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# Herbal food supplements

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## Distinctive features of food supplements

- According to the definition adopted by EU (Directive 2002/46/CEE), ASEAN, USA and New Zealand, the food supplements are “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”.
- A dietary supplement is a product that:
  - ✓ is intended to supplement the diet
  - ✓ contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and certain other substances or their constituents);
  - ✓ is intended to be taken by mouth, in forms such as tablet, capsule, powder, softgel, gelcap, or liquid;
  - ✓ is labeled as being a dietary supplement.
- Due to their composition and recommendation of use, food supplements could be placed at the borderline between natural drugs and foodstuffs, having a large addressability and claiming health benefits for the consumers.





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## Main herbal ingredients used in food supplements

- Different substances originating in plant species (valuable bioactive compounds) could be found as ingredients in food supplements:
- vitamins: fruits of *Rosa canina*, *Hippophae rhamnoides*, *Malpighia glabra* (vitamin C), roots of *Daucus carota* (caroten, provitamin A); germs of *Triticum aestivum* (vitamin A, E);
- colouring agents: flowers of *Tagetes erecta* (lutein, zeaxanthin); petals of *Hibiscus sabdariffa*; roots of *Beta vulgaris var rubra* (anthocians); *Daucus carota* (Beta-caroten);
- enzymes: fruits of *Ananas comosus* (bromelaine), *Carica papaya* (papaine);
- fibers: roots/rhizoma of *Cichoryum intybus* (inulin), seeds of *Plantago ovata* (Psyllium)
- fat oils and fatty acids: seeds of *Cucurbita sp.*, *Linum ussitatissimum*, *Canabis sativa*, *Nigella sativa* (Omega-3, 6, 9) *Charthamus tinctorius* (fatty acids), fruits of *Serenoa repens*, *Olea europaea*;
- flavour and essential oils: bark of *Cinnamomum zeylanicum*; leaves/herba of *Mentha piperita*; seeds of *Foeniculum vulgare*, *Pimpinella anisum*, *Carum carvi*; fruits (orange, grape fruit, peach, apple);
- chlorofile: leaves of *Morus alba*, *M. nigra*;
- sweeteners: leaves of *Stevia rebaudiana* (plant extracts standardized in stevioglicosides)





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## Physiological effects of food supplements

- Taking into account the physiological effects of the main active ingredients, there are special categories of food supplements which address to different targets (organs/system) of human body
- Depending of the consumer specific needs, there are products which are supporting: bones and joints; blood, heart and circulatory system, immunity, liver activity and digestion, nervous system, weight control, eyes and view, etc.
- A large range of products are promoted due to their properties such as: pro-biotics, antioxidants, stimulants, depurative/detoxification, diuretic.
- During the last time food supplements became very popular and their use has been included in the current life habits of many people.





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## Consumer's access to food supplements

- The easy access to the food supplements, which are sold using various channels (pharmacies, herbalists, natural food and body care shops, company-owned retail stores, supermarkets, sex-shops, direct sales, e-commerce) could be one of the reason for the increasing consumption of dietary supplements at global level, as well as the intense promotion by mass-media and the consumers' perception of these category of products.
- One single example of the dimension of a successful network of distribution is relevant: the well known American company GNC (which is focused on premium, value-added nutritional products) was selling, at the end of 2014 (under proprietary brands and nationally recognized third party brands) in more than 8,900 locations (of which more than 6,600 retail locations are in the United States) and franchise operations in more than 50 countries.
- Main GNC proprietary brands include Mega Men (R), Ultra Mega (R), Total Lean (TM), Pro Performance (R), Pro Performance (R) AMP, Beyond Raw (R), GNC Puredge (TM), GNC Genetix HD (R), Herbal Plus (R).





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## Size and dynamics of the most important European markets

- From 2013-2018, the Western Europe regional market is expected to grow by 13%, reaching €5.65 billion in 2018 (Euromonitor International, 2014).
- Countries leading the market in terms of market size and dynamics are:
  - ✓ Italy (€ 1.2 billion)
  - ✓ Germany (€ 935 million)
  - ✓ France (€ 611 million)
  - ✓ the UK (€ 538 million)
- The rest of Western Europe recorded sales of \$2.8 billion.
- Although Italy posted the highest sales of food supplements, **herbal food supplements** represent a relatively small part of sales
- Eastern Europe regional market is estimated to grow substantially: in 2018, the region is projected to reach a market size of €3.2 billion (from €2 billion in 2013), of which the Russian market makes up around two thirds (Euromonitor International, 2014)
- Part of this Russian market is supplied by producers in Latvia and Lithuania adding to industrial demand in these countries
- Other fast growing East European countries include Turkey, the Ukraine and Belarus.

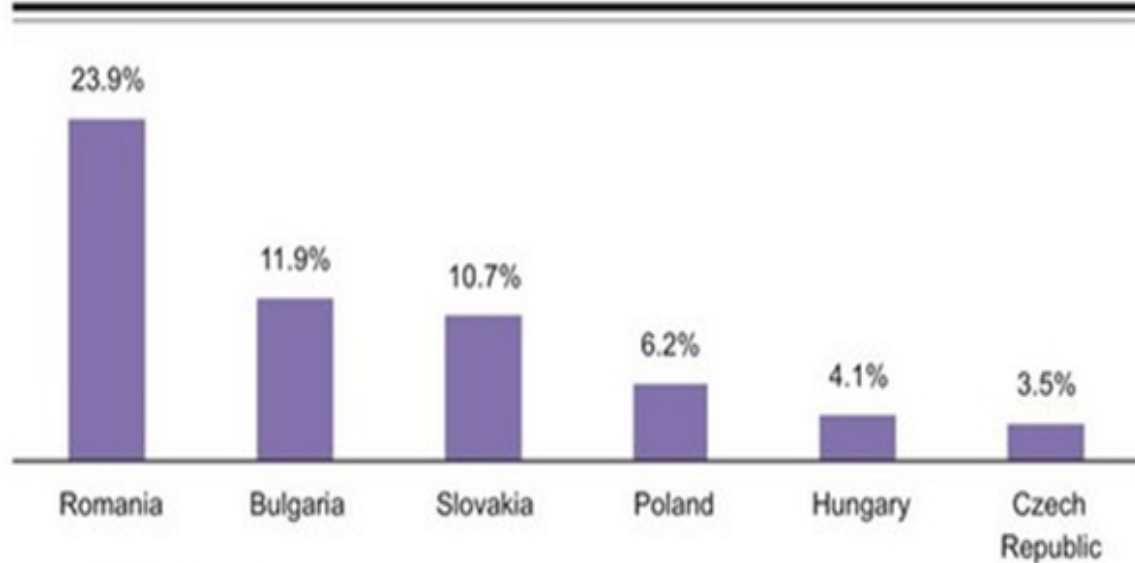


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## Growing rate of some food supplement markets of Central Europe

Average CAGR for dietary supplement markets in the analysed CE countries (%), 2010-2011



Note: growth in local currency.  
Pharmacy sales.

Source: report "Dietary supplements market in Central Europe 2012. Comparative analysis and development forecasts for 2012-2014", PMR, 2013

[www.pmrpublications.com](http://www.pmrpublications.com)







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## Value growth of other important markets

- In **SUA** vitamins and dietary supplements continued to see current value growth of 4% to reach US\$ 27.2 billion in 2015
- in **Canada** it increased by 4% in current value terms in 2015, which was slightly slower than the growth seen in 2014. It is expected a sustained growth, with a value CAGR of 1% at constant 2015 prices over the forecast period, to reach C\$1.8 billion in 2020.
- In **Japan** current value sales of vitamins and dietary supplements increased by 1% to reach ¥1.1 trillion. Value sales of vitamins and dietary supplements are expected to rise at a 1% CAGR at constant 2015 prices over the forecast period to stand at ¥1.2 trillion in 2020.
- With improving standards of living and rising disposable incomes and increasing health awareness, the consumption of vitamins and dietary supplements will also become increasingly important in **Chinese** consumers' daily lives.





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## General trends in market development

- In most of the countries it was registered a positive trend and an increasing interest of users in naturally positioned consumer health products. This was explained by different socio-economic and behavioural reasons:
  - ✓ people are living longer, are more educated, have wider access to information and feel more responsible as individuals and more active as consumers, becoming the managers of their health capital;
  - ✓ it has increased the awareness about healthy ageing, the desire of individuals to feel good, which is reflected in a proactive and preventive approach to health and wellness;
  - ✓ people became interested to invest in their long-term health and to improve their underlying health conditions rather than merely treating symptoms;
- It was increasing the preference of use, when possible only natural products, free of chemicals, in order to maintain the physical and intellectual health;
- it was observed a strong emphasis on nutrition (natural ingredients, healthy diets) and lifestyle;
- strong media has also influenced the perception of the food supplements as products which can improve health and wellness without any potential risks related to their intake;
- All these encouraged self-medication and the new regulation from EFSA had as result the consumers' trust in quality and safety of such products;
- it was also registered an increasing numbers of doctors that have started to advise their patients to take vitamins and dietary supplements to help them cope with minor health issues, often in combination with Rx-medicine based therapies.





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## Future prospects

- The ageing population will be a major contributor to the development of this category of products over the forecast period; people want to live longer and stay in shape, so they are increasingly adopting healthy lifestyles; they also are able to afford higher budgets for their healthcare, which is expected to motivate them to dedicate more of their budgets for food supplements;
- static performance in certain countries is explained by the growing number of alternatives and the increasing pressure on average unit prices;
- sales decline was associated to consumer scepticism (about health claims) and confusion over the benefits offered by certain herbal food supplements (evening primrose oil, echinacea, ginseng, garlic, St John's Wort, starflower oil and vitamin E); all set to see double-digit value decline at constant 2015 prices in United Kingdom, while around 3% volume decline each was registered during the forecast period as a whole in Slovakia;
- Although the size of the category and per capita consumption is still low in Spain, for example, this allows further room for growth in the near future;
- Many areas will continue to see competition from combination dietary supplements and multivitamins; this will also impact the domain of single vitamins, for example or glucosamine and minerals, which registered 1-2% decline in 2015;
- Affordable products with well-proven benefits are expected to prove most successful, with price-sensitive consumers seeking good value-for-money in addition to health benefits.





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## Categories of Consumers

- Rather well-educated persons (with quick access to information/ use internet) with an accelerated rhythm of life, often stressful
- Young people eager to improve their shape, physical aspect, (body building) and sexual activity (enhancement)
- Poor people with low education level, who trust the power of medicinal plants
- Discomfort due to the pregnancy or menopausal periods, with hormonal deficiencies and increased needs for vitamins and minerals
- Elder people threatened by osteoporosis which have problematic absorption of minerals or deficient omega-3 rich diet
- Children with low immunity, raised far from nature with parents who want the best for them
- Media consumers who love modernity and want to be “in trend”, buying everything fashionable







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## Interest of consumers in food supplements

- Age and sex differences were evident in motivations for use.
- Older adults were more likely to use supplements for site-specific health reasons (bone, heart, eye), whereas younger adults were more likely to use products with a short-term effect, such as enhanced energy or to boost immune function.
- Women were more likely to report use for bone health (calcium and vitamin D among for the purpose of maintaining bone health throughout the lifespan and preventing the onset of osteoporosis during aging) and men for heart health. However, men were also more likely to report use of products to improve and maintain health (vitamin D, botanical supplements, vitamin B12,  $\omega$ -3 and fish oils) or for mental health, whereas women were more likely to report use of products to enhance energy (vitamin B12 and vitamin B6) or for colon health (botanical supplements).
- Supplement users are making a greater effort to seek health and wellness. They try to consume a better diet, to have somewhat higher intakes of nutrients, they participate in physical exercise, avoidance of obesity, moderate alcohol use and abstinence from smoking. Thus the users of dietary supplements tend to incorporate these food stuffs into their lifestyles as part of a broader focus on healthy living.





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# American Food supplement user's profile

## WHO takes dietary supplements?

68% of all U.S. adults reported taking dietary supplements.

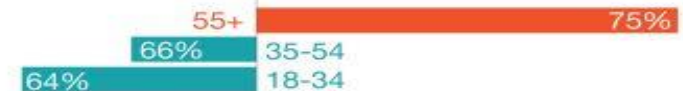
Based on all U.S. adults:

Reported taking



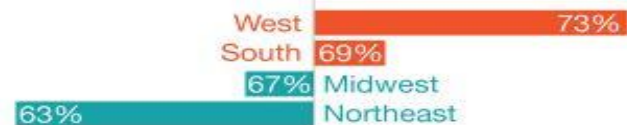
### AGE

75% of U.S. adults 55+ take dietary supplements.



### REGION

73% of U.S. adults in the Western U.S. take dietary supplements.



### GENDER

72% of U.S. adult women take dietary supplements.



### INCOME

72% of U.S. adults with household incomes over \$50k take dietary supplements.



### EDUCATION

72% of U.S. adults with a college degree take dietary supplements.







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## Herbal food supplements - a particular category of dietary supplements

- The motivations behind botanical supplement use have been studied more extensively than for other types of dietary supplements. In adults, use of herbs and botanical supplements has been related to being uninsured, using more prescription and over-the-counter medications, and for certain health conditions.
- National survey data find that most botanical supplement users do not report this information to their health care providers. This may be cause for concern because some botanical supplements have the potential to interact negatively with prescription medications. While some have suggested that botanical supplements are increasing in popularity to replace costly prescription medications.
- Patients' freedom of choice of a practitioner is also encouraging their utilization of alternative treatments and herbal remedies, although many select herbal medicines from a deductive approach based on anecdotal information, that is, "it worked for my friend or relative"
- This situation is similar in most of the European countries: people are looking to new sources of food, functional ingredients and to diseases prevention by a holistic approach including diet, life style, organic products.
- Herbal food supplement market development was also correlated to the increasing of the category of 55-64 years old in the population. This age group is more susceptible to chronic and degenerative diseases, so is positively correlated to the need for food supplements and their usage.





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## Botanicals as medicinal products

- Generally, herbal products are classified as medicinal products (if they claim therapeutically or prophylactic indication), but in most cases they belong to the food or cosmetic areas, although they sometimes contain plants which have pharmacological properties. For example, senna pods (from *Cassia* plants, used as laxatives) can be marketed as food in Belgium.
- In general, market regulators in France, the Netherlands, Belgium and especially Italy are more open to new herbal products than in Germany and the UK.
- Specific categories of non-medicinal products could exist in some member states, such as “therapeutic supplement products” in Austria, for example or “medicinal products” which are under specific conditions exempt from licensing requirement in Spain, Ireland or UK.
- In Germany, where herbal products are sold as ‘phytomedicines’, they are subject to the same criteria for efficacy, safety and quality as are other drug products.
- In the USA, by contrast, most herbal products in the market place are marketed and regulated as dietary supplements, a product category that does not require pre-approval of products on the basis of any of these criteria.





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## Ambivalent herbs

- A plant-based food supplement is intended for a person with a normal physiological profile and aimed at keeping that person in a state of homeostasis. The dividing line between “therapeutic effect” and “physiological effect” is not always easy to be pinpoint, mainly because some constituents are present both in plants used for food and food supplements and in plants used as herbal medicine. These plants are called “ambivalent herbs” and the dosage is an important criterion to distinguish between both application fields.
- The scientific justification for the safety and purpose of the supplement must be based on all available data, including experimental studies, but also referring to clinical and epidemiological findings. Especially when the product moves away from traditional usage, the level of scientific, toxicological and clinical requirements must be higher, as much for the safety in use, as for the physiological effects and consequently for the health claims.





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## Reasons of worry for human health

- **toxicity** of certain plants and substances extracted from them, which could be found in the composition of herbal food supplements (piperizidinic alkaloids from *Symphytum officinale* and *Tussilago farfara*; aristolochic acids from *Aristolochia sp.*, active pyrones constituents from *Piper methysticum*; ephedrine from *Ephedra sinica*) proved to have hepatotoxic and nephrotoxic effects, induced permanent damage of liver or kidney tissues, stroke and heart attack or cancer and even death;
- **adverse reactions** in case of consumption of herbal food supplements simultaneously with synthesis medicines, even if they are common species: *Ginkgo* (cautious use must be advised in individuals on anticoagulant therapy); *Hypericum* (interaction with antidepressants and anticoagulants; allergic reactions, dizziness, headache, fatigue, nausea, photosensitivity); *ginseng* (insomnia, headache, elevation of blood pressure, epistaxis, vaginal bleeding in large excessive doses);
- **misidentification** of plant species with similar vernacular names and mislabelling of the herbal products) in case of *Stephania tetrandra* (Fang-Ji) and the confusion with *Aristolochia fangchi* (Guang-Fang-Ji) produced dramatic adverse reactions which led to nephrotoxic and carcinogenic events;
- **the content of secondary metabolites** could register high variations especially in the wild-crafted species (concentration above permitted limits until the quasi-total inexistence) that dramatically influence the efficacy of the herbal products;
- **lack of stability** of the quality end efficacy indicators, especially in case of certain plant extracts, fat oils, herbal teas;
- **contamination** with heavy metals (As, Hg, Pb) of herbal products resulted in toxic effects on children, who reported learning disabilities and behavioural problems;
- **adulteration** of herbal food supplements with active pharmaceuticals have been observed with Sexual Enhancement or Men's Virility products (PDE-5 inhibitors); Sports Nutrition supplements (steroids); Diet and Weight Management supplements (anorectics like Sibutramine and Phentermine; diuretics like Bumetanide and Furosemide); stimulant adulteration (Caffeine, Methamphetamine, Amphetamine or Methylphenidate), etc;
- **substitution** of some useful plants with similar species as aspect, sold as raw materials proved to be inefficient or dangerous surrogates for public health, which may affect an increasing part of population, as the sales volume of food supplements in continuously increasing.





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# Quality and safety requirements for herbs and herbal food supplements

Markers of tracers must be taken into account as there are essential tools able to provide proof of:

- **quality** (a tracer is a chemically-defined constituent of a plant that can be very useful in calculating the quantity of plant or preparation in finished product);
- **physiological effect** (the biochemical nature of a marker allows an objective evaluation of any influences on organic functions associated with the consumer's psychological and physical performance);
- **absence of toxicity** (a relevant indicator of chemical, biological, clinical or epidemiological nature to explain the benefit to health);
- the **daily amount** to be taken must be planned as precisely as possible since plant constituents (which may be highly concentrated in certain extracts) can reach intake levels causing pharmacological effects. In herbal food supplements, the daily intake of plant substances must take account of normal traditional usage;
- **complex mixtures** of plants should be limited in the number of different plants or plant preparations in one product in order to allow a correct chemical analysis;
- particular attention have to be given to the characteristics and differences between **matrices**, whose effect may alter digestive absorption and the bio-availability of active substances, or could induce molecular interactions which may enhance the risks;
- **Health claim** evaluation must be consistent with the recognized physiological effect and the degree to which the claimed effect is demonstrated.
- The proofs required in support of a claim must be internally consistent; where based on tradition must rely on generally recognised knowledge; must be experienced in vitro and in vivo; may be obtained from several sources, including human intervention studies or even epidemiologic studies, when available;
- **Scientific assessment** means that the fullest possible information must be available.
- **Public information** and communication concerning these products must be fair, supported by scientific data or studies and make it possible to guarantee safety of use, so that the products' consumption is risk-free.





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## Consumers' information

- Public information and communication concerning these products must be fair, supported by scientific data or studies and make it possible to guarantee safety of use, so that the products' consumption is risk-free.
- In order to inform the public, the manufacturer must be able to provide information about the anticipated uses of a product and the purpose for use; he should have knowledge about the population at risk (vulnerable categories of consumers, to which the product must not be recommended) and geographic limitation of use (when appropriate).
- Regarding the conditions of a product use, the consumer must be informed clear and with the maximum transparency about the product formula, the nature of the plant used, the period of use, the maximum permitted daily amount, the adverse effects and possible interaction with certain medicines or food.