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MASTER COURSE IN: FOOD AND BEVERAGE INNOVATION AND MANAGEMENT

AN EXPLORATIVE STUDY ON CONSUMERS' KNOWLEDGE, INTEREST AND PERCEPTION TOWARD FUNCTIONAL FOODS

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To Giacomo, to my family, to my friends
and to all those who have always believed in me.
Thanks for always being there.

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ACRONYMS AND ABBREVIATIONS

ALA	Alpha Linoleic Acid
ART.	Article
BEUC	European Consumer Organization
CAGR	Compound Annual Growth Rate
CLA	Conjugated Linoleic Acid
EC	European Community
EFSA	European Food Safety Authority
EU	European Union
FHC	Food with Health Claims
FUFOSE	Functional Food Science in Europe
FOSHU	Foods for Specified Health Use
FOSDU	Food for Special Dietary Uses
ILSI	European International Life Science Institute
No.	Number
OR	Odds ratio
PASSCLAIM	Process for the Assessment of Scientific Support for Claims on Foods
RDAs	Recommended Daily Allowances
RNIs	Reference Nutrition Intakes
PUFAs	Polyunsaturated Fatty Acids
UK	United Kingdom
US	United States
USA	United States of America

WTP	Willingness to Pay

INTRODUCTION AND THESIS PURPOSE

The commercialization of functional foods was born in Japan just over twenty years ago, then, in a relatively short period of time, it expanded in most of the developed countries such as the United States, the European Union and Canada. Nowadays, at one global level, there is a growing interest among consumers towards this type of healthy products and the functional foods market's value is expected to continue increasing in the future. In recent years, there has been a change in the mindset of consumers, shifting and increasing their demand towards healthier food products, such as functional foods, as a result of the growing awareness of the role and influence of diet on overall health.

However, it is difficult to define consumers' factors determining the demand for functional foods that are universally accepted, since this category of product is very numerous and heterogeneous. In fact, the attitude and the demand of consumers towards functional foods change according to the type of functional food itself (Urala and Lähteenmäki, 2004). In addition, the regulatory framework for functional foods at both European and international levels is unclear and remain complex, there is not a regulatory definition of functional foods and there is also no overall uniformity regarding functional food legislation. Functional foods are not uniquely recognizable and the definition and perception of consumers towards them remain a very confusing concept (Roberfroid, 2002). Furthermore, functional foods have been analysed and studied just recently by a large number of empirical studies that have provided important information, although still fragmented and limited. In addition, few empirical studies have been carried out on European and Italian consumers' acceptance and on factors influencing their demand for functional foods. In this scenario, the idea of this study was born, to deepen the knowledge, interest and perception of Italian consumers towards functional foods. In particular, the main objectives of the thesis are:

1. Investigate the knowledge, interest, perception and purchasing behaviour of consumers towards functional foods, through an explorative analysis.
2. Estimate consumers' willingness to pay for a specific functional food product compared to the conventional one.

The analysis is performed using a survey-based approach with an online questionnaire, which primarily explores knowledge, perception, awareness and willingness to pay for functional foods in an Italian sample.

Furthermore, a logistic regression model is used to:

1. analyse the factors that influence consumers' consumption of functional foods;
2. analyse the factors that influence consumers' willingness to pay for functional foods and in particular, identify which characteristics of the sample significantly determine a greater probability of being willing to pay more.

Specifically, the structure of the thesis consists of 5 chapters in which the main aspects of functional foods are treated. The first chapter is an overview of the main definitions and concepts of functional foods. The second chapter is a description of the functional food market at global, European and Italian level, with some examples of the main functional food products available on the market. Chapters 3 considers the current regulatory framework for functional foods at European level, including the current authorization procedure of health claims for functional foods. Chapter 4 represents a literature review of several studies on consumers' preferences, acceptance and willingness to pay for functional foods. At last, in the chapter 5, the case study on consumers' perception of functional foods is outlined.

Chapter 1
FUNCTIONAL FOODS: DEFINITIONS AND CONCEPTS

1.1 From the concept of "adequate" nutrition to "optimal" nutrition

To understand what functional foods are and their importance, it is first necessary to highlight the changes that occurred during the evolution of modern nutrition science. The role of nutrition has progressed from a past concept of "adequate" nutrition, based on the prevention of deficiency diseases and in adequate basic nutrition to one of "optimal" nutrition, in which food has an important role in the promotion of health, in term of both mental and physical well-being and reduction of disease risk.

During the twentieth century the essential nutrients have been identified and the focus of nutrition science was on establishing nutrition standards (such as the recommended daily allowances (RDAs) or reference nutrition intakes (RNIs)), dietary guidelines and food guides mainly to ensure the avoidance of deficiency diseases. More recently, recommendations have also been made to avoid excessive consumption of some of these nutrients, after recognizing their potential role in the etiology of various chronic-degenerative diseases. Another important contribution of nutritional science has been the definition of the concept of a balanced diet:

> «an appropriate mixture of food items that provides, at least, the minimum requirements of nutrients and a few other food components needed to support growth and maintain body weight, to prevent the development of deficiency diseases and to reduce the risk of diseases associated with deleterious excesses ("James, 1988").»

At the beginning of the twenty-first century, most of the occidental/industrialized countries, met new difficulties; on one hand the increasing costs of health care linked to the increase in average life and lifestyle changes and a consequent increase in chronic degenerative diseases. On the other hand, the steady increase in life expectancy and the desire of older people for improved quality of life but also improved scientific knowledge and development of new technologies.

Table 1-1: The challenges for nutrition at the beginning of the twenty-first century

(Roberfroid, M. B., 2000)

- Application of new scientific knowledge in nutrition
- Improved scientific knowledge on diet–disease relationships
- Exponential increase of health-care costs
- Increase in life expectancy
- Consumer awareness of nutrition and health relationships
- Progress in food technology

Nutritional science had to adapt to these changed contexts and began to develop the concept of optimal nutrition (Milner, J., 2000), with the aim of maximising individual's physiological functions in order to ensure maximum individuals health and well-being and at the same time minimize the risk of disease for the whole life.

In addition, at the turn of the new century, consumers' demand for food production has changed considerably. Consumers are increasingly interested in the potential benefits of foods and believe that food may directly affect their health (Mollet et al., 2002). A study of consumers in Germany, France and the UK found that for them the first important factor in maintaining good health is the diet, even more so than physical exercises and hereditary factors (Hardy, 2000). In the last few decades, the growing awareness of the close relationship between nutrition and human health has dramatically modified consumers' food preferences in developed countries, leading consumers to increase their demand and attention for healthy foods (Ozen et al., 2012).

In this scenario, nutritionists, who traditionally concentrated on the concept of a balanced' diet, have shifted their focus on reaching optimal nutrition, maximizing quality and life expectation, by detecting food ingredients, which included in a balanced diet, may improve individuals health and their ability to resist to diseases. Thus, the idea of "functionality" and the relatively new concept of functional foods has emerged, as a food product aimed to promote general health and well-being and reduce the risk of nutrition-related diseases.

1.2 The origins and diffusion of functional foods

The origins of the term and the concept of "functional foods" was born in Japan in the early 1980s. The Japanese were the first to observe that food could play a role beyond gastronomic pleasure and nutrient supply to the human organism. Traditionally, food has two important roles, first providing sufficient nutrients that are essential for the individual metabolism (nutritional function) and second, concurring to the individual well-being and

satisfaction through its taste (sensory or hedonistic function). However, a third potential role has emerged over two decades ago, that of carrying out a specific "physiological" function. The latter role was based on new evidence that food, by modulating specific target functions in the body, can have beneficial physiological and psychological effects beyond the nutritional function.

Since the early 1980s, the Japanese government has had to face new difficulties due to the increase in the elderly population, following the increase in life expectancy, which has led to an ever higher national health expenditure. In this context, it decides to invest and launch systematic and large-scale research programs in order to analyse and identify food functions, their physiological regulation and functional foods, aimed to improve the quality of life. The scope of this research was to reduce the escalating cost of national health care. As a result, a specific category of food products was established in 1991, the Foshu (Foods for Specified Health Use), also known in Japan as *Tokutei Hokenyo Shokuhin*.

Inside the national regulatory framework, all food products that bear nutritional or health functions claims belong to the class called “Food with Health Claims" or FHC. The “Food with Health Claims" class is divided into two subclasses:

1) Foods With Nutrient Function Claims, and

2) Foods for Specified Health Use (FOSHU).

Foods With Nutrient Function Claims are all food products labelled with claims about the nutritional functions of the ingredients such as vitamins and minerals. Unlike FOSHU products, they are not subject to a preliminary approval process by the Japanese Ministry of Health and Welfare prior to their commercialization. The FOSHU category is foods containing ingredients with health enhancing properties and bearing officially approved indications of its physiological effects on the organism. According to the Japanese Ministry of Health and Welfare, FOSHU is:

- foods that have a specific effect on health due to the presence of relevant components or the absence of removed allergens, and
- food in which the specific health effect is based on scientific evaluation and has been authorized to make claims on beneficial health effects.

In addition, the final FOSHU product, not the individual components, must have a positive effect on health when consumed with the normal diet, in the form of common foods, for example, not pills or capsules. Furthermore, the FOSHU is also subject to a further regulatory subset, as they also belong to the FOSDU (Food for Special Dietary Uses).

The Japanese Ministry of Health and Welfare has to approve a food as FOSHU by adopting

a specific iter of approval, in order to ensure the safety of the food product, the effectiveness of the functions on human health based on scientific evidence and the acceptance of the claim.

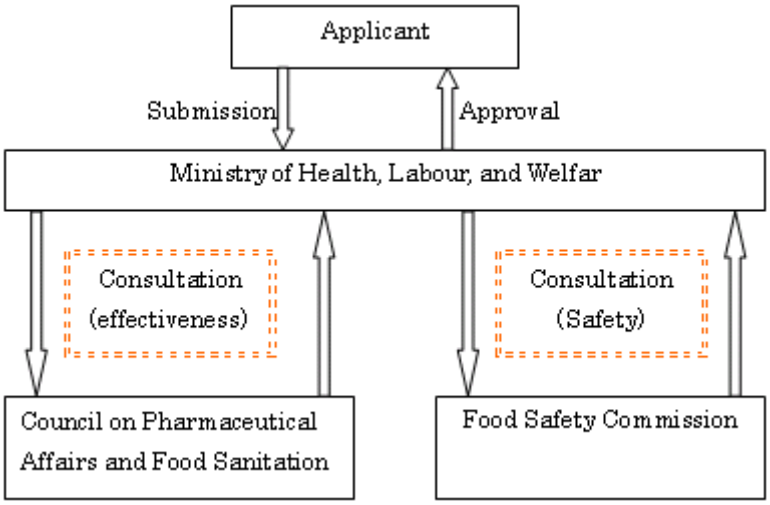


Figure 1-1: Flow Chart of FOSHU approval (MHLW, 2020).

Five basic requirements are established and must be met for the approval of food as FOSHU:

1. Effectiveness must have clearly proven;
2. There must be no safety problems (animals toxicity tests must be carried out and tests about effects in the cases of excess intake, ...);
3. Using nutritionally adequate ingredients (by avoiding the use of excessive salt,..);
4. At the time of consumption the compatibility with the product specifications must be guaranteed;
5. Quality control methods must be determined, such as product and ingredient specifications, processes and methods of analysis.

At the end of this verification process, the products, with positive results, can bear the FOSHU brand characterized by a logo on the products' label, recognizable in an easy way by consumers.

Figure 1-2: Seal for FOSHU approval (MHLW, 2020).

There is an official list of the approved FOSHU products that may carry health-related claims.

Table 1-2: Approved FOSHU Products (MHLW, 2020).

Responsible ingredients for health functions	Specified health uses
Paratinose, maltitiose, erythritol, etc.	Food related to dental hygiene
Calcium citrated malate, casein phosphopeptide, hem iron, fracuto-oligosaccharide, etc.	Food related to mineral absorption
Soybeen isoflavone, Milk Basic Protein (MBP), etc.	Food related to osteogenesis
Indigestible dextrin, wheat albumin, guava tea polyphenol, L-arabiose, etc.	Food related to blood sugar levels
Lactotripeptide, casein dodecaneptide, tochu leaf glycoside (geniposidic acid), sardine peptide, etc.	Food related to blood pressure
Middle chain fatty acid, etc.	Food related to triacylglycerol
Chitosan, soybean protein, degraded sodium alginate	Food related to blood cholesterol level
Degraded sodium alginate, dietary fiber from psyllium seed husk, etc.	Cholesterol plus gastrointestinal conditions, triacylglycerol plus cholesterol
Oligosaccharides, lactose, bifidobacteria, lactic acid bacteria, dietary fiber 8 ingestible dextrin, polydextrol, guar gum, psyllium seed coat, etc.	Food to modify gastrointestinal conditions

There are four different types of FOSHU products: “Regular/ordinary FOSHU”, “Qualified FOSHU”, “Standardized FOSHU” and “Reduction of disease risk FOSHU”. Regular FOSHUs are food products with ingredients that have a beneficial effect on the human body. Before their commercialization, the Japanese government approved them, evaluating its safety and the scientific evidence on which the specific effect on health is based. The claim presents on the product’s label must be prior validated by the Japanese Ministry of Health, Labour and Welfare. In addition to regular FOSHU, “Qualified FOSHU” and “Standardized FOSHU” were created to facilitate the approval iter by applicants. “Qualified FOSHU” are food products with insufficient scientific evidence supporting the health enhancing effect, while the “Standardized FOSHU” refers to food with sufficient evidence supporting the health effect. For this reason, the label of “Qualified FOSHU” should be also present the following statements “grounds for this effectiveness have not necessarily been established” (Malla, et al., 2013). Finally, “Reduction of disease risk FOSHU” is the only one food category that can have risk reduction claims on the label. This claim is only authorized if the reduction of disease risk is clinically and nutritionally demonstrate in an ingredient. By now,

there are only two types of disease risk reduction claims permitted, one related to calcium and osteoporosis and the other about folic acid and neural tube defect: “Intake of proper amount of calcium contained in healthy meals with appropriate exercise may support healthy bones of young women and reduce the risk of osteoporosis when aged” and “Intake of proper amount of folic acid contained in healthy meals may support women to bear healthy baby by reducing the risk of neural tube defect, such as spondyloschisis, during fetal development” (MHLW, 2020).

In the 1990s, many Japanese FOSHU related food terms came out in different countries. These terms include: ‘functional foods’ , ‘nutraceuticals’, ‘designer foods’, ‘f(ph)armafoods’, ‘medifoods’, ‘vitafoods’ but also ‘dietary supplements’ and ‘fortified foods’, etc. For many authors, these terms are interchangeable and are used to identify food products or ingredients having a beneficial effect on human health, in addition to a nutritional value (Hasler,1998). Hillian identified these terms as ‘food substances that provide medical or health benefits including the prevention and treatment of disease’ (Hillian, 1995). For other authors, they include ‘foods that can prevent or treat disease’(Goldberg, 1994) or ‘foods or isolated food ingredients that deliver specific nonnutritive physiological benefits that may enhance health (Mazza, 1998). However, these terms appear to be different and can not be used a unique definition for all of them.

Indeed, according to Defelice, S.L., (1995) nutraceuticals are defined as ‘any substance that is a food or part of a food that provides medical and/or health benefits, including the prevention and treatment of disease’ or ‘a product produced from foods but sold in powders, pills and other medicinal forms not generally associated with food and demonstrated to have physiological benefits or provide protection against chronic disease’ (Health Canada, 1997).

Vitafoods are ‘foods and drinks to meet the needs of modern health conscious consumers which enhance the bodily or mental quality of life, enhance the capacity to endure or flourish or to recover from strenuous exercise or illness. They may also increase the health status of the consumer or act as a potential deterrent to health hazards’(Ministry of Agriculture, Fisheries and Food, 1996).

Dietary supplements have a different definition, referring to them as ‘a product intended to supplement the diet and that bears or contains one or more of certain specified dietary ingredients (vitamins, minerals, herbs or other botanicals, amino-acids, a dietary supplement) to supplement the diet by increasing total dietary intake, a concentrate, metabolite, constituent, extract or combination. It is a tablet, capsule, powder, softgel, gelcap or liquid droplet or some other form that can be a conventional food but is not represented as a

conventional'(FDA, 1998). In these scenario, the term "functional foods" stands out from all previous definitions, but a scientific definition, unanimously recognized, was only formulated in the mid-nineties.

1.3 Definitions of functional foods: an overview

What are functional foods? By now, do not exist a unique definition for these categories of food products. Indeed, a lot of definitions has already been outlined about the term "functional food" but in most of the countries do not exist a legal definition and it's difficult to distinguish them from conventional foods, even for nutritionist and food experts. Functional foods are specific groups of food products and cannot be defined as a single well-defined entity. In fact, there are and there will be a lot of food products classified as functional foods, based on a variety of classified or not classified nutrients, influencing a lot of body functions related to a state of health and of well-being and/or the reduction of disease risk. Thus, probably a universally accepted definition of functional foods will never exist, because they should be understood as a concept rather than a specific category of food products (Roberfroid, 2002). Furthermore, if it is a function-driven concept rather than a product-driven concept, it is more universal and not influenced by native characteristics and cultural traditions (diplock et al., 1999).

Functional foods have many definitions based on the authors who described them. These are simple statements, such as:

1. foods that may provide health benefits beyond basic nutrition (IFIC Foundation, 1995) and
2. foods or food products marketed with the message of the benefit to health (Riemersma, 1996),

but also very complicated definitions such as:

1. food and drink products derived from naturally occurring substances consumed as part of the daily diet and possessing particular physiological benefits when ingested (Hillian, 1995);
2. food derived from naturally occurring substances, which can and should be consumed as part of the daily diet and which serves to regulate or otherwise affect a particular body process when ingested (Smith et al. 1996);
3. food similar in appearance to conventional food, which is consumed as part of the usual diet and has demonstrated physiological benefit and/or reduces the risk of chronic disease beyond basic nutritional functions (Health Canada, 1997); and

4. food that encompasses potentially helpful products, including any modified food or food ingredient that may provide a health benefit beyond that of the traditional nutrient it contains (Food and Nutrition Board, 1994).

Following these definitions, functional foods represent a unique concept and cannot be included in other categories such as nutraceutical, f(ph)armafood, medifood, designer food or vitafood, and dietary supplements. Furthermore, functional foods must remain foods, not medicines, they are based on a nutritional concept without any therapeutic effect. The only role in diseases is to prevent them and not cure them (Roberfroid, 2002).

Therefore, the lack of an official definition of the term "functional foods" and the different regulations between different countries, generate confusion and ambiguity about what functional foods are, creating confused and uninformed consumers. However, functional foods have unique features: (Bellisle et al. 1998; Knorr, 1998):

- are conventional or everyday foods,
- consumed in the normal/usual diet,
- composed of naturally occurring (not synthetic) components, maybe in unnatural concentration or present in foods that would not normally include them,
- having a positive effect on target body function(s) beyond nutritive value/basic nutrition,
- enhance general well-being and health and/or reduce diseases' risk or provide health benefits to improve the quality of life including physical, psychological and behavioural performances,
- have authorised claims based on scientific evidence.

It is only between 1995 and 1999 that a most authoritative scientific definition was outlined in an attempt to clarify the concept of functional foods and investigate their content. This definition was developed by a group of more than 100 European experts in the medical and nutritional fields, who worked on the Functional Food Science in Europe (FUFOSE) project, a concerted action between the European International Life Science Institute (ILSI) and the European Commission. This Concerted Action led to the drafting of the European Consensus on 'Scientific concept of functional foods', which was published in 1999 in the British Journal of Nutrition (Diplock et al. 1999). The program has tried to define a scientific approach based on scientific evidence, necessary for the development of functional food products which are able to promote beneficial effects on a specific physiological function of the organism, enhance well-being and health and / or reduce diseases' risks. In order to achieve this objective, three main steps were undertaken:

1. Critical evaluation of the scientific evidence needed to demonstrate that a specific nutrient positively affects target body functions;
2. Investigation of the available science from a function-driven point of view rather than product-driven;
3. Developing a consensus on specific modifications of food and food components and their applications.

The 'target functions' are genomic, biochemical, physiological, psychological or behavioural functions that have a role in the maintenance of a state of well-being and health or to the reduction of diseases' risks. Modulation of these target function should be properly measured by determining a change in serum, or other body fluids, of the amount of a metabolite, hormone, protein, or modification in the activity of enzymes or physiological, physical or intellectual parameters such as blood pressure, gastrointestinal transit time, etc.

This Concerted Action presents three publications:

1. *Functional Food Science in Europe* examines published literature about specific body systems, the methodologies to distinguish and measure specific related functions, the nutritional aspects modulating these functions and their safety implications, the role of food technology and the scientific evidence required to demonstrate the role of the nutrients in affecting body function.
2. *Technological Aspects of Functional Food Science* reviews the influence of the processing and its modulation of the functionality, the impact of the raw materials and also their safety implications and process monitoring of functions.
3. *Scientific Concepts of Functional Foods in Europe,* a consensus document about the development of functional foods and the scientific evidence required for claims.

Thus, that consensus document proposes a 'working definition' of functional foods:

> «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.,1999").»

The main features of functional foods descripted by this working definition are:

- the nature of the functional food that must not be a pill, a capsule or any form of dietary supplement;
- the validation of health effects by the scientific community;

- the positive effects on body functions, beyond basic nutrition effects, that are relevant to enhance the state of health and well-being and/or reduce, not prevent, the risk of disease;
- the consumption as part of a normal diet.

Furthermore, the consensus document also provides specifications on potential consumers of the functional food category. It highlighted that a functional food can be functional for all members of a population, but it can also be functional only for a specific group of individuals, defined on the basis of different genetic or personal characteristics.

The consensus document, at the stage in which the legislation about health claims was not yet in place, proposes two main types of health claims for functional foods "advanced function" claim and "reduced risk of disease" claim, defined according to Codex Alimentarius (1999):

- *Enhanced function claims* or type A: "claims that concern specific beneficial effects of the consumption of foods and their constituents on physiological or psychological functions or biological activities but do not include nutrient function claims. Such claims relate to a positive contribution to health or a condition linked to health, to the improvement of a function or to modifying or preserving health." (Roberfroid, 2002).
- *Risk of disease reduced claims* or type B: "claims that concern the reduction of a disease risk related to the consumption of a food or a food constituent in the context of the daily diet that might help reduce the risk of a specific disease or condition." (Roberfroid, 2002).

In order to support the FUFOSE claim system, a second Concerted Action initiative was conducted: the project "Process for the Assessment of Scientific Support for Claims on Foods" (PASSCLAIM). Indeed, the FUFOSE project concluded that any 'Enhanced function' and 'Reduced disease risk' claims on functional foods must be based on approved scientific evidence and established the need to identify criteria to validate this scientific evidence. These conclusions were the starting point of the PASSCLAIM project, for which the main objective was to establish common criteria for the scientific substantiation of health claims on food and provide the framework about the requisites of validation, substantiation and communication for the acceptance and the use of these claims.

In the studies conducted by Diplock et al. 1999 and Ashwell, 2003, a more practical definition of functional food is given:

- a natural food with some improved specific components through particular cultivation techniques (for example, whole foods);
- a food with added particular components in order to produce a benefit (for example, foods with the addition of probiotics or prebiotics, vitamins, mineral salts, calcium, omega-3);
- a food with a removed component in order to reduce or eliminate possible negative health effects (for example, the reduction of saturated fats, sugars, salt, lactose, gluten);
- a food with a chemically modified structure of one or more components to improve the state of health (for example, hydrolyzed proteins used to reduce the risk of food allergies in infants);
- a food with increased nutritional bioavailability of one or more components, to enhance the absorption of a beneficial component (such as lycopene in tomatoes);
- a food that is the result of any combination of these possibilities.

In these complex contexts with many definitions of functional foods, a study conducted by Doyon and Labrecque (2008) tried to simplify it. They analysed and collected all the existing definitions of functional foods in the literature to obtain and propose a main definition of functional foods, also taking into account the presence of temporal and cultural aspects, evaluating the limits and the key concepts around the functional food sector.

They examined more than one hundred definitions and chose among them twenty-six definitions, the most representatives. Then, identified, among these selected definitions, four keys concepts:

1. *Health benefits*. It was a central concept of many definitions, and could be defined as "enhancing target function" or as "reducing the risk of specific diseases". However, few definitions showed that health benefits should be demonstrated by relevant and specific proof.
2. *The nature of the food*. It was another identified concept. Some definitions specify that functional foods should be traditional food, others mention that they must be fortified, enriched, or have an ingredient added, or removed as for allergens or other components that could adversely affect health if consumed excessively such as salt and sugar.
3. *Level of function.* Many definitions agreed with the fact that the main difference between food and functional food was that the latter provides benefits beyond its basic nutritional functions.

4. *Consumption pattern.* A functional food must be part of a normal diet or adapt to a normal consumption pattern in a specific geographical environment and / or cultural specific. For this reason, food can be considered functional in one country but not necessarily in another.

The above concepts permitted the authors to provide and formulate the following definition of functional foods:

> «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").»

In the study conducted by Bigliardi and Galati (2013), the main objective was to identify the state of the art on functional foods, with particular attention to the definition and main examples. They analysed more than one hundred definitions of functional foods and selected 39 definitions, based on three main concepts:

1. *The concept of health benefits:* almost all definitions (35 out of 39) stated the importance of the health benefits in order to label food as functional;
2. *The technological process at the basis of the functional food:* some definitions (18 out of 39) mentioned that food must be fortified, enriched or contain added ingredients or allergens, or other unhealthy compounds removed;
3. *The nutritional function:* Many definitions (25 out 39) stated that food in order to be functional must have some nutritional functions.

Table 1-3 shows the main definitions collected by Bigliardi and Galati (2013), divided into the three concepts identified:

Table 1-3: The main definitions of functional foods. (Bigliardi and Galati, 2013)

No.	Definition	References	Main concepts		
			Nutritional function	Health benefits	Technological process
1	"Foods which are expected to have certain health benefits, and have been licensed to bear a label claiming that a person using them for specified health use may expect to obtain the health use through the consumption thereof"	FOSHU, by the Japanese Ministry of Health, Labor and Welfare (1991), cited in Anon. (2003)		×	
2	"Food that encompasses potentially helpful products, including any modified food or food ingredient that may provide a health benefit beyond that of the traditional nutrient it contains"	Food and Nutrition Board (1994)		×	×
3	"Food and drink products derived from naturally occurring substances consumed as part of the daily diet and possessing particular physiological benefits when ingested"	Hillian (1995), cited in Robertfroid (2002)	×	×	×
4	"Foods that may provide health benefits beyond basic nutrition"	IFIC Foundation (1995, 2006: p. 4)	×	×	
5	"Foods or food products marketed with the message of the benefit to health"	Riemersma (1996)		×	
6	"Food derived from naturally occurring substances, which can and should be consumed as part of the daily diet and which serves to regulate or otherwise affect a particular body process when ingested"	Smith, Marcotte, and Harman (1996)	×		×
7	"Food similar in appearance to conventional food, which is consumed as part of the usual diet and has demonstrated physiological benefit and/or reduces the risk of chronic disease beyond basic nutritional functions"	Health Canada (1997)	×	×	
8	"Modified foods or food ingredients that provide health benefits beyond their traditional nutrients"	Adelaja and Schilling (1999)	×	×	
9	"Foods with added ingredients that claim to provide a health benefit to consumers beyond the benefits provided by ordinary foods themselves"	Center for Science in the Public Interest (1999: p. 55)		×	×
10	"A food product can only be considered functional if together with the basic nutritional impact it has beneficial effects on one or more functions of the human organism thus either improving the general and physical conditions or/and decreasing the risk of the evolution of diseases. The amount of intake and form of the functional food should be as it is normally expected for dietary purposes. Therefore, it could not be in the form of pill or capsule just as normal food form"	Diplock *et al.* (1999)	×	×	×
11	"Functional foods are products formulated with naturally occurring chemicals (or combination of chemicals) — found in many fruits, vegetables, grains, herbs and spices — to provide a health benefit, to reduce the risk of certain diseases, or to affect a particular body process. They go beyond correcting diseases such as pellagra and scurvy, caused by nutritional deficiencies. Functional foods are akin to novel macro ingredients in that their formulation is intended to provide a health benefit to consumers. However, functional foods are designed to reduce the risk of specific diseases such as lung cancer by removing certain ingredients, by adding or combining ingredients not normally found in a food product, or by concentrating substances in higher than usual quantities"	General Accounting Office (2000: p. 47)	×	×	×

According to the above definitions, functional food can be both a natural food but also fortified, enriched or be modified by biological, chemical or technological tools. However, it is not defined if a functional food should only be a novel food or it can also be a "normal"

food product with a significant content of beneficial components. The study of Vidal Carou (2008) stated that some foods become novel foods by adding some functional ingredients, not before present, while the same functional components are naturally occurring in other foods, for instance omega-3 fatty acids generally added to dairy products but naturally present in from bluefish and dried fruit.

Functional foods have been developed, over the last few decades, in almost all food sectors, but they are not evenly distributed in all food segments. One classification of functional foods provided by Kotilainen et al. (2006), Sloan (2000) and Spence (2006) from a product point of view, is presented in Table 1-4.

Table 1-4: Classification of functional foods from a product point of view (Kotilainen et al., 2006, Sloan, 2000, Spence, 2006).

Functional food	definition	examples
FORTIFIED PRODUCTS	food fortified with additional nutrients	fruit juices fortified with vitamin C, vitamin E, folic acid, zinc and calcium;
ENRICHED PRODUCTS	food with additional new nutrients or components not normally found in a particular food	probiotics or prebiotics;
ALTERED PRODUCTS	food from which a deleterious component has been removed, reduced or replaced by another with beneficial effects	fibers as fat releasers in meat or ice cream;
ENHANCED COMMODITIES	food in which one of the components have been naturally enhanced	eggs with increased omega-3 content.

The Table 1-5 shows another classification based on the aim of functional foods was given by Makinen-Aakula, (2006).

Table 1-5: Purpose-based classification of functional foods (Makinen-Aakula, 2006).

1. functional foods that add good to life or improve children's life, like prebiotics and probiotics;
2. functional foods that reduce an existing health risk problem such as high cholesterol or high blood pressure;
3. functional foods which makes life easier, such as lactose-free or gluten-free products.

In addition, the study of Bigliardi and Galati (2013) classified, among the existing literature, functional foods based on the main types present on the market, and for each of them, they reported some examples of food and the relative function on human health (Table 1-6).

Table 1-6: The main type of functional foods available on the market (Bigliardi and Galati, 2013).

Type of functional food and definition	Objective	Example	Main references
Probiotics *"live microorganisms, as they are consumed in adequate numbers confer a health benefit on the host"* Charalampopoulos, Pandiella, and Webb (2003)	Influence on human health, including influence on gastrointestinal health, immune function and cancer (Jones & Jew, 2007).	Lactic acid bacteria (LAB) and bifidobacteria.	Alzamora *et al.* (2005), Jones and Jew (2007) and Saarela, Lahteenmaki, Crittenden, Salminen, and Mattila-Sandholm (2002).
Prebiotics *"non-digestible food ingredients that beneficially affect the host by stimulating the growth and/or activity of one or a limited number of bacteria in the colon"* Charalampopoulos *et al.* (2003)	To stimulate the growth and/or activity of one or a limited number of bacteria in the colon, thus improving host health (Stanton *et al.*, 2005).	Fructo-oligosaccharide (FOS), inulin, isomalto-oligosaccharides (IMO), polydextrose, lactulose and resistant starch.	Bosscher (2007), Bosscher *et al.* (2006), Cani, Neyrinck, Maton, and Delzenne (2005) and Ouwehand (2007).
Functional drinks *"non-alcoholic beverages fortified with vitamins A, C and E or other functional ingredients"* Menrad (2003) and Side (2006)	To reduce the cholesterol level, to stimulate the antioxidant function and to avoid the inhibition of growth and the deformation of the bones (Tammsaar, 2007).	ACE drinks, cholesterol-lowering drinks, "eye health" drinks or "bone health" drinks.	Keller (2006) and Tammsaar (2007).
Functional cereals *"Cereals containing dietary fiber, such as β-glucan and arabinoxylan, oilgosaccharides, such as galacto- and fructo-oligosaccharides and resistant starch"* Oatles and Cagindi (2006)	Fermentable substrates for the growth of probiotic microorganisms, sources of non-digestible carbohydrates, stimulator of the growth of lactobacilli and bifidobacteria present in the colon (Brennan & Cleary, 2005; Charalampopoulos, Wang, Pandiella, & Webb, 2002).	Oat, barley, rye, spelt.	Alldrick (2007), Benkouider (2005), Monàr (2007) and Poutanen (2006).
Functional meat *"meat modified by adding ingredients considered beneficial for health or by eliminating or reducing components that are considered harmful"* Bhat and Bhat (2011)	To reformulate the fatty acid profiles or inclusion of antioxidants, dietary fiber or probiotics (Sirò *et al.*, 2008).	Meat with the control of the composition of raw and processed materials.	Jiménez-Colmenero, Carballo, and Cofrades (2001), Kovács, Zsarnóczay, and Gasparik Reichardt (2007), Mendoza, Garcìa, Casas, and Selgas (2001) and Ricondo and Ayo (2007).
Functional eggs *"eggs with increased omega-3 fatty acid content"* Sirò *et al.* (2008)	To reduce the possible formation of blood clots and for blood pressure control (Sirò *et al.*, 2008).	Egg enriched with omega-3 fatty acids simultaneously with antioxidants and other vitamins.	Sirò *et al.* (2008) and Surai and Sparks (2001).

A further classification of functional foods was developed by Euromonitor. It created the "Health and Wellness" category, subdivided into the following types:

- *Fortified / Functional*: includes enriched foods and beverages which contain added components that provide health benefits beyond basic nutrition (vitamins, mineral salts, omega-3, calcium, probiotics, etc. …);
- *Better For You:* includes pre-packaged foods and beverages that are modified during production by removing substances that are harmful to health (fats, sugars, salt).
- *Food Intolerance*: contains lactose-free, gluten-free or diabetic food products. Generally, these foods are intended for individuals affected by intolerances or allergies to some substances;
- *Natural Health*: includes natural foods and beverages containing components that positively affect body health beyond their caloric value, such as foods rich in fiber, cereals, nuts, fruit snacks and muesli, olive oil, fruit juices, drinks based on

antioxidants such as green tea;

- *Organic*: consists of food and drinks whose production is based on an organic farming system, therefore without the use of pesticides and certified by certifications of authorized bodies.

Finally, another way to classify functional foods can be based on the additional health benefits that they provide, as shown in Table 1-7 (Sunil K. Khatkar et al., 2016).

Table 1-7: Categories of functional foods based on health benefits provided (Sunil K. Khatkar et al., 2016).

Functional food categories	**Functional foods used**
Early development and growth	Enriched bakery products, flour, cereals, infant formula, growth milk, baby foods
Regulation of basic metabolic processes	Fiber rich foods, skimmed dairy products, calcium and vit. D rich foods
Defence against oxidative stress	Antioxidant rich foods: Vitamin C, anthocyanins, lycopene, phenols
Cardiovascular physiology	Foods enriched with MUFA's and PUFA's, Fish oils, omega-3 fatty acids, phytosterol added to foods
Gastrointestinal physiology	Probiotics, Prebiotics, Symbiotics
Cognitive and mental performance, including mood and alertness	Caffeine, theophylline/theobromine rich foods, valerian, ginseng, balm extracts
Physical performance and fitness	Energy bars, antioxidant beverages, isotonic beverages

Chapter 2
FUNCTIONAL FOODS MARKET: AN OVERVIEW

2.1 Introduction

It's difficult to analyse the development of functional food market due to the fact that does not exist a single well-characterized definition of functional food. In addition, few studies analysed the market of functional food and this is an innovative trend that appear recently. The commercialization of functional foods was born in Japan just over twenty years ago, then, in a relatively short period of time, it expanded in most of the developed countries such as the United States, the European Union and Canada but it is also started in the developing countries. Nowadays, at one global level, there is a growing interest among consumers towards this type of healthy products. In recent years, there has been a change in the mindset of consumers, shifting and increasing their interest in healthier food products as a source of well-being. Consumers have a new prospective about food like a means of control and prevention of diseases, not only as a medium necessary for nutrition. Consumers are now more and more healthy and pay attention to food, in particular they are more conscious about the interrelation between health and diet and are attentive to their diet and food ingredients that they eat. According to the *Health / Wellness: food as medicine* research conducted by Nielsen, in 2017 on a sample of 30 thousand people in 63 different countries,

> "consumers around the world are increasingly attentive to their diet and increasingly interested in discovering new healthy foods. Italians, in particular, are riding this trend: almost one in two (40% of consumers interviewed) declares that a controlled diet is part of their lifestyle " (Nielsen, 2017).

This desire to make food as medicine has created a very growing demand for functional foods with healthful properties. In this scenario, food industry was encouraged to develop and market many products with nutritional and functional claims on the label, that are sold at higher price and have a higher profit margins that conventional food. The main factors involved in the rapid spread of the functional food market are related to the recent advances made by science and technology that have permit to increase the individual's level of well-being, raising also life expectancy and the desire of older people for an improved quality of life and are related to the increasing cost of healthcare. The increase in well-being together

with the modern lifestyle and the change in the dietary pattern have also led to an increase in some diseases such as: obesity, diabetes, coronary heart disease, etc., All these factors have led consumers to search for nutritional "solutions" to prevent certain diseases linked to a sedentary lifestyle and high-calorie diet and therefore have increased the demand for functional food products.

According to the report "Functional Foods Market Size, Share & Trends Analysis Report, 2019-2025", published by Grand View Research, the functional food market, on a global level, can be subjected to a different segmentation:

1. By Product Type: Bakery & Cereals, Dairy Products, Meat, Fish & Eggs, Soy Products, Fats & Oils, Others;
2. By Application: Weight Management ,Sports Nutrition, Digestive Health, Immunity, Cardio Health, Clinical Nutrition, Others;
3. By Regional Outlook: North America (U.S., Canada, Mexico), Europe (EU28, Russia), Asia Pacific (China, Japan, India, Philippines, Indonesia, Malaysia, Australia) Central & South America (Brazil), Middle East & Africa (South Africa);
4. By ingredients: Carotenoids, Dietary Fibers, Fatty Acids, Minerals, Prebiotics & Probiotics, Vitamins, Others.

According to the report published by Allied Market Research, "Functional Food Market by Ingredient, Product, and Application: Global Opportunity Analysis and Industry Forecast, 2021–2027," the functional food market at a global level is anticipated to be US $ 267,924.40 million by 2027 at a CAGR of 6.7% from 2021 to 2027. It also states that based on the type of ingredients

> "the vitamins segment was valued at $25,733.00 million in 2019, and is projected to reach $41,625.30 million by 2027, registering a CAGR of 7.7% from 2021 to 2027 and the probiotic segment accounted for the around one-third half of the global functional food market share in 2019, and is expected to sustain its share from 2021 to 2027"(Allied Market Research, 2020).

According to the functional food market analysis based on the product *"the soy products segment was valued at $17,306.40 million in 2019, and is expected to reach $30,539.40 million by 2027, registering a CAGR of 8.8% from 2021 to 2027"*. In addition, based on the application *"the cardio health segment is estimated to reach $94,936.70 million by 2027, at a CAGR of 7.1% and sports nutrition is projected to grow at $ 72,114.6 million by 2027, registering a CAGR of 6.5%".*

2.2 The functional food market segmented by relevant product categories

The products representing the largest share of sales of functional foods are: confectionery, bakery and cereal products, dairy products and non-alcoholic beverages. The products that have a greater market are those that contain, as main bioactive compounds, dietary fiber, vitamins and minerals. The highest number of functional foods produced today are dairy-based, followed by baked goods and cereals.

According to Jago, 2009, among the products that bear health claims on the label in the worldwide functional food market, the main are represented by dairy products with 44%, following by non-alcoholic beverages with 21%, and then other food categories, with percentages between 2 and 6%, such as baked food, snacks, chewing gum, etc.

2.2.1 Dairy products

According to the report published by Allied Market Research, "Functional Food Market by Ingredient, Product, and Application: Global Opportunity Analysis and Industry Forecast, 2021–2027," *"the dairy product segment was valued at $48,831.8 million in 2019, and is expected to grow to $73,030.0 million by 2027, with a CAGR of 6.6%".* Dairy products are milk and any other foods made by milk such as butter, cheese, ice cream, yogurt, etc. Functional dairy products have been related to different bioactive compounds such as: bioactive peptides, oligosaccharides, probiotic, antioxidants, vitamins, minerals, conjugated linoleic acid, specific proteins, organic acids, and other. Among them, probiotics, defined as "live microorganisms which when administered in adequate amounts confer a health benefit to the host", give many beneficial health effects to human organism as they are able to modulate the balance of the intestinal bacterial flora and strengthen the immune system (Saarela & Paquin, 2009). Dairy beverages are good carriers to deliver probiotics and among them, the most common are yogurt drinks, fermented milk, and fresh milk. Species of *Bifidobacterium* and *Lactobacillus* bacteria are the most studied and widely used probiotics. Some commercially available probiotic products are listed in Figure 2-1.

Brand/trade name	Description	Producer
Actimel	Probiotic drinking yogurt with *L. casei Imunitass*® cultures	Danone, France
Activia	Creamy yogurt containing *Bifidus ActiRegularis*®,	Danone, France
Gefilus	A wide range of LGG products	Valio, Finnland
Hellus	Dairy products containing *Lactobacillus fermentum ME-3*	Tallinna Piimatööstuse AS, Estonia
Jovita Probiotisch	Blend of cereals, fruit and probiotic yogurt	H&J Bruggen, Germany
Pohadka	Yogurt milk with probiotic cultures	Valašské Meziříčí Dairy, Czech Republic
ProViva	Refreshing natural fruit drink and yogurt in many different flavours containing *Lactobacillus plantarum*	Skåne mejerier, Sweden
Rela	Yogurts, cultured milks and juices with *L. reuteri*	Ingman Foods, Finland
Revital Active	Yogurt and drink yogurt with probiotics	Olma, Czech Republic
Snack Fibra	Snacks and bars with natural fibers and extra minerals and vitamins	Celigüeta, Spain
SOYosa	Range of products based on soy and oats and includes a refreshing drink and a probiotic yogurt-like soy–oat product	Bioferme, Finland
Soytreat	Kefir type product with six probiotics	Lifeway, USA
Yakult	Milk drink containing *Lactobacillus casei* Shirota	Yakult, Japan
Yosa	Yogurt-like oat product flavoured with natural fruits and berries containing probiotic bacteria (*Lactobacillus acidophilus, Bifidobacterium lactis*)	Bioferme, Finland
Vitality	Yogurt with pre- and probiotics and omega-3	Müller, Germany
Vifit	Drink yogurts with LGG, vitamins and minerals	Campina, the Netherlands

Figure 2-1: Some commercially available probiotic products (Sirò et al, 2008).

Another type of functional dairy products are fermented milk enriched with plant sterols, such as phytosterols and phytostanols. Products enriched with plant phytostanols confer health benefit to human because sterols are plant origin substances capable of reducing the absorption of cholesterol or lowering its levels in the blood. Benecol, manufactured by Raisio Benecol Ltd., Finland, is one of the main brand that produce products with plant sterols. Other types of dairy functional foods are milk enriched with minerals, such as magnesium, calcium, and iron, which have an essential roles in the human organism but also dairy beverages enriched with other bioactive components such as omega-3 fatty acids, eicosapentaenoic acid, alpha linoleic acid (ALA), conjugated linoleic acid (CLA) and docosahexaenoic acid, with antioxidant and anti-cancer properties.

In Italy in 2009, the value of the dairy products sector with health and functional claims was about 844 million euros, with a growth of 7.3% respect to 2008, while the total turnover of the national dairy sector in 2008 was 14.5 billion euros (A.C.Nielsen – Nucci, 2009). More than 60% of the turnover of the functional food segment (1.4 billion euros) is occupied by the dairy sector and in particular by two categories of them: "fermented milk" and "milk". The "milk" category, which also includes enriched milks with omega 3, fibers, etc., shown a growth trend from 2007 to 2009 (+ 15.6%). The same for the "fermented milk" category, which in the same period of time, had a growth of more than 21.1%. The latter category includes a wide range of commercially available foods such as Actimel, Yakult, Danacol, etc In particular, the greatest growth was recorded for fermented milk with anti-cholesterol function (10.9%) followed by fermented milk with probiotics (7.3%). However, the probiotics, in the "fermented milk" category, have a primary role and account for 82% of the total fermented milk value.

2.2.2 Bakery product

The category of functional foods also includes enriched baked products such as bakery functional foods biscuits, breakfast cereals, bread, energy or sports nutrient bars and various types of snacks, etc., Functional bread, present on the market, contain fibers, soy isoflavones, omega-3 and omega-6 fatty acids, prebiotics like inulin or L-carnitine, etc., While the dairy or functional confectionery food sector has rapidly increased in popularity, the bakery and snack functional food sector has developed more slowly. In 2003, Unilever company introduced in the bakery sector a white bread, the Blue Band Goede Start, which was the first white bread enriched with other nutritional elements, normally available in brown bread such as fibers, vitamins B1, B3 and B6; iron; zinc and inulin.

In 2014, functional bakery products and snacks bars, represented from 12% to about 55% of the total of packaged functional foods in Europe. Spain bakery products market was 106.00 thousand tons compared to 894.90 thousand tons of the total of packaged functional foods. France bakery products market was 96.70 thousand tons compared to a total of about 766.00 thousand tons of functional foods packaged. Italy was 50.20 thousand tons of baked goods out of a total of 407.20 thousand tons. In Germany, bakery products (130.80 thousand tons,) represented about 32% of the total functional packaged products (405.30 thousand tons). Finally, the highest consumption of functional bakery products was in the United Kingdom (403.70 thousand tons) which represented almost 55% of the total of functional foods packaged (Figure 2-2).

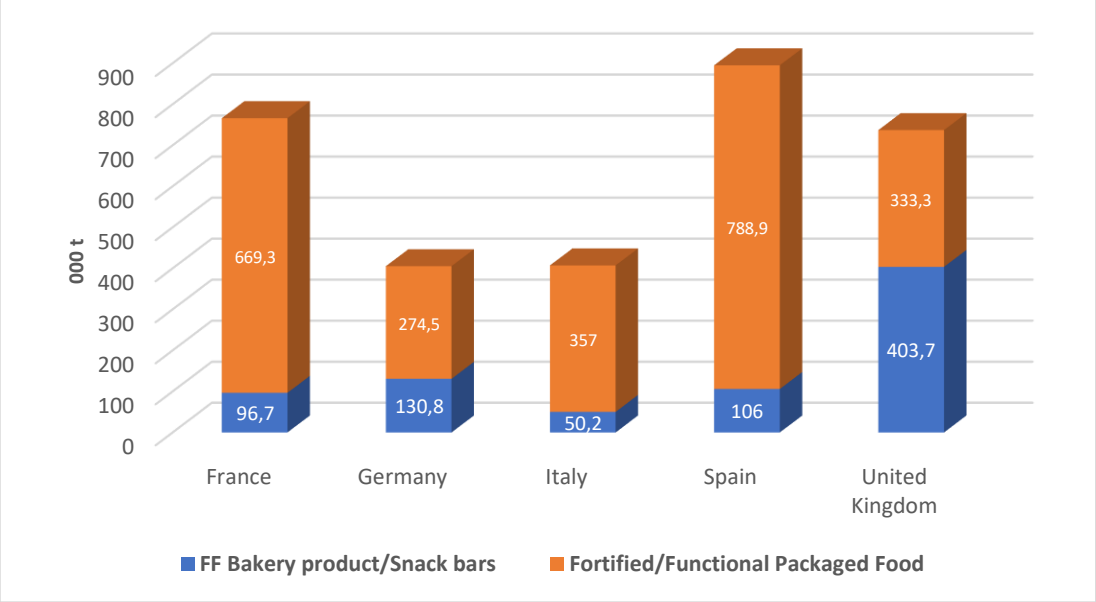


Figure 2-2: Size of the " Bakery Product/Snacks Bars " market in EU in 2014 (000 t) (Euromonitor).

The most important market value in 2014 of functional bakery products was in the United Kingdom with a market of almost 1,800.00 million euros and which represent approximately 44 % of the total functional foods compared to the market of the other countries (Figure 2-3).

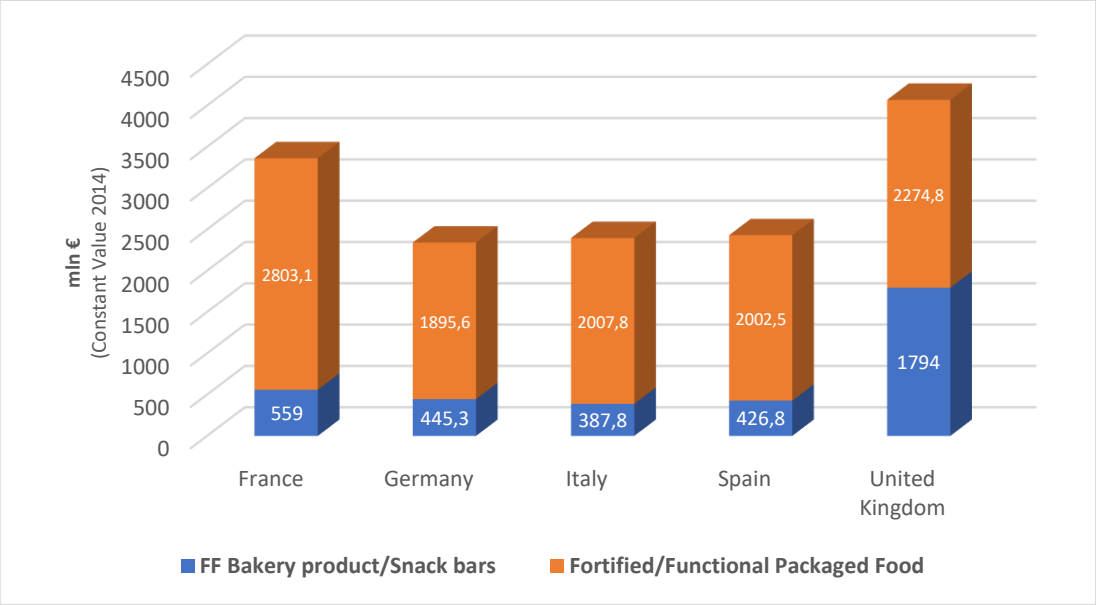


Figure 2-3: Size of the " Bakery Product/Snacks Bars " market in EU in 2014 (mln €) (Euromonitor).

2.2.3 Oils and fats

Polyunsaturated fatty acids (PUFAs) are one of the main functional components. The market for Omega-3 PUFAs in the Europe, Switzerland and Norway was estimated at € 172 million in 2004, representing 28 % of the global market size. An example of fat-based functional food products are cholesterol-lowering spreads enriched with plant sterols. The first company that produce a margarine with plant sterol esters, named “Benecol”, was the Finnish company called Raisio. Other type of commercially available functional foods are low-cholesterol milk products, like cheese, cream or butter.

2.2.4 Beverages

A wide variety of functional beverages are commercially available for example: dairy-based beverages, vegetable and fruit-based beverages, sports drinks, energy drinks, whey and soy proteins-based beverages, non-alcoholic beverages fortified with vitamins (for instance

A, C and E) or with other functional compounds. The functional beverage market represents the fastest growing sector among function al food category, estimated at $25 billion in 2005.

In 2012 in the the U.S., functional beverages accounted for about 59% of the total functional food market. It is estimated that by 2025 the functional drinks market will account for 40% of overall consumer demand (Bagchi & Nair, 2016). At global level, the market trends of functional beverages are heterogeneous among different countries, due to socio-demographic and cultural differences in consumers and acceptance of functional foods. Recently, the United States has increased the production of probiotic dairy beverages, but they are still vastly underdeveloped compared to the market in the U.K., German, French, and Spanish. On the other hand, energy and fortified drinks in Japan and U.S. dominate the beverage market, but in other countries they are largely underdeveloped.

Finally, Table 2-1 shows some examples of functional products available on the market in the various categories, expressed above, and their related health benefits.

Table 2-1: Some examples of commercially available functional foods (Zanichelli).

FOODS	**FUNCTION PERFORMED**
Foods enriched with fibers Eg. : biscuits; crackers; milk; pasta; drinks; fruit; cereals; yogurt	Fiber has a positive effect on the functionality of the intestine. It acts positively, in the sense that it reduces the absorption of fats and cholesterol and protects against cardiovascular disease.
Enriched with A.G.E. omega-3 type Eg. : milk	The fatty acids of the omega-3 series act by reducing the risk of myocardial infarction, as they improve the control of triglycerides and reduce platelet aggregation.
Enriched with iodine Eg. : iodized salt	Iodine ensures the proper functioning of the thyroid. Its deficiency is widespread and iodized salt helps to counteract it. It should be used in moderation for its sodium intake.
Vitaminized Eg. : corn flakes, vitaminized seed oil, fruit juices and vitaminized nectars.	They may contain fat-soluble (A, D, E, K) or water-soluble (C, group B) vitamins. Each vitamin is essential for maintaining health (many act as biological enzymes). It must be said that while an excess of the water-soluble ones can be easily eliminated by the body, the fat-soluble ones can accumulate and be a possible cause of toxicity. These foods are useful only in case of proven vitamin deficiency, remembering that the

	bioavailable vitamins with food are more easily absorbed.
Enriched in phytochemicals (flavonoids, carotenoids, anthocyanins, etc.) Eg. : cereal bars, fruit, fruit drinks, green tea enriched with antioxidants.	Some phytochemicals are effective in the prevention of many cancers and cardiovascular disorders. They act in a favourable way as they fight the formation of free radicals and seem to have a protective action on the functions of the central nervous system.
Enriched with mineral salts Eg. : vegetable milks; puddings; dessert; flaked cereals; fruit juices.	Among the saline supplements, those of calcium and iron are the most justified, given the widespread lack of these mineral salts, especially among children. An integration of calcium in the growth, if necessary, promotes the strength of the skeleton.
Enriched with iron and folic acid Eg. : cereal flakes, rusks	Iron is an essential component for the correct oxygenation of the blood, while folic acid (vitamin Bc) performs numerous functions: it intervenes in the construction of the genetic heritage, in the production of amino acids, in the formation of red blood cells, in the constitution of myelin (the sheath protective surrounding nerve fibers). Both are particularly useful for pregnant women who have a specific need for these micronutrients.
Probiotics Eg. : yogurt; probiotic fermented milks.	There is now a lot of scientific evidence on the benefits of probiotic enzymes and the consumption of these foods helps regulate intestinal functions.

2.3 Overview of the global functional foods market

This paragraph is focused on the analysis of the market of functional food in the world, however its analysis is subject to variations due to the lack of an unambiguous definition on a global level; by taking in consideration the definition of functional food given by the European FUFOSE project, coordinated by the International Life Sciences Institute (ILSI) Europe,

> "the functional food market, dominated by Japan (over 38% of the world market), Europe (29%), the USA (31%), although it is still "niche", has grown rapidly over the years recent years, going from a value of nearly 8 billion dollars in 1999 to over 24 billion dollars in 2010 and recording annual growth rates 4% higher than those of food and beverages" (Digital for Academy, 2015).

The global market for functional foods and beverages was worth a total of US $ 19.4 billion in 2007 and US $ 24.2 billion in 2011 (Valls et al., 2013). Euromonitor International estimated the global market value of functional foods in 2010 at $ 168 billion, which was 2.5 times greater than the market for vitamins and other food supplements (Euromonitor, 2010). From 2009 to 2013 it has increased by 26.7% (Research, 2014) and it is expected to exceed US $ 305.4 billion by 2020 with an average growth rate of 8.5% every year (Bigliardi & Galati, 2013).

According to other articles, the global functional foods market value was US $ 129.39 billion in 2015 and Figure 2-4 represents the anticipated functional food market growth between 2014-2024 (Functional Foods Market Analysis).

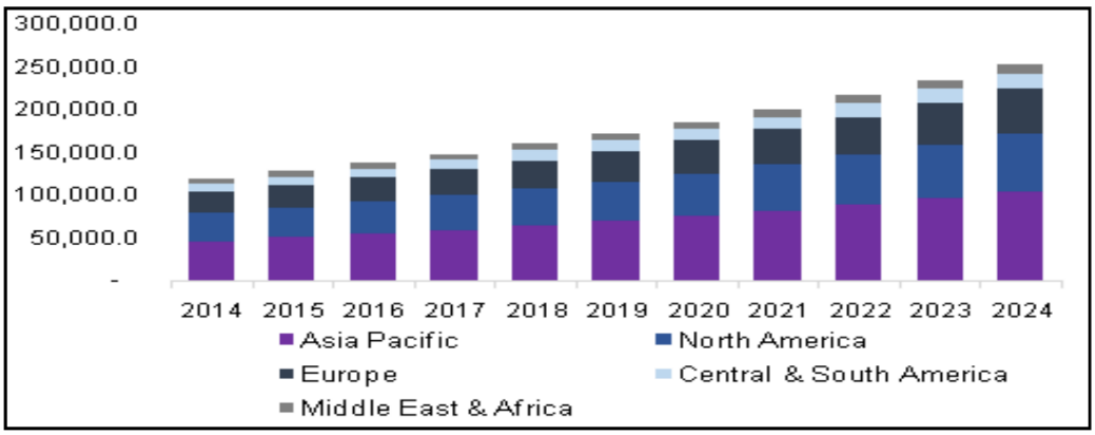


Figure 2-4: Global Functional Food Market share by region (Functional Foods Market Analysis).

The functional food market has produced a revenue worldwide that is expected to increase from about 212 billion U.S. dollars in 2013 to about 320 billion U.S. dollars in 2022 (Global functional food market revenue 2013 & 2022).

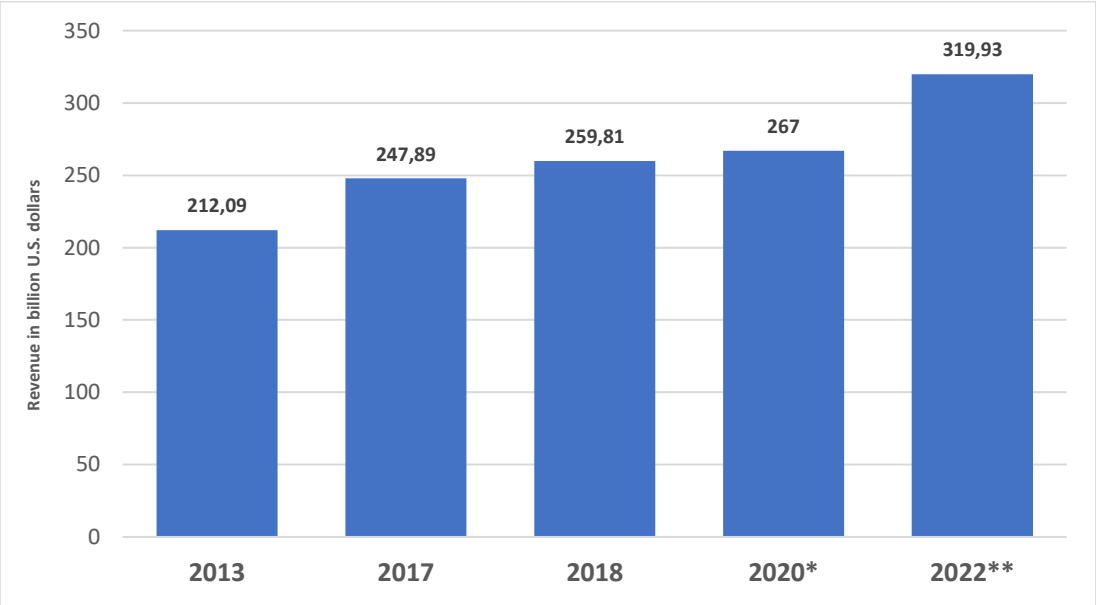


Figure 2-5: The functional food market revenue generated worldwide between 2013 and 2022 (Global functional food market revenue 2013 & 2022, 2020).

According to the article *Global healthy food & beverage sales 2020, by category*, Health food and beverage sales of the fortified/ functional food category reached US $ 267 billion against US $ 105 billion of organic category, at a global level in 2020.

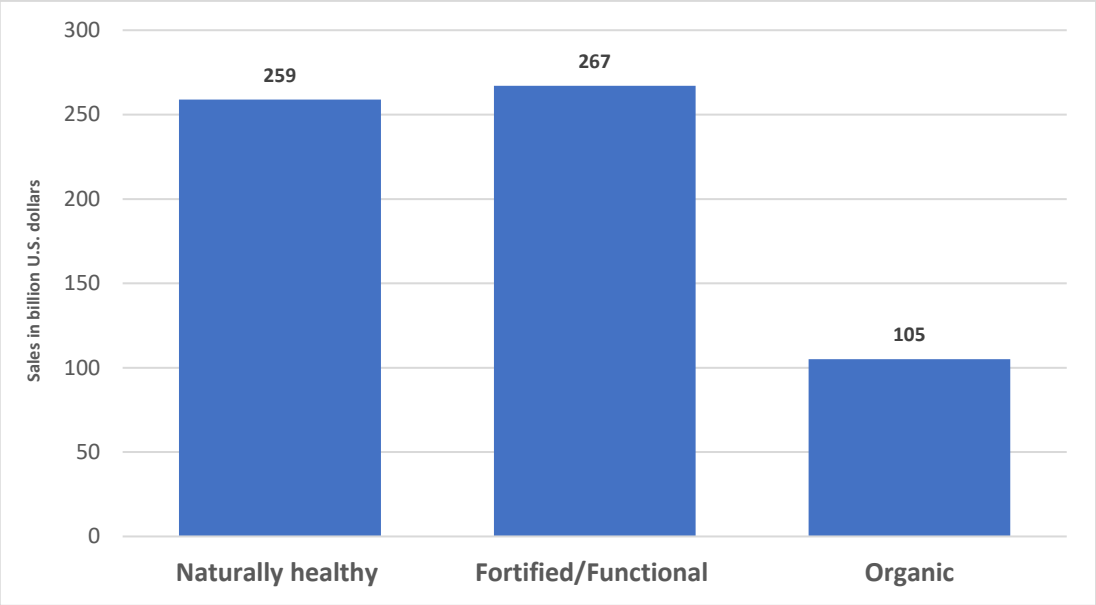


Figure 2-6: Global health food and beverage sales divided by product category, 2020 (Global healthy food & beverage sales 2020, by category).

However, the report *Functional Food Market Global Report 2020-30: Covid 19 Growth And Change* of the Business Research Company states that

> "The global functional food market is expected decline from $174.6 billion in 2019 and to $169.5 billion in 2020 at a compound annual growth rate (CAGR) of -2.9%. The decline is mainly due to economic slowdown across countries owing to the COVID-19 outbreak and the measures to contain it. The market is then expected to recover and reach $209.9 billion in 2023 at CAGR of 7.4%" (Business Research Company, 2020).

At global level the market of functional food is concentrated in three main regions: the United States and Japan, that represent the leading markets, and Europe. In these three areas, more than 90% of functional food product sales occur.

If, as stated by the report *The Top 10 Functional Food Trends*, at global level the category of fortified/functional food sales exceed $267 billion and the category of naturally healthy food sales was $ 259 billion in February 2020, the U.S. sales for these categories are $ 63 billion and $ 42 billion, respectively (Euromonitor, 2020). The U.S. functional food market sales were $ 43.9 billion in 2012, and compared to 2011 it increased by 6.9%. The U.S. dominates the functional food market and is projected to have a global compound annual growth rate (CAGR) of 8.7% by 2020 (Bagchi & Nair, 2016; Euromonitor, 2014). Asia Pacific region had the highest functional food market share of 46.8% in 2019 and is expected to continue to dominate in the future. China is first on the list of markets and has

the highest growth potential for the fortified food market; it is followed by Indonesia, Japan, Hong Kong, India, Vietnam, Saudi Arabia, Mexico, Malaysia, and Brazil (Mascaraque, 2018). According to the report published by Allied Market Research, "Functional Food Market by Ingredient, Product, and Application: Global Opportunity Analysis and Industry Forecast, 2021–2027," In 2019, the Japan was the most prominent market in Asia Pacific market in 2019 and is estimated to be US $ 64,983.70 million by 2027, growing at a CAGR of 6.2% from 2021 to 2027.

The Chinese functional food market value was estimated at US $ 24.6 billion in 2012, and is anticipated to expand continuously (Bagchi & Nair, 2016). The value of the Brazilian functional food market was estimated at US $ 8.7 billion in 2014 and is expected to increase by 12% by 2019 (Bagchi & Nair, 2016; Euromonitor, 2015).

The functional food and beverage market in India is just getting started and in 2014-15 it was between Rs 46 billion and Rs 49 billion (More, 2016). The main products in India are functional yoghurt, fortified biscuits and bread, fortified breakfast cereals and also a more recent trend is represented by functional drinks and juices.

Europe accounts for 20.2% of the functional food value of the global market and the main markets are in France, United Kingdom (U.K.) and Germany (Bagchi & Nair, 2016).

The lack of accuracy regarding the global sales data for functional foods is due to the lack of a universal definition of functional food and to the fact that the different criteria used for the inclusion of products in the market analysis, have led to large variations in the functional food market data. However, functional foods represent one of the main trends in the food industry (Valls et al., 2013).

Finally, focus on the main player, the report “Functional Food Market Global Report 2020-30: Covid 19 Growth And Change”, published by the Business Research Company, states that the major industry players for functional food market at a global level are: Unilever, BNL Food Group, Dean Foods, The Coca-Cola Company, Arla Foods, Abbott Laboratories, PepsiCo Inc., Kraft Foods Inc., Nestle, General Mills, BASF SE, Muurray Goulburn, Meiji Grup, Kirin Holdings, Kellogg Company, Danone, GlaxoSmithKline Company, Glanbia Plc, Dr PepperSnapple Group, Ocean Spray Cranberries Inc., Raisio Group, GFR Pharma, Red Bull GmbH, Sanitarium Health and Wellbeing Company, Royal FrieslandCampina.

2.4 The European market of functional foods

In Europe, functional food sales have grown significantly; The European market for functional foods was estimated from US $ 4 to 8 billion in 2003 and it was increased to US $ 15 billion by 2006 (Kotilainen et al., 2006). The main countries within the European functional food market are represented by Germany, France, United Kingdom and Netherlands. The Netherlands represents the sixth largest European market, in particular the Dutch functional foods market was estimated at US $ 384.27 million in 2004. In addition, Euromonitor estimated that functional foods sales will rise moderately from 2005 to 2009 in the newly emerging markets of Hungary, Poland and Russia. (Benkouider, 2005).

According to Euromonitor in 2014, the functional food market experienced a growing evolutionary trend in the main countries of the European Union. The Spanish market recorded the highest growth rates, in quantitative terms, from 11,214.30 thousand tons in 2009 to 17,898.90 thousand tons in 2014. Italy, France and Germany market had an increase of 5% and the United Kingdom of 4%. However, Germany, in absolute terms, was the country with the highest market (17.892,10 thousand tons), then France (14,304.60 thousand tons), Italy (13,179.50 thousand tons), Spain (11,898.90 thousand tons) and United Kingdom (11,473.90 tons).

In terms of value from 2009 to 2014, France (18.130,60 million euros in 2014), Germany (23.018,50 million euros in 2014) and the United Kingdom (24.218,00 million euros in 2014), remained stable, Italy recorded a market decrease of 5%, from 13,977.40 million euros to 13,285.90 million euros in 2014, and also Spain of 5%, from 13,486.60 million euros to 12,822.60 million euros.

Regard the evolution of "Fortified / Functional" (FF) food category in the period from 2009 to 2014 in the main countries of the European Union, the United Kingdom has seen an increase from 1,458.20 thousand tons to 1,679.20 thousand tons in 2014, with an increase of 15%. France from 14,305.00 thousand tons of "Fortified / Functional" (FF) to 881.00 thousand tons, in Germany the "Fortified / Functional" (FF) have a market of 1,167.00 thousand tonnes in 2014 and it has recorded growth rates of 3%, in Italy of 624.00 thousand tonnes and lost about 10% in the period and finally in Spain of 1.299.00 thousand tonnes, lost about 3% (Figure 2-7).

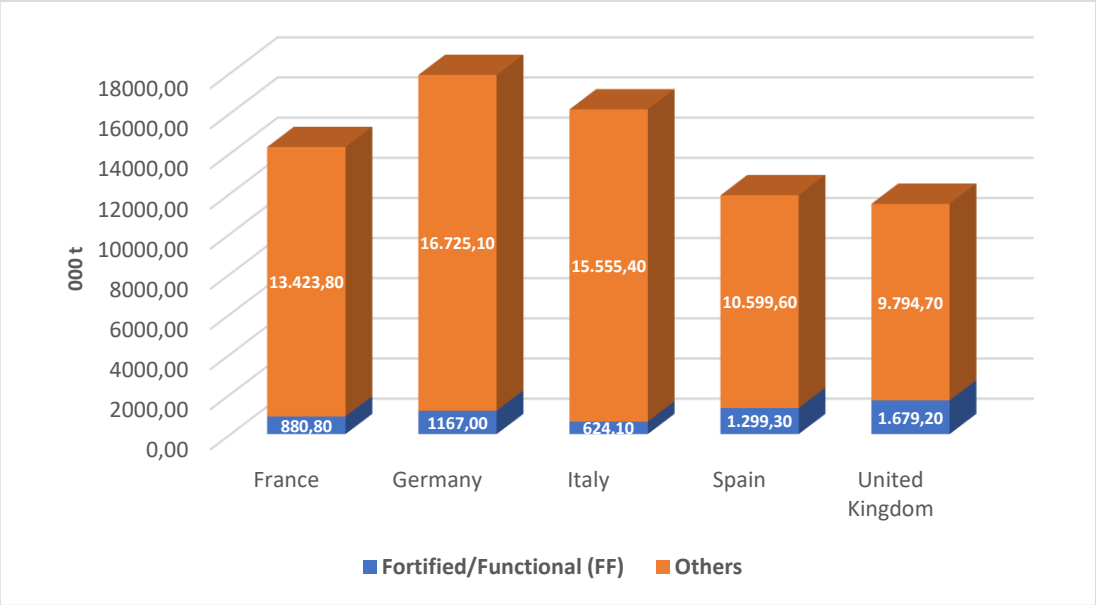


Figure 2-7: Size of the "Fortified / Functional" market in EU in 2014 (000 t) (Euromonitor).

In terms of value in 2014, the United Kingdom has shown an increase of 6%, from 6,224.10 million euros in 2009 to 6,458.90 million euros in 2014 (

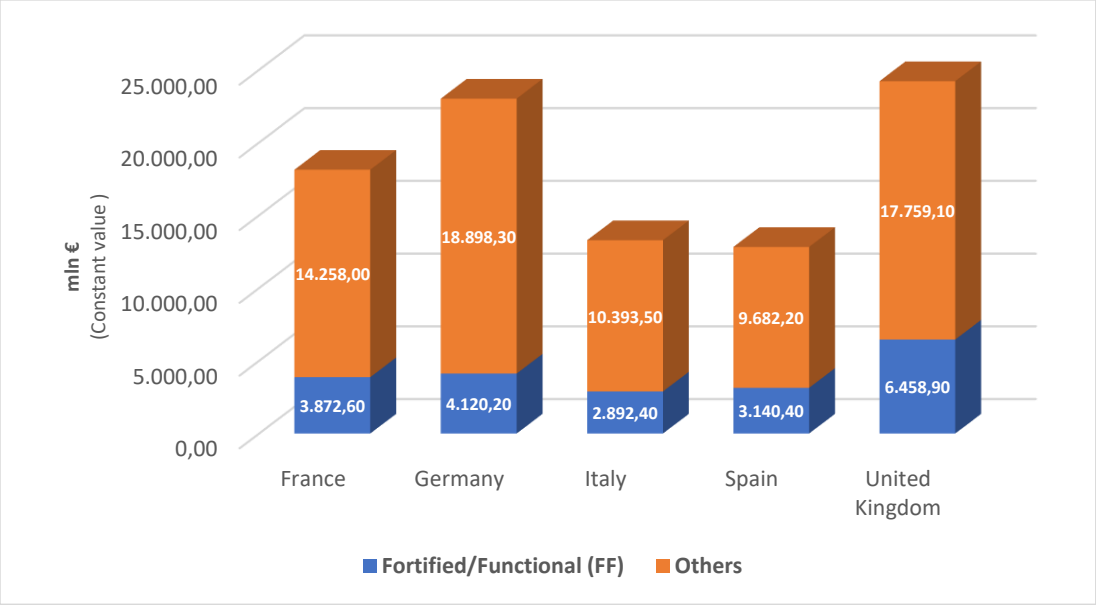


Figure 2-8).

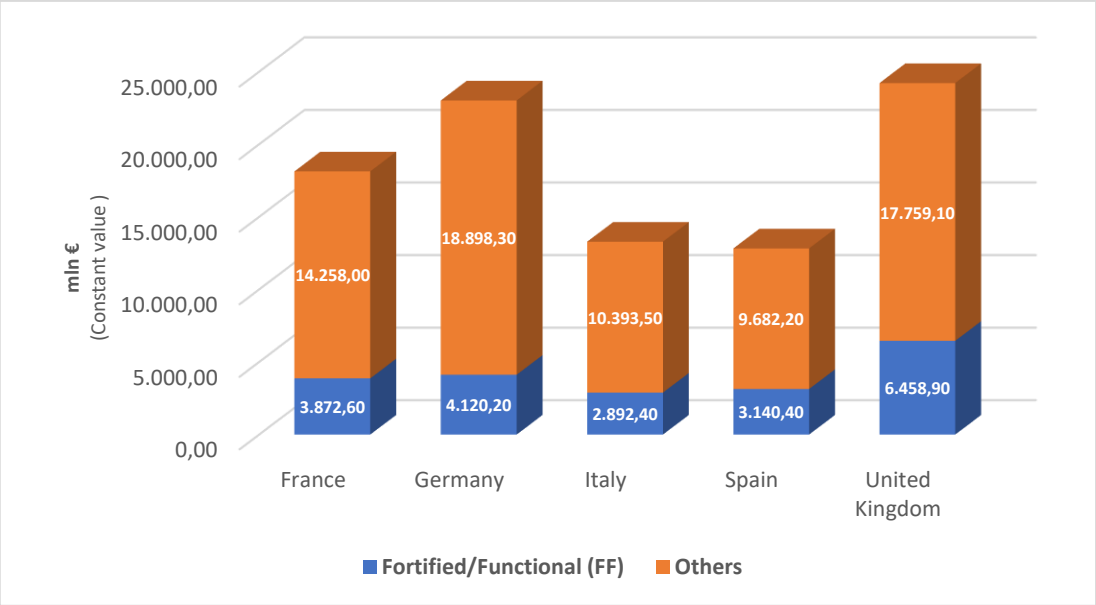


Figure 2-8: Size of the "Fortified / Functional" market in EU in 2014 (mln €) (Euromonitor).

2.5 The Italian market of functional foods

Furthermore, demand for functional food within the European market is heterogeneous and it changes considerably from country to country due to different food traditions and culture. It seems, in general, that the interest of consumers in the Central and Northern European countries is higher than in Mediterranean countries for functional food products (van Trijp & van der Lans, 2007). Finnish consumers shown a positive attitude towards functional foods compared to consumers in Denmark or in the United States (Bech-Larsen & Grunert, 2003). In Italy, although the functional food market size is less than the other countries, the consumption of functional foods has increased considerably recently, even though it is a Mediterranean European country (Sirò et al., 2008). Several studies have shown that Italian households—in particular families with children—before the price, they search for quality and healthiness of a food products (ACNielsen, 2007) in contrast to the general decrease in food purchases; 30% of Italian families declared that they consumed functional foods in 2007 (ISMEA, 2007).

In 2009, the Italian market for food with health and functional claims was around 1.4 billion euros, with growth rates in turnover between 2007 and 2008 of 7.2% and 4.4% between 2008 and 2009 (Figure 2-9) .

Most of the Italian functional food market (81%) refers to three main types of food: approximately 46.8% for fermented milk, 19.6% for fruit drinks and the 15% for milk. The

rest of the market includes baked goods, sports drinks and confectionery products (A.C. Nielsen- Nucci, 2009).

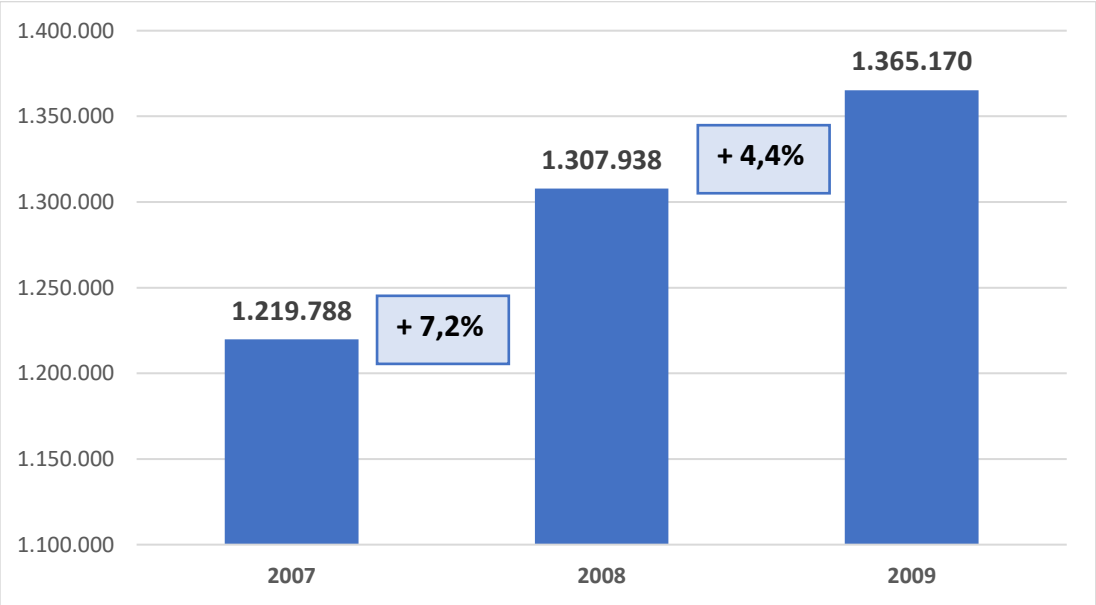


Figure 2-9: The evolution of the Italian functional food market (.000 €) (A.C. Nielsen-Nucci, 2009).

According to the report "Functional foods: origin, particularities and future scenarios" published by Digital for Academy, the market for foods with health and functional claims has had rapid growth over the last few years in Italy where, in 2013, is attested to around 1.946,5 million euros (Nielsen Market Track Healthcare research carried out for FederSalus).

According to the report "Italians more and more attention to the healthcare aspects to food" published by Nielsen in 2015 affirmed that

> " The most relevant data that emerges is undoubtedly that of a new approach to food, characterized by an increasing attention to the health aspects of food, in the awareness that a correct diet is the most appropriate tool to prevent and manage physical dysfunctions such as excess cholesterol, hypertension, diabetes and obesity " (Nielsen, 2015).

Among the characteristics most sought after by Italians, there are products such as*" "Lightened" products often offer an advantage for health: for consumers it is very important the absence of cholesterol in food (for 35% of the interviewees), of fat (29%), of sodium (28%), of sugar (27%), of calories (22%)."* In addition,

> " Having "more" of some nutrients is important for health: in particular, products with more whole ingredients are sought (a characteristic considered relevant by 22% of the sample), products enriched with calcium (19%), with a high value of proteins and vitamins (18%), fortified with minerals (16%), rich in unsaturated fats (15%), with a considerable presence of micronutrients (11%)" (Nielsen, 2015).

Therefore*, ''The interest of Italians for health products is growing, however 89% are not willing to sacrifice taste and only 16% are strongly inclined to pay more for these products, in particular for those identified as' less is more. 'and' more is more ''.*

In accordance with the previous article, the report named "Wide Italian consumptions:5 growth and positivity factors" published by Nielsen in 2017, states that one growth factor in the Italian consumption is represented by

> " the health and wellness segment: consumers are willing to pay more even for natural and healthy products. This new need explains the multi-year growth of the organic sector and highlights the emerging trend to seek as much information as possible before making a purchase (55% of Italians carefully read the nutritional information on labels) " (Nielsen, 2017).

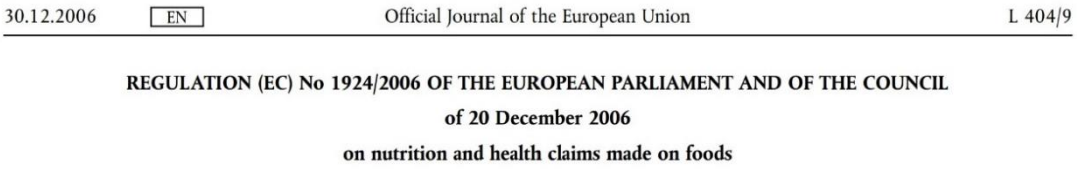
Chapter 3
REGULATORY FRAMEWORK ON THE FUNCTIONAL FOODS

The regulatory framework for functional foods at both European and international levels is unclear and remains complex. As described in the previous chapters, functional foods are not uniquely recognizable from a practical point of view and the definition and perception of consumers towards functional foods remain a very confusing concept as they do not represent a single and distinguishable food category (Roberfroid, 2002). There is not a regulatory definition of functional foods and there is also no overall uniformity regarding functional food legislation. Each country has a different approach on this issue and furthermore none of these legislations refer specifically to the category of "functional foods" but are enclosed within the regulations on “novel foods”, “food / dietary supplements" or " natural health products "(Baker et al., 2012). Having different definitions in the world, it’s difficult to insert functional foods from a legal point of view, these depend on the national concept of functional food itself. Furthermore, the classification of functional foods in the current regulatory framework is difficult due to their different origins, the different methodologies used to produce them and the different terms used to indicate them. In addition, the legal requirements applied to functional foods depend on the nature of each product, because they can contain different nutrients, bioactive compounds or other substances that are regulated by several legislations in the European market. This could create some confusion between functional foods and other products that have separate legislation.

3.1 Regulation No 1924/2006

The current regulatory framework for functional foods is the result of an evolution of European legislation aimed at harmonizing a fragmented and inhomogeneous situation between the different countries of the European Union. Indeed, each Member states had its own legislation on health claims made on food. For this reason, there was a great concern that the differences in claims would lead to misleading and confusing claims and even trade

barriers. In this scenario, the European Union started to develop new strict regulations on food claims in order to protect consumers from unclear and false information. Their first effort was in 2001 in which each statement on the prevention, treatment or cure of human diseases on products were prohibited. The second step was the proposal in 2003 made by the European Commission on nutrition and health claims made on foods and dietary supplements. However, the first step towards the harmonization of legislation was taken with the Regulation EC 1924/2006 of the European Parliament and of the council of 20 December 2006 on nutrition and health claims made on food products.



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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

Figure 3-1: Regulation (EC) No 1924/2006 on nutrition and health claims made on foods.

This was the first food related legislative act in the European Union, it applies to both foods and food supplements. It replaced all previous Member States regulations by adopting the same criteria and labelling for health claims in each Member State in order to provide a high level of protection for consumers from misleading information and to facilitate them to make healthier choices. Functional foods, placed on the European market, with any nutritional and health claims in its labelling, presentation or advertising have to meet the provisions established by the Regulation (EC) 1924/2006 (last amended in 2014). The main objectives of this regulation are:

1. to provide a high level of protection to the consumer;
2. to guarantee the effective functioning of the internal market of the EU by improving the free movement of goods;
3. to enhance legal security for food operators;
4. to ensure fair competition in the food area.

The regulation defines 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".

As stated in the article 3 of Regulation (EC)1924/2006, the use of any nutritional and health claims that are present on food commercial communication such as labelling, presentation or advertising shall not (EC 2006, Article 3):

a) *be false, ambiguous or misleading;*
b) *give rise to doubt about the safety and/or the nutritional adequacy of other foods;*
c) *encourage or condone excess consumption of a food;*
d) *state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general;*
e) *refer to changes in bodily functions which could give rise to or exploit fear in the consumer, either textually or through pictorial, graphic or symbolic representations;*

The general conditions for the use of the claims are established in article 5 of this regulation, in particular nutrition and health claims are permitted only if met strict conditions, such as:

1. *claims shall refer to ready for consumption food;*
2. *the average consumer can easily understand the beneficial effects as formulated in the claim;*
3. *the nutrient or substance that is absent or present (including in reduced content) in the product, has been shown to possess a beneficial nutritional or physiological effect as established by accepted scientific evidence and must be assimilable by the organism.*

Nutritional and health claims, as stated in article 6 "*Scientific substantiation for claims*", must be scientifically proven and accepted and must not mislead the consumer, in order to protect them and avoid misunderstandings towards the safety and nutritional adequacy of other food and ensure fair competition in the food industry.

The article 2.2 of Regulation (EC)1924/2006 defines three different categories of claims: "nutrition claims", "health claims" and "reduction of disease risk claims" (EC 2006, Article 2.4-2.6).

1. ***Nutrition claims***: any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to the energy or calorific value, it provides, provides at a reduced or increased rate, or does not provide; and/or the nutrients or other substances it contains, contains in reduced or increased proportions, or does not contain;

2. ***Health claims***: any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;
3. ***Reduction of disease risk claims***: any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease;

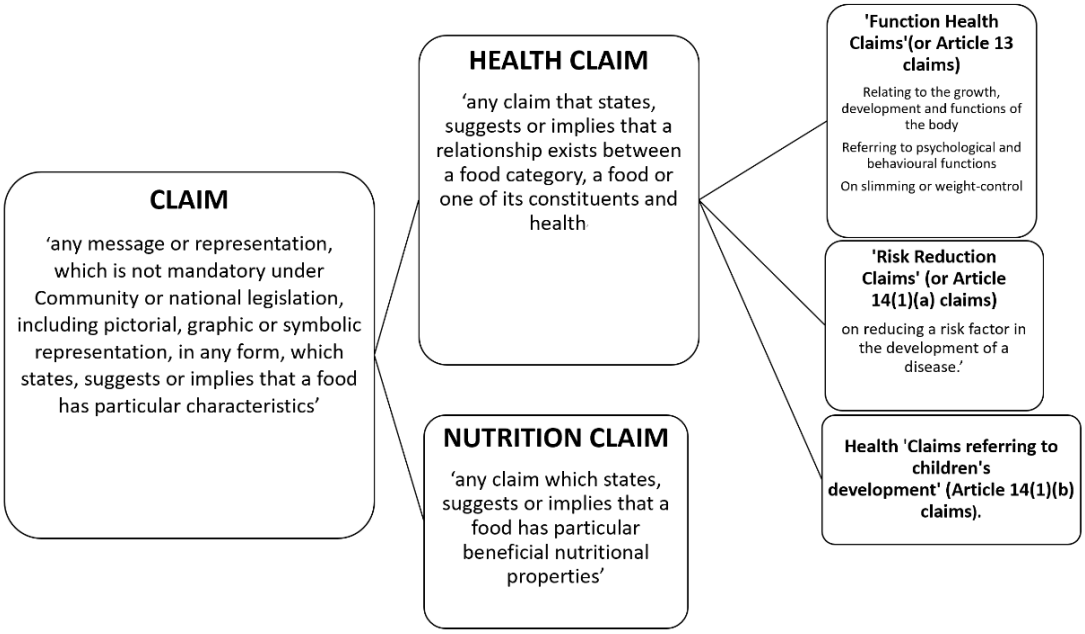


Figure 3-2: Different types of claims according to Regulation (EC) 1924/2006 (own elaboration).

3.1.1 Nutrition claims

Nutritional claims, shown in Table 3-1, are described in Chapter III and are only permitted if they are listed in the Annex of Regulation (EC) No 1924/2006, lastly amended by Regulation (EU) No 1047/2012, and complied with the specifications contained in this Regulation. Examples of nutritional claims are "high in vitamins, fibre or proteins" or "low in calories, salt or sugar".

Table 3-1: Nutrition claims and conditions applying to them based on the Annex of Regulation (EC) No 1924/2006, lastly amended by Regulation (EU) No 1047/2012 (own elaboration).

NUTRIENT	**CLAIM**
Energy	**LOW ENERGY**: < 40 Kcal (170 kJ)/100 g for solids or < 20 Kcal (80 kJ

	)/100 ml for liquids **ENERGY REDUCED**: energy value reduced by at least 30 % compared to analogue products, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value **ENERGY FREE**: < 4 kcal (17 kJ)/100 ml
Fat (g)	**LOW FAT**: < 3 g of fat per 100 g for solids or 1,5 g of fat per 100 ml for liquids **FAT FREE**: < 0,5 g of fat per 100 g or 100 ml **HIGH MONOUNSATURATED/POLYUNSATURATED/ UNSATURATED FAT**: > 45% of the fatty acids present in the product derive from mono/poly/unsaturated fat under the condition that mono/poly/unsaturated fat provides more than 20% of energy of the product.
Saturated Fat (g)	**LOW SATURATED FAT**: < 1,5 g per 100 g for solids or 0,75 g/100 ml for liquids . in either case the sum of saturated fatty acids and trans fatty acids must not provide more than 10 % of energy **SATURATED FAT FREE**: sum of saturated fat and trans fatty acids does not exceed 0,1 g of saturated fat per 100 g or 100 ml.
Sugar (g)	**LOW SUGARS**: < 5 g of sugars per 100 g for solids or 2,5 g of sugars per 100 ml for liquids **SUGARS FREE**: < 0,5 g of sugars per 100 g or 100 ml **WITH NO ADDED SUGARS**: product does not contain any added mono or disaccharides or any other food used for its sweetening properties. If sugars are naturally present in the food, the following indication should also appear on the label: 'CONTAINS NATURALLY OCCURRING SUGARS'.
Sodium (mg)	**LOW SODIUM/SALT**: no more than 0,12 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. For waters, other than natural mineral waters falling within the scope of Directive 80/777/EEC, this value should not exceed 2 mg of sodium per 100 ml. **VERY LOW SODIUM/SALT**: no more than 0,04 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. This claim shall not be used for natural mineral waters and other waters. **SODIUM FREE** or **SALT FREE**: < 0,005 g of sodium, or the equivalent

	value for salt, per 100 g. **NO ADDED SODIUM /SALT**: product does not contain any added sodium/salt or any other ingredient containing added sodium/salt and the product contains no more than 0,12 g sodium, or the equivalent value for salt, per 100 g or 100 ml.
Protein (g)	**SOURCE OF PROTEIN**: > 12 % of the energy value of the food is provided by protein. **HIGH PROTEIN**: > 20 % of the energy value of the food is provided by protein.
Vitamins and minerals	**SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S]:**at least a significant amount as defined in the Annex to Directive 90/496/EEC or an amount provided for by derogations granted according to Article 6 of 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 **HIGH [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S]**: at least twice the value of 'source of [NAME OF VITAMIN/S] and/or [NAME OF MINERAL/S]
Fiber (g)	**SOURCE OF FIBRE**: > 3 g of fibre per 100 g or > 1,5 g of fibre per 100 kcal **HIGH FIBRE**: 6 g of fibre per 100 g or at least 3 g of fibre per 100 kcal
Other nutrients	**CONTAINS [NAME OF THE NUTRIENT OR OTHER SUBSTANCE]**: product complies with all the applicable provisions of this Regulation, and in particular Article 5. **INCREASED [NAME OF THE NUTRIENT]**: > 30 % compared to a similar product. **REDUCED [NAME OF THE NUTRIENT]**: < 30 % compared to a similar product, except for micronutrients (< 10 %) and for sodium, (< 25 %); The claim "**reduced saturated fat**" may only be made: (a) if the sum of saturated fatty acids and of trans-fatty acids in the product is at least 30% less than the sum of saturated fatty acids and of trans-fatty acids in a similar product; and (b) if the content in trans-fatty acids in the product bearing the claim is

	equal to or less than in a similar product. The claim "**reduced sugars**" may only be made if the amount of energy of the product bearing the claim is equal to or less than the amount of energy in a similar product. **LIGHT/LITE**: same conditions as those set for the term 'reduced'; the claim shall also be accompanied by an indication of the characteristic(s) which make(s) the food 'light' or 'lite'. **NATURALLY/NATURAL**: food naturally meets the condition(s) laid down in this Annex for the use of a nutritional claim, the term 'naturally/natural' may be used as a prefix to the claim **SOURCE OF OMEGA 3 FATTY ACIDS**: > 0,3 g alpha linolenic acid per 100g and per 100kcal, or at least 40mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and per 100kcal. **HIGH OMEGA 3 FATTY ACIDS**: > 0,6 g alpha linolenic acid per 100 g and per 100 kcal, or at least 80 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal.

3.1.2 Health claims

Health claims are any statements that affirm, suggest or imply a relationship between food and health, which are described in Chapter IV of Regulation (EC) 1924/2006. Health claims could have a major impact on consumers' dietary behaviours and for this reason it's essential to consider all important matters. Any health claim describing a relationship between food and health-related benefit to the human body, must undergo a pre-market approval. The European Commission authorizes various health claims only if they are based on scientific evidence and can be easily understood by the average consumer. The European Food Safety Authority (EFSA) is responsible for evaluating the scientific evidence in support of health claims. The approval process for health claims is complex because they must be based on solid scientific evidence and a previous harmonized assessment, accepted by the European Food Safety Authority (EFSA), is required for their authorization. Health claims are authorized only if they comply with the requirements described in the Regulation and if they are included in the list of authorised claims provided by the European Commission. Health claims must include the following specific information in their labelling, presentation or advertising, as indicated in Article 10, in order to be permitted:

(a) a statement indicating the importance of a varied and balanced diet and a healthy lifestyle;

(b) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;

(c) where appropriate, a statement addressed to persons who should avoid using the food;

(d) an appropriate warning for products that are likely to present a health risk if consumed to excess.

In addition, as stated in article 12, there are some restrictions on the use of the following health claims, that must not be permitted:

(a) claims which suggest that health could be affected by not consuming the food;

(b) claims which make reference to the rate or amount of weight loss;

(c) claims which make reference to recommendations of individual doctors or health professionals and other associations not referred to in Article 11.

As defined in the Regulation (EC) 1924/2006 there are three different types of health claims.

The first are the so-called **'Function Health Claims'(or Article 13 claims)** which are:

1. related to the growth, development and functions of the body; or
2. referred to psychological and behavioural functions; or
3. on slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet;

The second are the so-called **'Risk Reduction Claims' (or Article 14(1)(a) claims)** on reducing a risk factor in the development of a human disease. For example: "Plant stanol esters have been shown to reduce blood cholesterol. Blood cholesterol is a risk factor in the development of coronary heart disease"

The last health claims are **'Health Claims referring to children's development' (Article 14(1)(b) claims).** For example: "Vitamin D is needed for the normal growth and development of bone in children".

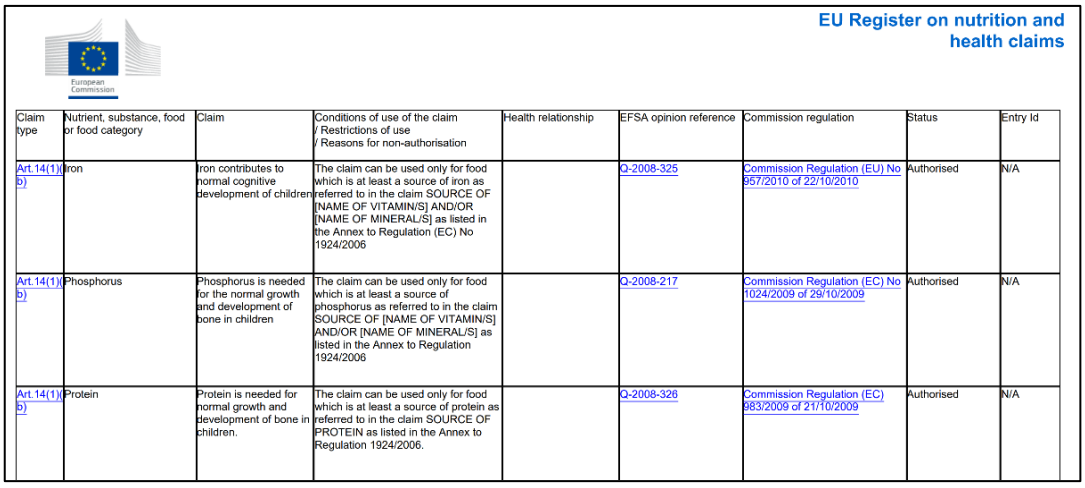
3.1.3 European register of nutrition and health claims

As stated in article 20 of the Regulation (EC) 1924/2006, the Commission has established "a Community Register of nutrition and health claims made on food", that must be available to the public. The public European register called "EU Register of nutrition and health claims made on foods" includes the list of:

- all permitted nutrition claims and their conditions of use,
- all authorised health claims and their conditions of use and restrictions,
- but it also includes non-authorised health claims and their reasons why,
- EU legal acts for the specific health claims,
- National measures described in Art. 23(3) of Regulation EC 1924/2006.

Health claims for which protection of proprietary data is allowed are listed in a separate Annex to register.

The European register is used as a reference and as a source of information for consumers and food business operators in order to guarantee full transparency towards them. The Commission will update the EU Register when required, for example when adopting EU decisions on the different conditions of use and restrictions of claims and on applications for claims.



EU Register on nutrition and health claims

Claim type	Nutrient, substance, food or food category	Claim	Conditions of use of the claim / Restrictions of use / Reasons for non-authorisation	Health relationship	EFSA opinion reference	Commission regulation	Status	Entry Id
Art.14(1)(b)	Iron	Iron contributes to normal cognitive development of children	The claim can be used only for food which is at least a source of iron as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006		Q-2008-325	Commission Regulation (EU) No 957/2010 of 22/10/2010	Authorised	N/A
Art.14(1)(b)	Phosphorus	Phosphorus is needed for the normal growth and development of bone in children	The claim can be used only for food which is at least a source of phosphorus as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation 1924/2006		Q-2008-217	Commission Regulation (EC) No 1024/2009 of 29/10/2009	Authorised	N/A
Art.14(1)(b)	Protein	Protein is needed for normal growth and development of bone in children.	The claim can be used only for food which is at least a source of protein as referred to in the claim SOURCE OF PROTEIN as listed in the Annex to Regulation 1924/2006.		Q-2008-326	Commission Regulation (EC) 983/2009 of 21/10/2009	Authorised	N/A

Figure 3-3: European register on nutrition and health claims (European Commission, 2020).

3.1.4 Authorization procedures for health claims

However, regarding the authorization procedures for health claims, there are different procedures for different types of health claims, all managed by the European Commission.

For '**Function Health Claims**' there is a list of allowed function claims for each nutrient, which is constantly updated. In order to prepare this list, EU-countries sent national lists of about 44.000 health-related claims to the European Commission in 2008. However, only 4637 were selected to be subjected to the European Food Safety Authority for an evaluation. Finally, 2758 claims were evaluated by the EFSA and only 222 health claims were approved to be used in December 2012. One of the main reasons for refusing so many health claims is

the type of scientific method employed by the applicants and supplied to the EFSA in the scientific dossier. Today, 239 function health claims have been authorised, including in particular:

- 10 claims related to fat,
- 5 related to carbohydrates,
- 14 related to fiber,
- 3 related to protein,
- 98 related to minerals,
- 68 related to vitamins,
- 24 related to other substances,
- 12 related to food and
- 5 related to food categories.

Some examples of allowed function claims included in this list are: "Vitamin C contributes to maintain the normal function of the immune system during and after intense physical exercise" or "Plant sterols/stanols contribute to the maintenance of normal blood colesterol in the development of a human disease".

Commission Regulation (EU) No 432/2012, started to apply on 14 December 2012, establishes the list of authorized health claims. The list of permitted health claims is regularly updated with newly authorised health claims subject to individual application. A food business operator intending to use a new health claim, which is not on the list, can request its inclusion by following a specific procedure:

1. The application for its inclusion shall be sent to the national competent authority of a Member State.
2. The valid application and any other information provided by the applicant shall be submitted to the Authority for a scientific evaluation and also to the Commission and the Member States for information. The Authority issues its opinion within a period of five months. In its evaluation, the Authority shall check that the health claim is based on scientific evidence and that the wording of the health claim satisfies the criteria set out in the Regulation.
3. Where the Authority, following its scientific evaluation, issues a positive opinion that support the inclusion of the claim in the list, *"the Commission shall take a decision on the application, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the*

matter under consideration, after having consulted the Member States and within two months of receiving the opinion of the Authority." (EC 2006, Article 18.4).

However, if the applicant request the protection of proprietary data for the claim and the Commission proposes to restrict the use of the claim its favour, this restricted use expires after five years.

LIST OF PERMITTED HEALTH CLAIMS

Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
Activated charcoal	Activated charcoal contributes to reducing excessive flatulence after eating	The claim may be used only for food which contains 1 g of activated charcoal per quantified portion. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with 1 g which should be taken at least 30 minutes before and 1 g shortly after the meal.		2011;9(4):2049	1938
Alpha-linolenic acid (ALA)	ALA contributes to the maintenance of normal blood cholesterol levels	The claim may be used only for food which is at least a source of ALA as referred to in the claim SOURCE OF OMEGA-3 FATTY ACIDS as listed in the Annex to Regulation (EC) No 1924/2006. Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 2 g of ALA.		2009; 7(9):1252 2011;9(6):2203	493, 568
Arabinoxylan produced from wheat endosperm	Consumption of arabinoxylan as part of a meal contributes to a reduction of the blood glucose rise after that meal	The claim may be used only for food which contains at least 8 g of arabinoxylan (AX)-rich fibre produced from wheat endosperm (at least 60 % AX by weight) per 100 g of available carbohydrates in a quantified portion as part of the meal. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained by consuming the arabinoxylan (AX)-rich fibre produced from wheat endosperm as part of the meal.		2011;9(6):2205	830
Barley grain fibre	Barley grain fibre contributes to an increase in faecal bulk	The claim may be used only for food which is high in that fibre as referred to in the claim HIGH FIBRE as listed in the Annex to Regulation (EC) No 1924/2006.		2011;9(6):2249	819
Beta-glucans	Beta-glucans contribute to the maintenance of normal blood cholesterol levels	The claim may be used only for food which contains at least 1 g of beta-glucans from oats, oat bran, barley, barley bran, or from mixtures of these sources per quantified portion. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of beta-glucans from oats, oat bran, barley, barley bran, or from mixtures of these beta-glucans.		2009; 7(9):1254 2011;9(6):2207	754, 755, 757, 801, 1465, 2934 1236, 1299

Figure 3-4: Examples of permitted function health claims based on Commission Regulation (EU) No 432/2012.

The authorization procedures for '**Risk Reduction Claims**' and' **Health Claims referring to children's development**' based on individual applications follow a different approach and involve several figures: the applicant, the competent national authorities, the European Food Safety Authority (EFSA), the European Commission.

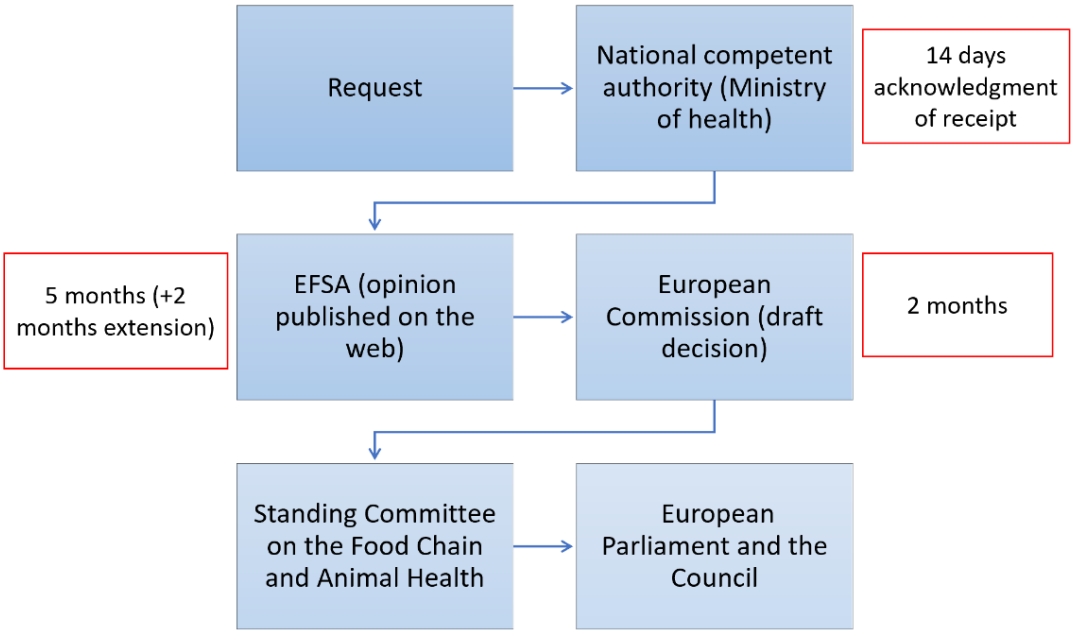


Figure 3-5: Scheme of the authorization procedure for 'Risk Reduction Claims' and' Health Claims referring to children's development' (own elaboration).

1. First of all, applicants must sent their application to the national competent authority of a Member State. The application shall enclose:
   (*a) the name and address of the applicant;*
   (b)) the nutrient or other substance, or the food or the category of food, in respect of which the health claim is to be made and its particular characteristics;
   (c) a copy of the studies, including, where available, independent, peer reviewed studies, which have been carried out with regard to the health claim and any other material which is available to demonstrate that the health claim complies with the criteria provided for in this Regulation;
   (d) where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;
   (e) a copy of other scientific studies which are relevant to that health claim;
   (f) a proposal for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;
   (g) a summary of the application. (EC 2006, Article 15.3).
2. The national competent authority shall: (i) acknowledge receipt of the application within 14 days and inform the Authority; (ii) make the application and any other information available to the Authority;

3. The Authority shall: (i) inform about the application the other Member States and the Commission and shall make it available to them; (ii) make a public summary of the application. The Authority issues its opinion within a period of five months. Whenever the Authority requests additional information from the applicant, this deadline is extended by up to two months. In its evaluation, the Authority shall verify that the health claim is based on scientific evidence and that the wording of the health claim satisfies the criteria set out in the Regulation.
4. The Authority shall send its opinion to the Commission, the Member States and the applicant, with a report describing its assessment of the health claim, the reasons for its opinion and the information on which its opinion was issued. The Authority makes its opinion public. The applicant or members of the public may submit comments to the Commission within 30 days of publication.
5. Within two months, after the Authority has published its opinion, the Commission shall submit to the Standing Committee on Plants, Animals, Food and Feed a draft decision on the lists of permitted health claims.
6. After a positive opinion of the Standing Committee on the Food Chain and Animal Health, the European Parliament and the Council have the right of scrutiny on the draft decision of the Commission.
7. If there is no objection by the European Parliament and the Council, the Commission adopts the draft decision.
8. The Commission shall inform the applicant of the decision taken, whether be positive or negative, and publish details of the decision in the Official Journal of the European Union.

NUTRIENT,SUBSTANCE, FOOD OR FOOD CATEGORY	**CLAIM**	**CONDITIONS OF USE/RESTRICTIONS OF USE**	**EFSA OPINION REFERENCE**
Calcium and vitamin D	Calcium and vitamin D help to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures	The claim may be used only for food supplements which provide at least 400 mg of calcium and 15 µg of vitamin D per daily portion. Information shall be given to the consumer that the claim is specifically intended for women 50 years and older and the beneficial effect is obtained with a daily intake of at least 1 200 mg of calcium and 20 µg of vitamin D from all sources. For food supplements with added calcium and vitamin D the claim may be used only for those targeting women 50 years and older	Q-2008-721, Q-2009-00940
Monounsaturated and/or polyunsaturated fatty acids	Replacing saturated fats with unsaturated fats in the diet has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of	The claim may be used only for food which is high in unsaturated fatty acids, as referred to in the claim HIGH UNSATURATED FAT as listed in the Annex to Regulation (EC) No 1924/2006. The claim may only be used on fats and oils	Q-2009-00458

	coronary heart disease		
Vitamin D	Vitamin D helps to reduce the risk of falling associated with postural instability and muscle weakness. Falling is a risk factor for bone fractures among men and women 60 years of age and older.	The claim may be used only for food supplements which provide at least 15 µg of vitamin D per daily portion. Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 20 µg of vitamin D from all sources. For food supplements with added vitamin D the claim may be used only for those targeting men and women 60 years and older	Q-2010-01233
Barley beta-glucans	Barley beta-glucans has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.	Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of barley beta-glucan. The claim can be used for foods which provide at least 1 g of barley beta-glucan per quantified portion.	Q-2011-00798
Barley beta-glucans	Barley beta-glucans has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease	Information shall be given to the consumer that the beneficial effect is obtained with daily intake of 3 g of barley beta-glucan. The claim can be used for foods which provide at least 1 g of barley beta-glucan per quantified portion.	Q-2011-00799
Sugar-free chewing gum	Sugar-free chewing gum helps neutralise plaque acids. Plaque acids are a risk factor in the development of dental caries.	Information shall be given to the consumer that the beneficial effect is obtained with chewing of 2-3 g of sugar-free chewing gum for 20 minutes, at least three times per day after meals.	Q-2010-00120
Sugar-free chewing gum	Sugar-free chewing gum helps reduce tooth demineralisation. Tooth demineralisation is a risk factor in the development of dental caries.	Information shall be given to the consumer that the beneficial effect is obtained with chewing of 2-3 g of sugar-free chewing gum for 20 minutes, at least three times per day after meals.	Q-2010-00119
Oat beta-glucan	Oat beta-glucan has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease	Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of oat beta-glucan. The claim can be used for foods which provide at least 1g of oat beta glucan per quantified portion.	Q-2008-681
Plant sterols/Plant stanol esters	Plant sterols and plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.	Information to the consumer that the beneficial effect is obtained with a daily intake of 1,5-3 g plant sterols/stanols. Reference to the magnitude of the effect may only be made for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude of the effect, the range "7 % to 10 %" for foods that provide a daily intake of 1,5-2,4 g plant sterols/stanols or the range "10 % to 12,5 %" for foods that provide a daily intake of 2,5-3 g plant sterols/stanols and the duration to obtain the effect "in 2 to 3 weeks" must be communicated to the consumer.	Q-2008-779, Q-2009-00530 & Q-2009-00718, Q-2011-01241
Plant sterols: Sterols extracted from plants, free or esterified with food grade fatty acids.	Plant sterols have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.	Information to the consumer that the beneficial effect is obtained with a daily intake of 1,5-3 g plant sterols. Reference to the magnitude of the effect may only be made for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude of the effect, the range "7 % to 10 %" for foods that provide a daily intake of 1,5-2,4 g plant sterols or the range "10 % to 12,5 %" for foods that provide a daily intake of 2,5-3 g plant sterols and the duration to obtain the effect "in 2 to 3 weeks" must be communicated to the consumer.	Q-2008-085, Q-2009-530 and Q-2009-718, Q-2011-01241

Plant stanol esters	Plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.	Information to the consumer that the beneficial effect is obtained with a daily intake of 1,5-3 g plant stanols. Reference to the magnitude of the effect may only be made for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude of the effect, the range "7 % to 10 %" for foods that provide a daily intake of 1,5-2,4 g plant stanols or the range "10 %-12,5 %" for foods that provide a daily intake of 2,5-3 g plant stanols and the duration to obtain the effect "in 2 to 3 weeks" must be communicated to the consumer.	Q-2008-118, Q-2009-00530 & Q-2009-00718, Q-2011-00851, Q-2011-01241
Chewing gum sweetened with 100% xylitol	Chewing gum sweetened with 100% xylitol has been shown to reduce dental plaque. High content/level of dental plaque is a risk factor in the development of caries in children	Information to the consumer that the beneficial effect is obtained with a consumption of 2-3g of chewing gum sweetened with 100% xylitol at least 3 times per day after the meals	Q-2008-321
Folic Acid	Supplemental folic acid intake increases maternal folate status. Low maternal folate status is a risk factor in the development of neural tube defects in the developing foetus.	The claim may be used only for food supplements which provide at least 400 µg of folic acid per daily portion. Information shall be provided to the consumer that the target population is women of child-bearing age and the beneficial effect is obtained with a supplemental folic acid daily intake of 400 µg for at least one month before and up to three months after conception.	Q-2013-00265
Calcium	Calcium helps to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures	The claim may be used only for food which provides at least 400 mg of calcium per quantified portion. Information shall be given to the consumer that the claim is specifically intended for women 50 years and older and the beneficial effect is obtained with a daily intake of at least 1 200 mg of calcium from all sources. For foods with added calcium the claim may be used only for those targeting women 50 years and older	Q-2008-721, Q-2009-00940

Figure 3-6: Reduction of disease risk claims authorized by EFSA (European Commission, 2020).

3.1.5 The nutrient profiles

As stated in article 5 of Regulation 1924/2006 the European Commission should have established specific nutrient profiles, including exemptions, which food must comply with in order to bear nutrition or health claims by January 2009. However, more than 10 years later we are still waiting for it.

The nutrient profiles play a very important role in order to prevent unhealthy foods from appearing healthier than they are by claiming nutrition or health. The nutrient profiles work as a filter, establishing criteria that decide whether a food product is healthy enough to bear a nutrition or health claim by setting maximum levels of worrying nutrients such as fat, sugar and salt. If a product not fit the nutrient profiles it would not be allowed to bear any health and nutrition claims. Nutrient profiles are needed to permit consumers to make healthier

choices in the context of a balanced diet and prevent the use of misleading claims that give a healthy image to products with a high content of sugar, salt or fat.

As stated in the article 5 of Regulation 1924/2006 the nutrient profiles shall be defined taking into account in particular:

(a) the quantities of certain nutrients and other substances contained in the food, such as fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium;

(b) the role and importance of the food (or of categories of food) and the contribution to the diet of the population in general or, as appropriate, of certain risk groups including children;

(c) the overall nutritional composition of the food and the presence of nutrients that have been scientifically recognised as having an effect on health.

In addition *"the nutrient profiles shall be based on scientific knowledge about diet and nutrition, and their relation to health".*

The profiles works differently depending on the type of claims:

- For Health claims (for example: 'Good for your bones', 'Good for your health')

If a product contains too much of either fat, saturated fat, trans fat, sugar, salt, it is not allowed to bear any health claims.

- For Nutritional claims (for example: 'Low in fat', 'High in fibre')

If a product is above the threshold for only one nutrient, it can only bear a nutrition claim if it states next to this claim which of these nutrients is high in content (for instance 'High in calcium' + 'High in sugar').

In this scenario, consumer organisations have repeatedly called on the Commission to create such profiles over the past 10 years. In 2018, The European Consumer Organization, BEUC, and 11 of its member organisations found numerous examples of unhealthy foods marketed as healthy and have called on the European Commission to tackle unhealthy food and drink products that still make heath-related claims. However, nothing has happened yet.

3.2 Other Regulations

The European legal framework for functional foods remains quite complex. In fact, due to the fact that there is no regulatory definition of "Functional Food", various types of foods fall or could fall into this category and follow different regulations.

However, it's important to remind that functional food in Europe fall under the category of "food products", as defined by the definition of the ILSI-FUFOSE project. The EU regulation governing all food production is constituted by Regulation (EC) 178/2002, called

General Food Law Regulation, which establishes “the general principles and requirements of food law, establishes the European Food Safety Authority and lays down procedures in matters of food safety".

This Regulation does not identify functional food as a food category on its own, therefore, functional foods must comply with the general rules laid down for any other food products. In particular, Regulation 178/2002 governs "all stages of food production, processing and distribution of foods", is focused on the general principles for food law and in particular about food safety and risk analysis, in order to guarantee a high level of consumers’ protection. It establishes the European Food Safety Authority which plays a central role in European food safety risk assessment.

However, there are other different legislations that can be applied to functional foods, depending on their type of functionality or the origin of the functional compounds or the different methodologies used to produce them. For example, some functional foods, certainly not all, can be classified as "novel food" (Robertfroid M., 2002) because “not yet used to any significant extent”. Some functional foods can be part of the novel food group, as their production has started very recently and their chemical composition is often changed by adding or removing a component, leading to the production of a completely new product, unprecedented on the market. ‘Novel Foods’ legislation called Regulation EU No 2015/2283, which replaces Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001, is applied to all categories of foods, included functional foods, that ‘were not used for human consumption to a significant degree’ within the European Union before 15 May 1997.

Certain functional foods, in particular the category of enriched or fortified foods, is regulated by EC Regulation No 1925/2006 about “the addition of vitamins and minerals and of certain other substances to foods”. Regulation (EC) No 1925/2006, amended by Regulation (EC) No 108/2008 of the European Parliament and of the Council, harmonises the national provisions regarding the addition of substances to foods and has the scope of ensuring the effective functioning of the internal market and guarantee a high level of consumer protection. This Regulation does not apply to food supplements and applies without prejudice to the specific provisions of Community legislation on:

(a) *foods for particular nutritional uses and, in the absence of specific provisions, compositional requirements of such products rendered necessary by the particular nutritional requirements of the persons for whom they are intended;*

(b) *novel foods and novel food ingredients;*

(c) *genetically modified food;*

(d) *food additives and flavourings;*

(e) *authorised oenological practices and processes* (EC 1925/2006, article 1,3).

As stated in article 3 of chapter II, the addition of vitamins and / or minerals to foods are only permitted if they are present in the list of Annex I of the Regulation and only in the forms established in the list of Annex II, named "Vitamin formulations and mineral substances which may be added to foods". In addition, vitamins and minerals can be added to foods in a form that is bio-available to the human organism and only if one takes into account:

(a) *a deficiency of one or more vitamins and/or minerals in the population or specific population groups that can be demonstrated by clinical or sub-clinical evidence of deficiency or indicated by estimated low levels of intake of nutrients;* or

(b) *the potential to improve the nutritional status of the population or specific population groups and/or correct possible deficiencies in dietary intakes of vitamins or minerals due to changes in dietary habits*; or

(c) *evolving generally acceptable scientific knowledge on the role of vitamins and minerals in nutrition and consequent effects on health.*

The addition of vitamins and minerals is not allowed on unprocessed foodstuffs, such as fruit, vegetables, meat, poultry and fish, and in beverages containing more than 1,2 % by volume of alcohol. In articles 5 and 6 are indicated the purity criteria for the vitamins formulations and mineral substances and the conditions for their additions.

Furthermore, regard the addition of certain other substances to foods, the Regulation in Annex III, provide a list of substances, other than vitamins or minerals, whose use in foods is: prohibited, restricted or under Community scrutiny.

Table 3-2: Main functional foods regulations (own elaboration).

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
COMMISSION REGULATION (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health
COMMISSION REGULATION (EU) No 1047/2012 of 8 November 2012 amending Regulation (EC) No 1924/2006 with regard to the list of nutrition claims
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
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
REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001

Chapter 4
LITERATURE REVIEW

4.1 Introduction

This section reviews previous studies on factors that influence consumer acceptance and preferences towards functional foods. Previous studies revealed many factors that influence functional food choices among consumers. However, they vary widely in terms of their object (consumer awareness of the concept, attitude towards functional foods, acceptance, choice), their methodologies used (qualitative or exploratory vs. quantitative or conclusive) and their results.

The literature review collects a lot of research on the preferences and acceptance of the consumers and their willingness to pay for functional foods. Scientific articles for the analysis of the literature were derived from online academic search engines such as Scopus, ScienceDirect and Google scholar. The investigation into the bibliography on functional foods was aimed to understand consumers' awareness, perceptions and attitudes in order to better know the behaviour and the factors that determine the purchase intention towards functional foods. Knowing consumer behaviours, for a company, is at the base of successful marketing strategies for the price, the positioning, the design and the promotion of a product (Askegaard et al 2006; Blythe 2008). Understanding consumer attitudes can be used to better perceive consumer behaviour about a product, service or idea (Ajzen and Fishbein 2005).

Many food companies, due to increasing margins and growing global market about foods with health-enhancing properties, have been developing new nutrition-modified and functional products (Khan, Grigor, Win, & Boland, 2014). However, contrary to these market estimates there is a high risk of product failure as nearly 70-90 per cent of novel functional food products leave the market within the first two years of their placing on the market (Hardy, 2010; Heasman & Mellentin, 2001; Stein & Rodríguez-Cerezo, 2008). One reason for the high failure rates is that companies are often more focus on technical feasibility (Bleiel, 2010) when designing their product and neglect consumers' preferences and acceptance (Van Kleef, van Trijp, & Luning, 2005). By using this approach, companies

produce new health-enhancing products in the market with features that do not meet consumer need (Van Kleef, van Trijp, Luning, & Jongen, 2002).

There are many researches that having given importance towards consumers' acceptance and preferences about functional foods (Ares & Gámbaro, 2007; Van Kleef et al., 2002;

Verbeke, 2005). However, knowledge is fragmented and the results seem difficult to reconcile because they come from different studies and managed in different contexts. Many of these scientific articles are based on only one or few features of consumers' behaviour and for this reason are not able to give a complete image of all the elements that affect the preferences and the acceptance of functional foods (Starling, 2014).

The systematic review is one approach that can be useful to collect important knowledge in fragmented fields, it consists of selecting several studies using a multi-step procedure (Cooper, 1998; Littell & College, 2006) and also permits an evaluation of their quality (Littell, Corcoran, & Pillai, 2008). Özen et al. (2012) and Özen et al. (2014) are two systematic reviews of functional foods. The first review analyses several studies on individual consumption of different categories of functional food products. According to the authors it was not possible to recognize how gender, age, level of education and socio-economic characteristics are aspects of consumers that influence the consumption of functional foods.

Similarly, the second study conducted by Özen et al. (2014), focused on research on European consumers, showed higher consumption of functional food in Northern Europe but didn't identify gender differences as a parameter influencing consumer consumption.

One of the likely reasons for the contradictory results highlighted in these reviews, may be due to the fact that the authors considered studies that focused on different functional food products and for which the preferences and acceptance of consumers can be intrinsically different. Therefore, consumers having different attitudes in different categories of functional food products, have prevented the authors from identifying patterns characterizing consumption.

These results are in contrast with other literature reviews (such as Sirò et al., 2008 and Lähteenmäki, 2013) which have instead identified specific patterns affecting consumers acceptance for functional foods, such as the role of consumer-related characteristics (gender, age and some psychological variables) and other product-related characteristics.

Finally, in order to take an overview of the previous studies on consumers acceptance and preferences for functional foods, we have classified the multiple factors that affected them, in two main categories:

1. consumers-related-characteristics category that comprehends: personal factors as age, gender, health consciousness, familiarity, income and education; psychological factors as health motivation, consumers attitude and food neophobia; and cultural and social factors.
2. product-related-characteristics category composed by factors related to price, taste, brand, features of the package and labelling.

Among them, the main factors that first affect the purchase decision of consumers are labelling, health motivation and consumers attitudes towards functional foods. These factors are interrelated, as consumers motivated to maintain and improve their health, tend to be more interested in the labelling information and show positive attitudes towards the purchase of functional foods.

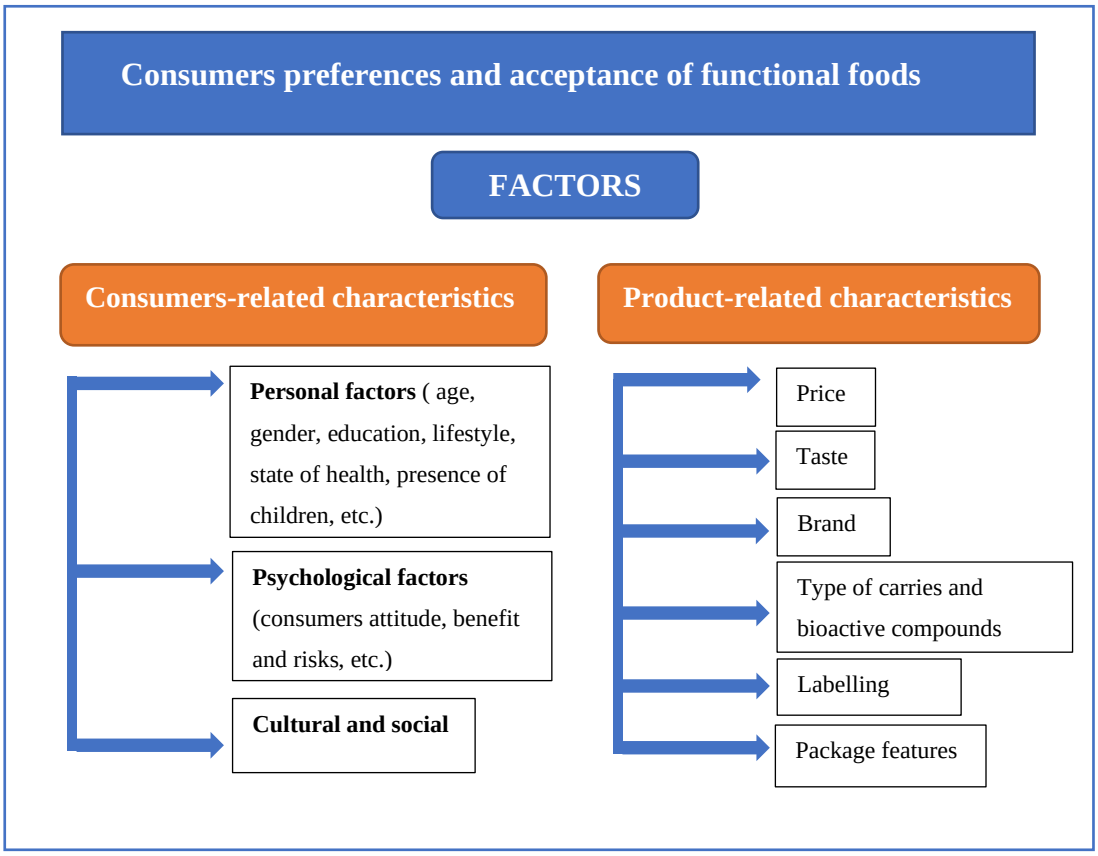


Figure 4-1: Consumers preferences and acceptance of functional foods and the general factors affecting them (Own elaboration).

4.2 Consumer-related-characteristics category

4.2.1 Personal factors

Gender

In line with this evidence, the article of Bimbo et al.,(2017), by using a systematic literature review methodology, has tried to identify common patterns in consumers' acceptance and preferences by focusing on one specific product category, functional dairy products. The findings of this systematic review confirmed the existence of consumer-related and product-related characteristics in the acceptance and preference for functional dairy products. Regard the consumer-related characteristics, the majority of the studies reviewed have shown the gender dimension, highlighting that women have higher levels of acceptance than men for functional dairy products and in particular for products that have a role in intestinal well-being, weight loss and bone health. Having a higher risk of developing osteoporosis than males, females prefer the consumption of functional dairy products that promote bone health (Ares & Gámbaro, 2007; Hailu et al., 2009). Other studies confirmed the preferences of females, in particular the findings obtained by Hailu, Boecker, Henson, and Cranfield (2009) have shown that Canadian females consumers prefer yogurt as a carrier for probiotics rather than ice cream or using pills. Even the study conducted by Annunziata and Vecchio (2013) obtained the preferences of Italian females consumers for functional dairy products, and in particular for yogurt with probiotics. Other findings from Landström, Hursti, Becker, and Magnusson (2007) found that female Swedish consumers consume and purchase more functional foods and particularly probiotic milk products. In contrast with previous results, the study of de Jong et al., (2003) didn't identify in the Dutch population the gender dimensions as positively connected with the consumption of yogurt with lactic acid bacteria. Similar results were obtained in other studies in which gender difference was not related to the acceptance of yogurt added with CLA (Conjugated Linoleic Acid), omega-3 (Cox et al., 2011; Peng et al., 2006) and antioxidants (Ares et al., 2010b) and other unknown ingredients conferring some health benefits to yogurt (Siegrist et al.,2008). The likely reasons for the lack of gender correlation were due to a general absence of consumers' interest in yogurt with CLA or omega-3, an absence of familiarity with the word "antioxidants" and the suspicion for health claims not related to specific functional compounds. In general, familiarity with the product, trust and suspiciousness are factors that can affect the acceptability of functional food products, because are strongly linked with their novelty side (Bower, Saadat, & Whitten, 2003; Urala & Lähteenmäki, 2007; Barrena & Sanchez, 2010). Urala & Lähteenmäki (2007) found in the Finnish consumers no differences

about the gender dimensions for the acceptance of probiotic/stomach-friendly yogurt and blood pressure-lowering milk drinks.

In general, it seems that female, especially if mother, are more likely to buy functional foods than male, because woman tends to get more information about food and health issues. In addition, women usually play a central role in preparing and is the person responsible to buy food for the family, for these reasons have more opportunities to interact with functional foods (Cranfield et al., 2011).

Age

Age is a socio-demographic factor that can influence the demand for functional foods. Studies have found mixed results. Some studies, in fact, identify individuals in adulthood and the elderly who are more focused on nutrition and healthy eating than young people, especially those who suffer from health problems related to aging (diabetes, osteoporosis, hypertension and cardiovascular diseases, etc.). Consequently, the adult population has a greater demand for functional foods in order to limit the negative effects of aging and reduce, if possible, the use of medicines (Bonanno, 2012). On the other hand, other studies show that younger population groups, particularly between the ages of 20 and 39, have a higher consumption of functional foods than older population groups, because functional foods are a relatively new concept and therefore more easily "accessible" by the younger population (Cranfield et al., 2011).

Many scientific articles found that older people have a higher interest toward dairy products with health-enhancing properties. Urala and Lähteenmäki (2004; 2007) confirmed that among Finnish consumers, older people were more willing to use functional foods with claims related to reducing the risk of diseases, for instance milk drinks that lower blood pressure (Urala and Lähteenmäki, 2004). The perceived reward for this category of products is higher among older than younger people, because they can contrast health problems linked to aging (Urala and Lähteenmäki, 2007). Urala and Lähteenmäki (2004; 2007) demonstrate that the best predictor for the willingness to use functional foods was the perceived reward from using them.

Another study conducted by Messina et al. (2008) found the same results of the previous one, identifying as likely reason the longer exposure to functional products than younger consumers ((Messina et al., 2008; Urala & Lähteenmäki, 2004; 2007).

Therefore, older consumers have higher acceptability of functional foods due to higher knowledge and familiarity and their effects on health.

De Jong, Ocké, Branderhorst, and Friele (2003) identified that being 65 or older is positively linked with higher consumption of many functional foods, for example yogurt with lactic acid bacteria. Both Bonanno's (2012) study on Italian consumers and Chase et al.'s (2009) on Canadian consumers, found that the demand for functional yogurts and omega-3 added dairy products increase as they become older.

However, the study conducted by Urala & Lähteenmäki (2004) and Hailu et al., (2009) show a higher acceptance by younger consumers about functional foods enhancing some physiological functions, for instance, some related to improve general well-being or those help to prevent fatigue.

In contrast, Landström et al., (2007) didn't identify differences in the acceptance for functional dairy products among different ages groups.

In brief, the most of studies identified in the systematic literature review of Bimbo et al.,(2017), indicates that older consumer has higher acceptability of functional products, in particular nutrition-modified and functional dairy products, and are more willing to use and include them in their diet. Thus, older people are the groups of consumers willing to accept such products, in particular functional foods with the risk reduction health claims.

Other personal factors

Many studies identified two good predictors for the acceptability of consumers for some functional food products, such as probiotics yogurt, products with added calcium, antioxidant and fiber. These predictors are variables linked to the level of knowledge of consumers regarding the relationship between health and nutrition (Ares, Giménez, & Gámbaro, 2008; Øvrum et al., 2012) and also the general nutritional knowledge of consumers (Labrecque, Doyon, Bellavance, & Kolodinsky, 2006; Wahba, Arrafa, Saleh, Mekkawy, & Ahmed, 2006; Viana, Cruz, Zoellner, Silva, & Batista, 2008; Barenna & Sànchez, 2010).

However, many other factors may affect the relationship between the consumers' knowledge related to the diet and health and their acceptability or preferences for functional food products, for instance, the size of the family and the presence of young children in the household. In families with young children, below 12 years of age, parents feel great responsibilities toward the health of their children (Annunziata & Vecchio, 2013; Barrios, Bayarri, Carbonell, Izquierdo, & Costell, 2008) and for this reason they have a greater tendency to stay informed and gain more knowledge about diet, health and nutrition. Likewise, individuals who have had a direct or indirect relationship with diseases show more

interest in being informed about diet and health related issues. (Van Kleef, 2005a; Annunziata & Vecchio, 2013).

Several studies have shown that the state of health and the presence of diseases (such as diabetes, hypertension and obesity) are one of the main factors that affect the decision to purchase functional foods (Sirò et al., 2008). According to this, the state of health is much more decisive than socio-demographic factors in influencing the demand for functional foods. Moreover, some nutritionists promote functional foods in order to reduce the risk of food-related diseases and consumers see them as an alternative to drugs, as they are more natural and with fewer side effects. In particular, groups of the adult population, more prone to diseases such as diabetes, osteoporosis and dysfunctions of the cardiovascular system, have a greater awareness of the role of nutrition in maintaining health and preventing specific diseases and have a greater acceptance for functional foods.

In addition, the consumer's cultural level and educational background can affect the demand for functional foods. For instance, some studies shown that people with a good scientific educational background are more aware of the health benefits related to functional foods and, therefore, more likely to buy them (Urala and Lahteenmaki, 2004).

Finally, other studies indicate lifestyle variables, such as practicing sport and taking supplements, influencing the acceptability of functional foods products, because consumers "wellness oriented" are more willing to renounce the taste of food for health benefits (Landström et al., 2007; Zandstra, de Graaf, & Van Staveren, 2001). Even though, at first glance, the health oriented consumer groups can be seen as the ideal target for foods with health-enhancing properties, they are only a niche market. The efforts of food manufacturers could otherwise be directed at improving the taste of functional food products to expand their potential market and reduce their price, because these are the main barriers to the consumption of healthy products. (Frewer, Scholderer, & Lambert, 2003; Landström,, Hursti, & Magnusson, 2009).

4.2.2 Psychological factors

Many studies focused on how psychological factors, recorded through specific scales, can affect the preferences of consumers for health-enhancing foods products. Some studies found that consumers' attitude towards health and taste has an important role in the acceptance of functional and nutrition-modified foods. However, the attitude of consumers towards functional foods is difficult to evaluate because it changes depending on the type of functional food itself (Urala & Lähteenmäki, 2004).

A study conducted by Labrecque et al. (2006) found that the attitudes towards health and taste can concur to explain intercultural preferences for milk with omega-3 between Canadian, French and American students, in spite of their low level of consumption.

The studies of Urala & Lähteenmäki (2004); (2007) concluded that functional foods are different from “conventional” healthy foods and so the general health scale was not a good predictor for the consumers’ selection of functional foods. For this reason, they developed and utilized seven scales to predict the consumers’ willingness to buy functional foods. These authors determined that the "perceived reward of improving one's health and performance" best predicted consumers' willingness to consume calcium-added milk, blood pressure-lowering milk drinks, and low-fat cheese. However, food habits and culture are different across different countries, so the perceived reward from using functional foods can only predict the Finnish consumers’ willingness to consume functional dairy products.

In addition, functional foods can also be designed by adding bioactive compounds to a food carrier, these newly added ingredients can affect acceptance of the whole product. Some studies have focused on the acceptance of consumers towards a new combination of functional ingredients and dairy products by adopting the food-neophobia scale, proposed by Pliner and Hobden (1992). Empirical results from different studies demonstrate the negative correlation of the food-neophobia with the consumers’ willingness to purchase probiotic yogurt, but also that food-neophobia does not influence consumers’ willingness to purchase other non-dairy functional food products (Siegrist et al., 2008). Furthermore, Urala and Lähteenmäki (2007) found the negative correlation between consumers’ neophobia and willingness to consume probiotic yogurts, while they found that consumers’ neophobia does not influence the consumption of other functional foods, like cholesterol-lowering spreads or blood pressure lowering milk. On the other hand, food neophobia may play a different role depending on the different bioactive compounds-carriers combinations. Furthermore, consumers with a high level of cholesterol in their blood, may feel a “virtual prescription” for food products that lower cholesterol and medical applications could suppress neophobia or risk perception (Alevizos, Mihas, & Mariolis, 2007). Therefore, Urala and Lähteenmäki (2007) results can be partial because they didn’t take in consideration the presence of cholesterol health problems in their respondents.

Products with health-enhancing properties have a relatively recent market introduction and the main goal of some studies was to investigate the relationship between consumers’ attitudes towards food innovation and the acceptance of these new products. Almli et al (2011) study had the objective to identify the preferences towards traditional cheese added

with omega-3 among French and Norwegian consumers. In neither country the addition of omega-3 in traditional cheeses had a positive influence on the willingness to purchase the product. Although the results of Almli et al. (2011) showed the presence of consumers' aversion towards innovative health-food combinations, their discovery may be partly due to consumers' aversion to omega-3 and dairy products combinations.

Cox, Evans, and Lease (2007) by using another approach in their study, a Protection Motivation Theory framework (Rogers et al., 1975), they identified the perceived self-efficacy as the best predictor for the probability to buy milk added with omega-3 in a sample of Australian consumers. The authors found that milk added with omega-3 had the low probability to be bought respect to other carrier with omega-3 (Cox et al., 2007).

In summary, as noted by the studies review, the psychological factors has an important role in affecting the consumers' acceptance and preferences for nutrition-modified and functional products. If consumers perceive and believe in the health-enhancing properties of the products for themselves or other closed people, they tend to be more interested in them.

4.3 Product-related-characteristics category

Type of carrier and bioactive compounds

Many literature studies evaluate consumers' acceptance and preferences in relation to the product characteristics and also consumers' perceived healthiness of different combinations of food carriers and ingredients. The intrinsic characteristics of the product are any informative stimuli that are physically part of the product and if modified, alter the essence of the product itself (Poulson et al., 1996). For functional food products and nutrition-modified foods, the intrinsic product characteristics are any combinations of bioactive compounds or functional ingredients and the type of carrier utilized.

Many studies have focused on consumers' perceived healthiness to nutrition-modified and functional foods, because the latter is strongly correlated to the success in the market of the product and it was established to be affected by both intrinsic and extrinsic product characteristics. It is usually calculated by using a seven-point Likert scale with a range from 1, 'not healthy', to 7, 'extremely healthy' (Bech-Larsen & Grunert, 2003). The combination of carriers-ingredients with the highest perceived health outcomes has a higher likelihood of being accepted by consumers and successful in the market (Grunert, 2000; Bech-Larsen & Grunert, 2003; Krutulyte et al., 2008, 2011; Johansen et al., 2011; Cox et al., 2011).

Several studies have identified that the perceived healthiness of dairy products depends on consumers' perceived healthiness of the carrier (Ares et al., 2008;Hailu et al., 2009).

Some research has shown that consumer interest in functional food is affected by the type of carrier enriched with different bioactive compounds (Annunziata and Vecchio, 2011). In particular, consumers are more likely to buy functional foods in which the carrier is already healthy or has an “healthy image”, such as yogurt with probiotic, vitaminized fruit juices and cereals enriched with fiber, etc.

Van Kleef et al., (2005a); Hailu et al., (2009); Johansen et al., (2011) found that yogurt is perceived as the healthiest among other carriers, maybe because yogurt is considered to be intrinsically healthy. In addition, other studies pointed out that consumers have major acceptance for certain ingredients such as calcium and fiber and perceive greater healthiness of functional foods in which the bioactive compound is “naturally added” or it is inherent to the carrier (Cox et al., 2011; Krutulyte et al., 2008, 2011). For example, consumers perceive yogurt with the addition of calcium to be healthier than yogurt with the addition of fiber, antioxidants and iron (Ares &, Gámbaro 2007). Instead, consumers have a negative perception of added omega-3 yogurts because the yogurt-omega-3 combination is perceived to be less natural than, for example, the combination of omega-3 and seafood products (Krutulyte et al., 2011). Furthermore, consumers associate the taste of omega-3 with fish and are skeptical of combining it with the sweet taste of yogurt. They also have some doubts about adding omega-3 to yogurt due to the potential of unpleasant flavours formation. (Krutulyte et al., 2011). The study conducted by Chase, Emunu, Nilsson, McCann-Hiltz, and Peng (2009), among Canadian consumers, confirmed their low acceptance for omega-3 added dairy products. They showed that over 90% of the families surveyed had never purchased products with added omega-3. Conversely, a greater acceptance of omega-3 added dairy products were found among people perceiving the health risks associated with a metabolic syndrome (O'Brien et al., 2012). Some studies have focused on whether and how adding "external" ingredients to an unhealthy product can improve its acceptance. Bech-Larsen & Grunert, (2003); Peng et al.,(2006) found that for example cheeses or spreads, which are carriers with an unhealthy public perception due to high cholesterol content, were perceived as optimal carriers for the adding of bioactive compounds such as polyunsaturated fat or omega-3, alleviating the negative consequence of cholesterol on health. In these cases consumers can prefer functional food dairy products whose bioactive compounds “improve” their innate or intrinsic characteristics, maintaining the same sensory properties, without being influenced by the fact that the ingredient is a "natural" addition to the vector or is external to it.

In light of these results, a "natural" connection among the carrier and the added bioactive compound, increases consumers' acceptance of functional dairy products with health-enhancing properties.

Labelling

A product's label and its components are examples of extrinsic product characteristics, these can be defined as informational stimuli which are not physically part of the product (Grunert, Hartvig Larsen, Madsen, & Baadsgaard,1996).

About functional foods with health enhancing properties, the extrinsic product characteristics are nutrition and health claims present on the label, their brand and their package. These are important elements used to inform consumers about the products and their properties and are also involved to influence and attract consumers to buy.

The current literature gives different results about the nutrition and health claims' influence on the consumers' acceptance of functional foods, in particular for dairy products (Ares et al., 2009,2010b; Bech-Larsen & Grunert, 2003).

Ares et al., (2009) and Bech-Larsen & Grunert, (2003) studies found that consumers prefer dairy products with nutrition and health claims rather than without, indicating that the perceived healthiness of labelled products and their acceptance is higher.

Contrary to previous findings, the report by Lähteenmäki et al. (2010) among Northern European consumers, didn't find any effect of the presence of health claims on a product on their perceived healthiness.

Other studies (Marette, Roosen, Blanchemanche, & Feinblatt - Mélèze, 2010; Øvrum et al., 2012), show that the presence of nutrition and health claims may help some groups of consumers to choose healthier food options and for this reasons they are willing to pay more for those products. These groups can be female consumers who have knowledge of diet and health (Øvrum et al., 2012) and also consumers having chronic diseases (Marette et al., 2010), they take in considerations the presence of health and nutrition claims during their food purchasing process and are willing to pay a premium price for functional foods with health-enhancing properties (Marette et al., 2010; Øvrum et al., 2012).

On the other hand, other studies show that the presence of nutritional claim on dairy products with reduced fats content, can negatively affect the consumers' perceived pleasantness (Johansen et al., 2011; Kähkönen & Tuorila, 1999). However, for groups of consumers that are health-conscious and are focused on healthy eating, they have less demands regard food taste and the negative effect on perceived pleasantness is alleviate (Johansen et al., 2011).

In the market there are different types of health claims, with different levels of health effectiveness and different health benefits, for example cholesterol-lowering effects, immune system support and bone health support (Bimbo, Bonanno, & Viscecchia, 2016).

Van Kleef et al., (2005a) and Williams, Ridges, Batterham, Ripper, & Hung, (2008) found that consumers tend to prefer health claims to nutritional claims, and the 'Risk Reduction Claims' to 'Function Health Claims'. Consumers preferring risk reduction claims are found to be highly educated females with direct or indirect exposure to diseases, but also in consumers with a high level of knowledge about the diet and health (Ares et al., 2010b; Williams et al., 2008), and in consumers taking nutritional supplements (Hailu et al., 2009).

Similar results were found in the study conducted by Annunziata and Vecchio (2013). In their research, they identified a consumer group consisting mainly of highly educated women with children under 12 years of age and of health conscious-consumers, who preferred risk reduction claims than others, on functional dairy products; the other group of consumers identified, preferred health claims for general functions such as for the improvement of general well-being (Annunziata & Vecchio, 2013). These results do not represent a defined pattern in consumer acceptance of nutrition and health claims on the market. The results may differ depending on the consumer groups considered and on the relevance of the specific claim for them.

However, many studies identified females with knowledge about diet and health and people with chronic disease to be the main consumers' group that take into account the presence of nutritional and health claims during their food decision process and also are willing to pay a premium price for health-enhancing food products. In addition, consumers interested in food health claims can have a greater capacity to comprehend them and to elaborate their information (Nocella & Kennedy, 2012). Furthermore, product claims are often difficult to understand and expressed in complex terms, so to increase consumer acceptability and the likelihood of product success in the market, it is better to make statements that are shorter and easier to understand (Siegrist et al.,2008).

Brand

One of the most significant extrinsic product characteristics in affecting consumers' food decision-making process is the brand (Deliza and MacFie, 1996). The brands are symbols of quality and guarantee the veracity of the labelling on the packaging of the manufacturer (Deliza & MacFie, 1996). In line with this evidence there are several studies evaluating consumers' acceptance and preferences for nutrition modified and functional foods

(Annunziata & Vecchio, 2013; Ares & Deliza, 2010; Barrena & Sanchez, 2010; Ares et al., 2010a).

Messina et al. (2008) found that brands influence older consumers in different ways, depending on their countries, for instance older consumers from South America and South Europe are more influenced in their purchasing decisions than those from other countries. Another study by Ares et al. (2010a) showed that brand affects willingness to buy functional milk dessert, while Ares et al. (2010b) found that the first attribute that affects consumer's preferences for functional yogurts among middle aged females, was the carrier while the second was the brand.

Annunziata and Vecchio (2013) showed similar results, actually the brand influences consumers' decision process for probiotics yogurts among a group of Italian consumers with an average educational level, less likely to undertake healthy eating habits, and low consumption of probiotics yogurts (Annunziata & Vecchio, 2013); Furthermore, they found that brand's influence on consumer choices increases with consumers' familiarity with the brand, while brands do not influence food choices in health-conscious consumers (Annunziata & Vecchio, 2013), confirming results of other studies (Barrios et al.,2008; Ares et al., 2010b).

Similar results showed that the products' brand positively influences consumer's attitudes and preferences towards functional food products (Barrena & Sanchez, 2010; Ares & Deliza, 2010). The study conducted by Barrena & Sanchez (2010) pointed out that consumers' familiarity with the brand is one of the characteristics of the products affecting families' decisions to buy probiotic dairy products. Ares and Deliza (2010) found that among the characteristics of the package of nutrition-modified milk products that influence the decision process to purchase, the brand was one of the attributes most frequently involved after the flavour, colour and shape of the package.

Furthermore, other studies show that consumers are positively influenced to buy functional foods from a recognized brand, on the contrary they are more sceptical of functional foods from less famous brands (Krystallis & Chrysochou, 2012).

In summary, there appears to be a widespread consensus that the brand increase acceptability and influence positively the consumers' decision making to buy nutrition-modified and functional food products rather than conventional food. This influence is particularly strong among consumers who are less likely to adopt a healthy lifestyle, while it appears to have no effect on the food choices of health-conscious consumers. Nevertheless, these results may be different depending on consumer's country, with differences in their

educational level, in the amount of individuals who are health conscious and engage in healthy lifestyle and also have a different development stage of functional foods' market.

Features packaging

Finally, another extrinsic product characteristic that attract and affect consumer's decisions to purchase health-enhancing products is the packaging. Ares and Deliza (2010) analysed the effect of the attributes of the package on consumers decision to buy nutrition-modified chocolate milk products. They pointed out that the major packaging's attributes that influence consumer willingness to purchase, were the color and shape and in particular the brown package color increase this influence on purchasing such milk products. However, Ares and Deliza (2010) identified also that the shape of package shows different effects on the influence of consumers to buy a low-fat dessert, depending on the fact that the shape of the packaging creates in the consumers' mind a specific expectations of the texture of the products (Ares and Deliza, 2010). In summary, the study conducted by Ares and Deliza (2010) shown that the acceptance and willingness of consumers to buy food products is influenced by the characteristics of the product packaging.

Taste

Furthermore, sensory characteristics play an important role in influencing consumers' acceptance of functional foods (Urala & Lähteenmäki, 2007). In particular, taste has a primary role, it is the main factor that influences the choice of consumers among functional foods. In general, consumers are unwilling to compromise on taste for the health benefits provided by functional foods. Conversely, some studies have shown that consumers are willing to compromise taste only for products with strong health claims (Urala & Lähteenmäki, 2004).

Furthermore, sometimes to design a functional food, a modification of the chemical composition can take place, which can lead to modify some organoleptic characteristics, such as taste and aroma. In this regard, several studies show that the consumer gives a primary importance to sensory satisfaction than to the healthy quality of food (Annunziata and Vecchio, 2011). For this reason, if the production technology leads to the modification of the taste or the formation of unpleasant flavours, the consumer is not led to purchase this food, even though he is aware of the beneficial effects deriving from its consumption.

Price

Price influences consumers' purchase decision in several ways: lower purchase intent due to greater monetary sacrifice, or positively impact purchase intent due to a perceived increase in product quality.

The increase awareness in the population of the relation between diet and health, and the role of the diet in prevent certain diseases, has lead consumers to perceive and associate to functional foods an added value. In general, consumers evaluate health as important part of food quality and associate to healthy foods, such as functional foods, an increased utility for which they are willing to pay a premium price for them.

Many socio-economic and demographic factors affect consumers' perception of functional foods such as age, income, education, nutritional knowledge, gender, etc. and also influence functional food choices among consumers. In particular, women are responsible for food choices for the family and are more attentive about food ingredients, the nutritional and healthy aspects of foods and focused on a healthy diet. Furthermore, people with good knowledge about nutrition and / or with high income demand better quality and healthier foods; In addition, elderly people are much more attentive to healthy diet than young people, for obvious physiological reasons (ISMEA, 2007). All these factors could influence the willingness to pay for functional food, in a positive or negative way.

Willingness to Pay (WTP) or Acceptance can be defined as *"the price or amount that someone is willing to pay or accept respectively to consume a good or service or to renounce it"* (Hanemann, 1991; Lusk, Hudson, 2004) or the maximum amount of money that someone must provide to equalize a change of utility. The WTP derives from the demand function and assess the price that an individual is willing to pay for a given quality level. Assuming that the maximum amount an individual would be willing to offer for an asset, it indicates the value of that asset to the individual.

Chapter 5
A CASE STUDY ON FUNCTIONAL FOODS: CONSUMERS' PERCEPTIONS

5.1 Introduction

The purpose of this chapter is to represent the phases of the methodological path used for this study. The data were collected through the administration of an online survey questionnaire. The survey provided a lot of information which, after careful and adequate analysis, was useful to better understand and interpret the consumer's profile, the level of knowledge, interest and perception towards functional foods and the willingness to pay for a specific functional food product.

The data of the survey were collected, checked and organized in a database to carry out subsequent processing.

In particular, the study carried out has two main objectives:

1. Investigate the factors that influence consumers' purchasing behaviour towards functional foods, their knowledge, interest and perception, through an explorative analysis.
2. Estimate the willingness to pay for a defined functional foods products, already present on the market, compared to conventional ones. The econometric analysis aims at identifying the existence of a greater willingness to pay (WTP) for functional foods among consumers, by assessing the premium price and analysing which consumer-related factors may influence the willingness to pay for them.

5.2 Methodology

The objective of this study is to determine factors influencing consumers' purchases of functional foods. In detail, utilizing a survey method, we investigated consumers' awareness, attitude and willingness to buy functional foods. Then a logit model was used to identify the main factors influencing purchasing desires.

5.2.1 Consumers questionnaire design

This analysis was performed by using a survey-based approach with an online questionnaire administered to the interview. The questionnaire contains mainly close-ended questions in which all possible answers are provided, but in some questions it is also possible to enter any answers not indicated.

The consumers' questionnaire mainly explores knowledge, perception and awareness of functional foods among Italian consumers, the reasons for the purchase and consumption or the reasons for not purchase and not consumption and the probable future purchasing behaviour; consumers' attitudes towards functional food, the willingness to pay, consumers' state of health, eating behaviour and lifestyle and finally socio-demographic information.

The questionnaire contains a total of 42 questions and it is structured into 5 main sections:

- Consumers' health and nutrition;
- Consumers' purchasing behaviour towards the label, with a focus on nutritional and health claims;
- Questions related to consumers of functional foods (knowledge, purchasing behaviour and motives, attitude);
- Willingness to pay;
- Socio-demographic information.

Section 1

The first section evaluates the behaviour of consumers with regard to nutrition, in particular the respondents are asked to indicate whether they are usually attentive to their own diet and if they follow a specific diet and, if so, specify the reason why they follow it.

Then, to assess the health of consumers, they are asked to indicate whether they suffer from food allergies and / or intolerances (for example gluten, lactose, ...) and if they suffer from diseases related to poor nutrition (such as: diabetes, cholesterol, obesity, hypertension, etc.). For both questions, if the answer is positive, the interviewee is asked to specify the type of allergy and / or intolerance and the type of pathology.

Finally, to evaluate lifestyles, the interviewee is asked if he/ she practices physical activity and if he/she buys food supplements and how often.

Section 2

In order to evaluate consumer purchasing behaviour towards the label, one of the factors influencing consumers' choice of functional foods, respondents are asked to indicate how

often they usually check the label when purchasing a food product. Then, they are asked to rate, on a Likert scale of 1 to 5 (where: 1: Not important at all; 2: Not important; 3: Important; 4: Very important; 5: Extremely important), how important Nutritional Claims on the packaging of a food product are to them.

Finally, they are asked to rate the three different types of Health Claims (Function Health Claims, Risk Reduction Claims, Claims referring to children's development) based on their level of importance on a scale of 1 to 5.

Section 3

It represents the main section of the questionnaire and can be divided into three different parts:

- Consumers' knowledge of functional foods;
- Consumers' consumption and purchasing habits, motivation for buyers or non-buyers of functional foods;
- Consumers' attitude towards functional foods.

First, in order to evaluate the level of consumers' knowledge, the interviewees are asked if they have ever heard of functional foods. Then, they are asked to provide their definition of functional foods in order to assess whether they really know a definition of this concept.

Next, the following definition of functional foods is provided in the questionnaire:

> "Functional foods are defined as natural or supplemented foods that contain biologically-active compounds which, in certain quantities, provide a scientifically proven benefit to human health" (Functional Food Center, 2020);

along with a more detailed explanation of them and some examples of commercially available functional foods (such as yogurt with probiotics, fermented milk drinks with probiotics or with plant sterols, cereals enriched with vitamins and minerals, fruit juices enriched with vitamins and minerals, milk with omega 3 and / or with vitamins and minerals, iodized salt, etc.).

The "functional foods" definition is given to better clarify it to all interviewees, in order to reduce the probability of errors in compiling subsequent questions.

After that, the next part of the section begins, which delves into consumers' consumption patterns, their purchasing habits and motivation to buy functional foods. Therefore, the respondents are asked if they, or a member of their family, consume some functional food products. If not, they are asked why they do not consume functional foods. In the event of an affirmative answer, they are asked about the type of functional food product consumed, among the following types:

- o Yogurt with probiotics

- Fermented milk beverages with probiotics or plant sterols
- Enriched milk (with omega 3 or fiber or calcium and vitamins)
- Vegetable drinks (soy, almond, etc.) enriched with vitamins and minerals
- Fruit juices / Fortified fruit drink (with vitamins and minerals or with beta-glucans or with polyphenols)
- Cereals fortified with vitamins and minerals
- Water with mineral salts and / or vitamins
- Butter with reduced cholesterol content
- Eggs enriched with omega 3
- Oils enriched with vitamins
- Energy drinks
- Snack bars with proteins, vitamins and minerals
- Rusks with vitamins and / or minerals
- Iodized salt
- Iodized potatoes
- Chewing gum with xylitol, vitamins, minerals
- Enriched biscuits (with beta-glucans or with vitamins and minerals or fibers).

Subsequently, they are asked about the frequency of consumption and where they usually buy functional food products.

Finally, the last part of the section aims to evaluate consumers' attitudes towards functional foods. For this reason the interviewee is asked to express his/her level of agreement and / or disagreement on a Likert scale from 1 to 5 (where: 1 Completely disagree; 2 Disagree; 3 Undecided; 4 Agree; 5 Completely agree) with a series of statements about functional foods. These statements were mainly derived from the study of Urala, N., & Lähteenmäki, L. in 2007, with some modification in order to update and contextualize them. Urala, N., & Lähteenmäki, L., have developed and improved with different studies (the last performed in 2007) an attitude measurements scale that can be used to explain consumers' willingness to use functional foods. Consumers' attitude in their studies is measured by 25 statements related to functional foods, formulated in a questionnaire and evaluated on a Likert scale from 1 to 7 points. The statements were classified into four main dimensions:

- Perceived reward from using functional foods
- Necessity for functional foods
- Confidence in functional foods
- Safety of functional foods.

In addition, this scale is implemented with other statements related to various factors influencing the food selection choice among consumers, such as healthfulness, taste or sensory appeal, natural content, price, convenience and familiarity. These factors were derived from the study of Steptoe et al., in 1995, aimed at developing the "*Food Choice Questionnaire"* to measure the motivations behind the choice of food by consumers.

Section 4

This section aims to assess the willingness to pay for functional food, in particular for a functional baked food product, such as functional rusks enriched with vitamins (e.g. folic acid, B1, D2) or minerals (e.g. iron and calcium) or low-sodium rusks.

First, a filter question is created in which respondents are asked if they usually buy rusks or not. If not, they are asked to specify the reasons. If yes, they are asked to express affirmatively or negatively their willingness to pay more for three different types of functional food rusks after a brief description of them and their health benefits. In addition, interviewees are asked to specify the maximum amount that they would be willing to pay for the product among the pricing options provided and after told them the average price of a conventional rusks packet. Then, they are demanded to specify the percentage of certainty they have in their answer. In the case in which they have less than 80% certainty, they are requested to indicate the price they would be willing to pay for that product.

In order to estimate the average price of a packet of conventional rusks and to attribute an average price to functional rusks, a market analysis was carried out. This survey was carried out in the period from September to October in 2020 at various Supermarkets, Hypermarkets and Discounts in the Emilia-Romagna and Marche regions. In particular, the stores analyzed are: Conad, Conad City, Coop, Eurospin, Lidl, IperConad, Despar, Margherita Conad, Natura Si, and Si con Te. The prices of conventional rusks and the prices of functional rusks, enriched with vitamins (e.g. folic acid, B1, D2) and/or minerals (e.g. iron and calcium) and/or low-sodium content, were observed during the survey. The market survey is available in the annex V.

Section 5

In the last section, the interviewee is asked for some personal and socio-demographic information such as: gender, age, educational qualification with specification of the degree course / field of study, profession, marital status, average annual family income, region of residence, number of family members and the possible presence of children under 13 and, in this case, specify their age.

Pre-test

The questionnaire was designed in the period from March to September 2020 and pre-tested in October 2020. The pre-test was conducted through a small focus group of 25 people, of the Department of Agricultural, Food and Environmental Sciences (D3A), who was gathered to discuss the understanding of the questionnaire and to evaluate its effectiveness before making the questionnaire available online and so avoiding subsequent revisions and adjustments. The purpose of the pre-test was to assess whether any changes need to be made to the designed questionnaire in order to make it clearer and more understandable. Based on the pre-test, some questions of the survey were restructured and reviewed.

Sampling and data collection

The data collection was carried out in the period of November 2020, through the use of an online questionnaire, designed and administered to a sample of 427 Italian people. People were reached using various social media such as Facebook and WhatsApp and also e-mail. The questionnaire was designed by using the software called "Google - forms", online available at: https://www.google.it/intl/it/forms/about/.

A copy of the whole questionnaire is available in the annex I (Annex I - Consumer questionnaire) of this thesis.

The questionnaire was anonymous, and the data collected have been processed in compliance with the law on privacy.

5.2.2 Logit model

A logistic regression model is used in order to pursue the objectives of the work and in particular to:

1) analyse the factors that influence consumers' consumption of functional foods;
2) and analyse the factors that influence consumers' willingness to pay for functional foods and identify which characteristics of the sample significantly determine a greater probability of being willing to pay more (based on the degree of certainty in the answer).

To adopt the logit model for this study and to obtain the estimates, the software Gretl version 2020e, an open-source software, written in the C programming language and mainly used for econometric analysis, is used.

Specifically, the consumers' intention to consume functional foods, which indicates their willingness to purchase them, is influenced by several factors. Therefore, the relationship between the intention to consume and the factors can be summarized as follows:

- consumers' consumption of functional food = F (Socio-demographics factors (such as age, education, income, etc.)
- consumers' health-nutrition factors (such as food allergies/intolerances, pathologies related to poor nutrition, etc.)
- functional food related factors (such as consumers' knowledge, attitude…).

In this study, consumers' consumption of functional food is a 0-1-type dependent variable (in which y = 1, when consuming functional food; otherwise, y = 0). Assuming that the probability of y = 1 is P, the function of y is as follows:

$$f(y) = P_y(1-P)_{1-y}\ , \qquad y = 0\ ,1$$

This study adopts the logit model of binary choice, limits the number of dependent variables within the range [0–1], and uses the maximum likelihood estimation method to calculate the regression parameter. The logit model's basic form is as follows:

$$P_i = F\left(\alpha + \sum\nolimits_1^m \beta_j X_{ij} + u\right) = \frac{1}{\left\{1 + e^{\left[-\left(\alpha + \sum_1^m \beta_j X_{ij} + u\right)\right]}\right\}}$$

where Pi is the probability of i, which is the serial number of consumer, βj is the regression parameter of influencing factors, j is the serial number of influencing factors, m is the number of influencing factors, Xij is the independent variable representing influencing factor j in sample i, α is the intercept and u is the error.

In addition, in order to study the factors influencing consumers' willingness to pay for functional foods, the same logit model is applied, but changing only the dependent variable. In particular, the dependent variable used assumes a value of 1 when consumers declare their willingness to pay more for food functional with a degree of certainty in the response equal to at least 70%, and value 0 otherwise.

In the logit model implemented in this analysis, in order to verify the factors that mostly influence the propensity to consume and the willingness to pay for functional foods, the following independent variables are used and they can be divided into three main types:

- variables connecting to socio-demographic characteristics of the sample (such as age, gender, education, income, etc.);

- variables about consumers' health and nutrition (specific diet, food allergies/intolerances, pathologies related to poor nutrition, physical activities, dietary supplements etc.);
- variables related to functional food (such as consumers' knowledge and attitude towards functional foods, probable future purchasing behaviour etc.).

These are the independent variables Xi, reworked and adapted to the model.

5.3 Results

In the following chapter, the main results, obtained from the online survey questionnaire, are examined.

5.3.1 Socio-demographic characteristics of the sample

The final sample is represented by 427 Italian people. Out of them, 70 % are female and regard the age, 1% of the respondents are less than 18 years old, 31% of the respondents are between 18 and 25 years old, 32% between 26 and 35 years old, 11 % between 36 and 45 years old and 14 % between 46 and 55 years old and 8% between 56 and 65 years old and the remaining 2% are over 65 years old.

As for the qualifications obtained, 33% have a high school diploma, 21% have a bachelor's degree, 36 % have a master's degree, 7% have doctorate or undergone post-graduate training and 4 % have a middle school license.

About occupation, 30% of the sample is represented by office workers, 29% by students, 8% by freelancers, 6% by teachers, 6% by unemployed and 4% by workers. The remaining 18% is made up of various occupation categories, which can be observed in the Table 5-1. Most of the respondents of the questionnaire are single, equal to 53%. However, there is a strong variability in the size of households, only 10% of the sample lives alone, while in most cases the households are formed by two, three and four individuals, respectively 21%, 23% and 32%. 15% of the sample has a family unit made up of more than 5 people, up to a maximum of 14. In addition, only 19 % of respondents have at least one child under 13 years in their family unit, and about the age of children, 42 % of children have less than 3 years, 27 % have between 4 and 7 years, 36 % between 8 to 12 years and 21% more than 12 years.

About the annual average household income, 52% of respondents are in the range between € 11,000 - € 35,000, 34% are between € 36,000 - € 75,000, while in the higher range, over € 75,000, there are the 10% of the interviewees and 4% in the lowest range, less than € 10,000.

The sample is distributed throughout the national territory, with particular concentration in the Emilia Romagna, which represents 57%. The concentration of the sample in this region is linked to the place of launch of the questionnaire and the methods of administration. Other highly represented regions are Marche with 13% and Lombardy with 12%, Sicily with 3% and Veneto and Abruzzo with 2 %.

Table 5-1 shows in detail the results descripted above from the socio-demographic analysis of the sample.

Table 5-1: Summary of personal and socio-economic data *(Own elaboration).*

DATA	**DESCRIPTION**	**PERCENTAGE**
Gender	Male	30%
	Female	70%
Age	< 18	1%
	18-25	31%
	26-35	32%
	36-45	11%
	46-55	14%
	56-65	8%
	> 65	2%
Educational qualification	No formal education	0%
	Primary school	0%
	Middle school	4%
	High school	33%
	Bachelor's degree	21%
	Master's degree	36%
	Doctorate or higher	7%
Occupation	Worker	4%
	Employee	30%
	Housewife/ Household	3%
	Merchant	2%
	Entrepreneur	3%
	Doctor/ paramedic	1%
	Teacher	6%

	Student	29%
	Freelance	8%
	Retired	2%
	Unemployed	6%
Marital status	Married	45%
	Unmarried	55%
Annual average household income class	Less than € 10.000	10%
	Between € 11.000 and € 20.000	20%
	Between € 21.000 and € 35.000	31%
	Between € 36.000 and € 50.000	21%
	Between € 51.000 and €75.000	13%
	More than € 75.000	4%
Number of family members	1	10%
	2	21%
	3	23%
	4	32%
	5	9%
	6	4%
	7	2%
	8	~ 0%
Children under 13 years in the family unit	Yes	19%
	No	81%
Age range of children	0-3 years	42%
	4-7 years	27%
	8-12 years	36%
	> 12 years	21%

5.3.2 Descriptive statistics

Analysing respondents' behaviour about nutrition, 89% of respondents are usually attentive to their diet and 11% do not (

Figure 5-1).

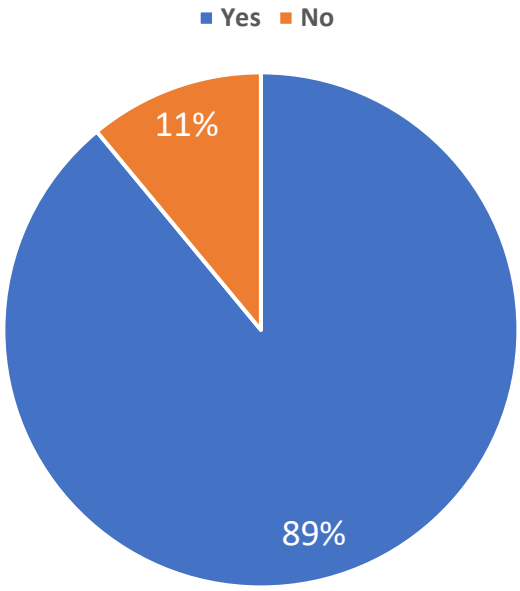


Figure 5-1: Respondents' attention to the diet

However, only 25% of the sample declares to follow a specific diet and among them, 50% to stay fit, 21% for health problems such as diseases, allergies and / or food intolerances, 11% to feel better (to improve mood), 7% for ethical reasons (vegan, vegetarian diet, etc.), 6% for sporting reasons and the remaining 6% to lose weight.

As regards the health status, 17% of respondents suffer from food allergies and / or intolerances (Figure 5-2Figure 5-2).

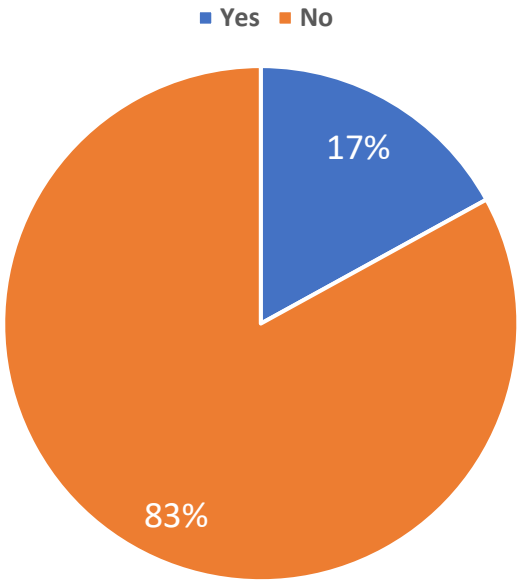


Figure 5-2: Respondents health status regarding food allergies and / or intolerances

In particular 58% of them are lactose intolerant, while 11% are intolerant to gluten and 9% are allergic to nuts (almonds, hazelnuts, walnuts, etc.).

In addition, 16% of the sample suffers from any pathology related to poor nutrition (Figure 5-3), mainly 36% of obesity and overweight, 22% of increased cholesterol and blood triglycerides (metabolic diseases), 13% arterial hypertension, 9% fatty liver (biliary lithiasis and hepatic steatosis), 4% diseases of the cardiovascular system, 3% diabetes, 4% of gastroesophageal reflux and 1% of osteoporosis and 1% of dental caries.

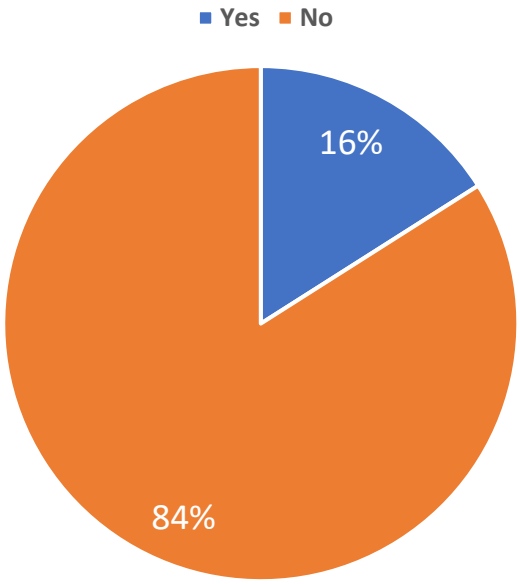


Figure 5-3: Sample's health status regarding pathologies related to poor nutrition

Furthermore, regarding the lifestyle of the interviewed sample, 75% practices physical activity such as walking, cycling, running, gym, etc., mainly from 1 to three hours a week (59%) and between 4 to 6 hours a week (24%). 28% of respondents buy dietary supplements, among them, 44% sometimes buy dietary supplements, 39% often, 10% rarely and 7% always.

Analysing consumers' purchasing behaviour towards the label, 34% of people often check the label when buying a food product, 30% always, 23% sometimes, 9% rarely and only 4% never check it.

Subsequently, it was asked how important are a series of nutritional claims, present in the packaging of a food product, and for each of them was asked to assign a score on a Linkert scale from 1 to 5 (where: 1: Not important at all; 2: Not important; 3: Important; 4: Very important; 5: Extremely important) in order to determine the actual impact on consumer choice. From this analysis, it is emerged that the sample considers mainly as "extremely important" the claim about the sugar content, as indicated by 31% of the respondents, equal to 131 people. While the second claim indicated as "extremely important" is the fat content, by 25% of the sample (equal to 105 people). The nutritional claim mainly considered as "Not important at all" is the light/lite claim, stated by 23% of the sample. The Figure 5-4 shows the mean of the answers for each type of nutritional claim.

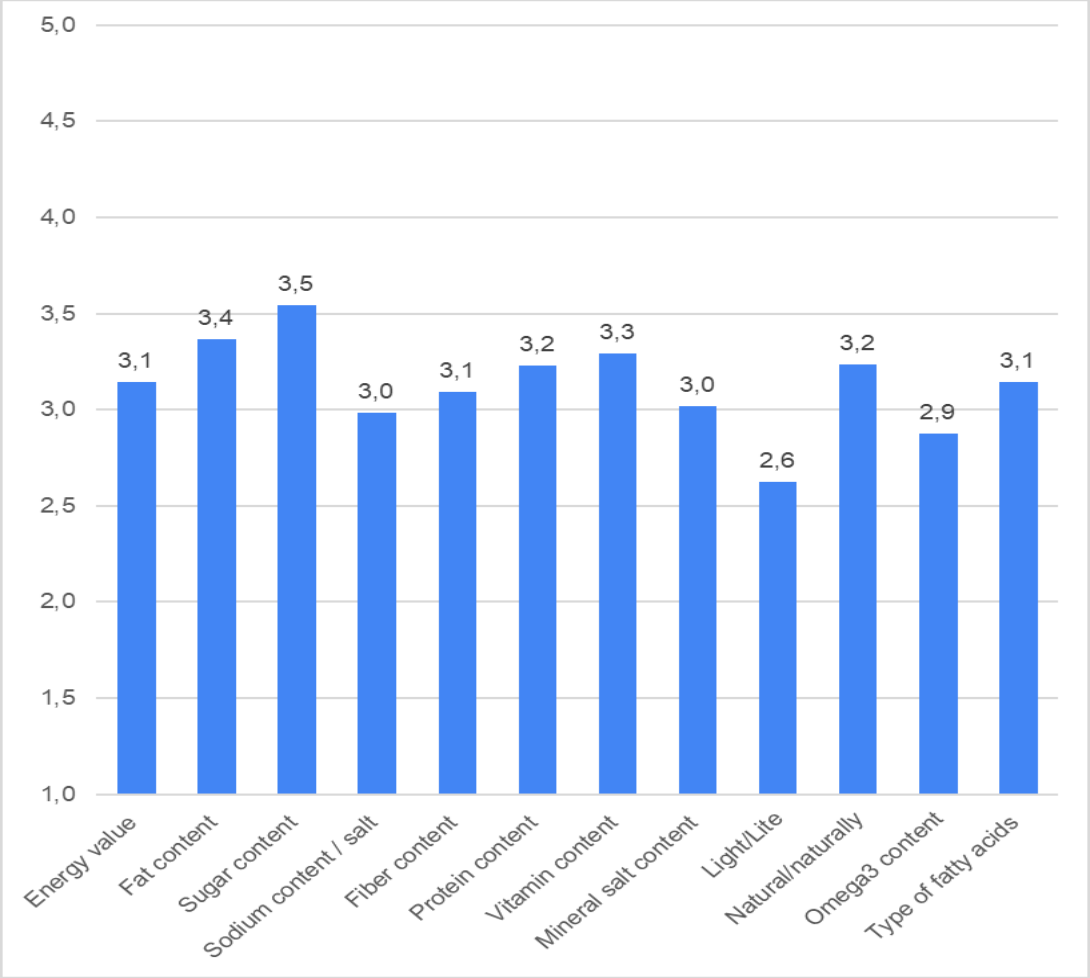


Figure 5-4: Interviewees' responses on the importance of nutritional claims (mean value).

Then, the interviewee was asked to rank, according to the scale of importance (from 1: Not important at all; to 5: Extremely important), the three different types of health claims that can be present on the package of a food product. Among them, people consider as "extremely important" mainly "claims referring to children's health and development" as stated by 21% of people. However, taking in consideration the mean of answers for each type, the majority of respondents rated 3 all health claims, indicating that the majority of respondents remained neutral (Figure 5-5).

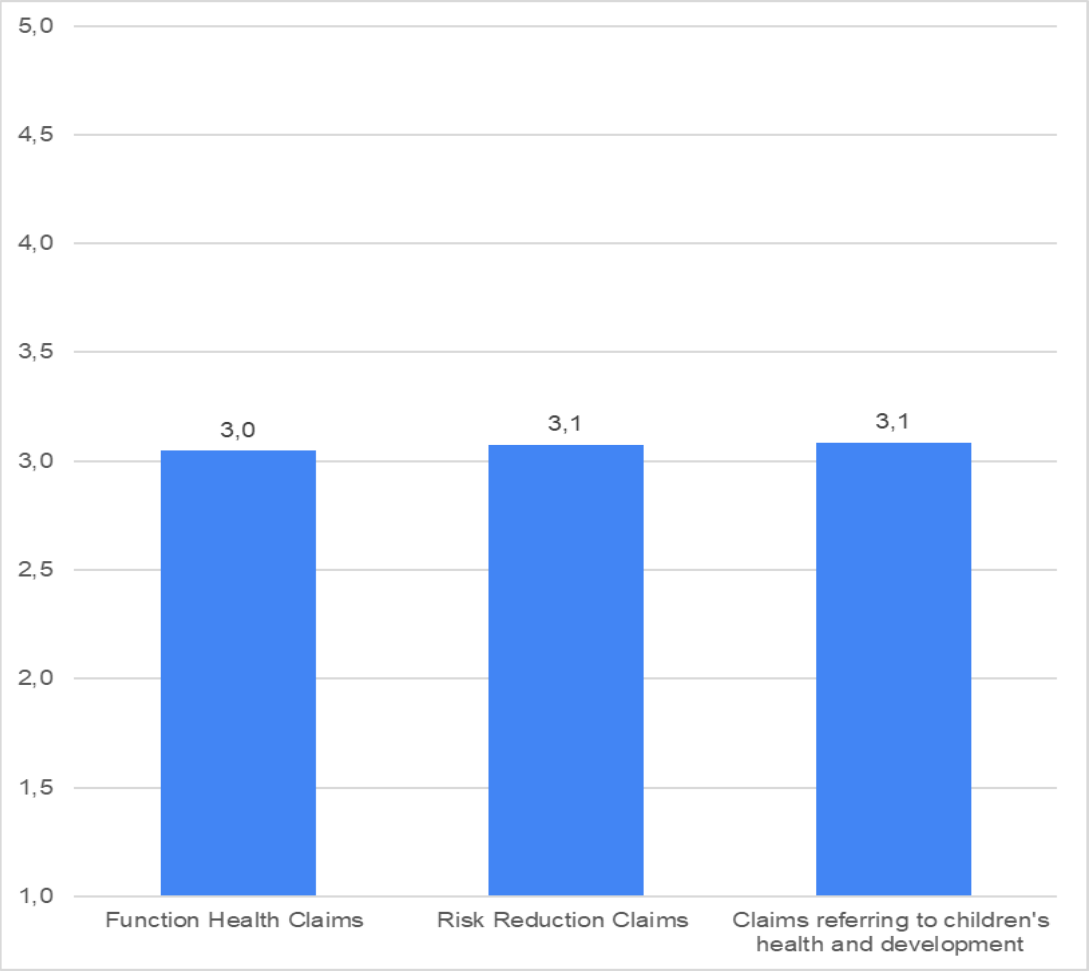


Figure 5-5 Interviewees' answers on the importance of different type of health claims (mean value).

Going to examine the answers regarding functional foods, it turns out that 60% of the sample (equal to 258 people) has never heard about functional foods (Figure 5-6).

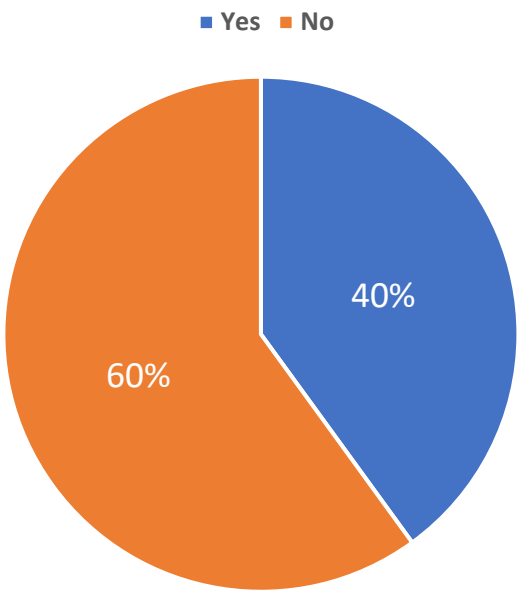


Figure 5-6: Respondents' knowledge of functional foods

Furthermore, they were asked to provide a definition, some of the most relevant are:

"Food characterized by a particular function for the body in addition to the simple nutritional and caloric function"
"They are foods that have a beneficial function for the body"
"Food with added substances such as vitamins"
"Foods that naturally have healing abilities".

The definitions received show a certain awareness of consumers with respect to this type of product, even if in most cases the respondents were unable to provide an answer. After reading a definition of functional food and some commercially available products, 87% of the sample (equal to 373 people) stated that they or a component of their family, have eaten functional foods at least once (Figure 5-7).

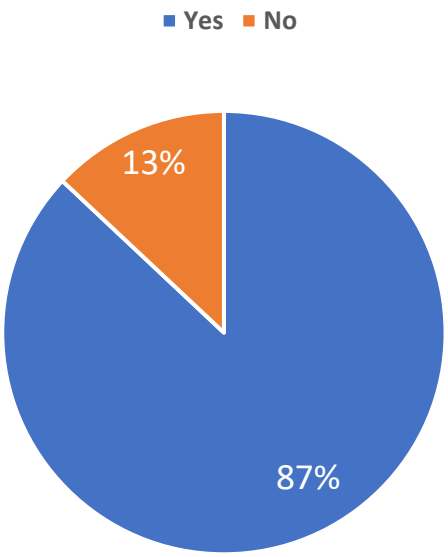


Figure 5-7: Consumers' consumption of functional foods

As can be seen in Figure 5-8, those who have never consumed functional foods in 35% of cases did so because they were not aware of the beneficial properties of the product, 33% of cases did so because they do not believe they needed them, 32% because they are not interested in this type of product, 17% because they don't believe in the beneficial potential of the product and the same percentage because they consider them exclusively a fashion, 15% because they are expensive and 11% because they think that functional foods are only needed for people with specific health problems and 11% because they consider them not natural, 7% because they don't believe in the health or nutrition claims on the label and 7% because they don't understand some of the health or nutrition claims on the label.

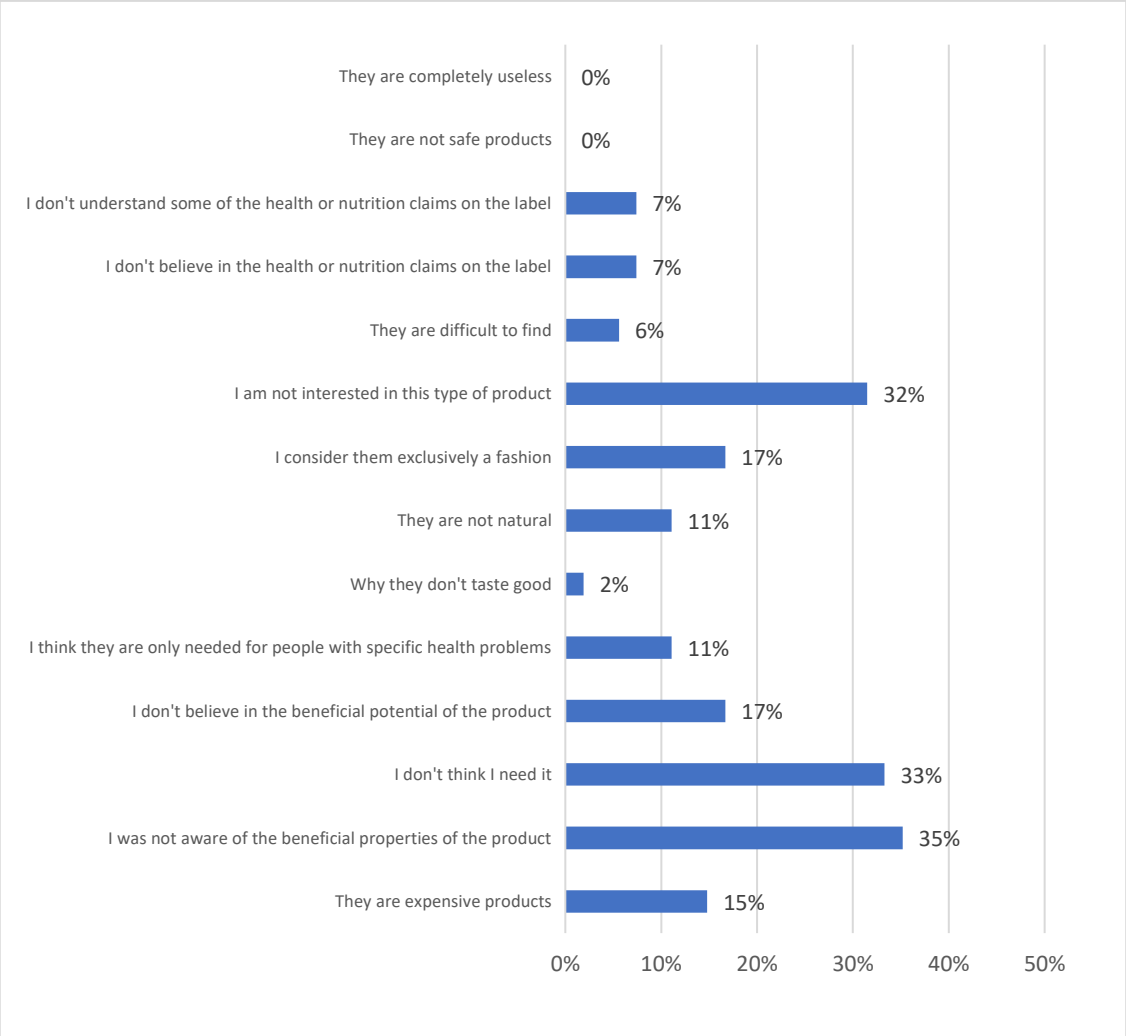


Figure 5-8: Respondents' reasons for not buying functional foods

In the field of functional foods, among 87% (equal to 373 people) of the sample who have tried this type of product, 52% of respondents declare that they mainly consume yogurt with probiotics (195 people), 42% iodized salt, 38% enriched cereals with vitamins and minerals, 27% snack bars with proteins, vitamins and minerals, 26% vegetable drinks (soy, almond, etc.) enriched with vitamins and minerals, 20% fruit juices / fruit drink fortified (with vitamins and minerals or with beta-glucans or with polyphenols), 12% chewing gum with xylitol, vitamins, minerals and 10% energy drinks.

Specifically, 2% of the sample has tried functional foods only once, 12% consumes them rarely (less than 5 times a year), 29% consumes them occasionally, about once a month, 24% consumes them frequently, about once a week, 26% consume them several times a week and 8% consume them every day (Figure 5-9). Furthermore, functional foods are mainly purchased in supermarkets for a percentage of 75% and 14% in hypermarket.

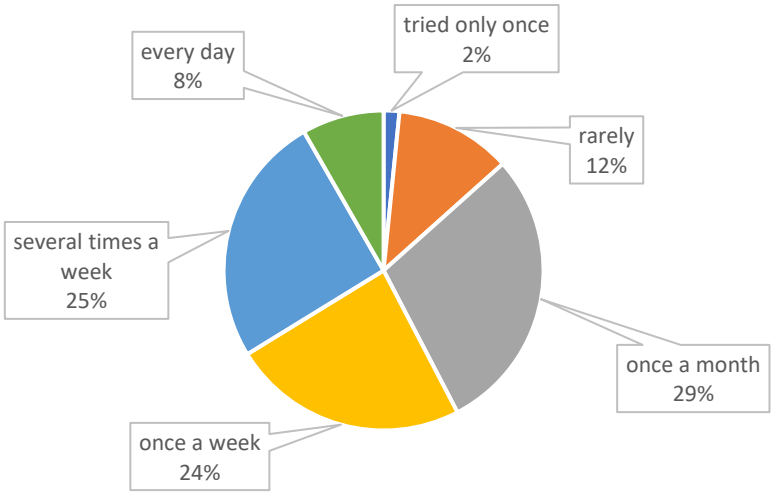


Figure 5-9: Frequency of consumption of functional food

In order to better understand how consumers perceive functional foods and analyse consumers' attitude towards them, they were asked to rank, on a five-point Likert scale (from 1 = Completely disagree to 5 = Completely agree), their level of agreement with several statements about functional foods. The Figure 5-10 shows the results of consumer attitudes towards functional foods. However, for a better interpretation, the results were classified and grouped into the main factors and dimensions that the functional food statements referred to. The results in Figure 5-10 indicate that consumers feel strongly agreed with the fact that functional foods have an higher price (mean value 3,6) and have a more convenience, in terms of availability (mean value 3,6). In addition, regards the four dimensions that were used in literature in order to measure consumers' attitude towards functional foods, in this study the necessity dimension for functional foods has an higher level of agreement (mean value 3,5), followed by the safety dimension (mean value 3,3). The highest level of disagreement (mean value 2,4) is found in the marketing and commercial motivations behind choice of functional foods, and mainly with the statement "I eat functional products because I recognize them from advertising / TV".

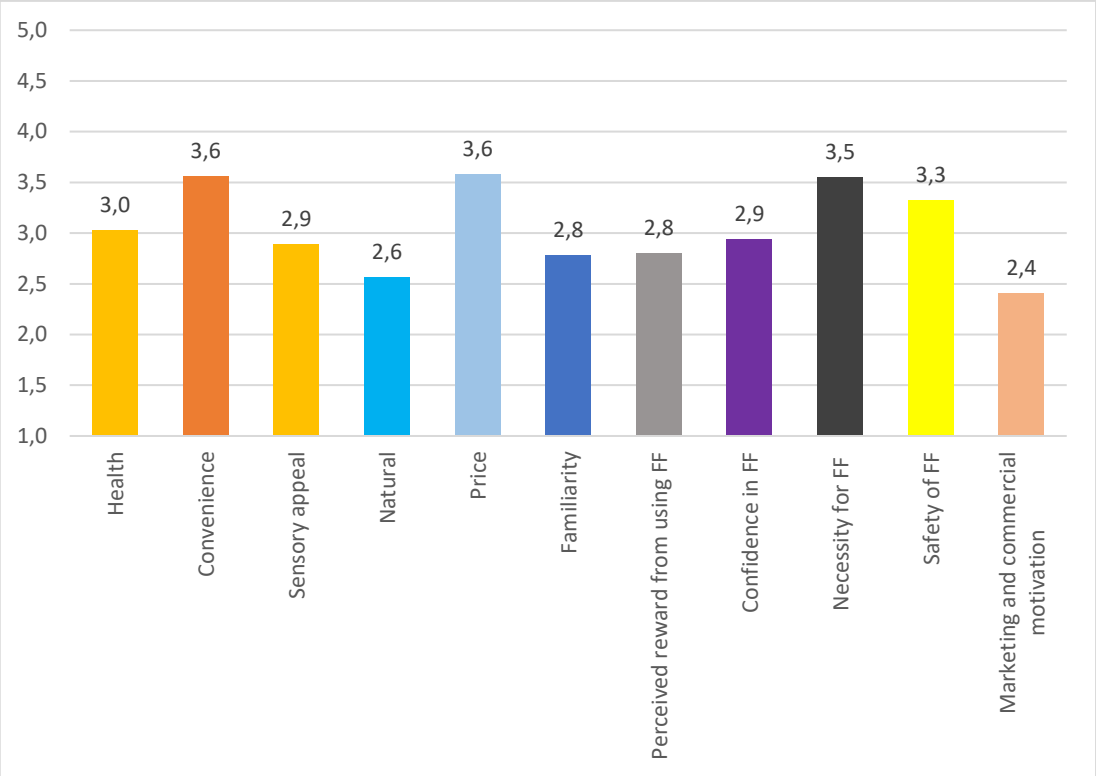


Figure 5-10: Consumers' responses on the level of agreement with different statements on functional foods (mean value).

In order to better understand how people perceive the regulations and labelling of functional foods, they were asked to rank, on a five-point Likert scale (from 1 = Completely disagree to 5 = Completely agree), their level of agreement with several statements about regulations and labelling. The results show that consumers feel strongly agreed on the importance of functional food regulations and labelling (mean value is 3,80). However, Figure 5-11 shows that the majority of respondents rated 3, indicating that most respondents remained neutral on the other statements.

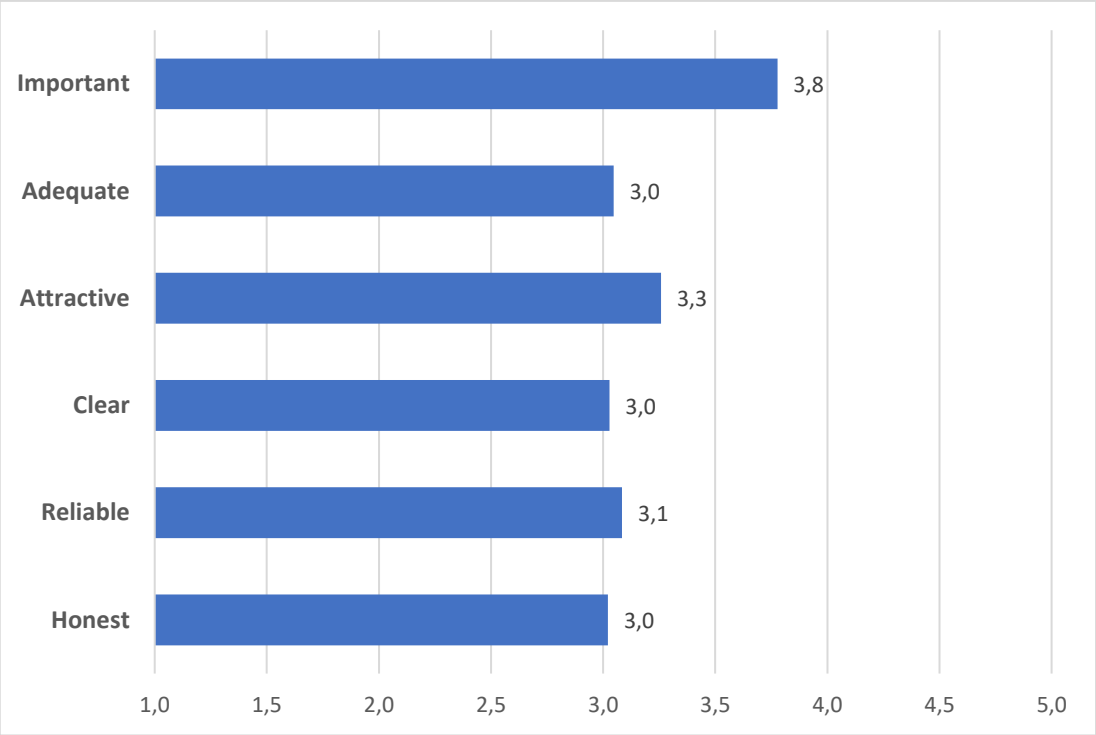


Figure 5-11: Respondents' attitude towards regulations and labelling of functional foods (mean value)

Furthermore, 81% of the sample thinks that they will buy functional food product in the future and 19% do not think so (Figure 5-12).

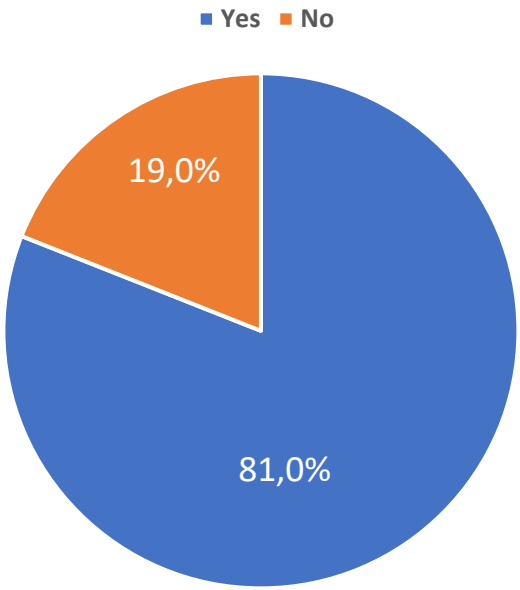


Figure 5-12: The probable future purchasing consumers' behaviour

The last part of the questionnaire is focused on the willingness to pay for functional rusks. Of the total of 427 people considered, 81% (equal to 344 people) habitually buy conventional rusks and among these about 70% declare that they are willing to pay more for functional rusks.

5.3.3 The econometric model for consumers'consumption

As previously mentioned, it is used the logit model in order to understand which factors influence consumers' consumption of functional foods.

Figure 5-13 highlights the results of the econometric model, in which it is possible to distinguish the variables, which exert a significant influence in the consumption of functional foods. These variables are:

- PAT: dummy variable that takes value 1 if the respondent suffers from pathologies related to poor nutrition and 0 otherwise;
- SCA_COMP: variable "components-rich food", it assumes values from 1 to 5 (on a 5-point Likert scale);
- SCA_REP: variable "availability", it assumes values from 1 to 5 (on a 5-point Likert scale);
- SCA_SM: variable "I usually eat", it assumes values from 1 to 5 (on a 5-point Likert scale);
- SCA_FAM: variable "familiarity", it assumes values from 1 to 5 (on a 5-point Likert scale);
- SCA_PRE: variable "performance", it assumes values from 1 to 5 (on a 5-point Likert scale);
- SCA_PROB: variable "well-being", it assumes values from 1 to 5 (on a 5-point Likert scale);
- SCA_BRAND: variable "brand", it assumes values from 1 to 5 (on a 5-point Likert scale);
- CONO: dummy variable that takes value 1 if the respondent knows functional foods and 0 otherwise;
- FAM: is the number of family members of the respondent.

	Coefficient	*Std. Error*	*z*	*p-value*	
const	−3,45803	1,70546	−2,028	0,0426	**
ALI	0,461691	0,597701	0,7724	0,4399	
REG	−0,590078	0,478029	−1,234	0,2171	
ALL	0,660032	0,622350	1,061	0,2889	
PAT	1,34922	0,616458	2,189	0,0286	**
ETI	−0,199067	0,201962	−0,9857	0,3243	
SCA_COMP	−0,749266	0,281400	−2,663	0,0078	***
SCA_REP	0,363131	0,182758	1,987	0,0469	**
SCA_SM	0,764921	0,282370	2,709	0,0067	***
SCA_FAM	0,577656	0,255464	2,261	0,0237	**
SCA_PRE	−0,565495	0,264675	−2,137	0,0326	**
SCA_PROB	0,952105	0,243367	3,912	<0,0001	***
SCA_BRAND	0,512206	0,204860	2,500	0,0124	**
SESSO	0,129317	0,440132	0,2938	0,7689	
ETA	−0,206452	0,158909	−1,299	0,1939	
RED	−0,0835538	0,161806	−0,5164	0,6056	
FAM	0,466570	0,176145	2,649	0,0081	***
BAMB	0,662180	0,550521	1,203	0,2290	
OCC	0,0161239	0,0648794	0,2485	0,8037	
IST	0,0283365	0,207485	0,1366	0,8914	
CONO	0,996548	0,552292	1,804	0,0712	*

Figure 5-13: Results of the econometric model applied to the consumption of functional foods

The variables that exert a significant influence on the probability of consuming functional foods, in this study, are the following:

- Among the socio-demographic variables, only the variable related to the number of components of the family exert a significant influence.
- Among the variables related to consumers' health and nutrition, those suffering from diseases have a significant influence.
- Among variables related to functional food, it was found that: those who think that functional foods are nutrients-rich foods, the easy availability of functional foods, those who usually eat functional foods, those who are familiar with functional foods, those who think that functional foods improve their performance, those who think that functional foods improve their well-being, those who think brand is important in selecting a functional food, and those who know functional foods, have a significant influence.

In order to better understand the results of the econometric model, it was calculated the odds ratio (OR). Odds ratio measures how the dependent variable changes in terms of probability following a unit change in the regressor. When the Odds ratio is equal to 1, the

effect of a unit change of the regressor on the dependent variable is zero. The greater the deviation from the unit value, the greater the effect of the regressor on the dependent variable will be.

Odds-ratios for CONS:

Variable	Odds-ratio	95,0% conf. interval
ALI	1,5868	[0,492, 5,120]
REG	0,5543	[0,217, 1,415]
ALL	1,9349	[0,571, 6,552]
PAT	3,8544	[1,151, 12,903]
ETI	0,8195	[0,552, 1,217]
SCA_COMP	0,4727	[0,272, 0,821]
SCA_REP	1,4378	[1,005, 2,057]
SCA_SM	2,1488	[1,236, 3,737]
SCA_FAM	1,7819	[1,080, 2,940]
SCA_PRE	0,5681	[0,338, 0,954]
SCA_PROB	2,5912	[1,608, 4,175]
SCA_BRAND	1,6690	[1,117, 2,494]
SESSO	1,1381	[0,480, 2,697]
ETA	0,8135	[0,596, 1,111]
RED	0,9198	[0,670, 1,263]
FAM	1,5945	[1,129, 2,252]
BAMB	1,9390	[0,659, 5,704]
OCC	1,0163	[0,895, 1,154]
IST	1,0287	[0,685, 1,545]
CONO	2,7089	[0,918, 7,997]

Figure 5-14 highlights the results after the calculation of the odds ratio (OR). The regressor that has the greatest effect on the consumption of functional foods is the factor “PAT”, those suffering from diseases, that has an effect of about 4 times on the probability of consuming functional foods. Furthermore, an important effect is also exerted by the following variables that approximately double the probability of consuming functional foods, in particular these are:

- “CONO”, those who know functional foods, (2,7089),
- “SCA_PROB”, those who think that functional foods improve their well-being (2,5912),

- “SCA_SM”, those who usually eat functional foods, (2,1488)
- “SCA_FAM”, those who are familiar with functional foods, (1,5945).

Odds-ratios for CONS:

Variable	Odds-ratio	95,0% conf. interval
ALI	1,5868	[0,492, 5,120]
REG	0,5543	[0,217, 1,415]
ALL	1,9349	[0,571, 6,552]
PAT	3,8544	[1,151, 12,903]
ETI	0,8195	[0,552, 1,217]
SCA_COMP	0,4727	[0,272, 0,821]
SCA_REP	1,4378	[1,005, 2,057]
SCA_SM	2,1488	[1,236, 3,737]
SCA_FAM	1,7819	[1,080, 2,940]
SCA_PRE	0,5681	[0,338, 0,954]
SCA_PROB	2,5912	[1,608, 4,175]
SCA_BRAND	1,6690	[1,117, 2,494]
SESSO	1,1381	[0,480, 2,697]
ETA	0,8135	[0,596, 1,111]
RED	0,9198	[0,670, 1,263]
FAM	1,5945	[1,129, 2,252]
BAMB	1,9390	[0,659, 5,704]
OCC	1,0163	[0,895, 1,154]
IST	1,0287	[0,685, 1,545]
CONO	2,7089	[0,918, 7,997]

Figure 5-14: Odds ratio calculated on the results of the logit regression for the dependent variable “consumption”

5.3.4 The estimation of the factors that influence the willingness to pay

In order to estimate the factors influencing the consumers’ willingness to pay for functional foods, the logit model was applied. The results were obtained, considering as a sample, only people who usually consume rusks while as variables, the same ones used previously. The results of the regression of the general logit model of the WTP for functional

foods are presented in the Figure 5-15, in which it is possible to distinguish the variables which exert a significant influence in the WTP more for functional foods. These variables are as follows:

- SCA_COMP: variable “components-rich food”, it assumes values from 1 to 5 (on a 5-point Likert scale);
- SCA_PRE: variable “performance”, it assumes values from 1 to 5 (on a 5-point Likert scale);
- SCA_PROB: variable “well-being”, it assumes values from 1 to 5 (on a 5-point Likert scale);
- BAMB: dummy variable that takes value 1 if the respondent has at least one child under 13 years in his/her family unit, and 0 otherwise;

	Coefficient	*Std.Error*	*z*	*p-value*	
const	−3,58510	1,21467	−2,952	0,0032	***
CONO	0,330096	0,342236	0,9645	0,3348	
CONS	0,0994874	0,454388	0,2189	0,8267	
ALI	0,386877	0,426604	0,9069	0,3645	
REG	0,0594404	0,355759	0,1671	0,8673	
ALL	−0,200651	0,387220	−0,5182	0,6043	
PAT	0,444706	0,432144	1,029	0,3034	
ETI	0,0255460	0,143760	0,1777	0,8590	
SCA_COMP	0,347858	0,194268	1,791	0,0734	*
SCA_REP	−0,213531	0,135891	−1,571	0,1161	
SCA_SM	0,176036	0,159011	1,107	0,2683	
SCA_FAM	−0,0789136	0,149873	−0,5265	0,5985	
SCA_PRE	0,303741	0,160835	1,889	0,0590	*
SCA_PROB	0,539949	0,161126	3,351	0,0008	***
SCA_BRAND	0,162256	0,125035	1,298	0,1944	
SESSO	−0,242725	0,317699	−0,7640	0,4449	
ETA	0,0899137	0,115280	0,7800	0,4354	
IST	0,106038	0,141857	0,7475	0,4548	
OCC	−0,0403036	0,0437574	−0,9211	0,3570	
RED	−0,00570350	0,104300	−0,05468	0,9564	
FAM	−0,0483859	0,0956461	−0,5059	0,6129	
BAMB	0,676096	0,382876	1,766	0,0774	*

Figure 5-15: Results of the econometric model applied to the consumers’ willingness to pay more for functional foods

What appears to emerge from the analysis, is the relevance that, with respect to an increase in the probability of consumers' willingness to pay more, have those who think that functional foods improve their well-being, those who think that functional foods are

nutrients-rich foods, those who think that functional foods improve their performance and those who have at least one child under 13 years in their family unit.

Figure 5-16 shows the results of the econometric model, after the calculation of the odds ratio (OR), in order to better understand the most associated factors with the willingness to pay more for functional foods.

The main variables are:

- BAMB, respondent who has at least one child under 13 years in his/her family unit (1,9662);
- SCA_PROB, those who think that functional foods improve their well-being, (1,7159);
- SCA_COMP, those who think that functional foods are nutrients-rich foods, (1,4160);
- SCA_PRE, those who think functional foods improve their performance, (1,3549).

Odds-ratios for VAR_DIP2:

Variable	Odds-ratio	95,0% conf. interval
CONO	1,3911	[0,711, 2,721]
CONS	1,1046	[0,453, 2,691]
ALI	1,4724	[0,638, 3,397]
REG	1,0612	[0,528, 2,131]
ALL	0,8182	[0,383, 1,748]
PAT	1,5600	[0,669, 3,639]
ETI	1,0259	[0,774, 1,360]
SCA_COMP	1,4160	[0,968, 2,072]
SCA_REP	0,8077	[0,619, 1,054]
SCA_SM	1,1925	[0,873, 1,629]
SCA_FAM	0,9241	[0,689, 1,240]
SCA_PRE	1,3549	[0,989, 1,857]
SCA_PROB	1,7159	[1,251, 2,353]
SCA_BRAND	1,1762	[0,921, 1,503]
SESSO	0,7845	[0,421, 1,462]
ETA	1,0941	[0,873, 1,371]
IST	1,1119	[0,842, 1,468]
OCC	0,9605	[0,882, 1,047]
RED	0,9943	[0,810, 1,220]
FAM	0,9528	[0,790, 1,149]
BAMB	1,9662	[0,928, 4,164]

Figure 5-16: Odds ratio calculated on the results of the logit regression for consumers' willingness to pay more for functional foods

After identifying the main variables that influence consumers' willingness to pay more for functional foods, we can analyse the estimated willingness to pay of the sample interviewed for functional rusks.

Of the total of 427 people considered, 81% (equal to 344 people) usually buy traditional rusks. Of people who usually consume rusks, around 70% say they are willing to pay more for functional rusks such as enriched rusks with vitamins (e.g. folic acid, B1, D2) or minerals

(e.g. iron and calcium) or low-sodium rusks. In particular, knowing that the average price of the same quantity of classic rusks is € 1.35, respondents are willing to pay for functional rusks an average price of € 1.90. In addition, those who say they have more than 70% confidence in the decision to be willing to pay more for functional rusks are 85% of people. The results show that the average willingness to pay of the sample interviewed for functional foods is around € 1.90. It is important to consider that this average is the expected value of the willingness to pay given the characteristics of the people interviewed.

5.4 Discussion

Our explorative analysis highlights that consumers are still confused about the concept of functional foods, often confused them with other types of products and a lot of studies in literature affirmed the same (e.g., Bech-Larsen & Grunert, 2003; Urala & Lähteenmäki, 2007; Verbeke, 2005). Furthermore, a common finding in the literature is that consumers do not perceive functional foods as a homogeneous group and therefore their attitudes influence differently the intention to purchase different functional products. (Urala & Lähteenmäki, 2003).

Consumer misunderstanding may probably be due to the lack of clear legislation with an official definition of functional foods but also to a fragmented variety of products currently available on the market and the large amount of general uncoordinated marketing and educational messages.

What appears to emerge from the analysis, made to understand which factors influence consumers' consumption of functional foods, is the relevance that several variables have. In particular, among the variables related to consumers' health and nutrition, it seems that those suffering from diseases have a significant influence, and among other, this is the main variable associated with the consumption of functional food. The result is in accordance with several studies, which identified that the state of health and the presence of diseases (such as diabetes, hypertension and obesity) are one of the main factors that affect the decision to purchase functional foods (Sirò et al., 2008). According to this study, the state of health is much more decisive than socio-demographic factors in influencing the demand for functional foods. Furthermore, the study conducted by Verbeke (2005) states that the presence of a family member with a specific health disease influences positively the functional foods' acceptance.

Among variables related to functional foods, it seems that those who think brand is important in selecting a functional food, have a significant influence in consumers'

consumption of functional foods. As found in literature, the brand is one of the most significant extrinsic product characteristics in affecting consumers' food decision-making process (Deliza and MacFie, 1996). In line with this evidence there are several studies evaluating consumers' acceptance and preferences for functional foods (Annunziata & Vecchio, 2013; Ares & Deliza, 2010; Barrena & Sanchez, 2010; Ares et al., 2010). A study conducted by Annunziata and Vecchio (2013) showed that the brand influences consumers' decision process for probiotics yogurts among a group of Italian consumers, and they found also that brand's influence on consumer choices increases with consumers' familiarity with the brand itself. In line with this evidence, the study conducted by Barrena & Sanchez (2010) pointed out that consumers' familiarity with the brand is one of the characteristics of the products affecting families' decisions to buy probiotic dairy products. Furthermore, other studies show that consumers are positively influenced to buy functional foods from a recognized brand, on the contrary they are more sceptical of functional foods from less famous brands (Krystallis & Chrysochou, 2012).

As results of the previous analysis, it seems that those who know functional foods, those who usually eat and those who are familiar with functional foods, have a significant influence in consumers' consumption of functional foods. Consumers' knowledge is fundamental in order to choose functional foods over conventional foods, and they can do this only if they are aware of and known enough about them. Furthermore, in general, familiarity with the product, trust and suspiciousness are factors that can affect the acceptability of functional food products (Bower, Saadat, & Whitten, 2003; Urala & Lähteenmäki, 2007; Barrena & Sanchez, 2010). A common result of many studies is that consumer acceptance of functional foods is determined by a lot of factors such as main health concerns and consumers' familiarity with the concept of functional foods and of functional ingredients but also other factors such as the nature of the carrier product, etc. (Annunziata & Vecchio, 2011; Sirò et al., 2008; Verbeke, 2005).

Another important variable related to functional food, found in our analysis, is the easy availability of functional foods, which have a significant influence in consumers' consumption. Specifically, Urala & Lähteenmäki, (2003) stated that convenience is one of the main factor in determining consumers choice of functional foods and could influence consumers' attitudes toward them. Considering the time constraints, consumers would probably not be willing to compromise convenience for health-related problems.

In addition those who think that functional foods improve their well-being, those who think that functional foods improve their performance, and those who think that functional foods

are nutrients-rich foods, are identified in our study as significative variables. Specifically, if consumers perceive and believe in the health-enhancing properties of the products tend to be more interested in them. The study conducted by Urala & Lähteenmäki, (2007), points out that the perceived reward from using functional food and the confidence in functional foods represent one of the most crucial factors in consumers' willingness to consume functional foods. In their study, the perceived reward from using functional foods, such as improving personal well-being, is the strongest dimension underlying consumers' willingness to consume functional foods because it describes the pleasure of individuals and the positive effects that derive from their use, so functional foods can represent a new convenient tool for taking care of yourself. In addition, the second dimension found in our analysis concerns the consumer confidence in functional foods, such as the improvement of individual's performance by them; this dimension describes if people consider functional foods as safe products and if they believe in the scientific basis of the information regards the health effects provided by them.

From the results of this study, among the socio-demographic variables, only the variable related to the number of components of the family seems to exert a significant influence in the consumption of functional foods. However, it is well known in literature and many studies state that the family is one of the main factors, among other social factors, that influence the purchasing behaviour of consumers (Krystallis A., et al., 2008).

What appears to emerge from the analysis, made to understand which factors influence the consumers' willingness to pay more for functional foods, is the relevance that several variables have. In particular, those who think that functional foods improve their well-being, those who think that functional foods are nutrients-rich foods, those who think that functional foods improve their performance and those who have at least one child under 13 years in their family unit, are the main variables. Among them, the most associated factors with the willingness to pay more for functional foods, is represented by the variable "BAMB", namely those who have at least one child under 13 years in their family unit. Many studies in literature point out that in families with young children, below 12 years of age, parents feel great responsibilities toward the health of their children (Annunziata & Vecchio, 2013; Barrios, Bayarri, Carbonell, Izquierdo, & Costell, 2008) and for this reason they have a greater tendency to stay informed and gain more knowledge about diet and health. Furthermore, many studies identify that the level of knowledge of consumers regarding the relationship between health and nutrition (Ares, Giménez, & Gámbaro, 2008; Øvrum et al., 2012) and also the general nutritional knowledge of consumers (Labrecque,

Doyon, Bellavance, & Kolodinsky, 2006; Wahba, Arrafa, Saleh, Mekkawy, & Ahmed, 2006; Viana, Cruz, Zoellner, Silva, & Batista, 2008; Barenna & Sànchez, 2010) are good predictors for the acceptability of consumers for some functional food products. Therefore, buyers with children are believed to be more likely to buy and are willing to pay more for functional foods.

CONCLUSION

Results derived from this study provide interesting insight that may contribute to deepen the information on consumers' awareness, perceptions and attitudes towards functional foods, in order to better understand the behaviour and factors that determine their purchase intention. Knowing consumer behaviours, for a company, is at the base of successful marketing strategies (Askegaard et al 2006; Blythe 2008). Many food companies, due to rising margins and increasing value of the global market on health-enhancing foods, have developed new functional products (Khan, Grigor, Win, & Boland, 2014). However, contrary to these market estimates, there is a high risk of product failure (Hardy, 2010; Heasman & Mellentin, 2001; Stein & Rodríguez-Cerezo, 2008). One reason for the high failure rates is that companies are often more focus on technical feasibility (Bleiel, 2010) when designing their product and neglect consumers' preferences and acceptance, not meeting consumer needs (Van Kleef, van Trijp, & Luning, 2005).

In light of the results obtained, it can be said that consumers are still confused about the concept of functional foods, and do not perceive functional foods as a homogeneous group. For this reason, consumers' attitudes influence differently the intention to purchase different functional food products. Furthermore, consumers are willing to pay more for the proposed functional rusks. The interviewed people, on average, have recognized a premium price to this type of functional rusks compared to traditional ones. In particular, they are willing to pay for a packet of 300 gr of functional rusks an average price of € 1.90, compared to € 1.35, the average price for the same quantity of conventional rusks.

In addition, what emerge from the analysis about the influence that several variables have on consumers' consumption and willingness to pay more for functional foods, is mainly represented by the variable "pathologies" and the variable "children".

In particular, the results of this study show that, among all variables, people suffering from pathologies related to poor nutrition have a significant influence and represent the main variable associated with the consumption of functional foods by consumers. The results, therefore, identify that the state of health and the presence of diseases (such as diabetes, hypertension, obesity, etc.) are one of the main factors influencing the decision to buy

functional foods; and also they point out that the state of health of consumers is even more decisive with respect to socio-demographic factors in influencing the demand for functional foods.

Furthermore, this study also indicates that the factor most associated with willingness to pay more for functional foods is the presence in the family of at least one child under 13 years. Probably because parents feel great responsibility towards the health of their children (Annunziata & Vecchio, 2013; Barrios, Bayarri, Carbonell, Izquierdo, & Costell, 2008) and tend to be more informed about the relationship between health and nutrition, consequently they are more likely to be willing to pay more for functional foods.

Finally, it is important to state that the study carried out is subject to various limitations that can be addressed in subsequent research. Particularly, the limitations of this study concern the sample size, which is not representative of the entire Italian population, and the fact that results are specific to the characteristics of this study area. Furthermore, the data are context-dependent and may change at different times with respect to their collection.

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ANNEX I
CONSUMERS QUESTIONNAIRE

QUESTIONNAIRE ABOUT CONSUMER PERCEPTION TOWARD FUNCTIONAL FOODS

Welcome to the online questionnaire aimed at investigating consumers' perceptions on FUNCTIONAL FOODS.

We kindly ask you to answer some questions. The compilation will take you only a few minutes and will be of great help for the development of a research in the context of a master's thesis in Food and Beverage Innovation and Management (FABIAM) of the Polytechnic University of Marche (UNIVPM), department D3A (Economics and agricultural policy).

We underline that the questionnaire is anonymous and the data collected will be processed in compliance with the law on privacy.*

Thank you in advance for your cooperation and availability.

Good compilation!

Margherita Rotordam

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* PRIVACY OF DATA PROVIDED WITH THIS QUESTIONNAIRE

In accordance with Regulation (EU) 2016/679, GDPR (General Data Protection Regulation), and Legislative Decree 196/2003, and subsequent amendments and additions, all information collected with the questionnaires will be used exclusively for scientific research purposes. Furthermore, the data collected in the context of this survey are protected by statistical secrecy and therefore cannot be communicated or externalized except in aggregate form, so that no individual reference can be made, and can only be used for purposes statisticians.

*Obligatory questions

1. Are you usually attentive to your diet? *

- o Yes
- o No

2. Do you follow a specific diet? *

- o Yes
- o No (question 4)

3. Why do you follow a specific diet? *

- o Health problems (diseases, allergies and / or food intolerances, etc.)
- o For ethical reasons (vegan, vegetarian diet, etc.)
- o For sporting reasons
- o Pregnant and / or breastfeeding
- o To stay fit
- o To feel better (to improve mood)
- o Because it is trendy
- o Other: _____

4. Do you suffer from food allergies and / or intolerances (for example gluten, lactose, ...)? *

- o Yes
- o No (question 6)

5. Please, specify the type of food allergy / intolerance you suffer from *

- o Nickel intolerance
- o Lactose intolerance
- o Gluten intolerance
- o Allergy to eggs
- o Shellfish allergy
- o Allergy to fish
- o Allergy to cereals
- o Allergy to soy
- o Allergy to nuts (almonds, hazelnuts, walnuts, etc.)
- o Celery allergy
- o Other: _____

6. Do you suffer from any pathology related to poor nutrition (examples: diabetes, cholesterol, obesity, high blood pressure, etc.)? *

- o Yes
- o No (question 8)

7. Please, specify the type of pathology related to poor nutrition *

- o Arterial hypertension
- o Diseases of the cardiovascular system
- o Overweight and obesity
- o Increased cholesterol and blood triglycerides (metabolic diseases)
- o Diabetes
- o Osteoporosis
- o Fatty liver (biliary lithiasis and hepatic steatosis)
- o Dental caries
- o Iodine deficiency goitre
- o Other (please specify)

8. Do you practice physical activity (walking, cycling, running, gym, etc.)? *
- Yes
- No (question 10)

9. How often do you practice physical activity? *
- Less than 1 hour a week
- Between 1 and 3 hours a week
- Between 4 and 6 hours a week
- More than 7 hours a week

10. Do you buy food supplements? *
- Yes
- No(question 12)

11. How often ? *
- Always
- Often
- Sometimes
- Rarely
- Never

12. When buying a food product, do you usually check the label? *
- Always
- Often
- Sometimes
- Rarely
- Never

13. How important is it on a scale of 1 to 5 that the following nutritional claims are present in the packaging of a food product? (where: 1: Not important at all; 2: Not important; 3: Important; 4: Very important; 5: Extremely important) *

	1	2	3	4	5
Energy value (low, reduced, calorie free)					
Fat content (Low fat, Free fat, Low saturated fat, Free saturated fat)					
Sugar content (Low sugar, No sugar, No added sugar)					

Sodium content / salt (Low, Very low, Absent, Not added)					
Fiber content (Source of fiber, high)					
Protein content (source of protein, high)					
Vitamin content (source of vitamin, high, enriched)					
Mineral salt content (source of minerals, high, enriched)					
Light/lite					
Naturally / natural					
Omega-3 content					
Type of fatty acids (rich in monounsaturated, polyunsaturated, unsaturated fats)					

14. How important is it on a scale of 1 to 5 that the following health claims are present in the packaging of a food product? (where: 1: Not important at all; 2: Not important; 3: Important; 4: Very important; 5: Extremely important) *

	1	2	3	4	5
Function Health Claims (eg "Vitamin D contributes to the maintenance of normal bones" or "Calcium is necessary for the maintenance of normal bones" or "Calcium contributes to normal muscle function" or "Vitamin B12 contributes to the normal functioning of the nervous system")					
Risk Reduction Claims (e.g. “Plant sterols and plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.” or “Calcium and vitamin D help to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures”)					
Claims referring to children's development (e.g. “Vitamin D is necessary for normal bone growth and development in children” or “ Iron contributes to normal cognitive development in children” or “Calcium is necessary for normal bone growth and development in children.”)					

15. Have you ever heard about functional foods? *
- Yes
- No

16. What do you mean by a functional food? * (Please give a definition)

- _____

17. Definition of functional food and examples *

"Functional foods" are defined as natural or supplemented foods that contain biologically-active compounds which, in certain quantities, provide a scientifically proven benefit to human health (Functional Food Center).

Functional foods can be natural foods or natural foods characterized by the addition, removal or modification of one or more components or in which the bioavailability of the latter has been modified. For example, functional foods include foods with added minerals, vitamins, healthy fatty acids, phytosterols, dietary fiber or probiotics.
In order to claim health benefits (the claims shown on the packaging), the producers of functional foods must rely on objective, consistent and plausible scientific evidence that must be authorized and scientifically proven. Such evidence may derive from biological observations, epidemiological data or experimental studies.

Examples of functional foods: yogurt with probiotics, fermented milk drinks with probiotics or with plant sterols, cereals enriched with vitamins and minerals, fruit juices

enriched with vitamins and minerals, milk with omega 3 and / or with vitamins and minerals, iodized sale, etc.

18. Have you and / or a member of your household ever consumed functional foods*
- o Yes (question 20)
- o No

19. Why don't you buy functional foods? (indicate 2 options) *
- o They are expensive products
- o I was not aware of the beneficial properties of the product
- o I don't think I need it
- o I don't believe in the beneficial potential of the product
- o I think they are only needed for people with specific health problems
- o Why they don't taste good
- o They are not natural
- o I consider them exclusively a fashion
- o I am not interested in this type of product
- o They are difficult to find
- o I don't believe in the health or nutrition claims on the label
- o I don't understand some of the health or nutrition claims on the label
- o They are not safe products
- o They are completely useless
- o Other: _____

(question 23)

20. Which of these functional foods do you mainly consume? (it is possible to indicate more than one answer up to a maximum of 3) *
- o Yogurt with probiotics
- o Fermented milk beverages with probiotics or plant sterols
- o Enriched milk (with omega 3 or fiber or calcium and vitamins)
- o Vegetable drinks (soy, almond, etc.) enriched with vitamins and minerals
- o Fruit juices / Fruit drink fortified (with vitamins and minerals or with beta-glucans or with polyphenols)
- o Cereals fortified with vitamins and minerals

- o Water with mineral salts and / or vitamins
- o Butter with reduced cholesterol content
- o Eggs enriched with omega 3
- o Oils enriched with vitamins
- o Energy drinks
- o Snack bars with proteins, vitamins and minerals
- o Rusks with vitamins and / or minerals
- o Iodized salt
- o Iodized potatoes
- o Chewing gum with xylitol, vitamins, minerals
- o Enriched biscuits (with beta-glucans or with vitamins and minerals or fibers)
- o Other: _____

21. How often do you consume this type of products? *
- o I only tried once
- o Rarely (<5 times a year)
- o Occasional consumption (≈once a month)
- o Frequent consumption (≈once a week)
- o Usual consumption (several times a week)
- o Daily consumption (every day)

22. Where do you usually buy functional foods? *
- o Hypermarket
- o Supermarket
- o Discount
- o Traditional detail (butcher, bakery, etc.)
- o Specialized shops
- o City market
- o Pharmacy / parapharmacy
- o Other (specify) _____

23. Please indicate how much you agree / disagree with the following statements about functional food (where: 1 Completely disagree; 2 Disagree; 3 Undecided; 4 Agree; 5 Completely agree)*

	1	2	3	4	5
Functional products are nutritious					
Functional products keep me healthy					
Functional products contain many vitamins and minerals					
Functional products are rich in protein					
Functional products are good for my skin / teeth / hair etc.					
Functional products can be purchased in stores near where I live or work					
Functional products are readily available in shops and supermarkets					
Functional products taste good					
Functional products look good					
Functional products smell good					
Functional products do not contain additives					
Functional products contain natural ingredients					
Functional products contain no artificial ingredients					
Functional products are not expensive					
Functional products are inexpensive					
The functional products have a good value for money					
I usually eat functional foods					
Functional products are familiar to me					
Functional foods help to improve my mood					
My performance improves when I eat functional foods					
Functional foods make it easier to follow a healthy lifestyle					
I can prevent disease by eating functional foods regularly					
The idea that I can take care of my health by eating functional foods gives me pleasure					
Functional foods can repair the damage caused by an unhealthy diet					
I am prepared to compromise on the taste of a food if the product is functional					
I actively seek out information about functional foods					
Functional foods are completely unnecessary					
Functional foods are a total sham					
The growing number of functional foods on the market is a bad					

trend for the future					
For a healthy person it is worthless to use functional foods					
It is great that modern technology allows the development of functional foods					
I only want to eat foods that do not have any medicine-like effects					
Health effects are not appropriate in delicacies					
Functional foods are consumed mostly by people who have no need for them					
It is pointless to add health effects to otherwise unhealthy foods					
Functional foods promote my well-being					
The safety of functional foods has been very thoroughly studied					
I believe that functional foods fulfil their promises					
Functional foods are science-based top products					
If used in excess, functional foods can be harmful to health					
In some cases functional foods may be harmful for healthy people					
Using functional foods is completely safe					
The new properties of functional foods carry unforeseen risks					
Exaggerated information is given about health effects					
I usually buy functional products that instinctively attract me (by sight, by color, by packaging, etc.)					
I eat functional products because I recognize them from advertising / TV					
The brand is important to me when I choose a functional food					
Advertisements increase my desire to eat functional foods					
When I go shopping, I prefer to read the functional food label rather than believe in advertising campaigns					

24. Would you say that the regulations and the labelling of functional foods are: (where: 1 Completely disagree; 2 Disagree; 3 Undecided; 4 Agree; 5 Completely agree) *

	1	2	3	4	5
Honest					

Reliable					
Clear					
Attractive					
Adequate					
Important					

25. Are you interested in buying functional foods in the future? *
- o Yes
- o No

26. Do you or any member of your family buy rusks? *
- o Yes (question 28)
- o No

27. Why don't you buy rusks? *
- o _____

28. The average price of a 300 g packet of classic rusks is 1.35 €. Would you be willing to pay more for a package of functional rusks such as enriched rusks with vitamins (e.g. folic acid, B1, D2) or minerals (e.g. iron and calcium) or low-sodium rusks that have beneficial effects on one or more functions of the organism in order to improve your state of health / well-being and / or reduce the risk of diseases (for example they contribute to the maintenance of normal muscle function, the immune system, energy metabolism or help reduce tiredness and fatigue) . *
- o Yes
- o No (question 32)

29. If YES, how much would you be willing to pay for this product? *
- o 1,35 €
- o 1,45 €
- o 1,55 €
- o 1,65 €
- o 1,75 €
- o 1,85 €

- 1,95 €
- 2,05 €
- 2,15 €
- 2,25 €
- 2,35 €
- 2,45 €
- 2,55 €
- 2,65 €
- 2,75 €
- 2,85 €
- 2,95 €
- 3,05 €

30. Could you indicate how confident you are in your decision? *
- 100%
- 90%
- 80%
- 70% (question 31)
- 60% (question 31)
- 50% (question 31)
- Less than 50% (question 31)

31. If your answer is less than 80%, you could indicate below how much you would be willing to pay for a 300g pack of functional rusks enriched with vitamins and / or minerals and / or low-sodium, remembering that the price of a pack of rusks is € 1.35. *
- ---------

32. Gender *
- Male
- Female

33. Age *
- < 18

- 18-25
- 26-35
- 36-45
- 46-55
- 56-65
- > 65

34. Educational qualification *
- No formal education
- Primary school
- Middle school
- High school
- Bachelor’s degree (question 35)
- Master’s degree(question 35)
- Doctorate or higher(question 35)

35. Field of study or degree*
- _____

36. Occupation *
- Worker
- Employee
- Housewife/ Household
- Merchant
- Entrepreneur
- Doctor/ paramedic
- Teacher
- Student
- Freelance
- Retired
- Unemployed
- Other (please specify)

37. Marital status *

- Married
- Single
- Separated
- Widowed
- Cohabitant

38. Annual average household income *
- Less than € 10.000
- Between € 11.000 and € 20.000
- Between € 21.000 and € 35.000
- Between € 36.000 and € 50.000
- Between € 51.000 and € 75.000
- More than € 75.000

39. Region of residence *
- Abruzzo
- Basilicata
- Calabria
- Campania
- Emilia-Romagna
- Friuli-Venezia Giulia
- Lazio
- Liguria
- Lombardia
- Marche
- Molise
- Piemonte
- Puglia
- Sardegna
- Sicilia
- Toscana
- Trentino-Alto Adige
- Umbria
- Valle d'Aosta

- Veneto
- Others (specify)

40. Number of family members *
- _____

41. Is there at least one child under 13 years in the family unit? *
- Yes (question 42)
- No

42. Age range of children *
- 0-3 years
- 4-7 years
- 8-12 years
- > 12 years

ANNEX II
NUTRITION CLAIMS AND CONDITIONS APPLYING TO THEM BASED ON THE ANNEX OF REGULATION (EC) NO 1924/2006, LASTLY AMENDED BY REGULATION (EU) NO 1047/2012

NUTRIENT	**CLAIM**
Energy	**LOW ENERGY**: < 40 Kcal (170 kJ)/100 g for solids or < 20 Kcal (80 kJ)/100 ml for liquids **ENERGY REDUCED**: energy value reduced by at least 30 % compared to analogue products, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value **ENERGY FREE**: < 4 kcal (17 kJ)/100 ml
Fat (g)	**LOW FAT**: < 3 g of fat per 100 g for solids or 1,5 g of fat per 100 ml for liquids **FAT FREE**: < 0,5 g of fat per 100 g or 100 ml **HIGH MONOUNSATURATED/POLYUNSATURATED/ UNSATURATED FAT**: > 45% of the fatty acids present in the product derive from mono/poly/unsaturated fat under the condition that mono/poly/unsaturated fat provides more than 20% of energy of the product.
Saturated Fat (g)	**LOW SATURATED FAT**: < 1,5 g per 100 g for solids or 0,75 g/100 ml for liquids . in either case the sum of saturated fatty acids and trans fatty acids must not provide more than 10 % of energy **SATURATED FAT FREE**: sum of saturated fat and trans fatty acids does not exceed 0,1 g of saturated fat per 100 g or 100 ml.
Sugar (g)	**LOW SUGARS**: < 5 g of sugars per 100 g for solids or 2,5 g of sugars per 100 ml for liquids **SUGARS FREE**: < 0,5 g of sugars per 100 g or 100 ml **WITH NO ADDED SUGARS**: product does not contain any added

	mono or disaccharides or any other food used for its sweetening properties. If sugars are naturally present in the food, the following indication should also appear on the label: 'CONTAINS NATURALLY OCCURRING SUGARS'.
Sodium (mg)	**LOW SODIUM/SALT**: no more than 0,12 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. For waters, other than natural mineral waters falling within the scope of Directive 80/777/EEC, this value should not exceed 2 mg of sodium per 100 ml. **VERY LOW SODIUM/SALT**: no more than 0,04 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. This claim shall not be used for natural mineral waters and other waters. **SODIUM FREE** or **SALT FREE**: < 0,005 g of sodium, or the equivalent value for salt, per 100 g. **NO ADDED SODIUM /SALT**: product does not contain any added sodium/salt or any other ingredient containing added sodium/salt and the product contains no more than 0,12 g sodium, or the equivalent value for salt, per 100 g or 100 ml.
Protein (g)	**SOURCE OF PROTEIN**: > 12 % of the energy value of the food is provided by protein. **HIGH PROTEIN**: > 20 % of the energy value of the food is provided by protein.
Vitamins and minerals	**SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S]**:at least a significant amount as defined in the Annex to Directive 90/496/EEC or an amount provided for by derogations granted according to Article 6 of 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 **HIGH [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S]**: at least twice the value of 'source of [NAME OF VITAMIN/S] and/or [NAME OF MINERAL/S]
Fiber (g)	**SOURCE OF FIBRE**: > 3 g of fibre per 100 g or > 1,5 g of fibre per 100 kcal **HIGH FIBRE**: 6 g of fibre per 100 g or at least 3 g of fibre per 100 kcal
Other	**CONTAINS [NAME OF THE NUTRIENT OR OTHER**

nutrients	**SUBSTANCE]**: product complies with all the applicable provisions of this Regulation, and in particular Article 5. **INCREASED [NAME OF THE NUTRIENT]**: > 30 % compared to a similar product. **REDUCED [NAME OF THE NUTRIENT]**: < 30 % compared to a similar product, except for micronutrients (< 10 %) and for sodium, (< 25 %); The claim "**reduced saturated fat**" may only be made: (a) if the sum of saturated fatty acids and of trans-fatty acids in the product is at least 30% less than the sum of saturated fatty acids and of trans-fatty acids in a similar product; and (b) if the content in trans-fatty acids in the product bearing the claim is equal to or less than in a similar product. The claim "**reduced sugars**" may only be made if the amount of energy of the product bearing the claim is equal to or less than the amount of energy in a similar product. **LIGHT/LITE**: same conditions as those set for the term 'reduced'; the claim shall also be accompanied by an indication of the characteristic(s) which make(s) the food 'light' or 'lite'. **NATURALLY/NATURAL**: food naturally meets the condition(s) laid down in this Annex for the use of a nutritional claim, the term 'naturally/natural' may be used as a prefix to the claim **SOURCE OF OMEGA 3 FATTY ACIDS**: > 0,3 g alpha linolenic acid per 100g and per 100kcal, or at least 40mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and per 100kcal. **HIGH OMEGA 3 FATTY ACIDS**: > 0,6 g alpha linolenic acid per 100 g and per 100 kcal, or at least 80 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal.

ANNEX III
REDUCTION OF DISEASE RISK CLAIMS AUTHORIZED BY EFSA

NUTRIENT,SUBSTANCE, FOOD OR FOOD CATEGORY	CLAIM	CONDITIONS OF USE/RESTRICTIONS OF USE	EFSA OPINION REFERENCE
Calcium and vitamin D	Calcium and vitamin D help to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures	The claim may be used only for food supplements which provide at least 400 mg of calcium and 15 µg of vitamin D per daily portion. Information shall be given to the consumer that the claim is specifically intended for women 50 years and older and the beneficial effect is obtained with a daily intake of at least 1 200 mg of calcium and 20 µg of vitamin D from all sources. For food supplements with added calcium and vitamin D the claim may be used only for those targeting women 50 years and older	Q-2008-721, Q-2009-00940
Monounsaturated and/or polyunsaturated fatty acids	Replacing saturated fats with unsaturated fats in the diet has been	The claim may be used only for food which is high in unsaturated fatty acids, as referred to in the	Q-2009-00458

	shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease	claim HIGH UNSATURATED FAT as listed in the Annex to Regulation (EC) No 1924/2006. The claim may only be used on fats and oils	
Vitamin D	Vitamin D helps to reduce the risk of falling associated with postural instability and muscle weakness. Falling is a risk factor for bone fractures among men and women 60 years of age and older.	The claim may be used only for food supplements which provide at least 15 µg of vitamin D per daily portion. Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 20 µg of vitamin D from all sources. For food supplements with added vitamin D the claim may be used only for those targeting men and women 60 years and older	Q-2010-01233
Barley beta-glucans	Barley beta-glucans has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.	Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of barley beta-glucan. The claim can be used for foods which provide at least 1 g of barley beta-glucan per quantified portion.	Q-2011-00798
Barley beta-glucans	Barley beta-glucans has been shown to lower/reduce	Information shall be given to the consumer that the beneficial effect is obtained with daily intake	Q-2011-00799

	blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease	of 3 g of barley beta-glucan. The claim can be used for foods which provide at least 1 g of barley beta-glucan per quantified portion.	
Sugar-free chewing gum	Sugar-free chewing gum helps neutralise plaque acids. Plaque acids are a risk factor in the development of dental caries.	Information shall be given to the consumer that the beneficial effect is obtained with chewing of 2-3 g of sugar-free chewing gum for 20 minutes, at least three times per day after meals.	Q-2010-00120
Sugar-free chewing gum	Sugar-free chewing gum helps reduce tooth demineralisation. Tooth demineralisation is a risk factor in the development of dental caries.	Information shall be given to the consumer that the beneficial effect is obtained with chewing of 2-3 g of sugar-free chewing gum for 20 minutes, at least three times per day after meals.	Q-2010-00119
Oat beta-glucan	Oat beta-glucan has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease	Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of oat beta-glucan. The claim can be used for foods which provide at least 1g of oat beta glucan per quantified portion.	Q-2008-681
Plant sterols/Plant stanol esters	Plant sterols and plant stanol esters have been shown to	Information to the consumer that the beneficial effect is obtained with a daily	Q-2008-779, Q-2009-00530 & Q-2009-

	lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.	intake of 1,5-3 g plant sterols/stanols. Reference to the magnitude of the effect may only be made for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude of the effect, the range "7 % to 10 %" for foods that provide a daily intake of 1,5-2,4 g plant sterols/stanols or the range "10 % to 12,5 %" for foods that provide a daily intake of 2,5-3 g plant sterols/stanols and the duration to obtain the effect "in 2 to 3 weeks" must be communicated to the consumer.	00718, Q-2011-01241
Plant sterols: Sterols extracted from plants, free or esterified with food grade fatty acids.	Plant sterols have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.	Information to the consumer that the beneficial effect is obtained with a daily intake of 1,5-3 g plant sterols. Reference to the magnitude of the effect may only be made for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude of the effect, the range "7 % to	Q-2008-085, Q-2009-530 and Q-2009-718, Q-2011-01241

		10 %" for foods that provide a daily intake of 1,5-2,4 g plant sterols or the range "10 % to 12,5 %" for foods that provide a daily intake of 2,5-3 g plant sterols and the duration to obtain the effect "in 2 to 3 weeks" must be communicated to the consumer.	
Plant stanol esters	Plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.	Information to the consumer that the beneficial effect is obtained with a daily intake of 1,5-3 g plant stanols. Reference to the magnitude of the effect may only be made for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude of the effect, the range "7 % to 10 %" for foods that provide a daily intake of 1,5-2,4 g plant stanols or the range "10 %-12,5 %" for foods that provide a daily intake of 2,5-3 g plant stanols and the duration to obtain the effect "in 2 to 3 weeks" must be communicated to the consumer.	Q-2008-118, Q-2009-00530 & Q-2009-00718, Q-2011-00851, Q-2011-01241

Chewing gum sweetened with 100% xylitol	Chewing gum sweetened with 100% xylitol has been shown to reduce dental plaque. High content/level of dental plaque is a risk factor in the development of caries in children	Information to the consumer that the beneficial effect is obtained with a consumption of 2-3g of chewing gum sweetened with 100% xylitol at least 3 times per day after the meals	Q-2008-321
Folic Acid	Supplemental folic acid intake increases maternal folate status. Low maternal folate status is a risk factor in the development of neural tube defects in the developing foetus.	The claim may be used only for food supplements which provide at least 400 µg of folic acid per daily portion. Information shall be provided to the consumer that the target population is women of child-bearing age and the beneficial effect is obtained with a supplemental folic acid daily intake of 400 µg for at least one month before and up to three months after conception.	Q-2013-00265
Calcium	Calcium helps to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures	The claim may be used only for food which provides at least 400 mg of calcium per quantified portion. Information shall be given to the consumer that the claim is specifically intended for women 50 years and older and the beneficial effect is obtained with a daily	Q-2008-721, Q-2009-00940

		intake of at least 1 200 mg of calcium from all sources. For foods with added calcium the claim may be used only for those targeting women 50 years and older	

ANNEX IV
MAIN FUNCTIONAL FOODS REGULATIONS

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
COMMISSION REGULATION (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health
COMMISSION REGULATION (EU) No 1047/2012 of 8 November 2012 amending Regulation (EC) No 1924/2006 with regard to the list of nutrition claims
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
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
REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001

ANNEX V
MARKET ANALYSIS OF CONVENTIONAL AND FUNCTIONAL RUSKS

Conventional rusks

BRAND	SHOP	CITY	gr	€
Grissinbon	Conad	MisanoAdriatico	250	0,99
Monviso	Conad	MisanoAdriatico	300	2,19
Verso Natura bio conad	Conad	MisanoAdriatico	315	1,69
Mulino bianco	Conad	MisanoAdriatico	630	1,69
Colossi	Conad	MisanoAdriatico	645	1,69
Buitoni	Conad	MisanoAdriatico	600	1,69
San carlo	Conad	MisanoAdriatico	125	1,19
Grissinbon	Despar	MisanoAdriatico	250	0,79
Mulino bianco	Despar	MisanoAdriatico	315	1,29
Mulino bianco	Despar	MisanoAdriatico	630	1,69
Despar	Despar	MisanoAdriatico	320	0,99
Monviso	Conad	Riccione	300	2,29
Conad	Conad	Riccione	324	0,95
Grissinbon	Conad	Riccione	250	0,99
Buitoni	Coop	Riccione	600	1,74
Grissinbon	Coop	Riccione	250	0,99
Coop	Coop	Riccione	320	0,89
Coop	Coop	Riccione	640	1,46
Mulino bianco	Coop	Riccione	315	1,07
Mulino bianco	Coop	Riccione	630	1,75
Monviso	Coop	Riccione	500	3,85
San carlo	Coop	Riccione	125	1,2
Buitoni	Si con te	Macerata	600	1,83
gentilini	Si con te	Macerata	185	1,65
Vale	Si con te	Macerata	640	1,39
Grissinbon	Si con te	Macerata	250	1,15
Mulino bianco	Si con te	Macerata	315	1,49
Tre mulini	Eurospin	Macerata	300	1,45
Tre mulini	Eurospin	Macerata	640	1,25
Mulino bianco	Lidl	Macerata	630	1,79
Despar	Despar	Riccione	320	0,99

Monviso	Despar	Riccione	400	3,39
Mulino bianco	Despar	Riccione	630	1,65
Colussi	Despar	Riccione	320	1,39
Monviso	Despar	MisanoAdriatico	400	3,39

Functional rusks

BRAND	**SHOP**	**CITY**	**gr**	**€**
Monviso	Conad	Misano adriatico/rimini	230	1,89
Buitoni	Conad	Misano adriatico/rimini	300	1,29
Vital	Despar	Misano adriatico/rimini	155	1,69
Buitoni	Conad	Riccione/Rimini	300	1,39
Monviso	Conad	Riccione/Rimini	230	1,99
Monviso	Coop	Riccione/Rimini	230	2,14
Monviso	Conad	falconara/ancona	230	1,89
Buitoni	Conad	falconara/ancona	300	1,29
Buitoni	Conad	Macerata	300	1,38
Monviso	Conad	Macerata	230	2,69
Buitoni	Conad	Macerata	300	1,99
Monviso	Conad	Macerata	230	2,69
Buitoni	Iperconad	Macerata	300	1,39
Buitoni	Si con te	Macerata	300	1,46
Vital	Despar	Riccione/Rimini	155	1,69
Buitoni	Conad	Riccione/Rimini	300	1,39
Buitoni	Conad	Fermo	300	1,41

ANNEX VI
ECONOMETRICS MODEL RESULTS

Modello 1: Logit, usando le osservazioni 1-425
Variabile dipendente: CONS
Errori standard basati sull'Hessiana

	Coefficient	*Std. Error*	*z*	*p-value*	
const	−3,45803	1,70546	−2,028	0,0426	**
ALI	0,461691	0,597701	0,7724	0,4399	
REG	−0,590078	0,478029	−1,234	0,2171	
ALL	0,660032	0,622350	1,061	0,2889	
PAT	1,34922	0,616458	2,189	0,0286	**
ETI	−0,199067	0,201962	−0,9857	0,3243	
SCA_COMP	−0,749266	0,281400	−2,663	0,0078	***
SCA_REP	0,363131	0,182758	1,987	0,0469	**
SCA_SM	0,764921	0,282370	2,709	0,0067	***
SCA_FAM	0,577656	0,255464	2,261	0,0237	**
SCA_PRE	−0,565495	0,264675	−2,137	0,0326	**
SCA_PROB	0,952105	0,243367	3,912	<0,0001	***
SCA_BRAND	0,512206	0,204860	2,500	0,0124	**
SESSO	0,129317	0,440132	0,2938	0,7689	
ETA	−0,206452	0,158909	−1,299	0,1939	
RED	−0,0835538	0,161806	−0,5164	0,6056	
FAM	0,466570	0,176145	2,649	0,0081	***
BAMB	0,662180	0,550521	1,203	0,2290	
OCC	0,0161239	0,0648794	0,2485	0,8037	
IST	0,0283365	0,207485	0,1366	0,8914	
CONO	0,996548	0,552292	1,804	0,0712	*

Media var. dipendente	0,872941	SQM var. dipendente	0,333431
R-quadro di McFadden	0,399049	R-quadro corretto	0,269277
Log-verosimiglianza	−97,24697	Criterio di Akaike	236,4939
Criterio di Schwarz	321,5878	Hannan-Quinn	270,1109

Numero dei casi 'previsti correttamente' = 390 (91,8%)
f(beta'x) nella media delle variabili indipendenti = 0,333
Test del rapporto di verosimiglianza: Chi-quadro(20) = 129,15 [0,0000]

Odds-ratios for CONS:

Variable	Odds-ratio	95,0% conf. interval
ALI	1,5868	[0,492, 5,120]
REG	0,5543	[0,217, 1,415]
ALL	1,9349	[0,571, 6,552]
PAT	3,8544	[1,151, 12,903]
ETI	0,8195	[0,552, 1,217]
SCA_COMP	0,4727	[0,272, 0,821]
SCA_REP	1,4378	[1,005, 2,057]
SCA_SM	2,1488	[1,236, 3,737]
SCA_FAM	1,7819	[1,080, 2,940]
SCA_PRE	0,5681	[0,338, 0,954]
SCA_PROB	2,5912	[1,608, 4,175]
SCA_BRAND	1,6690	[1,117, 2,494]
SESSO	1,1381	[0,480, 2,697]
ETA	0,8135	[0,596, 1,111]
RED	0,9198	[0,670, 1,263]
FAM	1,5945	[1,129, 2,252]
BAMB	1,9390	[0,659, 5,704]
OCC	1,0163	[0,895, 1,154]
IST	1,0287	[0,685, 1,545]
CONO	2,7089	[0,918, 7,997]

Modello 2: Logit, usando le osservazioni 1-342
Variabile dipendente: VAR_DIP2
Errori standard basati sull'Hessiana

	Coefficient	*Std.Error*	*z*	*p-value*	
const	−3,58510	1,21467	−2,952	0,0032	***
CONO	0,330096	0,342236	0,9645	0,3348	
CONS	0,0994874	0,454388	0,2189	0,8267	
ALI	0,386877	0,426604	0,9069	0,3645	
REG	0,0594404	0,355759	0,1671	0,8673	
ALL	−0,200651	0,387220	−0,5182	0,6043	
PAT	0,444706	0,432144	1,029	0,3034	
ETI	0,0255460	0,143760	0,1777	0,8590	
SCA_COMP	0,347858	0,194268	1,791	0,0734	*
SCA_REP	−0,213531	0,135891	−1,571	0,1161	
SCA_SM	0,176036	0,159011	1,107	0,2683	
SCA_FAM	−0,0789136	0,149873	−0,5265	0,5985	
SCA_PRE	0,303741	0,160835	1,889	0,0590	*
SCA_PROB	0,539949	0,161126	3,351	0,0008	***
SCA_BRAND	0,162256	0,125035	1,298	0,1944	
SESSO	−0,242725	0,317699	−0,7640	0,4449	
ETA	0,0899137	0,115280	0,7800	0,4354	
IST	0,106038	0,141857	0,7475	0,4548	
OCC	−0,0403036	0,0437574	−0,9211	0,3570	
RED	−0,00570350	0,104300	−0,05468	0,9564	
FAM	−0,0483859	0,0956461	−0,5059	0,6129	
BAMB	0,676096	0,382876	1,766	0,0774	*

Media var. dipendente	0,660819	SQM var. dipendente	0,474125
R-quadro di McFadden	0,178653	R-quadro corretto	0,078218
Log-verosimiglianza	−179,9143	Criterio di Akaike	403,8287
Criterio di Schwarz	488,1945	Hannan-Quinn	437,4377

Numero dei casi 'previsti correttamente' = 260 (76,0%)

f(beta'x) nella media delle variabili indipendenti = 0,474
Test del rapporto di verosimiglianza: Chi-quadro(21) = 78,2671 [0,0000]

Odds-ratios for VAR_DIP2:

Variable	Odds-ratio	95,0% conf. interval
CONO	1,3911	[0,711, 2,721]
CONS	1,1046	[0,453, 2,691]
ALI	1,4724	[0,638, 3,397]
REG	1,0612	[0,528, 2,131]
ALL	0,8182	[0,383, 1,748]
PAT	1,5600	[0,669, 3,639]
ETI	1,0259	[0,774, 1,360]
SCA_COMP	1,4160	[0,968, 2,072]
SCA_REP	0,8077	[0,619, 1,054]
SCA_SM	1,1925	[0,873, 1,629]
SCA_FAM	0,9241	[0,689, 1,240]
SCA_PRE	1,3549	[0,989, 1,857]
SCA_PROB	1,7159	[1,251, 2,353]
SCA_BRAND	1,1762	[0,921, 1,503]
SESSO	0,7845	[0,421, 1,462]
ETA	1,0941	[0,873, 1,371]
IST	1,1119	[0,842, 1,468]
OCC	0,9605	[0,882, 1,047]
RED	0,9943	[0,810, 1,220]
FAM	0,9528	[0,790, 1,149]
BAMB	1,9662	[0,928, 4,164]