

## **Functional Foods: Between New Consumption Trends and Renewed Perceptions of Health**

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### **How to cite**

Aiello M. (2011). Functional Foods: Between New Consumption Trends and Renewed Perceptions of Health . [Italian Sociological Review, 1 (3), 45-58]

Retrieved from <http://dx.doi.org/10.13136/isr.v1i3.23>

[DOI: 10.13136/isr.v1i3.23]

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### **3. Article accepted for publication (*data*)**

October 2011

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## *Functional Foods: Between New Consumption Trends and Renewed Perceptions of Health*

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### **1. The Background of Functional Foods**

Although people have always been aware of the need to eat to survive and of the fact that, under certain circumstances, some kinds of foods could cause disease, a number of authors – including Alviórez-Morales *et al.* (2002), Araya *et al.* (2003) and Roberfroid (2002) – claim that it is only since the end of the twentieth century that people have gained a greater awareness of how good or poor nutrition can positively or negatively affect health.

During the first half of the twentieth century, nutritional studies determined the characteristics and quantities of essential nutrients necessary and sufficient to satisfy humans' basic nutritional needs and avoid the risk of contracting diseases related to nutritional deficiencies (Arai, 2002; Vidal Carou, 2008).

However, in the latter part of the last century, the focus of nutritional studies profoundly changed, in conjunction with the significant changes in nutritional circumstances typical of developed societies. In those years, it was noted that excessive consumption of certain nutrients could have a negative impact on health and, as a consequence, the first warnings about the need to moderate intake of fats, salt and sugar were issued (Ashwell, 2003; Vidal Carou, 2008).

Marcel B. Roberfroid (2000a, 2000b) asserts that the main purpose of diet is unquestionably to provide enough nutrients to satisfy people's nutritional needs; however, in recent years the concept of food has undergone such a radical transformation that food – in addition to its classical sensory and nutritional properties – has been assigned an important role in maintaining proper health and in reducing the onset of certain diseases. Today, in fact, more and more scientific evidence supports the hypothesis that certain foods – and their bioactive components – have physiological effects and psychological benefits that go beyond the mere supply of basic nutrients (Roberfroid, 2000a, 2000b).

The science of nutrition has moved from the identification of the classical concept of *adequate nutrition*, the main purpose of which was to avoid nutritional deficiencies, to embracing the idea of *optimum nutrition*<sup>1</sup> (Ashwell, 2003; Roberfroid, 2002; López Nomdedeu, 2011), which underpins the goal of achieving better health but also minimizing the risk of contracting certain diseases during one's life (Milner, 2000).

Recent developments in the control of infectious diseases coupled with better diets have led to a significant increase in life expectancy, while chronic diseases have become one of the main causes of death in the population. In fact, according to a World Health Organization report (2002)<sup>2</sup>, chronic diseases are responsible for 79% of the total mortality in developed countries; the report also states that among the ten most significant risk factors for the development of these illnesses, five are related to diet and lifestyle: obesity, sedentarism, arterial hypertension, high cholesterol levels and inadequate consumption of fruit and vegetables.

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<sup>1</sup> The concept of *optimum nutrition* implies the aim of obtaining the highest possible development of each person's physiological functions.

<sup>2</sup> WHO, *Diet, Nutrition and the Prevention of Chronic Diseases*, WHO Technical Report Series, 2002, p. 916.

In agreement with Roberfroid's (2002) assertions, Foster and Lunn (2006) confirm that the increased incidence of illnesses such as obesity, cardiovascular diseases, diabetes, cancer and the increasing average age of the population have led to an overall rise in healthcare costs. In reaction to this state of affairs, governments have begun to place more emphasis on prevention, helping to increase opportunities for access to a wide range of products that must be consumed in the presence of certain health problems. At the same time, consumers' and professionals' acceptance of treatment options that do not involve drugs and medicines has increased, whereas these options were previously categorized only in terms of "alternative treatments".

Moreover, as stated by Ogden (1998), the idea that health and illness are increasingly perceived as a result of individual behavior rather than the result of external variables beyond our control plays an important role. All these factors strengthen consumers' awareness about the importance of diet for their health, an awareness that is supported and enhanced by the publication of many statistical studies on the general state of health and on the consumption patterns of various populations, confirming that certain foods (or certain components) seem to have a direct impact on the incidence of certain diseases (A.C. Nielsen, 2008; European Food Information Council, 2005; Food Marketing Institute, 2004; Health Focus International, 2005; ISMEA, 2007; WHO, 2006).

Consequently, according to Vidal Carou (2008), it is natural that nutritional research now focuses primarily on the study of the connections between certain food components and a possible protective or preventive effect regarding some diseases; at the same time, we can easily understand the ongoing proliferation of food products with health claims such as "helps lower cholesterol", "boosts your immune defences", "helps improve intestinal flora", etc.. Indeed, Roberfroid (2002) points out that in recent decades the focus of research has increasingly tended towards identifying biologically active components in foods that have a clear potential to optimize physical and mental wellness and that can also reduce the risk of developing certain diseases. Therefore, following a healthy and balanced diet is not only crucial for achieving an optimal state of health, but also plays a key role in reducing the risk of developing certain diseases.

In addition, Kok (1999) argues that an ever greater understanding of the interactions between genes and nutrition is being developed, with the aim of meeting the specific and unique biochemical needs of each person by making a detailed selection of the nutrients that each precise individual should take. This illustrates how, in the new millennium, one of the biggest challenges for the science of nutrition is to move from raising life expectancy to improving quality of life: in other words, to wellness.

As Secondulfo (2011) underlines, today there is widespread awareness of the concept of *wellness*, which even becomes predominant over the concept of *health*.

*"This spread of the concept of wellness in our society is converted particularly into a supply of goods and services that is multiplied geometrically as part of an overall tendency to transform all sorts of attention towards the body and the health into services, but especially into objects that validate and radically privatize the pursuit of wellness"*  
(Secondulfo, 2011: 24).

The new perceptions of health and wellness – as well as the evolution in the concept of diet – derive from a series of elements that characterize most of the industrialized Western world, namely the so-called 'society of abundance'. Roberfroid (2002) points out that among the many existing factors, the most important are:

- the sharp increase in healthcare costs;
- the growing numbers of older people and their increased life expectancy, with the consequent desire to improve their quality of life;
- the increase in scientific evidence supporting the existence of a strong link between diet and health;
- technological advances in food production;
- the application of new scientific knowledge in the sphere of nutrition;

- people's increased awareness of the role of diet in determining health and personal wellness.

According to Roberfroid (2000b), these factors have pushed governments, researchers, health professionals and food industry professionals to find a way to more effectively deal with these socioeconomic changes. Along the path to this historic transformation concerning foods and the concepts of nutrition and diet, the concept of *functional foods*<sup>3</sup> (i.e. foods that can potentially improve health and wellness, and reduce the risk of developing or delay the onset of serious diseases) has emerged. Indeed, many authors (Arai, 2002; Araya and Lutz, 2003; Ashwell, 2003; Doyon and Labrecque, 2008; Roberfroid, 2000a, 2000b, 2002; Sanz Porras, 2008; Vidal Carou, 2008) believe that one of the main causes behind the growth in demand for products with functional components is undoubtedly the growing consumer awareness of the link between diet, lifestyle and health.

### 1.1 The Historical Development of Functional Foods

As part of a guide<sup>4</sup> to functional foods directed at Spanish consumers, Cadaval *et al.* (2005) describe in detail the historical overview of this food category.

The first written evidence on the existence of foods with functional connotations comes from China and dates as far back as 1000 BC. In Asia, in fact, there is a long tradition of attributing healing and therapeutic properties to certain foods and herbs, although for a long time this tradition has been considered anecdotal and based solely on popular beliefs. It can be noted that already around the year 100 BC, there was a frequent use of the term *medicinal food* in the literature of the Eastern Han Dynasty. Later, beginning approximately from the year 1000, the term *special foods* began to be used in many medical studies of the Song Dynasty.

Coming back to our age, the current interest for physiologically functional foods originated in the early Eighties in Japan, where several demographic studies showed that the average lifespan of the population had significantly increased in parallel with the rise in life expectancy and an increase in health care costs. Therefore, the Japanese health authorities recognized the need to improve the quality of life for a growing number of elderly citizens, in order to keep healthcare costs under control. To this end, the Ministry of Education funded 86 specific research programmes that initially included a systematic analysis of the development of functional foods, and in the following years, an analysis of their characteristics in terms of the regulation of physiological functions and their molecular make-up.

In the ILSI monographs, Ashwell (2003) summarizes all the most important events in relation to the development of the “functional foods” category. In 1991, consequent to the Research Committee on Functional Foods Action, the Japanese Minister of Health and Welfare issued a decree in which a number of foods with a specific function for improving health were approved, the so-called *Foods for Specified Health Use* (FOSHU). In the same year, the rules for FOSHU products were also drawn up and these products were officially defined as a subgroup of foods for the “special dietary uses” category.

Even in the West, the belief that the type of food a person consumes is in close relationship with their health is not new. Hippocrates<sup>5</sup>, in fact, left in legacy a phrase that became very famous:

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<sup>3</sup> The development of the Science of Food and Nutrition has helped to identify and isolate a large number of natural food ingredients that, with their biological activity and their beneficial effects on the physiology of the human body, are called *bioactive* ingredients. They confer additional benefits, and, once isolated and concentrated in a compound, can be added to other foods that do not contain them - or only in a small proportion - thus making healthier, or, in other words, functional food products.

The main classes of foods with functional components are: foods with *probiotics* and *prebiotics* (Bifidobacteria, Lactobacillus, etc.); foods with the addition of milk and soy protein; foods with *functional lipids* (Omega 3; Omega 6, phytosterols, etc.); foods with *antioxidants* (polyphenols, carotenoids, etc.). Consult Recio and Lopez-Fandillo (2005) for a detailed analysis about the characteristics and effects on health of the various functional components mentioned above.

<sup>4</sup> See CADAVAL *et al.* (2005), *Alimentos Funcionales. Para una alimentación más saludable*, SENC.

<sup>5</sup> Hippocrates was the well-known Greek doctor of the VI-V century BC.

*“Let food be your medicine and medicine be your food”.*

Carrying this idea of food as a means of healing forwards to our own times, it is possible to better understand the substrata and the source of the new paradigm for functional foods.

In 1990 the *Nutrition Labeling and Education Act* (NLEA) was established in the U.S. – and finally implemented in 1994; this act allows the use of *health claims*<sup>6</sup> about food for which the *Food and Drug Administration* (FDA) has scientifically based evidence on the correlation between their intake and the treatment/prevention of a specific disease (Roberfroid, 2000b).

In Europe, the interest in the concept of *functional food* has emerged more recently, primarily as a result of the increasing scientific evidence supporting the relationship between diet and health. As stated above, until the early Eighties scientific studies were focused mainly on nutritional deficiency diseases, but from that time onwards, they began to focus increasingly on the preventive potential of foods.

Following these trends, in 1995 the European Commission promoted the Concerted Action on Functional Food Science in Europe (FUFOSE), which involved approximately 100 experts on nutritional and medical subjects. The work was coordinated by the International Life Sciences Institute (ILSI) Europe and led to the production of the document “Scientific Concepts on Functional Foods in Europe” containing the guidelines for identifying functional foods and for developing a scientific approach to them, based on the evidence required to support the development of food products with beneficial effects on a specific biological function. From this Concerted Action, Diplock *et al.* (1999) were able to outline the first definition of functional food, which is still accepted and approved in Europe:

*“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,<sup>7</sup> in a way that is relevant to either improved state 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”.*

Today, research on this food category is still in progress and is constantly evolving, leading to new definitions and knowledge about the properties and the effects these products may have on the physiological functions of the human body.

## **2. The Definition of Functional Foods**

In *Defining Functional Food* (2000), Roberfroid argues that the extent of the world of functional foods cannot be established univocally because it is more a concept than a specific set of food products. A wide variety of nutritional components that influence health form part of many foods (or will do in the future); for this reason, it is practically impossible to reach a universally accepted and approved definition.

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<sup>6</sup> The legislation defines a “claim” as *any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics.*

A “nutrition claim” is *any claim that states, suggests or implies that a food has particular beneficial nutritional properties due to the energy, nutrients or other substances provided, not provided or provided in reduced/increased amounts (e.g. high in fibre).*

A “health claim” is *any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health (e.g. aids digestion).* See CODEX ALIMENTARIUS, Codex General Guidelines on Claims, CAC/GL 1-1979 Revision 1, Geneva, WHO.

<sup>7</sup> The term “adequate nutritional effect” refers to the role of nutrients in growth, development, and the maintenance of vital organs and the human body as a whole. Therefore, one basic function of food is to provide a sufficient amount of vitamins, minerals and energy to keep the body healthy as a result of the intake of proteins, carbohydrates and fats.

In scientific literature, as well as in marketing-oriented literature, we find many definitions. Some suggest that any type of food with a message about health benefits is a functional food (including Riemersma, 1996; Hollingsworth, 1999); other authors define as “functional” only fortified foods that have been enriched or added to with a component that has beneficial effects beyond basic nutritional characteristics (including IFIC Foundation, 2006; Kleinschmidt, 2003). While some definitions are relatively simple, such as the one that considers as “functional” all the foods (or their components) that have a positive impact on health or that may reduce the risk of certain diseases (National Institute of Nutrition, 2000), others – as we saw in the previous section – are much more elaborate (Diplock *et al.*, 1999).

Whatever definition we choose, functional food appears to be a unique concept that refuses to be incorporated into a pre-existing category, although it is clearly distinguishable from other categories that deal with pharmacology rather than nutrition.

The study that helps most to simplify this complex framework of definitions is the one conducted by Doyon and Labrecque (2008). Through an analysis of all the existing definitions in the literature and discussions with various experts, the authors aimed to arrive at an operational definition of functional foods that would also take cultural and temporal aspects into account, in order to be able to then identify the key concepts and the boundaries of the functional foods universe. Beginning from an analysis of over one hundred definitions, they selected the twenty-six definitions they considered the most representative. From these, the authors went on to identify four key concepts that characterize all the definitions of functional foods:

- *Health benefits.* However, it is not indicated whether these positive effects should be scientifically proven, nor is the type of proof required stated (among the numerous definitions that convey this concept we can mention: Health Canada, 2006; FOSHU Japan, 1991 - quoted in Anon, 2003; The European Food Information Council – quoted in Anon, 2003; National Institute of Nutrition, 2000; Center for Science in the Public Interest, 1999; International Life Science Institute – quoted in Milner, 2002; Adelajia and Schilling, 1999; Riemersma, 1996; Diplock *et al.* 1999; Hasler, 2000; Roberfroid, 2002; Smith *et al.* – quoted in Roberfroid, 2002; Jansen and Krijger, 2003; Kleinschmidt, 2003; etc.).<sup>8</sup>
- *The nature of the food.* To be functional, it should maintain traditional food characteristics; in some cases it is specified that the food must be enriched, fortified or have had an ingredient added, while others stress the elimination of components considered harmful to the health (Health Canada, 2006; FOSHU Japan, 1991; National Institute of Nutrition, 2000; Center for Science in the Public Interest, 1999; Adelajia and Schilling, 1999; Diplock *et al.*, 1999, Jansen and Krijger, 2003; Roberfroid, 2002; Kleinschmidt, 2003, etc.).<sup>9</sup>
- *Level of function.* More than half of the selected definitions state that the crucial feature of a functional food is its ability to produce benefits over and above its basic nutritional functions. This type of food is not categorized as a particular product, but according to its function (Health Canada, 2006; FOSHU Japan, 1991; The European Food Information Council – quoted in Anon, 2003; Center for Science in the Public Interest, 1999; International Life Science Institute – quoted in Milner, 2002; Diplock *et al.*, 1999; Jansen and Krijger, 2003; Adelajia and Schilling, 1999; Hasler, 2000; Kleinschmidt, 2003; etc.).<sup>10</sup>
- *Consumption pattern.* According to many definitions these foods should be part of a normal diet, in relation to the typical consumption pattern in a specific cultural and geographical context (Health Canada, 2006; Jansen and Krijger, 2003; Diplock *et al.*, 1999; Smith *et al.* – quoted in Roberfroid, 2002, etc.).<sup>11</sup>

Using these elements as their starting-point, the authors outline the following definition:

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<sup>8</sup> The authors emphasize that each of the twenty-six functional food definitions selected contains a direct reference to the beneficial effects of the foods on health.

<sup>9</sup> The authors specify that almost a third of the definitions analyzed emphasize this aspect of the functional components.

<sup>10</sup> The authors underline that more than half of the selected definitions mention this aspect of functional foods.

<sup>11</sup> The authors note that only nine out of twenty-six definitions mention this aspect in the functional food conceptualization.

*“A functional food is, or appears similar to, a conventional food. It is part of a standard diet and is consumed on a regular basis, in normal quantities. It has proven health benefits that reduce the risk of specific chronic diseases or beneficially affect target functions beyond its basic nutritional functions”.* (Doydon e Labrecque, 2008: 1144)

From a more practical point of view, Diplock *et al.* (1999) and Ashwell (2003) – authors of the two key works<sup>12</sup> about the definition of these products – say that a functional food can be:

- a natural food in which specific components have been introduced or improved through particular farming techniques (for example, whole foods);
- a food where there has been the addition of a particular component with the aim of producing a benefit (for example, foods with the addition of *probiotics* or *prebiotics*<sup>13</sup>);
- a food in which one component has been removed in order to reduce or eliminate possible adverse health effects (for example, the reduction of saturated fat);
- a food in which the structure of a nutrient has been chemically modified in order to improve health (for example, hydrolyzed proteins used to reduce the risk of allergies in infant formulas);
- a food where the nutrient bioavailability<sup>14</sup> has been increased or reduced, in order to enhance the assimilation of a beneficial component (such as *lycopene* in tomatoes);
- a food that is the result of any combination of the possibilities mentioned above.

It is important to specify that the *Consensus Document* itself highlights that some foods may be categorized as “functional foods” even though the benefit produced does not necessarily involve every member of the population. Therefore, a functional food could be “functional” for everyone or, conversely, only for particular groups of potential users defined, for example, by their personal or genetic characteristics.

If we analyze the aforementioned definition model, it emerges that a functional food can be both a natural food and a food that has been processed using technological, chemical or biological means.

A crucial issue in the current debate is precisely whether the description as “functional” should be applied only to new foods, or can also be extended to “ordinary” foods with a significant content of beneficial components. On this subject, Vidal Carou (2008) points out that even though the functional ingredients are natural, they can be new for certain foods because they are generally found in others. For example, Omega-3 fatty acids are generally added to cultured dairy products, but originally come from fatty fish.

Some authors (such as Kleinschmidt, 2003; Jansen and Krijger, 2003; Center for Science in the Public Interest, 1999) argue that the label as functional should be applied only to processed foods, or rather to the products to which some kind of addition has been made in order to give them a greater health-giving value than ordinary foods, without damaging their normal nutritional value. Thus, for example, a fruit juice with fructose and sweeteners, enriched with vitamins A, C and E, would be a functional food. Obviously, though, we can expect the same antioxidant effects as found in fruit or vegetable juices processed with “light” technologies, because vitamins and antioxidants also number among their ingredients. In all probability, the first product is more able

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<sup>12</sup> See DIPLOCK, A.T. *et al.* (1999), *Scientific Concepts on Functional Foods in Europe: Consensus Document*, British Journal of Nutrition, no. 81, pp. S1-S27; ASHWELL M. (2003), *ILSI Europe Concise Monograph on Concepts on Functional Foods*, The International Life Institute, Washington, DC.

<sup>13</sup> *Probiotics* form beneficial live cultures, the result of fermentation or additions, for improving the intestinal microbial balance, for example *Lactobacillus* and *Bifidobacteria*. *Prebiotics* are non-digestible components that have a beneficial effect by stimulating the growth of bacteria such as *oligofructose* in the colon. See RECIO I., LÓPEZ-FANDILLO R., *Ingredientes y Productos Lácteos Funcionales: Bases Científicas de sus Efectos en la Salud*, in JUAREZ M., OLANO A., MORAIS F., (Eds), “Alimentos Funcionales”, Fundación Española para la Ciencia y la Tecnología, Madrid, 2005, (pp. 23-100).

<sup>14</sup> *Bioavailability* is the fraction of a nutrient – or other bioactive substance – that, once ingested, becomes usable to satisfy certain functional requirements of specific tissues.

to ensure the appropriate doses of the active ingredients, but it does not automatically follow that is better in absolute terms (Vidal Carou, 2008).

Assuming a critical position, Scrinis (2008) wonders where the real boundary that distinguishes functional foods from all the others is set, since most foods – both processed and natural – are somehow “functional” if they contain nutrients that may be related to specific health benefits.

The inclusion of traditional foods in the category seems to be in contradiction to the definition that considers functional foods as products able to create beneficial effects on the human body above and beyond normal nutritional effects: traditional food, or rather food unadulterated by technological and biological processes, would seem to provide only nutrition that is basic and, therefore, not sufficient. In addition, we can deduce that every kind of food that is somehow healthy should be included in this category. For this reason, Scrinis (2008) states that the inclusion of non-processed and non-modified foods in that category can even be seen as a marketing strategy for expanding the “healthy aura” attributed to natural foods, and at the same time for legitimizing the category of functional foods.

This makes the concept of functional food very vague, giving this food category an identity imbued with great uncertainty and confusion, both about its nature and its purpose. For these reasons, in fact, there is an increased risk that the growing prevalence of enriched food products (and those deprived of some components), accompanied by promises of health benefits, will lead to a strong distortion in consumers’ perceptions, and in their assessment of how to create a healthy, balanced diet.

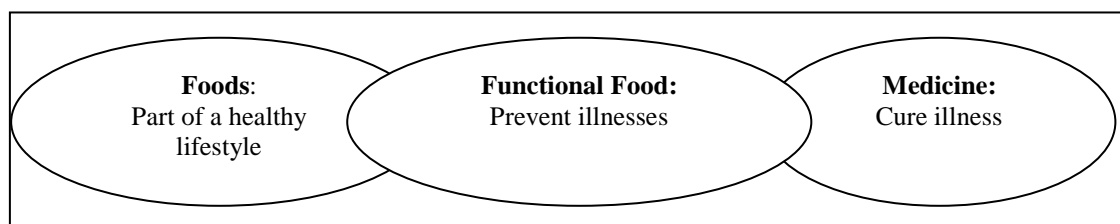
### 3. Food, Medicine or Something Different?

In *Functional Foods for Added Value* (2002), Mark-Herbert points out how the term “functional food” immediately calls up the image of a product that has very specific effects or functions. This kind of food can vary in form or in its promised function, but the collectively desired result is to have a scientifically proven medical effect. It can be a preventive effect, which delays or prevents the development of certain diseases, or even a healing effect. In the latter case, as the author points out, the communication to consumers about these products’ functions blurs the distinction between *food* and *medicine*.

The concept of “functional food”, therefore, fails to identify either a specific product or the form in which it is marketed, but is closely related to the function or the specific effect that the food must scientifically demonstrate that is has over and above the standard nutritional amount. Ruderus (1992) argues that if functional foods are perceived as food products, it is expected that they will look like food and have a pleasant taste, but if they take the form and the taste of medicines, they will be perceived as medicines.

According to Mark-Herbert (2002), consumers’ perceptions would seem to represent a way to define the three different categories of *food*, *functional food* and *medicine*. There are other parameters that help to better distinguish these categories (as we can see graphically in Figure 1), which arise for example from a study of their purpose and effect, from an analysis designed to aid understanding of whether they are products of natural origin or have been modified by an industrial process, or from a study of how they are marketed.

Fig. 1: Differences between foods, functional foods and medicines



Source: Mark-Herbert (1993: 4)



Moreover, Vidal Carou (2008) stresses the importance of analyzing dosage and effects in order to provide a foundation for any possible functional nature of these products. This type of evaluation is similar to what is done for drugs, but with two significant differences: first, since it is food, any possible effect is much slighter than drugs, and therefore very difficult to observe and determine; secondly, food should not present any side effects, while they are tolerated in the case of medicines.

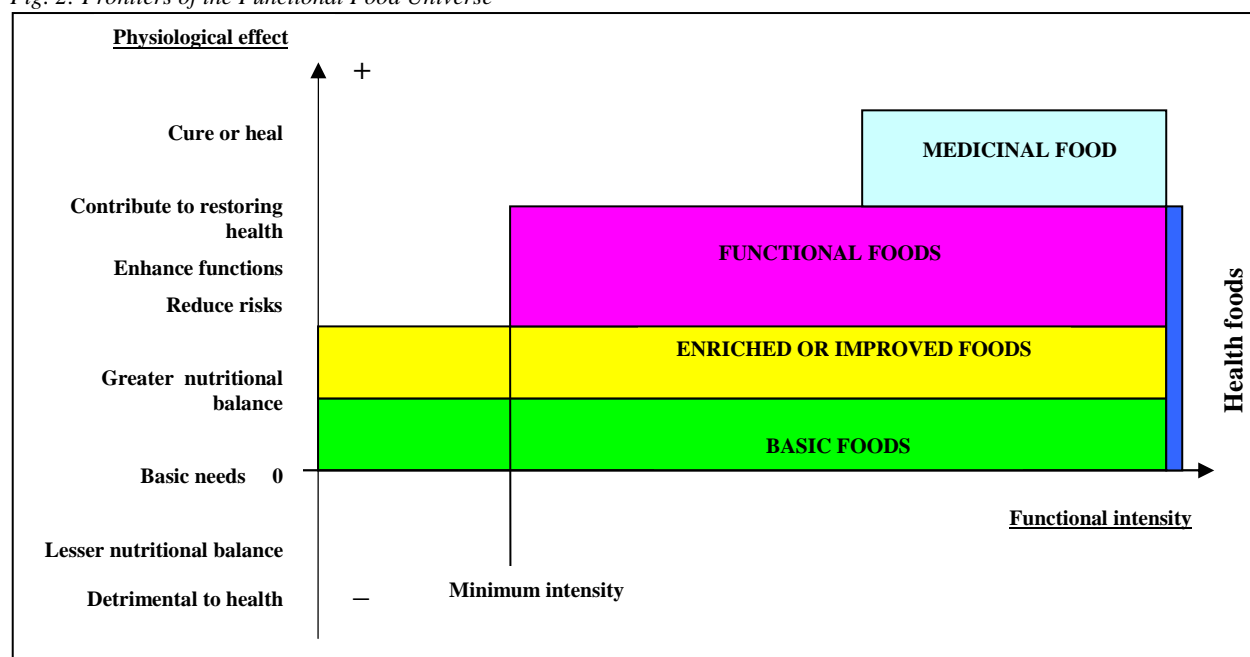
Doydon and Labrecque (2008) identify two dimensions that they consider fundamental in defining the “functional foods” universe, especially because they are very useful to mark out the boundaries between these and other categories of products.

The first dimension regards the physiological effects of the various types of food: in fact, it is food that provides benefits beyond basic nutritional functions.<sup>15</sup>

This is why a product that improves nutritional balance should not be considered functional solely for that reason and should be so only if it reduces the risk of disease and also helps to improve health. In this sense, the universe of functional foods includes the following: products that improve nutritional balance, products that reduce the risk of certain diseases related to diet, and those that enhance some functions improving general health, each one with a *minimum level of intensity*.

This last phrase, in fact, is the second fundamental dimension: given that all foods – especially health foods – have a certain degree of function intensity, a purely functional food should have a minimum level of such intensity (generally higher than normal) measured through its physiological effects and starting from the concentration of bioactive components. Pharmaceuticals, however, are outside the boundaries of functional foods, which in fact follow a statute governed by completely different laws. As can be seen in Figure 2, Doydon and Labrecque (2008) provide an interesting graphic summary of what we have stated above.

Fig. 2: Frontiers of the Functional Food Universe



Source: DOYON e LABRECQUE (2008: 1143)

<sup>15</sup> We would like to remind the reader that a functional food, in order to be defined as such, should maintain the appearance of food (otherwise it would fall into the category of nutritional supplements, in the form of capsules, tablets or sachets), but should also possess a number of components (usually artificially added or modified) capable of improving certain features of our body beyond the effects of basic nutrition (that is to say, beyond the simple amount of vitamins, minerals and energy necessary to the body’s wellness resulting from normal intake of proteins, carbohydrates and fats). See Diplock *et al.* (1999) and Ashwell (2003). A functional food, however, contains additional components that enhance the level of health and helps to reduce the risk of certain diseases (for example: yogurt with *probiotics* that helps to improve intestinal functions, or milk with *Omega 3* that helps to reduce levels of fat in the blood).

Therefore, as can be easily realised, the concept of *healthy food* is very generic and includes both traditional foods and “new” foods. Traditional foods, once it has been established that they are safe, can be considered as wholesome as part of a good diet, while those designed to contribute to some specific aspect of human health follow a separate path.

In the *ILSI Monographs* (2008), Howlett asserts that a functional food is not a medicine and is distinct from curative products and drugs: despite its purpose being to positively change the body’s physiological functions, its mode of action remains that of reinvigorating, improving or maintaining normal physical and physiological processes. Functional foods can normalize or improve bodily functions within normal parameters, with the aim of optimizing health and wellness, or they may reduce the onset of factors associated with the risk of contracting certain diseases.

Medicines, on the other hand, act on altered physiological processes or enhance these processes beyond the standard boundaries in order to obtain a precise result. Therefore, they have the function of treating or preventing diseases, or of enhancing physiological performances beyond the levels considered normal (Table 1).

Although there is not a clear and binding division between food and medicines in terms of their functionality, it is essential to make a distinction between them, starting with an analysis of each; in this regard, we should take into account the type of product (food, supplement or pill) and its effects.

Agreeing with the definition propounded by Diplock *et al.* (1999), Howlett (2008) states that the generally accepted rule is that functional foods form part of a normal diet and have the normal appearance of food. Medicines, on the contrary, form part of a special, controlled regime (normally dictated by a specialist practitioner), and take the shape of tablets, pills, capsules or syrups, which facilitate the subdivision of the precise doses to be taken. In addition, the production and sale of medicines is subject to a very different regulatory and control system from the one applied to functional foods, which are included under the laws on food control.

Finally, Howlett (2008) also cites the category of *nutritional supplements*, which generally take a form similar to that of medicines (pills, capsules, etc.), but cannot be considered as products that treat or prevent diseases: in fact, they are also governed by food laws. Moreover, given that they have not got the shape of food, and that they are not consumed as part of a normal diet, nutritional supplements do not fall into the category of functional foods.

The table below provides a summary of some typical medicines and functional food characteristics. Although it is not exhaustive, it allows us to view the main differences between these two products.

Tab. 1: Some differences between functional foods and medicines

	FUNCTIONAL FOOD	MEDICINE
<b>Mode of action</b>	Modulation of a physiological process within the normal range.	Intervention in a disturbed physiological process, or modulation of a physiological process outside the normal range.
<b>Purpose</b>	To restore or enhance normal function in order to optimise health, wellbeing and performance. To reduce risk factors for disease	To treat or prevent disease. To enhance performance beyond normal range.
<b>Form</b>	Food, consumed as part of the normal diet.	Pill, tablet, capsule or syrup taken in controlled dose according to a timetable.

Source: HOWLETT (2008: 23)

#### 4. Conclusions

There can be no doubt that the science of nutrition continues to impart important knowledge for helping people to work out a suitable diet according to various physiological conditions, so that a

good level of health in the population at large can be maintained. For this reason, as noted by Vidal Carou (2008), many nutritionists and dieticians argue that it would not be necessary to develop *foods for specific health use*, because they consider it sufficient to utilize traditional foods, on condition that they are appropriately combined and consumed as part of a balanced diet.

Reglero (2011) instead emphasizes how it is difficult to follow a balanced diet, because it requires mastery of specific knowledge about nutrition, especially the properties and composition of foods. In addition, one must have the necessary time to find the right foods, and have sufficient willpower and discipline to be able to follow a diet with the correct parameters and with constancy. Moreover, we must remember that a diet is appropriate only if it takes into account the individual components attributable to each person's genetic characteristics. Therefore, foods for specific health use are giving rise to a phenomenon with profound social, economic, scientific and technological implications.

As mentioned above, in postmodern society there has been a great spread of the collective aspiration for a long life lived in perfect physical and mental shape in order to improve the functionality, efficiency and performance of our body (Viviani, 2009) and therefore, for the attainment of general wellness. The new trend towards individualism<sup>16</sup> and the greater attention paid to the body move the concept of health from an exclusively medical dimension to the world of daily consumption (Viviani, 2011).<sup>17</sup>

Because of these changes, today we tend to give more importance to the relationship between food and its beneficial features (see Díaz Méndez and Gómez Benito, 2005; Secondulfo, 2000; 2011). Therefore, in the present time, people are increasingly looking for foods that offer preventive or even therapeutic applications, as well as being nutritious. It is not just a matter of better combining traditional foods, but of modifying them or designing them in order to obtain a "bonus" of healthy effects, not easily to be found simply by consuming ordinary food.

This approach seems not only to create a renewed perception of health and wellness<sup>18</sup>, but also of *naturalness*. As Maturo (2011) rightly states, in the postmodern society technology seems to act in order to bring us back to our nature, which has now become an *artificial nature*, because the "traditional nature" is no longer sufficient to satisfy the health and wellness aspirations of the new consumers. This fact contributes more and more to exacerbating the phenomenon of the increasing medicalization of everyday life (Conrad, 2007; Viviani 2010).

The development of functional foods as a method of prevention permeating contemporary society can also be interpreted as the materialization of the new principles that revolve around the current concept of health (Secondulfo, 2011). Furthermore, functional foods represent a source of information about our society, because they describe features of our material culture (Secondulfo, 2001) shedding light on new aspects of health and wellness perceptions. In particular, Viviani (2012) points out that functional foods, compared with medicines, besides being a consequence of the social changes mentioned more than once above, are inexorably bringing the world of medicines closer to that of daily consumption.

In addition, functional foods constitute a category of food that can boast of having the ability to reduce the incidence of the so-called *abundance* or *civilization diseases*.<sup>19</sup> Beginning from this, in recent decades the research on the effects of natural food components has grown steadily: the

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<sup>16</sup> It is interesting to note that because of increasing individualism, wellness is a consequence of how individuals assess their own life: it is the result and the form of "[...] *something that the subject judges and evaluates by himself on himself. It is the individual that evaluates his own condition, deciding whether it is wellness or not, and to what extent*" (Lonardi 2011: 69).

<sup>17</sup> In the traditional view of the biomedical paradigm, health was a condition that had to be reclaimed (a condition that emerged in contrast to that of illness), while in the new vision of the body and health, wellness plays a central role: it is a form of success that must constantly be striven for (Viviani, 2011).

<sup>18</sup> In the past it was believed that health was given to people, but today it is considered a direct consequence of individual action: people tend to feel "obliged" to keep their body healthy in order to ensure themselves overall wellness.

We have to stress that here we will omit a whole series of key aspects to a full description and definition of the concept of wellness (for example, the political and economic dimensions, the dimension regarding networks of family and friends, etc.). For a more thorough examination of these points, consult the following texts: Di Nicola (2003; 2011); Di Nicola, Stanzani e Tronca (2008); Stanzani (2007).

<sup>19</sup> Among the so-called abundance diseases, the most common are obesity, cardiovascular problems, osteoporosis and diabetes.

number of scientific experiments is growing exponentially in order to obtain evidence on the actual cause-effect relationship between the intake of food/functional components and the health status that follows (for a thorough examination of the scientific and technical aspects, see the following works: Playne *et al.*, 2003; Fitzgerald *et al.*, 2004; Recio and López-Fandiño, 2005; Mayo and Delgado, 2008; Olano and Corzo, 2009; Van Baarlen *et al.*, 2010). This evidence represents the starting point and the scientific basis on which the modern industry of functional food has developed.

Leaving aside for the moment an analysis of the debate on whether or not such food products are needed to prevent diet-related diseases, and whether they really contribute to improving our health – an issue that will be resolved when the results of scientific experiments in progress emerge – it is much more interesting here to reflect upon the kind of food certain additions are incorporated into.

Can these new products be risky in terms of food safety?

Consider, for example, the fact that *phytosterols*<sup>20</sup> are often added to margarine: to obtain any effects, we should consume these added ingredients on a regular basis, which may lead to side effects, because in a balanced diet, these kind of fats should be taken only occasionally, and of course, it is a type of food that is totally unsuited to people who need to control their cholesterol levels. Indeed, a distorted perception of the real effects associated with consumption of these products can pose a very serious risk.

As stated by Vidal Carou and Mariné Font (2006), it may happen that a consumer with cholesterol problems comes to believe that by consuming all the foods offered by the market with the claim “helps reduce cholesterol”, they would be able to neglect or abandon any possible drug treatment. In addition, it may happen that a consumer, confident in the knowledge they are taking products that lower cholesterol levels, will allow themselves to consume foods that may aggravate their condition. Currently, in fact, we can find many products rich in fibre or vitamins, but at the same time many contain sugar, fats or salt, so that the overall nutritional benefits are poor.

If it is a fact that before being placed on the market, these products must prove they do not have toxic effects on the consumer in the recommended doses, on the other hand they may represent a risk when (Vidal Carou and Mariné Font, 2006):

- they are not used correctly (in excess quantities or abused);
- if their consumption replaces a drug treatment;
- if parallel consumption recommendations are not taken into account; in fact, it is preferable to incorporate them into a diet rich in plant products.

This is a very complex and delicate theme, because a possible outcome is precisely the misuse of these products, which depends ultimately on the *consumer*. It is not easily understood to what extent we can expect the consumer to be a nutrition expert, capable of always correctly interpreting the information on labels and on product packaging. Moreover, the vast boom in health concerns, typical of today's society, makes consumers more vulnerable to any distorted messages that may excessively enhance some properties of a food, separating them from the overall context of diet and lifestyle (Vidal Carou, 2008).<sup>21</sup>

The fact that functional foods are available to everybody, with much fewer controls than happens in the case of medicines (they do not require a prescription), is certainly a problematic issue of great importance. Consumers are totally responsible for the food they eat and thus for the possible effects, which is why they should have the right to be well-informed.

Besides the various negative and problematic aspects, however, we should not underestimate the great potential of these products (Roberfroid, 2000b):

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<sup>20</sup> Given the large amount of concordant clinical results, in Europe the health claim according to which *the consumption of 1.6 grams per day of Plant Sterols is demonstrated to decrease cholesterol in blood, and consequently, to reduce the risk of contracting cardiovascular diseases* has been approved. See Señoráns Rodríguez (2011).

<sup>21</sup> For these reasons, there is a precise regulation of these products, and especially of the type of information and advertising that can be conveyed for their promotion (See Regulation (EC) No. 1924/2006 of the European Parliament and the Council of 20 December 2006 on nutrition and health claims on food products; it completes the Directive 2000/13/EC on the labelling of foods and the Directive 2006/114/EC on comparative and misleading advertising).

- they represent an opportunity for *consumers* interested in their health, because they help to improve the nutritional quality of food and to raise the level of general wellness;
- they stimulate *scientific and technological development* on the subject of food, facilitating the flow of communication between science, industry and civil society;
- they represent an economic opportunity for the *food industry* that can add value to its products by adhering more closely to the consumer sensibilities.

It would certainly be helpful if also in Italy – through cooperation between the Ministry of Health, the media and doctors (general practitioners and specialists) – a *guide* was published to provide simple and easily accessible information to consumers about the main characteristics of functional foods and the *pros* and *cons* of consuming them.

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