

## II. Functional food

Another important field of innovation in the production of processed food is functional food.<sup>334</sup> Functional food results from biotechnology as well as from the new developments in traditional food technology like fortification and extraction. "Functional food"<sup>335</sup> describes nutrients or nutrient-enriched food that is designed to prevent diseases. Functional food<sup>336</sup> is "any food or ingredient that has a positive impact on an individual's health, physical performance, or state of mind, in addition to its nutritive value."<sup>337</sup> Functional food is rather a concept than a well-defined food. Functional food addresses various components affecting body functions and belongs to nutrition and not to pharmacology, as it does not comprise pharmaceuticals with therapeutic effects. The borderline between functional food and pharmaceuticals becomes more and more fluent with progress in nutrition science.<sup>338</sup> Table 12 shows areas of human physiology addressed by functional food.<sup>339</sup>

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334 Dietetic food is intended for individuals with a specific disease or condition. While functional food improves or maintains health for consumers, dietetic food aims at physicians or health professionals. Dietetic food must fulfill the requirements set out by the EU: "A particular nutritional use must fulfill the particular nutritional requirements: of certain categories of persons whose digestive processes or metabolism are disturbed; or of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs." Art. 2(1), Art. 1(2)(b)(i)(ii) of the EU Directive 89/398/EEC.

335 Functional food is also described by "nutraceuticals" and has to be distinguished from the so called "medical food", which the U.S. Food and Drug Administration (FDA) defines as "formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, on the basis of recognized scientific principles, are established by medical evaluation.", 21 U.S.C. 360ee(b)(3). For more details see *DellaPenna*, Nutritional Genomics: Manipulating Plant Micronutrients to Improve Human Health, 285 Science 375 (1999), *Mazut, Krebbers&Tingey*, Gene Discovery and Product Development for Grain Quality Traits, 285 Science 372 (1999), *Pridmore et al.*, Genomics, Molecular Genetics and the Food Industry, 78 Journal of Biotechnology 251 (2000).

336 The European Commission's Concerted Action on Functional Food Science in Europe (FUFOSE = Functional Food Science in Europe) involving about 100 European experts in nutrition and medicine developed a parallel definition of the term functional food: "A food can be regarded as functional if it is satisfactorily demonstrated to affect beneficially one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either improved stage of health and well-being and/or reduction of risk of disease. A functional food must remain food and it must demonstrate its effects in amounts that can normally be expected to be consumed in the diet: it is not a pill or a capsule, but part of the normal food pattern." *Diplock et al.* (eds.), Scientific Concepts of Functional Foods in Europe: Consensus Document, 81 British Journal of Nutrition S1 (1999).

337 *Goldberg*, Functional Foods, Designer Foods, Pharmafoods, Nutraceuticals, London 1994, 3.

338 A European Consensus of Scientific Concepts of Functional Foods, 16 Nutrition 689 (2000).

339 For an overview see *Kotilainen et al.*, Health Enhancing Foods – Opportunities for Strengthening the Sector in Developing Countries, World Bank Agriculture and Rural Development Discussion Paper 20, Washington 2006.

**Table 12:**  
**Areas of human physiology that are relevant to functional food.<sup>340</sup>**

Areas of human physiology	Functional food components to improve the relevant health area
Early development and growth	<ul style="list-style-type: none"> <li>- Intake of polyunsaturated fatty acids, iron, zinc and iodine (pregnancy)</li> <li>- Oligosaccharides, gangliosides, high-molecular-weight glycoproteins, salt-activated lipases, pre-<sup>341</sup> and probiotics<sup>342</sup> (maturation)</li> <li>- Antioxidant vitamins, trace elements, fatty acids, arginine, nucleotides, probiotics and altered allergenic components (immune system)</li> <li>- Combined effects of calcium and other constituents of growing bone, such as proteins, phosphorus, magnesium and zinc, as well as vitamins D and K, fluorine and boron (osteoporosis)</li> </ul>
Regulation of basic metabolic processes	Slower absorption of glucose into the bloodstream, so that insulin requirements are lowered (diabetes mellitus <sup>343</sup> )
Defense against oxidative stress	Small-molecular-weight antioxidants, e.g. vitamin E, vitamin C, carotenoids and polyphenols, including flavonoids

340 *Ashwell*, Concepts of Functional Foods, ILSI 2002, 6, available at [www.europe.ilsil.org/file/ILSIFuncFoods.pdf](http://www.europe.ilsil.org/file/ILSIFuncFoods.pdf). *Goldberg*, Functional Foods, Designer Foods, Pharmafoods, Nutraceuticals, London 1994, 3.

341 A non-digestible food ingredient that beneficially affects the host by selectively stimulating the growth and/or modify the metabolic activity of one or a limited number of bacteria in the colon, that have the potential to improve host health.

342 A live microbial food ingredient that, when ingested in sufficient quantities, exerts health benefits on the consumer. *Mercenier et al*, Genomics of Probiotic Lactic Acid Bacteria : Impacts on Functional Foods, in: *Neeser&German* (eds.), Bioprocesses and Biotechnology for Functional Foods and Nutraceuticals, CRC 2004, 63.

343 Metabolic disorder in which the hormone insulin is ineffective, either because of failure in its secretion by the pancreas or because target tissues are insensitive to its action. In the first one, patients require regular administration of insulin.

**Table 12 - continuation:**  
**Areas of human physiology that are relevant to functional food.<sup>344</sup>**

Areas of human physiology	Functional food components to improve the relevant health area
Cardiovascular physiology	<ul style="list-style-type: none"> <li>- Balance of dietary lipids (heart health)</li> <li>- Increase in potassium and reduction in sodium (blood pressure)</li> <li>- Folate, vitamins B6 and B12 (cardiovascular risk)</li> <li>- Soy protein and plant sterol and stanol esters, soluble fiber, antioxidants, including plant flavonoids (LDL<sup>345</sup> cholesterol)</li> </ul>
Gastrointestinal physiology	Probiotic bacteria (intestinal microflora)
Cognitive and mental performance, including mood and alertness	<ul style="list-style-type: none"> <li>- Elevation in blood glucose, caffeine (mental performance, including memory, reaction time)</li> <li>- High-carbohydrate meals, tryptophan (sleepiness and calmness)</li> <li>- Sucrose (distress)</li> <li>- Activation of beta endorphins (pain perception)</li> </ul>
Physical performance and fitness	<ul style="list-style-type: none"> <li>- Oral rehydration products (rapid gastric emptying, fast intestinal absorption, improved water retention, improved thermal regulation, improved physical performance and delayed fatigue)</li> </ul>

344 *Ashwell*, Concepts of Functional Foods, ILSI 2002, 6, available at [www.europe.ilsil.org/file/ILSIFuncFoods.pdf](http://www.europe.ilsil.org/file/ILSIFuncFoods.pdf). *Goldberg*, Functional Foods, Designer Foods, Pharmafoods, Nutraceuticals, London 1994, 3.

345 Low Density Lipoproteins, Plasma lipoproteins containing high concentrations of lipids (low density compared with that of water), including cholesterol, increased concentrations are a risk factor for coronary heart disease.

### III. Nutraceuticals

A further important field of innovation in the production of processed food are nutraceuticals. A nutraceutical is defined as "any substance that may be considered a food or part of a food, and provides medical or health benefits, including the prevention and treatment of disease."<sup>346</sup> Nutraceuticals range from isolated nutrients, dietary supplements and diets to genetically modified food, herbal products and processed food such as cereals, soups and beverages. A nutraceutical maintains, supports and normalizes any physiologic or metabolic function. Nutraceuticals can also potentiate or antagonize physiologic or metabolic functions. Drugs are pharmacologically active substances that potentiate, antagonize and modify any physiological or metabolic function. Thus, the differentiation between nutraceuticals and drugs is becoming more difficult.<sup>347</sup> The ongoing research softens the distinction between food and drugs. Public health authorities consider prevention and treatment with nutraceuticals as a vital tool in maintaining health by addressing nutritionally induced acute and chronic diseases.<sup>348</sup>

Nutraceuticals represent the fastest growing segment of the food sector. The market is estimated at U.S.\$30 billion, growing 5% yearly.<sup>349</sup> This increase is "a horror vision for one - a fantastic fulfillment, indeed, for others."<sup>350</sup>

One class of nutraceuticals is represented by polyunsaturated fatty acids, the so-called PUFAs. Current interest is devoted to fish oils containing a high share of omega-3 fatty acids, eicosapentaenoic and docosahexaenoic acids. These fatty acids exercise a protective effect on the development of cardiovascular and inflammatory diseases. Fish oils could play a key role in the treatment of dermatitis and psoriasis. Premature infants have limited dietary support of the omega-3 fatty acids required for the normal composition of brain and retinal lipids. Fish oils influence tumor-derived lipolytic and proteolytic factors, receptors and enzymes of cellular signaling.<sup>351</sup>

The essential amino acid tryptophan has often been employed as a drug. The non-essential amino acid arginine has the potential to improve cellular immune response, phyto-cytosis and maintenance of T-cell function. Arginine retards tumor growth and formation of metastases. Arginine also acts on immunomodulation comprising cellular response, trauma-induced reduction in the T-cell function and phagocytosis.<sup>352</sup>

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346 The Foundation for Innovative Medicine, The Nutraceuticals Initiative: A Proposal for Economic and Regulatory Reform, 46 Food Technology 77 (1992), available at [www.fimdefelice.org/archives/arc.revolution.html](http://www.fimdefelice.org/archives/arc.revolution.html).

347 Hardy, Nutraceuticals and Functional Foods: Introduction and Meaning, 16 Nutrition 688 (2000).

348 Andlauer&Fürst, Nutraceuticals: A piece of History, Present Status and Outlook, 35 Food Research International 171 (2002).

349 Hardy, Nutraceuticals and Functional Foods: Introduction and Meaning, 16 Nutrition 688, (2000).

350 Andlauer&Fürst, Nutraceuticals: A Piece of History, Present Status and Outlook, 35 Food Research International 171, 175 (2002).

351 Fürst&Kuhn, Fish Oil Emulsions: What Benefits can they Bring?, 19 Clinical Nutrition 7 (2000).

352 Andlauer&Fürst, Nutraceuticals: A Piece of History, Present Status and Outlook, 35 Food Research International 171, 173 (2002).