or cut plants, plant parts, algae, fungi and lichens).'

'Botanicals' is also the term now commonly used to describe plant materials when used in foods and food supplements, thereby differentiating them from plant materials used in herbal medicines which are more usually described as 'herbs'.



¹ Heinrich M, Leonti M, Nebel S, Peschel W.: "Local Food - nutraceuticals": an example of a multidisciplinary research project on local knowledge. *J Pharmacol./ Physiol.* 2005; 56 (suppl):5-22

² Coppens P., Delmulle L., Gulati O., Richardson D, Ruthsatz M., Sievers H., Sidani S.: Use of Botanicals in Food Supplements; Regulatory Scope, Scientific Risk Assessment and Claim Substantiation. *Ann Nutr Metab* 2006;50:538-554

³ European Food Safety Authority. Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements. Guidance document of the Scientific Committee. <http://www.efsa.europa.eu>

A brief history of the use of botanicals to maintain health

02

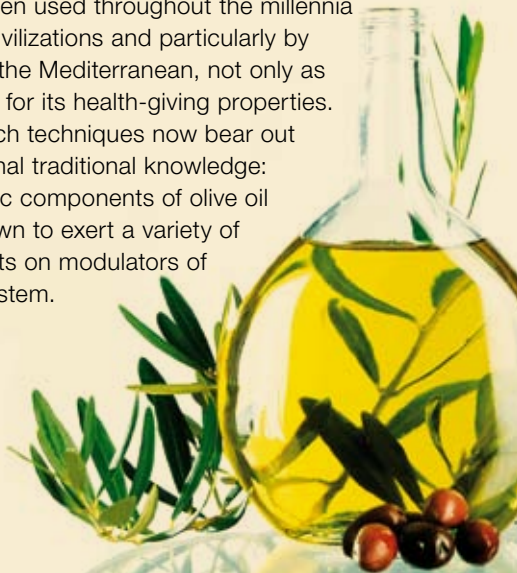
Botanicals have been used by mankind since early history

The beneficial effects of foods beyond their nutrient function have been recognised since early times: in the 5th century BC, the Greek healer Hippocrates famously advocated, 'Let food be thy medicine, and thy medicine thy food'.

This is not surprising: evidence of the use of plants such as yarrow and marshmallow, both of which are still used in botanical food supplements today to help maintain a healthy appetite and to help maintain respiratory health, has been found in Neanderthal graves dating as far back as 60,000 BC.¹ The Bible contains many references to herbs and plants. To quote one instance from the Old Testament: 'The house of Israel called it manna; it was like coriander seed, white, and the taste of it was like water made with honey'.² Coriander is still used today in botanical food supplements to help maintain healthy digestion.

Wine has long been a component of the diet, and not just for pleasure. In the New Testament, St Paul, in his first letter to Timothy, tells him to 'Stop drinking nothing but water; take a little wine for your digestion, for your frequent ailments'.³ 'Tonic' wines have been consumed throughout the millennia for their health-promoting properties and are still popular today. Now, with the benefit of modern science, it is known that wine, and in particular red wine, contains microcomponents of a polyphenolic nature that are potent antioxidants.

Olive oil has been used throughout the millennia by numerous civilizations and particularly by the peoples of the Mediterranean, not only as a food but also for its health-giving properties. Modern research techniques now bear out this observational traditional knowledge: the polyphenolic components of olive oil have been shown to exert a variety of beneficial effects on modulators of the vascular system.



Botanicals in the Middle Ages

The castles and great houses of the Middle Ages were commonly equipped with a 'still room' where soothing drinks of herbs infused in ale, milk, vinegar and honey were prepared, and herbs were pounded with butter to make ointments.

Religious houses throughout Europe were another well-known source of possets, health-promoting draughts and elixirs. Abbeys and monasteries, large and small, had herb-gardens where many botanicals still well-known and used today were grown – among them feverfew (*Tanacetum parthenium*), used for a variety of indications in relation to inflammation; lavender (*Lavandula officinalis*), sage (*Salvia officinalis*) and peppermint (*Mentha piperata*) for the digestion, and dandelion (*Taraxacum officinale*) for the health of the urinary system.



The Renaissance

Interest in the properties of botanicals and their uses continued and became more formalised in the 16th and 17th centuries, when European universities teaching botany and herbalism planted 'Physic' or Botanical gardens where a wide variety of species of health-promoting plants were grown. Many such gardens still exist today in university towns and cities throughout Europe, providing a living history of the health benefits of botanical materials.



02

Traditional use

Lemon Balm (*Melissa officinalis*) has a centuries-old tradition of use. The English diarist, John Evelyn (1620–1706), wrote 'Balm is sovereign for the brain, strengthening the memory and powerfully chasing away melancholy'. A concoction of spirit of Lemon Balm combined with lemon peel, nutmeg and Angelica root was claimed to be one of the main factors contributing to the longevity of Llewellyn, an 18th century Prince of Glamorgan in Wales, who lived to be 108.⁴ Very similar recipes are still used today and Lemon Balm is a common ingredient of herb teas, tisanes and food supplements for the digestion and to support relaxation and general well-being.

Moving to modern times, herbs were used in both World Wars to treat soldiers wounded on the battlefield. One important treatment involved the use of sphagnum moss and garlic (*Allium sativum*), both of which have antiseptic properties.¹ Bilberry (*Vaccinium myrtillus*) was used by English soldiers during World War II to help them to see better during night-time bombardments, and is still used today in botanical food supplements for the maintenance of eye-sight.

The common Dandelion (*Taraxacum officinale*, pictured above), considered a weed by most gardeners, is a good example of a botanical with a long history of multi-faceted use, including health promotion, which is still used for the same purposes today. It has several culinary uses: the leaves can be eaten cooked or raw in soups or salads, the flowers can be used to make wine, and the root is a coffee substitute, which, drunk before meals, stimulates digestive functions and acts as a liver tonic. However, one of the several common names for Dandelion is 'pissenlit', literally 'wet the bed'. The plant has also long been known for its beneficial effect on the urinary tract and is used in botanical food supplements to help maintain the health of the urinary system, to promote healthy appetite and digestion, and to promote healthy liver function.

Botanicals today

Many botanicals are today used for both food and medicinal purposes. These include plants such as parsley, rosemary, sage, thyme, mint, and caraway which are regularly used as culinary herbs, for flavour or fragrance. Others, such as cinnamon, nutmeg, cloves and pepper, are valued as food spices, and garlic and ginger feature in many recipes for family meals. Yet the historical use of many of these herbs and spices to help maintain health can be traced through the centuries, and their ongoing use for this purpose is readily demonstrated by the many health-promoting herbal teas, tisanes and digestive drinks prepared from these plants that are still commonly consumed in the European Union. Nowadays the science of Ethnobotany investigates, by detailed observations and studies of the use society makes of plants, how humans have used and domesticated botanicals for their health properties. In many rural regions, especially of Southern and Central/Eastern Europe, non-cultivated food plants are gathered or grown on a small scale and consumed as healthy 'snacks', or are produced on a small scale giving rise to local varieties or cultivars.^{5,6}

Supplements: a convenient way of supplying consumer benefit from traditional practices

Ready access to fresh plant material is no longer the norm for most consumers. As science has evolved, so plant preservation methods have become more sophisticated and botanicals no longer need to be used freshly picked, or painstakingly dried by the fireside before being brewed into teas or tisanes. The role of individual constituents within plants has also become better understood and modern processing and manufacturing methods mean that botanicals can be treated to purify and concentrate the benefits of these constituents. As a result, the health promoting properties of botanicals can still be made available to town and country dweller alike, offering, via a wide range of botanical food supplements, a safe and convenient method of optimising health.

1 Leroi-Gourhan, A (1975) 'Flowers found with Shanidar IV, a Neanderthal burial in Iraq'. *Science* 190: 562 - 564
2 The Old Testament, Exodus 16:31
3 The New Testament, The First letter of Paul to Timothy, 1:23
4 Grieve, M. A Modern Herbal: The Medicinal, Culinary, Cosmetic and Economic Properties, Cultivation and Folk Lore of Herbs, Grasses, Fungi, Shrubs and Trees. Dover Publications, 1971

5 Heinrich M, Leonti M, Nebel S, Peschel W: 'Local food – nutraceuticals': an example of a multidisciplinary research project on local knowledge. *J Pharmacol Physiol* 2005; 56 (suppl): 5-22
6 Local Mediterranean Food Plants and Nutraceuticals. Heinrich, M; Müller, WE; Galli, C. *Forum of Nutrition* Vol. 59. ISSN 1660-0347 5th Framework Program of EU

The benefits of botanical food supplements

03



The Quest for Optimal Health

The World Health Organization definition of 'health' is:¹

“Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”

This definition of health is a broad and positive statement. Rather than relying on a negative - the absence of illness - it proposes that true health equates with an all-round optimum state of well-being. The achievement of this optimum - the best health to which one can reasonably aspire - has been an underlying factor in the growth of interest in the effect of nutrition on health. It is paralleled by developments in understanding of the role of nutritional and botanical supplements in promoting health and wellness, and even reducing risk of disease.

The 2004 Nutritional Status Survey carried out by the Food Standards Agency in the United Kingdom showed that:

48% of the men and women surveyed had levels of total cholesterol above the optimal and that this increased with age.²

Such a statistic not only demonstrates the size, scope and seriousness of modern-day health issues, but also the need for the development of new perspectives and new approaches, distinct from those offered by pharmaceutical medicines, to promote and maintain health and reduce disease-risk factors.



Buckwheat flowers and corns (Fagopyrum esculentum)

Plant sterols and stanols are typical examples of the role of plant material in maintaining optimum health. Taken as part of a balanced diet, it is now generally acknowledged that foods that contain plant sterols or stanols can help maintain a healthy blood cholesterol level: a daily intake of about 2g of plant sterols or stanols can reduce low density lipoprotein (LDL) cholesterol by about 9%.³ (LDL cholesterol is often referred to as 'bad cholesterol' because it is an underlying risk factor of cardiovascular disease). Plant sterols have been used in food supplements for decades and are now also readily available in retail outlets in margarine spreads, yoghurts, milk drinks and other regular foods.

Dietary recommendations and nutritional goals

A varied diet and regular exercise are recognised as being central to the goal of optimum health. The following recommendations are indicative of the dietary advice given by the food authorities of most European Member States:

- ✓ At least five portions, and ideally 7-9 portions, of a variety of fruit and vegetables should be consumed each day.
- ✓ The bulk of most meals should be starch-based foods (such as cereals, wholegrain bread, potatoes, rice, pasta), plus fruit and vegetables.
- ✓ Consumption of fatty foods such as fatty meats, cheeses, full-cream milk, fried food, butter, etc. should be kept to a minimum. Low fat, mono or poly-unsaturated spreads should be used instead.
- ✓ 2-3 portions of fish, least one of which should be 'oily', should be eaten each week.
- ✓ Salt consumption should be limited to no more than 6g a day (and less for children).





However, despite the prevalence of dietary advice and despite numerous consumer education programmes, nutritionists and food policy-makers in the European Union recognise that many people who perhaps could and should achieve a healthy diet, fail to do so. Additionally, certain population groups, such as the elderly, children, teenagers and women of child-bearing age, may have particular difficulties in meeting their optimum nutritional goals. As an example, the Dutch National Food Consumption Survey of Young Children for 2005/6 found that only a small proportion of children in the Netherlands consumed sufficient amounts of vegetables, fruit, fish and fibre, and insufficient intake of vitamin D and folate was the norm.⁴



Horse chestnut (Aesculus hippocastanum)

Fortification and supplementation

The problems resulting from inadequate nutrient intake have meant that the benefits that supplementation can offer in terms of efficient, natural and nutrition-related solutions to help maintain the body in optimum condition, have become much more widely recognised.

As understanding of nutrition has developed, government health policies have primarily focussed on the benefits to health offered to particular population groups by supplementation with particular vitamins and minerals. The fortification of food with nutrients is now common - even mandatory for some foods in some Member States of the European Union. The aim of such programmes is to correct dietary shortcomings, particularly iodine, vitamin D, vitamin K and folate. The preferred method of delivery for mandatory fortification is generally via common foodstuffs such as bread. For other nutrients, government health departments may offer advice to particular population groups on how to use food supplements in addition to diet to obtain optimum intake.

However, it is also important that consumers who choose to supplement their diet with vitamins and minerals and botanical components such as antioxidants, can have the opportunity to do so via the availability of a wide range of food supplements.

Consumer expectations drive the availability of botanical food supplements for a wider choice

Today's consumer can hardly fail to be aware of the enormous amount of information about health and nutrition that is available. The television, the internet, book-stalls, libraries, magazines, newspapers, all carry articles devoted to informing the reader or viewer on how to achieve optimum health. While such information is by no means always accurate, and is sometimes downright misleading, it has meant that consumers' interest in nutrition and its relation to health has greatly increased, as have their expectations in the search for efficient, safe and naturally-based solutions for improving the quality of their lives. Supplementation is perceived as an important part of such solutions. Today more than ever before, to fulfil their particular needs consumers expect a wide choice of products with a similarly wide range of benefits.

Botanical supplements

The use of botanicals to maintain health has been the popular choice throughout Europe for many centuries. The consumption of teas, digestive drinks, juices, elixirs and extracts prepared from botanicals and used for health maintenance purposes has become part of European cultural heritage.

Botanical food supplements are a modern-day extension of this process. Dose forms such as capsules, pastilles, tablets, and pills provide a fast delivery method for the botanical of choice, with the added advantages for the consumer that the processing which botanical material undergoes in the manufacturing process for botanical supplements guarantees the absence of any potentially harmful substances; concentrates the beneficial components of the plant, and increases the stability of the end product.

This modernisation of traditional practices ensures a safe, durable product that is convenient to use, requires no preparation time, and can be made easily available to town and country dweller alike. By facilitating the production of a wide range of products, it also provides a practical method of greatly increasing the consumer's freedom of choice to experience the benefits of botanicals.

Citrus fruits





How do botanical supplements work? *Homeostasis*

Botanicals have diverse effects on the body. In some cases the effects are medicinal and useful for treating diseases. In other cases the effects are beneficial for maintaining and optimising health. Some botanicals – so-called ambivalent botanicals – can therefore be found as constituents of both food supplements and medicinal products, depending on their intended use.

The use of botanicals for health promotion purposes can be explained by their effects on the body's homeostasis. 'Homeostasis' is appropriately defined by the Council of Europe in their 2005 'Guidelines on the Quality, Safety and Marketing of Plant-based Food Supplements' as,

'...the status of a person whose physiological parameters function within the limits considered as normal'.⁵

The body and body cells need to be in an 'internal environment' where the conditions do not change much and never reach extremes that are damaging to them. Homeostasis is the keeping of this internal environment stable.

Special 'homeostatic processes' are needed to maintain this stability, and conditions that are regulated in homeostasis include blood glucose level, temperature, water content of the body, and the amount of carbon dioxide and urea being carried by the blood. When the body is out of homeostasis – during illness – and needs to be brought into homeostasis again, medicinal products are indicated. Botanical supplements however, are taken with the aim of supporting, maintaining or optimising normal physiological processes and keeping the body in homeostasis in the best possible way.

Some examples of the benefits of botanical supplements

- ✓ **Garlic** (*Allium sativum*) has a health relationship with the cardiovascular system and a beneficial effect in helping to maintain a healthy cholesterol level.
- ✓ **Green Tea** (*Camellia sinensis*) has a health relationship with the metabolism of lipids, making it a natural and useful aid to maintaining normal weight.
- ✓ **Black Cohosh** (*Cimicifuga racemosa*) is often used by women with menopausal discomfort, helping to maintain maximum comfort at this time of life.
- ✓ **Artichoke Leaves** (*Cynara scolymus*) have beneficial effects on the functioning of the liver and digestion, and are eaten to help maintain a healthy digestive system.
- ✓ **Ginkgo** (*Ginkgo biloba*) works on the vascular (arterial) system, helping to maintain healthy blood circulation, which in turn impacts positively on mental and cognitive processes.
- ✓ **Lemon Balm** (*Melissa officinalis*) also has a beneficial effect on cognitive and mental health, and helps to maintain positive mood and cognitive function.
- ✓ **Soy** (*Glycine max*) and in particular soy isoflavones have a health relationship with the menopause, and, like Black Cohosh, help to maintain maximum comfort at this time of life.

Understanding the benefits of botanicals

In seeking to achieve optimum nutrition, for many years attention has been focussed on nutrients because their lack in the diet leads to deficiencies with characteristic clinical symptoms. However, the role of other food components in achieving optimal health is now better understood. Most of these food components are from plants which are rich in bioactive secondary metabolites. These are substances produced by the plant in adaptation to local environmental conditions, which, for example in the Mediterranean area, are often pro-oxidative. This requires an adaptative response from the botanical, producing protective bioactive compounds such as polyphenolic molecules. This is particularly relevant for human health because the intake of these plants results in the transfer of those protective compounds to the human organism – hence the interest in research that further explores the application of these effects.

'Metabolomics' - a new way to assess the effects and benefits of botanical supplements?

For the future development of botanicals and new botanical products intended to help maintain/optimize health, a relatively new concept entitled 'Metabolomics' may offer a new perspective in understanding the multi-faceted nature and effects of botanicals.

Metabolomics is defined as:

'the systematic study of the unique chemical fingerprints that specific cellular processes leave behind'

Specifically, the study of their small molecule metabolite profiles.⁶

Metabolomes refer to complete sets of small molecule metabolites (such as metabolic intermediates, hormones and other signalling molecules and secondary metabolites) to be found within a biological sample such as a single organism. While only some 2500 human metabolites have yet been catalogued, over 50,000 metabolites have been characterised from the plant kingdom, and many thousands of metabolites have been identified and/or characterised from single plants. However, much more work is needed before the study of metabolomics can fully fulfil its aim of providing a detailed description of metabolic pathways and their workings, and hence a more complete picture of how living organisms work.

Nutraceutical research and the benefits of botanicals: the Fifth Framework programme

The long history of use of locally used traditional foods and their potentially positive effects on health is also prompting new research projects. One such is a proposed joint-funded three-year academic/industry/European Commission project to evaluate 150 species of food plants.⁷ Researchers will be looking at their health effects and in particular their antioxidant, anti-diabetes and memory mediating activities, which, it is hoped, will contribute to the development of new foods offering a positive effect on the maintenance of health.

1 Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19 – 22 June 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, No 2, p.100) and entered into force on 7 April 1948

2 Food Standards Agency, National Diet and Nutrition Survey (Volume 4), Ref: 2004/0457

3 EFSA - Scientific substantiation of a health claim related to plant sterols and lower/reduced blood cholesterol and reduced risk of (coronary) heart disease pursuant to Article 14 of Regulation (EC) No 1924/2006 (Question No EFSA-Q-2008-085), adopted on 11 July 2008

4 RIVM report 350070001/2008. Dutch National Food Consumption Survey-Young Children 2005/2006

5 Council of Europe, Guidelines on the Quality, Safety and Marketing of Plant-based Food Supplements, 24.006, 2005

6 Davis, B. 'Growing pains for metabolomics', The Scientist, 19(8):25-28, April 2005

7 Lucas, J. EU funded Research on Functional Foods, British Journal of Nutrition (2002) 88, Suppl. 2, S131-S132

The co-existence of botanical food supplements and herbal medicinal products

04

Introduction

Botanicals and botanical ingredients are used in a variety of products including foodstuffs, food supplements, cosmetics and medicinal products. Their use in these products is regulated by European and national legislation. Food law and medicinal law have a different scope but are of equal importance and exist legally next to each other. The choice of the legal framework to apply lies with the manufacturer and is determined by the intended use of the product.

European law has a number of mechanisms to safeguard the free movement of goods and consumer protection. These include the principle of mutual recognition and specific laws laying down authorisation procedures, responsibilities of manufacturers, and mechanisms to deal with safety concerns. For historical reasons marked differences exist between national provisions applicable to botanical food supplements, resulting in diverging interpretation as to the legal framework applicable. Provisions contained in European Union (EU) law and European Court of Justice (ECJ) case law provide clear guidance on how to address such borderline cases.



The legal framework for botanicals

Food supplement law

General provisions for botanical food supplements are harmonised by Directive 2002/46.¹ They are part of the definition of food supplements ('food supplements' means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities). In most Member States, food supplements are subject to a notification procedure before being placed on the market. However, as compositional criteria in relation to botanicals have not yet been harmonised in other Member States, national rules may still be applicable.



Dandelion (*Taraxacum officinale*)

Medicinal law

Botanical ingredients are also used in medicines, regulated under medicinal law. Such products are often presented as traditional herbal medicinal products according to the terms of the Traditional Herbal Medicinal Products Directive (THMPD).² However, food supplement law is not applicable to medicinal products and medicinal product law is not applicable to food supplements. It is specifically stated in medicinal law that 'Where a product comes clearly under the definition of other product categories, in particular food, food supplements, medical devices, biocides or cosmetics, this (i.e. the medicinal product) Directive should not apply'.³ The reason that the definition of a medicinal product is so broad, is so as to be able to cover a very wide range of different medicinal products, including gene therapy, cell therapies, xenogenic somatic therapy, radiopharmaceutical products and certain medicinal products for topical use, etc. Such a broad definition could also bring within its scope products that were not intended to be covered. Because of this, the THPMD also specifies that it 'allows non-medicinal herbal products, fulfilling the criteria of food legislation, to be regulated under food legislation in the Community'.

So there cannot be any doubt that the EU legal framework intends that both food supplements and medicinal products coexist, even if they are presented in the same form and contain the same type of ingredients. The main difference is their intended use.

Mechanisms to ensure free movement of goods

Mutual recognition

The lack of harmonisation of the use of botanical ingredients used in food supplements should not represent a hindrance to the free movement of goods. Some Member States have specific rules, including positive and/or negative lists, while others only have general provisions. In some Member States, the use of botanicals is generally permitted while in others it is severely restricted. But in all cases, the principle of mutual recognition as laid down in articles 28 and 30 of the European Treaty applies - one of the key principles within the EU. It means that any product lawfully manufactured or marketed in one Member State can be sold in any other Member State. Member States are not allowed to prohibit the import of such a product, even if it is not in conformity with their national rules, unless the Member State can show that there is a safety issue and that restrictions are necessary for the protection of public health. These principles have been established and confirmed on multiple occasions by the ECJ, ever since its so-called 'Cassis de Dijon' case judgement in 1979.⁴ The rules for mutual recognition have recently been laid down in a new law which will apply from 13 May 2009.⁵

EU food law

Furthermore, it should be acknowledged that botanical food supplements are subject to all the provisions of food law. This includes first of all compliance with the General Food Law Regulation which specifies the responsibilities of the manufacturer and imposes a duty of notification in the case of a safety issue with the product.⁶ The legislation relating to novel foods, pesticides, contaminants, additives, genetic modification, irradiation, hygiene, and so forth is also applicable.

On top of that, the recent Regulation on the addition of vitamins and minerals and certain other substances to foods provides for a procedure to be followed in case a safety issue arises in relation to a substance.⁷ As foods, botanicals fall within the scope of this Regulation which enables the European Commission to take appropriate actions when safety issues arise, including a full prohibition, the establishment of conditions of use, or further assessment of safety by the European Food Safety Authority (EFSA).

Finally, the Food Supplement Directive also provides a so-called safeguard clause whereby a Member State may temporarily suspend or restrict the application of the Directive when it has detailed grounds for establishing that a product endangers human health as a result of new information or of a reassessment of existing information. The European Commission then follows a procedure to discuss and decide on action to be taken throughout the EU.

Borderline issues

Origin

Although food supplement and medicinal law clearly allow the coexistence of botanical use in food supplements and medicinal products, the use of some botanicals in foods is sometimes challenged by national authorities. This stems, simply for historical reasons, mainly from the improper interpretation of the definition of a medicinal product and of article 2.2 of the Medicinal Product Directive (MPD), which lays down the superiority of medicinal law.

The definition of a medicinal product contains two distinct parts: a part defining a medicinal product by virtue of its presentation, and a part defining a medicinal product by virtue of its function. This definition was adapted when medicines law was revised in 2004 but the essential elements of the original 1965 Directive remain largely unchanged.

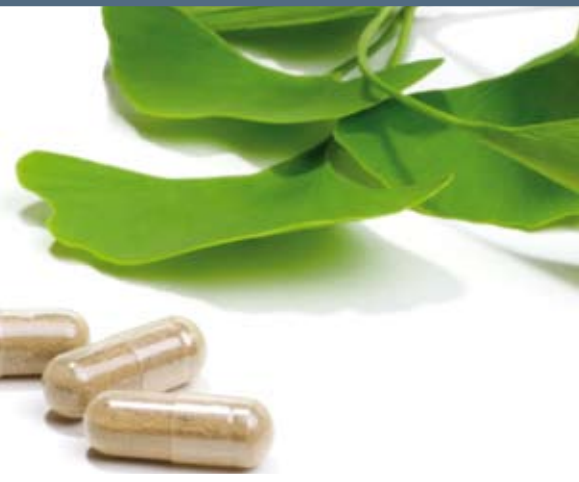


Medicinal by presentation

The first part of the definition of medicinal product is designed to cover 'any substances or combination of substances presented as having properties for treating or preventing disease in human beings'. This enables national authorities not only to assess the safety, quality and efficacy of a genuine medicinal product but also to refuse the marketing of any product that is not sufficiently effective or does not have the therapeutic effect which consumers would be entitled to expect from the way in which it is presented.

It follows that any product that is not presented for the treatment or prevention of diseases cannot by virtue of this part of the definition be considered a medicinal product.

The ECJ has ruled that a product can only be 'presented for treating or preventing disease' within the meaning of the medicinal product directive either when it is expressly 'indicated' or 'recommended' as such, possibly by means of labels, leaflets or oral representation or whenever any averagely well-informed consumer gains the impression that the product in question has the properties of treating or preventing a disease. If this is not the case, there is then no sufficient reason for Member States to apply medicinal product law, not even when similar products are covered under medicinal law. This is coherent with the Nutrition and Health Claims Regulation which provides for the use of health claims and reduction of disease risk claims on food products.⁸



Medicinal by function

'Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis' is also considered a medicinal product. This definition was intended to also cover products that are capable of fundamentally changing the physiology of the body without having a therapeutic or preventive effect in relation to a disease (e.g. anaesthetics, sedatives, contraceptives, hormones).

This definition of a medicinal product by virtue of its function is often interpreted by Member States more broadly than it was intended. Such Member States consider the use of certain botanicals as medicinal by function thereby prohibiting their use in food supplements. It is clear from ECJ case law that such an interpretation is not in line with the principles of EU law.⁹

European Court of Justice (ECJ) case law

The first real judgement on the borderline of medicinal law and other product categories came in 1979 with the Tervoort Case.¹⁰ Since then there have been numerous other cases which have led to a number of principles that have been consistently held by the ECJ.

The first one is that it is for the national authorities to determine whether a product falls within the definition of a medicine. But such judgements must be done on a case-by-case basis, taking account of all the characteristics of the product. Among these characteristics, the ECJ lists in particular the product's composition, its pharmacological properties to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail.

This confirms the principle that no ingredient or group of ingredients as such can be judged to be 'medicinal by function'. Only end-products may be taken into consideration.

A borderline case therefore cannot be solved in a general way based upon one of its ingredients, but only after a case-by-case assessment of the final product.



Secondly, the ECJ also indicates that a product must have a certain pharmacological effect before it can be considered medicinal. Having a physiological effect is not sufficient. While the ECJ is clearly of the opinion that the scope of the terms 'restoring, correcting or modifying physiological functions' is broader than only 'treating or preventing disease', it warns against a literal interpretation which would not be in line with what the legislator intended.

The definition of medicinal product by function is designed to cover products whose pharmacological properties have been scientifically observed and which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions. A physiological effect is not specific to medicinal products but is also among the criteria used for the definition of food supplements and health claims.

Therefore, in order to preserve the effectiveness of that criterion, it is not sufficient that a product has properties beneficial to health in general, but it must strictly speaking have the function of treating or preventing disease. The effect should be significant and a certain pharmacological activity would be required. The ECJ also acknowledges that there are many products generally recognised as foodstuffs which may also have therapeutic effects, but that fact alone is not sufficient to confer on them the status of medicinal products.⁹

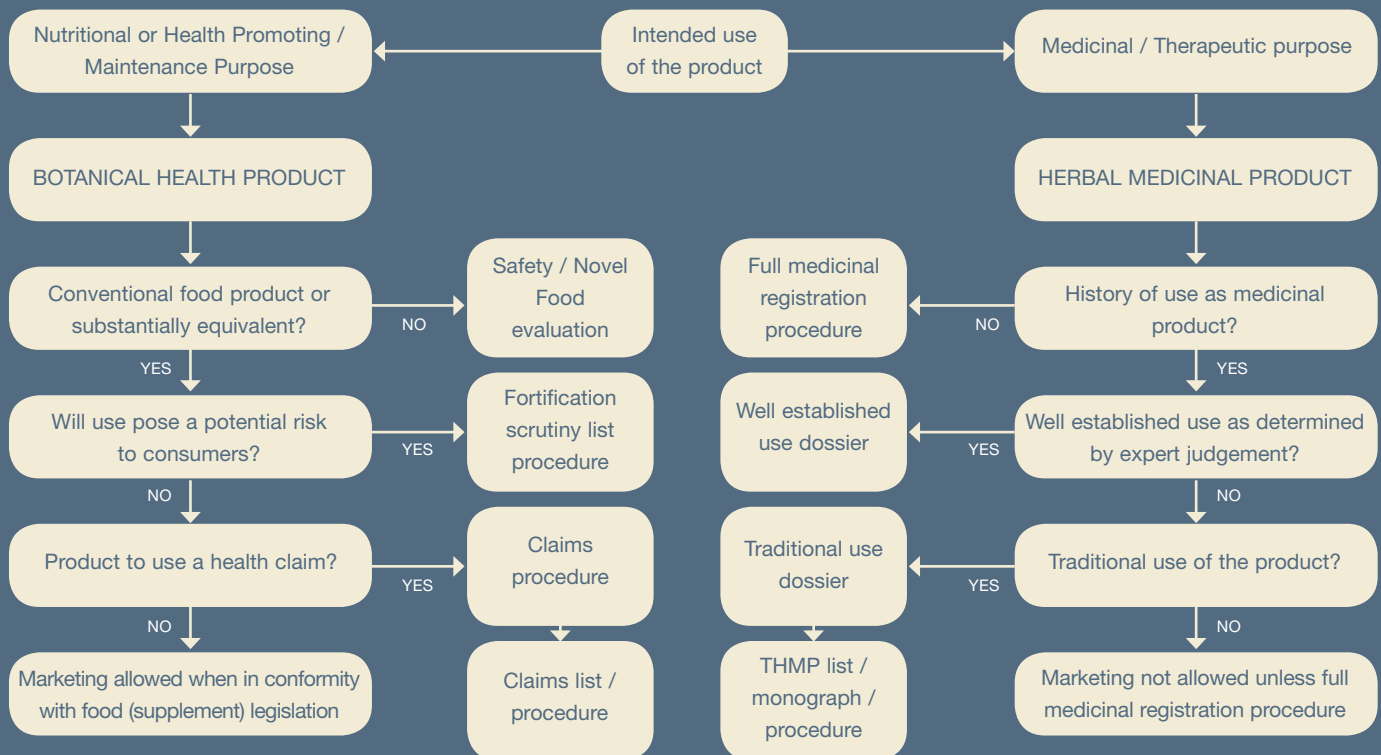
Superiority of medicinal law?

In 2004, with the revision of the Medicinal Product Directive (MPD), these ECJ case law principles were introduced in article 2.2. It states that 'in cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation, the provisions of the MPD shall apply'. The scope of this provision is firmly limited to 'cases of doubt' and is restricted to individual products. It confirms the case-by-case assessment approach as established by case law: that any assessment must be undertaken on an individual product, taking into consideration all the product's characteristics. In other words, food ingredients or substances used in foods cannot by virtue of the definition of medicinal product be considered falling under medicinal law; only individual products containing them could.



The legal framework of botanicals under food and medicinal law

Taking into consideration the legal texts described, ECJ Case law and the principle of mutual recognition, a legal framework based upon the product's intended use emerges for companies that wish to market their products in the EU.¹¹



References

- 1 Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. Official Journal of the European Union: L136/85, 12 July 2002
- 2 Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use. Official Journal of the European Union: L136/85 30 April 2004
- 3 Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use. Official Journal of the European Union: L136/34 30 April 2004
- 4 European Communities: Communication from the Commission concerning the consequences of the "Cassis de Dijon" judgment; 3 October 1980
- 5 Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC. Official Journal of the European Union: L218/21. 13 August 2008

- 6 Regulation (EC) no 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Official Journal of the European Union: L31/1, 1 February 2002
- 7 Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. Official Journal of the European Union: L404/26, 30 December 2006
- 8 Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. Official Journal of the European Union: L12/3, 18 January 2007
- 9 Case 319/05: Judgment of the Court (First Chamber) of 15 November 2007. Commission of the European Communities v. Federal Republic of Germany. Official Journal of the European Community C8/3, 12 January 2008
- 10 Case C219-91, judgement of the Court of 28 October 1992, Criminal proceedings against Johannes Stephanus Wilhelmus Ter Voort, European Court Reports 1992:I:5485
- 11 Coppens P. The Use of Botanicals in Food Supplements and Medicinal Products. European Food and Feed Law Review (3);2-2008; 93-100

The safety and quality of botanical food supplements

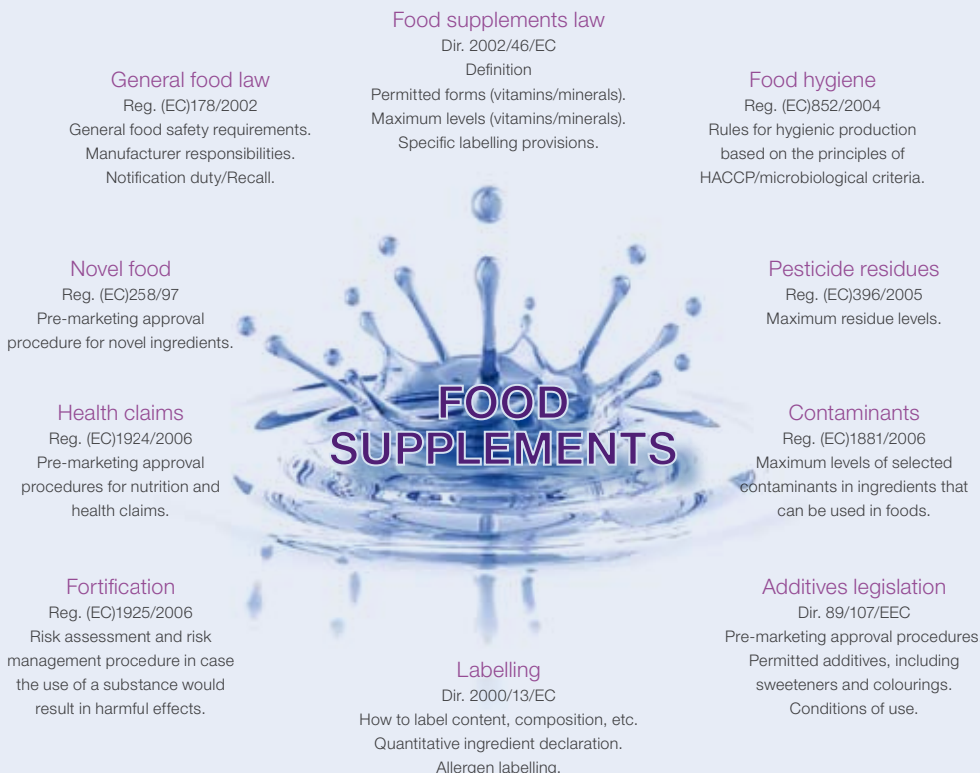
05

Introduction

Contrary to the view that botanical food supplements lack a regulatory structure sufficient to ensure their quality and safety, foods and botanical food supplements have a full and specific set of Directives and Regulations covering every aspect of manufacture, from the gathering of the raw material, through to the production process, the eventual placing of the finished product on the market, and to post-market monitoring. This comprehensive regulatory framework ensures that the products are safe to use and meet the required quality standards.

The General Food Law Regulation (GFLR) sets the overall legal framework, laying down the principles of food law, including the definition of foodstuffs, the responsibilities of food operators and food authorities with regard to food safety, and the installment and functioning of the European Food Safety Authority (EFSA).¹ The GFLR contains provisions and procedures to ensure that food put on the market is safe. It includes a notification procedure whereby the competent authorities must be informed in cases where a food may have injurious effects on human health. Additionally, full traceability of the product and all of its ingredients - the tracking of the food/food ingredient from 'farm to fork' - is mandatory. It is the manufacturer who is legally responsible for fulfilling the requirements of the GFLR and the many other regulations relating to hygiene, quality testing, manufacturing and processing requirements, and so forth.

Figure 1: Main legislation applicable to food supplements



The safety of botanical food supplements is also strengthened by additional legal requirements at national and EU level.



'Negative' lists

In the case of botanicals, 'natural' is not synonymous with 'safe' – and some botanicals or parts of botanicals are poisonous. Some of these cannot be rendered safe to use and are never used in food supplements. For others, appropriate processing and quality assurance measures are used to get rid of harmful substances and render the botanical fully suitable for consumption as food.

Those botanicals with safety concerns are well-known and documented, and most Member States of the European Union have their own 'negative' lists of botanicals/parts of botanicals where safety concerns mean that their use may be banned or restricted.

It must be emphasised that botanicals that may be harmful when consumed raw can be rendered safe by appropriate processing techniques, for example:

- The harmful components may be associated only with one of the plant's components (e.g. the leaves, fruits, seeds, roots). Removing it makes the plant fit for consumption, as is the case with potatoes, where the leaves are toxic but the tubers valuable foods.
- A plant may be used as raw material for the production of additives, flavours, and functional food ingredients using processing techniques such as isolation, extraction and purification and appropriate controls to remove undesirable components, for example it is generally accepted that the oil from the borago species is acceptable for food use when it can be demonstrated analytically that the oil does not contain pyrrolizidine alkaloids.
- A plant may be subjected to a treatment that inactivates or destroys the undesirable components. For instance, it is well known that it is necessary to cook beans (*Phaseolus vulgaris*) at adequate temperature to destroy the phytohaemagglutinin or lectins they contain.
- A plant may show harmful effects at high doses but not at a lower dose. Assessment of the dose and ways in which to ensure that such doses are not exceeded are part of the safety assessment. Some Member States have established maximum levels for plant components.
- A plant may show undesirable effects for specific population groups, even when used in an appropriate way, or it may interact with other foods or medicinal products. In such cases the labels of the botanical products carry appropriate warning information.
- Undesirable properties may be restricted to one single species of an entire plant family. In such a case appropriate methodology or measures are required to make sure that the toxic species is identified and separated from other members of the same family and contamination thus avoided.

'Positive' lists

Whether or not they have a 'negative' list, some European Member States prefer a 'positive' list approach: a list of botanicals considered appropriate for use in food products.



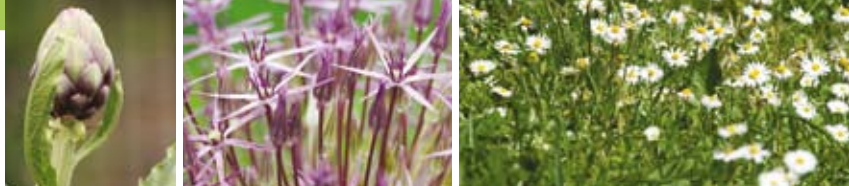
The Novel Food Regulation

The Novel Food Regulation 258/97 is another safety check.² This Regulation applies to the placing on the market within the European Community of foods and food ingredients which have not been used for human consumption to a significant degree within the European Community prior to May 1997 and which fall under the following categories:

- Foods and food ingredients with a new or intentionally modified primary molecular structure;
- Foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;
- Foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use;
- Foods and food ingredients to which a production process not currently used has been applied, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

Under the Novel Food Regulation, any food or food ingredient in the above categories, (including botanicals), which cannot demonstrate the required history of use in the European Union, must go through an authorisation process.

It must provide a dossier of safety information and receive safety clearance from the European Food Safety Authority before it can be used.



Substances 'under scrutiny'

Further safety measures are provided by Chapter 3 of Regulation 1925/2006 on the Addition of Vitamins and Minerals and Certain Other Substances (a category which includes botanicals) to Foods.³



If substances, or ingredients containing substances other than vitamins or minerals, are added to or used in the manufacture of foods at conditions that would result in the ingestion of amounts of the substance greatly exceeding those reasonably expected under normal conditions of consumption of a balanced and varied diet, and when, following an assessment by EFSA, a harmful effect on health has been identified, the substances and/or ingredients containing the substances are either prohibited or only allowed under certain conditions.

Specifically, if a harmful effect on health is identified, the substance or ingredient is either:

- Placed in Part A of Annex III of the Regulation, which means its use in the manufacture of foods is prohibited;
- Placed in Part B of Annex III which means its addition to or use in the manufacture of foods is only allowed under specific conditions;

or, where the possibility of harmful health effects is identified, but scientific uncertainty persists:

- The substance is placed in Part C of Annex III and remains 'under scrutiny' for up to four years, during which time either safety data sufficient to allow its continued use is provided, or continued safety concerns means it moves to Part A or B of Annex III.



The safeguard clause

One further safeguard is common to all Member States. When, as a result of new information or reassessment of existing information, there are detailed grounds for establishing that a product endangers human health, a Member State may temporarily suspend or restrict its availability/use in that Member State, even if it fully complies with the Directives/Regulations relevant to it.

Other Member States and the European Commission must be informed immediately, with reasons for the action. As soon as possible, the Commission must then examine the grounds adduced by the Member State concerned, consult the Member States within the Standing Committee on the Food Chain and Animal Health, and then deliver its opinion and take any appropriate measures.

The Rapid Alert System

Despite comprehensive food safety regulation, problems can still arise - often related to the contamination of imported ingredients. However, the European food safety system is still designed to cope. The requirements of the General Food Law Regulation cover the manufacturer's duties in relation to notification and product recall, and the European Union Rapid Alert System for Food and Feed (RASFF) is an effective tool which provides the control authorities with a fast, efficient and European-wide mechanism for exchange of information on measures taken to ensure food safety.⁴

Rapid Alert notifications are sent when a food or feed presenting a serious risk is on the market and when immediate action is required. Alerts are triggered by the Member State that detects the problem and initiates the relevant measures, such as withdrawal/recall. The notification aims to give all the members of the network the information to verify whether the product concerned is on their market, so that they also can take the necessary measures. The Commission publishes on its website a weekly overview of Rapid Alert notifications, information notifications, and border rejections. Thus consumers can be reassured that products subject to an Alert notification have been withdrawn or are in the process of being withdrawn from the market.

A good example of RASFF in action is an Alert in July 2007 which informed Member States of the contamination of Guar gum from India with dioxins and pentachlorophenol.⁵ (Guar gum is extracted from the Guar bean and is used as a thickener, emulsifier, binding or gelling agent in foods). This resulted in the European Commission rapidly requiring the removal from the market of any stock found to be contaminated, the tracing of the contamination back to source, and the requirement for additional analytical testing requirements to be implemented in the Member States so as to ensure that no further contaminated stock could enter the food chain.



Safety guidance from the European Food Safety Authority (EFSA)

Currently, EFSA is preparing a comprehensive safety guidance document specifically for botanical food supplements: 'The safety assessment of botanicals and botanical preparations intended for use as food supplements'. The current draft proposes a grading of safety requirements whereby those botanicals or botanical preparations for which, '...an adequate body of knowledge (relating to their safety) exists...', will be presumed to be safe and will not need further testing. However, where such knowledge of safety is lacking, a thorough safety assessment will be required before the product can be used. The guidance sets out the methodology to be used for the safety assessment, which EFSA is now testing on a selection of botanical ingredients.⁶

Quality

The safety and quality of botanicals are closely inter-related and apply right from the beginning of the manufacturing process. Correct plant identification and raw material control, avoiding any inadvertent adulteration of the raw material, are of prime importance. Potential contamination with pesticides, or with toxic metals such as lead or cadmium, or mycotoxins, must also be avoided and European food law sets out specific levels that must be met, often stricter than those for medicines. The requirements of the Hygiene regulations must also be followed, as must the principles of a Hazard Analysis and Control of Critical Points (HACCP) procedure, to ensure good manufacturing practices.

Microbiology

Achieving an acceptable microbial count can be a difficulty for a botanical material. It is generally dried before use, but unless the drying process is properly carried out, problems can occur. There are specific rules about the methods that may be employed to ensure lack of microbial contamination: Only a very few named 'culinary' botanicals can be irradiated, and treatment with ethylene oxide has not been permitted at all for food products in all EU Member States since 1989.^{7,8} Fortunately, however, the development of other methods such as water vapour treatment means that the good microbiological quality of a product can be assured.

Processing techniques

Many quality-related aspects of botanical products are dealt with via appropriate processing: for instance, techniques of extraction and isolation can not only increase the bioavailability of the product, producing a more concentrated extract, they can also increase preservation and stability and reduce solvent residue in the environment. Permitted extraction solvents are laid down in Directive 88/344/EEC.⁹



Quality Assurance, Good Manufacturing Practice and self-regulation

While the safety and quality of botanical supplements is fully covered by statutory requirements, rules are only effective if they are properly adhered to, and to ensure that all aspects of product manufacture are properly covered, self-help and self-regulation have an important role to play.

If quality is to be assured, strict adherence to the principles of Good Manufacturing Practice is essential throughout the different stages of the manufacturing process: from the obtaining of the plant, through to its preparation and to the final finished product. Each stage in the process must be clearly documented, and the appropriate tests and checks carried out at the appropriate time.

There are a number of different national guidelines which deal with quality issues. Most recently, the European Federation of Associations of Health Product Manufacturers (EHPM) has produced a 'Quality guide for food supplements' which harmonises these different guidelines, providing comprehensive guidance to the food supplement industry to ensure that it is complying with both the relevant legislative requirements and best practice.¹⁰ The guide details both the legal and recommended production requirements from raw materials to finished products, including manufacturing, quality control, packaging, distribution and storage. Its recommended requirements are based on examples of best practice, to help maintain the safe and consistent production of high quality food supplements across the EU.



³ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. Official Journal of the European Union: L404/26, 30 December 2006

⁴ <http://ec.europa.eu/food/food/rapidalert>

⁵ Rapid Alert System for Food and Feed (RASFF) of the European Commission. 25.07.07, Alert No. 2007.0499

⁶ <http://www.efsa.eu.int>

⁷ Directive 1999/3/EC of the European Parliament and of the Council of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation. Official Journal of the European Union: L66/24, 13 March 1999

⁸ Council Directive 89/365/EEC of 30 May 1989 amending Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances. Official Journal of the European Union L 159/58, 10 June 1989

⁹ Council Directive 88/344/EEC of 13 June 1988 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients. Official Journal of the European Union: L157/28, 24 June 1988

¹⁰ <http://www.ehpm.org>

¹ Regulation (EC) no 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Official Journal of the European Union: L31/1, 1 February 2002

² Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. Official Journal of the European Union: L043/1, 14 February 1997

Health claims for botanical food supplements in the EU

06

Introduction

Communication on the health effects and benefits of botanical food supplements is essential for the consumer to understand the product's purpose in relation to a particular aspect of health maintenance, health optimisation or disease risk reduction, and how to use it. Such information helps the consumer to make the appropriate product choice. Under the new claims rules that are applicable to all foodstuffs, such communications, whether on pack or in brochures or websites, are considered to be 'health claims' and therefore must be in conformity with the new rules. This comprehensive regulatory framework for foods and botanical food supplements aims to ensure that their claims for effect are neither misleading nor exaggerated.



Right: Ginseng root

The regulatory structure for the use of health claims for foods

Regulation 1924/2006/EC on Nutrition and Health Claims made on Foods has tightened the regulatory framework by introducing a process for the pre-approval of health claims on European food products.¹

The Regulation recognises several different categories of health claims, including nutrient content claims, 'generic' or well-established health maintenance/health optimisation claims, disease risk reduction claims and claims referring to children's development and health. Each category of claims has its own specific rules, but all have the same underlying principles: that all health claims should be:

- Capable of substantiation;
- Based on generally accepted scientific evidence;
- Well understood by the average consumer.

New claims, reduction of disease risk claims and children's claims are all subject to authorisation procedures. Applications for such health claims must be reviewed by the European Food Safety Authority (EFSA) and approved by the European Commission before they can be used on food products. This means that for each claim a dossier of data with the name of the food or food component and, for botanicals, the plant part used, the relationship between the botanical and its contribution to health (the 'health relationship'), the conditions of use, the nature of the substantiating evidence, the relevant references, and an example of the desired claim wording, must be submitted to EFSA. If EFSA's opinion is positive - that the evidence submitted substantiates the claim - the European Commission will give the final approval for the claim to be used.





Rhubarb (*Rheum officinale*)

The Article 13 claims list

Currently several hundreds of 'generic' or well-established health claims, relating to several hundred herbs and based on their relationship to particular aspects of health, are being reviewed by EFSA for potential inclusion on a Community Register of approved claims. These claims will then be available for use in the European Community and any manufacturer/marketer may apply such a claim to a relevant product, providing he or she holds the substantiating evidence for the claim and can produce it on request. EFSA's work on these claims is due to be completed by 2010.

The totality of the evidence

Recital 17 of the Nutrition and Health Claims Regulation says that claim substantiation should be carried out by review of, '...the totality of the available scientific data and by weighing the evidence'. This means that not only in vivo data, but also other relevant information, including epidemiological, traditional usage, observational and in vitro data, should be taken into account when assessing the strength of the evidence.

The requirement for the assessment and weighing of the totality of the evidence is particularly relevant for botanicals, many of which have a long tradition of use: for instance, full scale double blind clinical trials to prove the effects of a simple botanical tea, such as chamomile tea, long used for its calming, soothing properties, would be wholly disproportionate when so much historical data substantiating its effects exists.

History of use and efficacy

The validity of history of use data in demonstrating the effect of a product is accepted in the regulation of medicines: the basic requirement to register a product under the European Traditional Herbal Medicinal Products Directive (THMPD) is the demonstration of 30 years history of use of the product to treat a particular condition.² No further evidence of efficacy is required and the registration approval includes the approval of a medicinal claim.

Examples of claims permitted for THMPD registered products include:³

- **Calendula (*Calendula officinalis*):** the flowers are used for 'the symptomatic treatment of minor inflammations of the skin (such as sunburn) and healing of minor wounds. For the symptomatic relief of minor inflammations of mouth and throat.'
- **Valerian (*Valeriana officinalis*):** the root is used for 'support of mental relaxation and normal sleep, exclusively based on long-standing use.'

History of use and safety

Data demonstrating history of use is also acceptable as evidence of safety under another branch of food law: food ingredients (including botanicals) that can be shown to have been on the market in 'reasonable quantity' prior to May 1997 do not have to be approved for use under the Novel Food Regulation.⁴

History of use for botanicals? Traditional usage?

Like traditional herbal medicines, many botanicals are also supported by extensive historical data substantiating their safe and effective use in food products, where their purpose is not to treat or cure disease - as in a medicine - but to maintain or optimise an aspect of health. However, while historical data is taken into account in considering the safety of botanicals, the Nutrition and Health Claims Regulation does not formally take account of such data in assessing the substantiating evidence for a claim for the effect of a food product.



Approvals for 'Reduction of disease risk claims'

EFSA is also advising the European Commission on the acceptability of the other types of claims covered by the Nutrition and Health Claims Regulation, including those on products specifically intended for children, and disease risk reduction claims.

'Reduction of disease risk' claims are a particular type of health claim which state that a food or one of its components significantly reduces a risk factor for human disease (for example, phytosterols can help reduce blood cholesterol, thereby reducing a risk factor for cardiovascular disease).

To obtain approval for such claims, a very comprehensive dossier must be submitted to EFSA, which includes information on the characteristics of the food/constituent for which the claim is being made, (composition, physical and chemical characteristics, manufacturing process, stability and bioavailability). The proposed wording for the claim must also be submitted, with details of the target population for whom the claim is intended.

All pertinent scientific data (in favour and not in favour) that forms the basis for the substantiation of the claim must be submitted, including studies in humans. The evidence should demonstrate the extent to which:

- The claimed effect of the food/food constituent is relevant to human health;
- The cause and effect relationship between the consumption of the food/food component and the claimed effect in humans;
- The quantity of the food/pattern of consumption to obtain the claimed effect as part of a balanced diet.

The totality of the evidence will then be taken into account and weighed as part of a comprehensive review, which will result in either the granting or refusal of the claim. EFSA has issued detailed guidelines for such applications.⁵



Conditions of use

'Conditions of Use' provide important label information to ensure that the consumer uses the product correctly. The suggested amount of the botanical that should be taken each day must be shown on the label and must be sufficient to ensure that the user can achieve the claimed health effect. Conditions of Use also include any warning statements that may be necessary to alert consumers to the possible unsuitability of a product for particular sections of the population (pregnant women, for example).

Health relationships

Botanical food supplements have their own particular relationship or relationships with the maintenance of health and there are many hundreds of botanicals whose constituents offer health support. Some examples of European botanicals, commonly found in hedgerows and gardens, and their relationship to health include:

- **Elder** (*Sambucus nigra*) has a health relationship with the immune system and is used to help optimise the immune system.
- **Hawthorn** (*Crataegus laevigata*) has a beneficial effect on blood circulation and is used to maintain a healthy circulatory system.
- **Milk thistle** (*Silybum marianum*) has beneficial properties in relation to the liver and is used to maintain its health.
- **Meadowsweet** (*Filipendula ulmaria*) has been used to maintain the health of the lower urinary system and the respiratory tract and is useful to support the excretory function of the kidneys, and to soothe the throat.
- **Nettle** (*Urtica dioica*) has health relationships to both the circulatory and the muscular system and is used to maintain blood flow and flexible joints.
- **St John's Wort** (*Hypericum perforatum*) has a health relationship with mental health and contributes to emotional balance and optimal relaxation.
- **Vervain** (*Verbena officinalis*) has health relationships with respiratory health and with lactation, and is used both to soothe the throat and pharynx and also to support lactation in nursing mothers.

Left: Shiitake mushrooms (*Lentinula edodes*)



Many botanicals support several different health relationships. Sometimes the whole plant is required to produce the desired effect, but sometimes only a part, such as the leaf, root or flower is needed. Some examples include:

- **Yarrow (*Achillea millefolium*):** the herb and flower are both related to digestion and appetite and are used in botanical supplements that contribute to maintaining a healthy appetite and digestion.
- **Garlic (*Allium sativum*):** the bulb and leaf show several different health effects: in relation to the liver, the immune system, the nervous system, the cardiovascular system and blood lipid levels, and to antioxidant activity. It is used in botanical supplements to help maintain a healthy liver function, a normal immune system, to contribute towards resistance to stress, to help maintain a healthy heart and normal cholesterol/blood lipid/homocysteine levels, and to optimise the antioxidant activity of the body.
- **Bilberry (*Vaccinium myrtillus*):** the fruit and leaf have a health relationship with the health of the cardiovascular system, the immune system, the digestive system and with antioxidant activity. It is used in botanical supplements to help maintain a healthy heart, to promote the health of the immune and the digestive systems and for its antioxidant properties. Used on its own, the leaf has a health relationship with glucose metabolism, and is used in botanical supplements to maintain a normal blood sugar level.

Not all botanicals commonly used in the European Union in food supplements are European native plants, but they all have a history of use for health maintenance purposes. Some commonly used botanicals originating from outside the European Union:

- **Cardamom (*Elettaria cardamomum*)** comes from India and is used in botanical supplements to help maintain a healthy digestion.
- **Rhubarb (*Rheum palmatum*)** also has Chinese origins. It has a relationship with intestinal health and is used for its contribution to intestinal transit and function.

- **Siberian ginseng (*Eleutherococcus senticosus*)** originates, as its common name suggests, from Siberia. The root has traditionally been used to promote the general health of the body and the immune system and to promote mental function. It is used in botanical supplements to help maintain energy levels, to support the body's natural defence system, and to help maintain cognitive performance.
- **Ginkgo (*Ginkgo biloba*)** originating from China, has health relationships with mental function, blood circulation and also has antioxidant properties. It is used in botanical supplements to help maintain memory and cognitive function, to support the venous system, and as an antioxidant to help strengthen the body's defences.

America is the home of a number of popular botanicals:

- **Evening primrose (*Oenothera paradoxa*)** has a number of health relationships - with the skin, heart, immune and menstrual systems - and is used to help maintain them in a normal and healthy condition. Another species of Evening Primrose, (*Oenothera biennis*) has a relationship with joint health and is used to maintain joint flexibility.
- **Saw palmetto (*Serenoa repens*)** has a health relationship with male urinary function and is used to maintain normal urinary function in men over 45.
- **Slippery elm (*Ulmus fulva*)** has a health relationship with intestinal function and is used to soothe the digestive tract.
- **Witch hazel (*Hamamelis virginiana*)** has a relationship with the health of the veins, and contributes to the blood circulation, particularly in the legs.
- **Wild yam (*Dioscorea villosa*)** has a health relationship with menopausal symptoms and helps to maintain comfort at this time of life.
- **Black cohosh (*Cimicifuga racemosa*)** has a similar health relationship and a similar function.

A selection of references on the health relationships of botanicals

- Williamson, E.M. *Potter's Herbal Cyclopaedia*. C.W. Daniel Co. Ltd. 2003
- Grieve, M. *A Modern Herbal: The Medicinal, Culinary, Cosmetic and Economic Properties, Cultivation and Folk Lore of Herbs, Grasses, Fungi, Shrubs and Trees*. Dover Publications, 1971
- Karaliedde, L. and Gawarammana, I. *Traditional Herbal Medicines*. Hammersmith Press, 2008
- Griggs, B. *The Food Factor*, Penguin Books Ltd. 1986
- Delmulle, L. and Demeyer, K., (Eds.) *Anthraquinones Containing Plants Reconsidered*. Standaard Uitgeverij nv, Antwerpen, 2008
- Bradley, P.R. (Ed.), *British Herbal Compendium*, Vols. 1 and 2, British Herbal Medicine Association, 1992 and 2006
- Bench, N. *The Healing Garden*, Grey House in the Woods, 2007
- McGuffin, M., Hobbs, C., Upton, R., Goldberg A., *Botanical Safety Handbook*. CREC Press 1997
- Barnes, J., Anderson, LA, Phillipson, J.D. *Herbal Medicines - A Guide for Healthcare Professionals*. Pharmaceutical Press, 2002
- Mills, S and Bone K., *Principles and Practice of Phytotherapy*. Churchill Livingstone, 2000
- McIntyre, R., *The Complete Woman's Herbal*, Gaia Books, 1994

- 1 Corrigendum to Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. Official Journal of the European Union: L12/3, 18 January 2007
- 2 Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use. Official Journal of the European Union: L136/85 30 April 2004
- 3 <http://www.emea.europa.eu/htms/human/hmpc>
- 4 Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. Official Journal of the European Union: L043/1, 14 February 1997
- 5 <http://www.efsa.eu.int>