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Public Health Policies and Functional Property Claims for Food in Brazil

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Additional information is available at the end of the chapter

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1. Introduction

Specific regulations for functional foods began in Japan in the middle of the 80's. Known as food for specific health use (FOSHU: *foods for specified health use*), these foods carry a label of approval from the Japanese Ministry of Health and Welfare [1]. The goal was to develop foods that would enable the reduction of expenses on public health, considering the high life expectancy in that country [2]. The term “functional foods” refers to processed foods, similar in appearance to conventional foods, consumed as part of a normal diet, but demonstrating physiological benefits and/or reduction in chronic diseases risk, in addition to its basic nutritional functions [1]. The principle was soon adopted worldwide [2]. In Brazil, functional foods were officially recognized in 1999, with the approval of specific legislation [3]. The designations of the claims, as well as the criteria for their approval vary according to the regulations of each country or economic block. Therefore, it is noteworthy considering the regulations of the intended market for the product.

The tendency of the Codex Alimentarius¹ and of several countries was disciplining these claims on the functional properties of foods or its components, as well as on the security scientific evidence-based, in order to avoid confusion and mistakes to the consumer with nomenclature and claims about properties not scientifically proved [4-7].

Functional foods are an important part of wellness, which also includes a balanced diet and physical activity [8]. The Food Guide for the Brazilian Population of the Ministry of Health

¹ The combined program of the United Nations for Food and Agriculture Organization (FAO) and the World Health Organization (WHO) is an international forum for standardization on food, created in 1962, and its rules aim to protect the health of the population, ensuring fair practices in international and regional trade of food, creating international mechanisms aimed at removing tariff barriers, promoting and coordinating all works held in standardization.

recommends stimuli to physical activity practice, adoption of a varied diet and warn not to mystify food functional components [9].

Brazilian legislation does not define functional food. It defines functional property claim and health property claim. It establishes the basic guidelines for risk assessment and safety, analysis and proof of functional and/or health properties claimed in labeling, as well as the conditions of registration for foods with claims of functional and/or health properties [5,6,10].

Among the guidelines for this type of food it is allowed functional claims related to the physiological role in the growth, development and normal functions of the body and/or also claims about the general maintenance of health and disease risk reduction, as optional. It is not allowed claims which make reference to the cure or prevention of disease. The food or ingredient that claim functional and/or health properties can, in addition to basic functions, when it is a nutrient, produce metabolic and/or physiologic effects and/or beneficial effects to health, and it must be safe for consumption without medical supervision. To submit claims of functional property and/or health, food, as well as bioactive substances and isolated probiotics must be, obligatorily, registered in the competent authority. The advertising content of these products can not be different in their meaning, from that approved for the labeling. The claims should also be in accordance with the guidelines of the public health policies [4-6,11].

The public health policy in Brazil for the specific area of food and nutrition is defined by the Food and Nutrition National Policy (PNAN in Portuguese for *Política Nacional de Alimentação e Nutrição*) [12]. It presents an interface with the National Policy for Health Promotion (PNPS in Portuguese for *Política Nacional de Promoção da Saúde*) [13]. The Food Guide for Brazilian People[10] constitutes compliance with one of the PNAN guidelines. This guide has incorporated the recommendations of the global strategy[14] and it establishes guidelines for healthy eating and physical activity. The guidelines of these policies are used as criteria for evaluating claims of functional and/or health properties in food.

The outlook reported in 2006 regarding the processes approvals flow in requests for registration of foods claiming functional properties, in the period from 1999 to 2004, evidenced a high proportion of refused cases [15]. There is the need of greater understanding by the industry, regarding the criteria used for evaluating the processes with regard to the terms employed in the law [6] "in accordance with the guidelines of the public health policy", "in light of current scientific knowledge" and "food of occasional consumption". For this understanding it is crucial to understand the meaning of terms employed in the regulations and in the public policies.

In March 2011, the National Agency of Sanitary Surveillance (ANVISA in Portuguese *Agência Nacional de Vigilância Sanitária*) presented in the Management Report for the years 2005 to 2010 the main achievements of the Agency. From the perspective of modernization of the management, from 2006 on, ANVISA has promoted a reform in the food control model, with emphasis on the reduction in bureaucracy of the sanitary registration and on the strengthening of the post-market control. The reduction on the sanitary registration bureaucracy was started in 2000, and broadened in 2005 and 2010.

Currently, the sanitary registration is required only for six categories of food, allowing the administrative machine to look over the control of the product directly offered to the consumer, an international trend in the food regulation [16].

It remains with mandatory registration foods claiming functional and/or health properties, infant feeding, food for enteral nutrition, new foods, new ingredients and bioactive substances and isolated probiotics claiming for functional or health properties. For its innovative character or consumption by specific population groups, these foods require the evaluation of safety and efficacy, reasons for maintaining the registration [16].

2. Brazilian legislation

Responsibilities of the National Health Surveillance Agency (ANVISA):

- To establish standards, monitor and execute policies, guidelines and actions of the health surveillance.
- To grant products registrations, according to the guidelines of its area of action.
- To control, monitor and track, under the prism of health legislation, advertising and publicity of products covered by the health surveillance scheme [17].

In Brazil, since 1990 there had been applications for registration of various products not recognized as food yet, within the traditional concept of food. Given the complexity of the issue and the change in the focus of food analysis, which now considers the risk criterion, ANVISA created the Advisory Technoscientific Commission on Functional Foods and Novel Foods (CTCAF in Portuguese for *Comissão de Assessoramento Tecnocientífico em Alimentos Funcionais e Novos Alimentos*), consisting of professors and outstanding researchers working in universities and research institutions, with the purpose of assisting the Board of Food and Toxicology in decisions related to this issue. The former term CTCAF was further changed to the Advisory Technoscientific Commission on Foods with Claims of Functional and/or Health Property and Novel Foods [18].

After extensive discussion in 1999, ANVISA has approved regulations that deal with basic guidelines:

- **Resolution nº 16/99:** procedures for registration of food and/or new ingredients [19].
- **Resolution nº 17/99:** risk assessment and food safety [20].
- **Ministerial Order 398/99 and Resolution nº 18/99:** basic guidelines for analysis and approval of claims for functional and/or health property mentioned on the labeling of the foods [5,6].
- **Resolution nº 19/99:** procedures for registration of foods claiming functional and/or health properties [10].

These categories of food must also comply with the legislation for food in general, and in no case it is allowed to claim medicinal or therapeutic properties. Other regulations such as:

- Resolution nº 22/2000: Technical Regulation on the basic procedures for registration and for exemption from obligatory registration of imported products relevant to food field, contained in the annex to this resolution [21].

- Resolution nº 23/2000: Demonstrates about the Manual of Basic Procedures for the Registration and for Exemption from Obligatory Registration of Products Pertinent to the Food Area [22].
- Resolution RDC nº 2/2002: Technical Regulation of bioactive substances and isolated probiotics with claim for functional and/or health properties, annexed to that resolution [23].
- Technical Report nº 9/2004: Guidance for use, on food labels, the claims of functional properties of nutrients which function is fully recognized by the scientific community (Item 3.3 of Resolution nº. 18/99) [4].
- Technical Report nº 19/2006: Procedures for adding edible mushrooms in capsules, tablets and pills in the food area [24].
- Resolution RDC nº 27/2010: Demonstrates about the categories of food and packaging which are excepted or compulsory to sanitary registration which apply to all types of food [25].
- Decree Law nº 986/1969: Instructs food basics rules [11].

3. Registration

The registration at ANVISA is compulsory both for bioactive substances and isolated probiotics, as well as for food claiming functional and/or health properties and for new foods and new ingredients, produced in Brazil or imported [21-23]. For this, it is necessary to demonstrate the efficacy and safety of the food consumption. Even for products of animal origin, such as dairy products, the competence of the Ministry of Agriculture Livestock and Supply (MAPA in Portuguese for *Ministério da Agricultura Pecuária e Abastecimento*), the proceedings on the confirmation of the claims must be submitted to ANVISA for analysis.

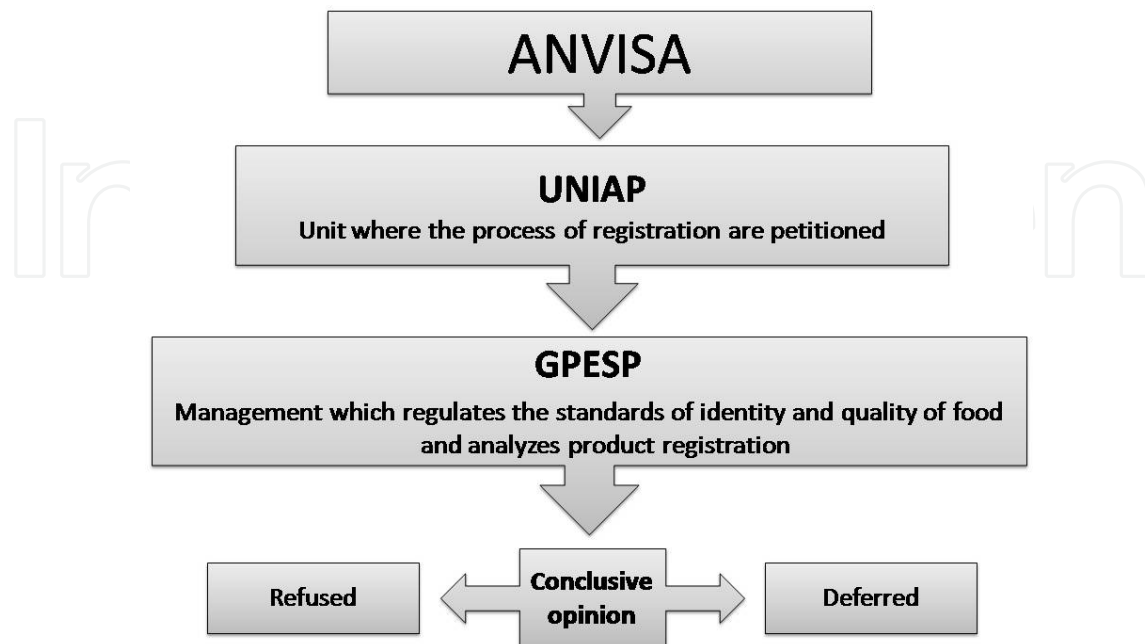
In the case of foods regulated by the MAPA, such as the dairy products, companies must first fill a petition in ANVISA, referring to the request "Evaluation of Foods with Claims of Functional and/or Health Properties." ANVISA shall send response about the assessment for the company, with a copy to the responsible area of MAPA [26]. For the assessment, it is necessary to include the information and documentation required in the Resolution nº18/1999 [6].

4. New food

According to ANVISA [19], "new food and/or new ingredients" are foods or substances with no history of consumption in this country, or foods with substances already consumed, but with additions or employed at levels much higher than those currently observed in the regular diet. For example: eggplant in capsules, *Agaricus blazei* mushroom in capsules, guarana in capsules.

Foods that may be consumed in the form of capsules, tablets or other dosage forms and which do not claim functional or health properties that are scientifically proven must bring on the label the words "The Ministry of Health warns: there is no proved scientific evidence

that this food will prevent, treat or cure diseases". For this category of foods it is not allowed to claim functional and/or health properties [19,24].



ANVISA - National Agency of Sanitary Surveillance (in Portuguese *Agência Nacional de Vigilância Sanitária*);

UNIAP - Public Unit Service (in Portuguese *Unidade de Atendimento ao Público*);

GPESP - Management of Special Products (in Portuguese *Gerência de Produtos Especiais*);

Figure 1. Steps to registration of food in Brazil

5. Bioactive substances and isolated probiotics

RDC nº 2/2002 [23] is applied to the guidelines to be adopted for the safety assessment, registration and commercialization of bioactive substances and isolated probiotics claiming functional and/or health properties, presented as dosage forms (capsules, tablets, pills, powders, granules, pastilles, suspensions and solutions). The products are classified as: carotenoids, phytosterols, flavonoids, phospholipids, organosulfur compounds, polyphenols and probiotics. Once approved, the claims proposed by the manufacturer are mandatory, and they must be presented in the manner and wording approved by ANVISA [23]. An example of a product registered in this category is lycopene in capsules.

6. Foods with claims of functional and/or health properties

To obtain the registration of food with claims, the company must present combined with the other documentation contained in the legislation for food in general, the scientific-technical report containing the following information [5,6,10]:

- Text and copy of the wording layout of the labeling.
- Description of the product
- Consumption that is foreseen or recommended by the manufacturer;

- Description of the analytical methodology for evaluation of the components which are object of claim;
- Chemical composition with molecular characterization, when appropriate and product formulation;
- Purpose, usage conditions and nutritional value, when appropriate;
- Scientific evidences applicable, when appropriate, to attest the efficacy when calaiming functional and/or health properties:
 - nutritional and/or physiological and/or toxicological tests in experimentation animals;
 - biochemical tests;
 - scientific description of the ingredients of the product, according to species of botanical, animal or mineral origin, when appropriate;
 - epidemiological studies;
 - clinical trials;
 - evidence of traditional use, observed in the population, without harm to health;
 - comprehensive evidence of the scientific literature, international health agencies and internationally recognized legislation on the properties and characteristics of the product;
 - documented information about approval of use of the food or ingredient in other countries, economic blocks, Codex Alimentarius and other internationally recognized authorities.

It shall be considered as scientific evidences, the copies of original papers published in journals of recognized scientific imprint. Therefore, book chapters, non scientific weekly journal articles, among others are not valid as scientific evidence.

The scientific papers in English or Spanish do not need translation. Copies of other works in foreign languages must be accompanied by translation, not necessary sworn.

It is the responsibility of the company submitting the copy of the scientific papers referenced in the Technical Scientific Report. It will not be considered as valid references the abstracts of papers and bibliographic citations.

The Technical Report nº 9, may 2004 [4] was established on the basis that the application of the item 3.3 of the resolution nº 18/99 “for the nutrients with function fully recognized by the scientific community, it is not required to demonstrate efficacy or to analyze this nutrient in order to have the functional claim in the labeling” [6] allowed situations that contradicted the guidelines of public health policies, as well as it was observed an increased use of claims on labels of products exempted from the mandatory register in the trade [4]. According to that report, the following criteria must be met for approval of claims for nutrients with function fully recognized by the scientific community:

- They must be related to nutrients intrinsic to the product, which must be present at least in the amount set for the attribute "source" according to regulations on supplementary nutrition (Ministerial Order nº 27/98) [27].
- They must be specific to the role of the nutrient which is claimed.

- They must be linked to the normal food intake of the population, which should not be of occasional consumption and shall not be present as capsules, tablets, pills, or other dosage forms.

The meeting to the criteria established for the use of the claims set forth in item 3.3 of the Resolution n° 18/99, which are of the company responsibility, dispense it to send the documentation for the technical assessment, noting that the claims can not refer to prevention, treatment and cure of diseases [6]. However, the exemption refers only to the necessity of proving the claims - Item 4.1.1.9 of the RDC 18/99 and not to registration and other items of the technical scientific report [6]. Foods added with essential nutrients, which claim for functional properties should be referred for evaluation of each case.

Regarding the expression “it should not be of occasional consumption” [4], according to RDC n° 359/2003, the following products are considered as occasional consumption: whole fruit preserved for adornment (maraschino cherry, raspberry), candies, lollipops and pastilles, chewing gum, chocolates, sweets and similar products; chocolate confectionery *dragees* in general; ice cream, individual units of ice cream; cereal bar with more than 10% fat, nougat, soft drinks, carbonated or not (tea, soy-based beverages and soda); powder for preparing refreshments, sweet biscuits, with or without filling, *brownies* and *alfajors*, candied fruits, *panettone*, fruit cake, cakes and similar with filling and cover; *snacks* prepared from cereals and flour for snack consumption, mix for preparation of sweets, topping for cakes, pies and ice cream [28].

In 2005 the products with claims of functional and/or health properties approved since 1999 were re-evaluated. It was used as basis the current scientific knowledge, as well as reports and studies that demonstrated the difficulties encountered by consumers in understanding the true meaning of the features announced for certain products containing claims. The review considered as assumptions, the need of the claims to be in accordance with the policies of the Ministry of Health and be easily understood by consumers, in addition to complying with the provisions of the resolutions n° 17/99, 18/99 and 19/99. The following products had their claims changed, in order to improve the consumer understanding about the properties of these foods: fatty acids of omega-3 family, carotenoids (lycopene and lutein), dietary fiber (fiber, beta-glucane, fructooligosaccharides, inulin, lactulose, *Psillium* ou *Psillium*, chitosan), phytosterols, probiotics (*Lactobacillus acidophilus*, *L. casei shirota*, *L. casei var. rhammosus*, *L. casei var. defensis*, *L. delbrueckii subspécie bulgaricus*, *Bifidobacterium bifidum*, *B. lactis*, *B. longum*, *Streptococcus salivarius*, *thermophilus* subspecies) and soy protein. The claims previously approved, regarding to caffeine, sorbitol, xylitol, mannitol, sodium stearate, sodium bicarbonate, omega-6 fatty acids, polyunsaturated and monounsaturated fat acids (in vegetable oils), and the liquid compound ready for consumption, were no longer allowed. Companies should adapt the wording on the label, following this new format of the claims by January 30, 2006 or within the deadline negotiated with regional surveillances for the depletion of the products package [18]. The list of approved claims was updated in July 2008. The list (Annex I) included the claims related to beta-glucane, resistant dextrin in powder, partially hydrolyzed guar gum and polydextrose [29]. The Figure 1 shows the steps to registration of food in Brazil.

The situation in Brazil in 2006, after the review of the claims in 2004, was as follows: no health claim was approved. It was approved 14 claims of generic functional properties with standardized language and 25 kinds of substances or microorganisms with functional claim [15]. The claims about nutrients with fully established function were under discussion [15, 17, 30].

7. Advertising

The advertising and publicity of these products are inspected by ANVISA, through the General Management of Inspection, Quality Monitoring, Control and Surveillance of Inputs, Drugs and Products, Advertising and Publicity (GGIMP in Portuguese for *Gerência Geral de Inspeção, Monitoramento da Qualidade, Controle e Fiscalização de Insumos, Medicamentos e Produtos, Propaganda e Publicidade*) which incorporated in February 2012 the General Managing of Surveillance and Monitoring of Advertising, Publicity, Promotion and Information about Products Subject to Sanitary Surveillance (GGPRO in Portuguese for *Gerência Geral de Monitoramento e Fiscalização da Propaganda, de Publicidade, de Promoção e de Informação de Produtos Sujeitos à Vigilância Sanitária*) [31]. Any consumer information booklet, which compose the product package, or an instrument for its disclosure, can not convey allusive information to their properties other than those approved by the competent authority of ANVISA to be present on its label [11, 18].

In studies performed for Pinto, in reference [32], the advertisements of foods *folder* with claim of functional and/or health properties, of bioactive substances and isolated probiotics, as well as of new foods were assessed regarding the current legislation, and a high proportion of samples did not attend to more than one requirement. The claim for medicinal or therapeutic properties, the omission of mandatory warning statements and the recommended forms of consumption of the products may lead to inadequate intake and cause undesirable reactions in specific groups of consumers, especially people with allergies, children, pregnant women, nursing mothers and those with celiac disease. Moreover, it can slow the search for appropriate treatment, and may worsen diseases. This deterioration increases public spending on curative health.

In Brazil there has not been regulation specific to food advertising yet, which complicates the understanding of the industries and inspection by the health authorities. There are requirements of the relevant legislation on foods that are applied to food advertising which claim functional and/or health properties, bioactive substances and isolated probiotics and new foods, in the same way it is upon approved for labeling [32].

8. Criteria for evaluating the scientific basis for claims

World Health Organization (WHO), combined with the United Nations for Food and Agriculture Organization (FAO/UN) published some recommendations on lifestyle, diet and food intake, suggesting levels of scientific evidence for the risk of development of chronic non-communicable diseases (CNCD) [33, 34]. The classification the strength of

evidence of FAO/UN for recommendations in clinical practice for disease prevention, according to the quality, quantity and results of available studies is established as evidence convincing, probable, possible and insufficient [33]. The strength of evidence that relates dietary factors and lifestyle with the risk of developing obesity, type 2 diabetes, cardiovascular disease (CVD) and cancer, classified according to the categories mentioned above are summarized in Table 1.

	Obesity	Type 2 Diabetes	CVD	Cancer
High intake of highly energy food	C↑			
Trans fatty acids			C↑	
Fish and fish oil (EPA and DHA)			C↓	
High intake of dietary fiber (NSP)	C↓	P↓	P↓	
High sodium intake			C↑	
Fruits (including red fruits) and vegetables	C↓ ^k	P↓ ^k	C↓	P↓ ^l
Overweight and obesity		C↑	C↑	C↑ ^s
Regular physical activity	C↓	C↓	C↓	C↓

Note: Only convincing evidence (C) and probable evidence (P) are included in this summary table.

C↑: convincing increased risk; C↓: convincing decreased risk; P↑: probable increased risk; P↓: probable decreased risk; EPA: eicosapentaenoic acid; DHA: docosapentaenoic acid; NSP: non-starch polysaccharides. k: based on contributions from fruits and vegetables with non-starch polysaccharides (dietary fibers). l: cancer of the oral cavity, esophagus and colorectal cancer. s: for esophageal cancer, colorectal, breast (in postmenopausal women), endometrium and kidney.

Table 1. Summary of strength of evidence for obesity, type 2 diabetes, cardiovascular disease and cancer [33].

9. General policies: Food and health promotion

There is a strong global interest to improve the quality of nutrition and reduce health care costs through prevention of chronic diseases, improving the quality and active life expectancy. The Brazilian health policies related to food and nutrition exhibit this trend and follow the recommendations of the global strategy on diet, physical activity and health, published by the World health [14]. The strategy recommends that member countries adopt policies that encourage healthy eating and physical activity, as a way to reduce the incidence of CNCD caused by unhealthy diet and sedentary lifestyle [35]. The policies that influence the approval of claims for foods are set out below.

10. National policy for Food and Nutrition

The National Food and Nutrition (PNAN), adopted in 1999, integrates the efforts of the Brazilian State that through a set of proposed policies is supposed to respect, protect, promote and provide human rights to health and nutrition [12].

PNAN, updated in November 2011, aims the improvement in food, nutrition and health conditions of the Brazilian population, by promoting healthy and adequate eating habits, food and nutrition surveillance and the comprehensive prevention of the problems related to food

and nutrição [34]. It integrates the National Health Policy (PNS) and presents an interface with the National Policy of Health Promotion (PNPS in Portuguese for *Política Nacional de Promoção da Saúde*), inserting itself in the context of Food and Nutritional Security. Figure 2 shows the interfaces of PNAN and PNPS with the National Health Policy [35].

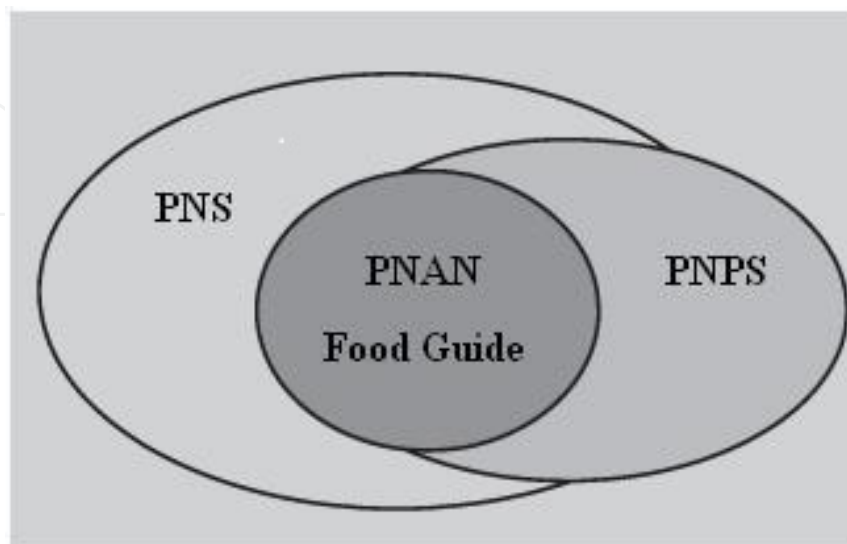


Figure 2. Interfaces of the National Brazilian Health Policies (adopted from Oliveira, 2006) [36].

Some considerations of the National Food and Nutrition are highlighted on the national reality [12]:

- The adoption of the concept of Food and Nutritional Security worldwide and in Brazil facilitated the understanding of the role of the health sector with regard to food and nutrition, recognized as essential to the promotion, protection and restoration of health.
- Obesity in the Brazilian population is becoming much more frequent than the child malnutrition, signaling an epidemiological transition process that should be properly valued in terms of health. Cardiovascular diseases, which are the leading cause of death and disability in adulthood and in old age and are responsible, in Brazil, for approximately 34% of all causes of death, and are related in large part, to obesity and inappropriate eating habits and lifestyles.
- Inappropriate eating habits are a major challenge. Popular culture preserves traditions and erroneous feeding practices on the nutritional value, healing properties, indication or prohibition of food. On the other hand, it emphasizes the proliferation of fast food trade and the increasing use of pre-cooked or quick-cooking food.
- The situation of food and nutrition in Brazil is very complex, where there are typical problems of underdeveloped societies and developed countries.

PNAN present nine guidelines that indicate the lines of action to achieve its purpose, capable of modifying the determinants of health and to promote health. It is consolidated in: 1. Organização of Nutritional Care; 2. Promotion of Healthy and Suitable Food; and 3. Food and Nutrition Surveillance; 4. Management Actions of the Food and Nutrition; 5. Participation and Social Control; 6. Qualification of the Labor Force; 7. Food Control and

Regulation; 8. Research, Innovation and Knowledge on Food and Nutrition; 9. Cooperation and coordination for Food and Nutrition Safety [12].

Some relevant definitions according to PNAN [12]:

- **Suitable and health nutrition:** suitable eating habits to the biological and socio-cultural aspects of individuals, as well as the sustainable use of the environment. They must comply with the requirements of each phase of the life course and with the special dietary needs; be referenced by the food culture and the dimensions of gender, race and ethnicity; be accessible from the physical and financial standpoint, harmonic in quantity and quality, based on adequate and sustainable production practices; with minimal amounts of physical, chemical and biological contaminants.
- **Food and nutritional safety:** consists in the achieving the right of everyone to the regular and permanent access to quality food in sufficient quantity, without compromising access to other essential needs, based on health promoting food practices that respect cultural diversity and that are environmentally, culturally, economically and socially sustainable.
- **Healthy eating practices:** uses, habits and customs that define patterns of food consumption in accordance with scientific knowledge and techniques of good nutrition.
- **Food safety and quality:** deals, in health surveillance, of attributes related to food safety and nutritional value. See also healthy eating.

11. WHO – Global strategy for diet, physical activity and health [14]

The global strategy for diet, physical activity and health approved by the World Health Organization, starting from the recognition that DCNT, such as cardiovascular disease, type 2 diabetes and certain cancers, imposes a significant economic burden on health systems and violates existing high costs on society. The overall strategy is aimed at two main risks of DCNT: diet and physical activity [14].

The overall objective of the global strategy on diet, physical activity and health is to promote and protect health by guiding the development of a qualification of the environment, to support actions at individual, community, national and global levels that, when taken together, lead to a reduction in rates of illness and deaths related to unhealthy diets and physical inactivity. The main specific objectives are:

- To reduce the risk factors for DCNT through the essential action in public health, health promotion and preventive measures.
- To increase the attention and knowledge about diet and physical activity.
- To encourage the development, strengthening and implementation of policies and plans at global, regional, national and community actions that are sustainable, including civil society, private sector and the media.

In relation to diet, it is recommended for individuals and populations:

- To keep the energetic balance and healthy weight.

- To limit energy intake from fats; replace saturated fats for unsaturated fats and eliminate trans fats (hydrogenated).
- To increase the consumption of fruits, vegetables, whole grains and nuts.
- To limit the intake of free sugar.
- To limit the intake of salt (sodium) from every origin and consume iodized salt.

Regarding to physical activity, the overall strategy recommends at least 30 minutes of regular, severe or moderate physical activity, almost every day, to reduce the risk of cardiovascular disease, diabetes, colon cancer and breast cancer and to improve functional status in different stages of life, especially in adulthood and in elderly [14].

12. Responsibilities

To achieve changes in eating habits and physical activity patterns is required the combined effort of many public and private actors (WHO, governments, international partners, civil society and nongovernmental organizations, private sector) for several decades. Among the responsibilities and recommendations, stand out:

- **For Member States:** governments should consider actions that will result in providing accurate and balanced information to consumers to enable them to make healthy choices. Information for consumers should be appropriate to their levels of literacy, communication barriers, local cultures and they should be understood by all segments of the population [14].
- **Marketing, advertising, sponsorship and promotion:** food advertising affects food choices and influences eating habits. The advertising of foods and beverages should not exploit children's credulity and inexperience. Messages that encourage unhealthy dietary practices or physical inactivity should be discouraged, while positive and healthy messages should be encouraged.
- **Labeling:** consumers need accurate, standardized and comprehensible information about foods contents to make healthy choices.
- **Health claims:** As interest in consumer health is increasing, the use of health-related messages by manufacturers is growing. These messages should not confuse the public about nutritional benefits or risks.
- **Promotion of food products consistent with a healthy diet:** Governments could consider measures to encourage the reduction, the salt content of processed foods, the use of hydrogenated fats and sugar content in drinks and sweets.
- **For the private sector:** the food industry, as one of the representatives of the private sector, can be a significant player in promoting healthy diets and physical activity. Initiatives by the food industry to reduce fat, sugar and salt content in processed foods and portion sizes, to increase the introduction of nutritious, healthy and innovative choices, and to review the current marketing practices, could accelerate health gains worldwide.
- Specific recommendations for the food industry
- To promote healthy diet and physical activity in compliance with the guidelines and the national and international standards and with the overall objectives of the global

strategy; limiting the levels of saturated fats, trans fatty acids, free sugars and salt in existing products.

- To continue to develop and provide nutritious, healthy and affordable choices for consumers.
- To consider the introduction of products with better nutritional value.
- To provide consumers with adequate and understandable information about nutrition and products.
- To practice responsible *marketing* that supports the strategy, particularly with respect to promotion and "marketing" of foods with high content of saturated fats, trans fatty acids, free sugars, or salt, especially for children.
- To issue simple, clear and consistent labels and health claims based on evidence, that help consumers make healthy choices regarding the nutritional value of foods.

The implementation of this strategy by all stakeholders contribute to the sustainable improvement of human health [14].

13. Food guide for the Brazilian population [9]

The editing of the first official dietary guidelines of Brazil was part of the implementation strategy of the National Food and Nutrition, a member of the National Health Policy. It consolidates itself as concrete evidence for implementation of recommendations issued by the World Health Organization [14]. The Guide aims to contribute to the direction of feeding practices aimed at health promotion and prevention of diseases related to food [9]:

- Malnutrition and micronutrient deficiencies, such as iron deficiency anemia, vitamin A deficiency and iodine deficiency disorders, which are still public health problems in the country.
- Chronic non-communicable diseases (DCNT): diabetes, obesity, hypertension, cardiovascular disease and some cancers.

Next, it is highlighted some considerations contained in the Food Guide for Brazilian People [9] and some aspects of Guideline 1 - Healthy foods and meals, and the Special Guideline 1 - Physical activity.

In the last two or three generations, Brazilian society has become predominantly urban. Chronic diseases of the total population in the country increased from 34.4% in 1979 to 48.3% in 2003. Services and public policies need to respond to these changes and the complexity of its manifestations in health [9].

14. The epidemiological transition in Brazil

With the urbanization of the population, the patterns of work and leisure shifted to lower energy consumption. On the other hand, the increased consumption of processed foods, high intake in fat, sugar and salt, associated with lower daily energy use due to reduced physical activity, explain the rising trends of overweight and obesity in the Brazilian population, and DCNTs associated [9].

The evolution of DCNT is an additional challenge to the food and nutrition security, which must be combined with efforts to reverse the prevalence of child malnutrition and the control and prevention of micronutrient deficiencies.

15. Healthy lifestyles

Recent scientific evidence shows that health may be more related to how people live than to their biological and genetic determination. The approach in promoting healthy lifestyles, it is identified two dimensions: one that aims to stimulate and encourage healthy behaviors, healthy eating and regular physical activity, and another, aims to inhibit habits and practices harmful to health as consumption of tobacco and alcohol. Healthy eating begins with the practice of breastfeeding, and extends to life by adopting good eating habits. Thus, the suitable nutrition of pregnant women and children must be understood and emphasized as a strategic action part, in order to promote health in adulthood.

16. Healthy eating: some considerations

In general, the food choices are not determined for such preference and habits, but rather for the system of production and food supply [9]. The State, through its public policies, has the responsibility to foster socio-environmental changes at the collective level, to promote healthy choices at individuals or families. Thus, the assumption is promoting healthy eating to expand and foster decision-making autonomy of individuals and groups, through access to information to the choice and adoption of healthy feeding (and life) practices [9].

An alternative action to promote healthy eating should be, for example, the shift in the consumption of unhealthy foods for healthier foods. Overvalue or mythologize certain foods because of their nutritional or functional characteristics should not constitute the practice of promoting healthy eating. Nutritionally rich foods should be valued and will come naturally in the adopted diet, without needing to mythologize one or more of its characteristics, a trend much exploited by advertising and marketing of functional foods and nutritional supplements.

According to the principles of healthy eating, all food groups should make up the daily diet. Some guidelines of the Food Guide for the Brazilian population are highlighted here as guidelines for actions of the government and of the productive sector [9]:

- Guideline 1 – healthy foods and meals
 - Ensure food quality – *in nature* and processed – placed on the market for consumption of the population.
 - Ensure the enforcement of legislation that promotes breastfeeding as the child's right to suitable diet.
 - Regulate food *marketing* strategies across all forms of media, particularly those directed towards children and adolescents.

- In relation to bioactive compounds present in vegetables, fruits and herbs native to Brazil, the guide points out that on the basis of updated knowledge, the orientation remains the same: "a meal rich in fruits, vegetables, natural sources of vitamins and minerals and bioactive compounds, is fundamental to the maintenance of health".
- The labels carry wealth essential information to the consumer. An example of a functional property claim that may appear on food labels, since previously evaluated and approved by ANVISA is "Dietary fiber helps the intestinal functioning. Its consumption should be associated with a balanced diet and healthy lifestyle". It is clear that the industry will give greater emphasis to the positive features of its product. Thus, it is important to analyze more than one piece of information. For example, a product with high fiber content - which is a positive feature - may, however, have a high fat, sugar or sodium content. Another product with a high calcium content may have a high concentration of saturated fat. Increasingly, it is important that the consumer has access to information, strengthening the capacity of analysis and decision to choose one product or another, against the indiscriminate amount of information available in various media outlets and advertising.
- Special guideline 1 – physical activity
 - The basic principle to maintain an energy balance is the balance between intake and energy expenditure. One of the guidelines on the recommended actions to government and business sector to develop disclosure forms and media to report and value the adoption of healthy lifestyles, combining the promotion of healthy eating and regular physical activity.

17. National policy for health promotion [13]

PNPS has as general objective "to promote quality of life and to reduce vulnerability and health risks related to its determinants and constraints - ways of living, working conditions, housing, environment, education, leisure, culture, access to essential goods and services".

The strategy for implementing the PNPS related to diet is stimulating the inclusion of health promotion actions at all levels of care, with emphasis on primary care, focused on the actions of body care and health, healthy eating and prevention and tobacco control.

18. Final considerations

The legislation aims to promote and protect the health of consumers through the registration and inspection of food products with claims of functional properties. The knowledge of the legislation and its updates is critical to the successful development and registration of products. It is noted the convergence of the presented policies to ensure reliable information to consumers and to strengthen their capacity to understand this

information, so that they can make healthier food choices. It also recognizes that a healthy diet, as a measure of health promotion, can not be dissociated from the adoption of healthy lifestyles, especially physical activity. Therefore, the messages of the claims have been developed and standardized by ANVISA, conditioning the benefit claimed by the consumption of food to the adoption of a balanced diet and healthy lifestyle. It was also established the observations and warning statements to be included in the labeling and advertising of the products. According to these policies, foods that support claims can not contribute to the increased incidence of overweight, obesity and other DCNT. Thus, it must not be approved claims for foods that may discourage breastfeeding, or containing high load of energy, high content of sugars, salt, saturated fats and trans fats. Moreover, the claims should have a solid scientific evidence.

Annex I

List of Claims Approved and Updated in July 2009

1. The horizontal claims, presented below, are part of a continuous and dynamic process of reassessment of approved claims based on scientific evidence, using the principles described in item III. In addition, it aimed the standardization of the claims in order to improve consumer understanding about the information and properties conveyed on labels of these foods.
2. In 2005, the claims, previously approved, were reevaluated, in order to standardize them to improve consumer understanding of the information and properties conveyed on food labels. With this reevaluation, the claims related to the caffeine, sorbitol, xylitol, mannitol, sodium stearate, sodium bicarbonate, omega 6 fatty acids, polyunsaturated and monounsaturated fatty acids (vegetable oils), and the liquid ready for consumption were no longer permitted.
3. Claims for chewing gum related to sorbitol, xylitol and mannitol were reassessed in 2007 based on new scientific evidence and it was approved the claim set out in the table below.
4. Foods that present in their label wording and/or in their advertising material, the claims listed below, must be registered in the category of "Foods with Claims of Functional and/or Health Property". Thus, they must be registered prior to marketing, as Annex II of the RDC nº 27/2010. The registration of food with claims and the evaluation of new claims will be made by scientific evidence of effectiveness of these, given the criteria present in Resolution nº 18/99 and 19/99.
5. The approved claims that relate the functional and/or health property to a nutrient or non-nutrient food, according to item 3.3 of Resolution 18/99. However, the effectiveness of the food claim must be evaluated case by case, considering that variations may occur in the action of the nutrient or non-nutrients, according to the matrix or formulation of product.
6. The portions of food shall be those provided in Resolution RDC nº 359/03 calculated based on food groups referred in that resolution. For further information consult the Guidance Manual for Industries.

7. In the case of combination of nutrients or non-nutrients in one product, the effectiveness of the claim must be proven in the product, with the concomitant use of non-nutrient or nutrients.
8. In the case of foods regulated by the Ministry of Agriculture, Livestock and Supply (MAPA), the companies should initially fill the 403 petition in ANVISA, referring to the request for the Evaluation of Foods with Claims of Functional and/or Health Properties. ANVISA shall send response assessment for the company, with a copy to the authority of the MAPA area.
9. The claims approved relate the functional and/or health properties of a nutrient or non-nutrient of the food, according to item 3.3 of Resolution nº 18/99. However, the proof of the effectiveness of claim must be performed in each case, considering the formulation and features of the food. Therefore, the use of the claims listed below, in any food, will only be allowed after approval by ANVISA.

Anexx II - List of approved claims

OMEGA-3
Claim
“The consumption of Omega-3 fatty acids helps in maintaining healthy levels of triglycerides, since combined to a balanced diet and healthy lifestyle habits”.
Specific requirements
<p>This claim should only be used for Omega-3 long chain fatty acids from fish oils (EPA - eicosapentaenoic acid and DHA - docosahexaenoic acid).</p> <p>The product must have a minimum of 0.1g of EPA and/or DHA in the portion or in 100g or in 100mL of the product ready for consumption, once the portion is bigger than 100g or 100mL.</p> <p>The processes must present analysis report, employing recognized methodology, the content of inorganic contaminants in ppm: Mercury, Lead, Cadmium and Arsenic. Using as reference the Decree nº 55871/65, category of other foods.</p> <p>For products in the form of capsules, pills, tablets and other similar forms, the above requirements must be met in the daily intake recommendation of the product ready for consumption, according to the manufacturers.</p> <p>The nutrition facts table shall contain the three types of fats: saturated, monounsaturated and polyunsaturated fats, describing below the content of omega-3 (EPA and DHA).</p> <p>The product label must include the warning highlighted in bold:</p> <p>“People who have diseases or physiological changes, pregnant or breastfeeding (nursing mothers) should consult their doctor before using the product”.</p>

Table 2. FATTY ACIDS

LYCOPENE
Claim
“Lycopene has antioxidant action that protects cells against free radicals. Its consumption must be combined with a balanced diet and healthy lifestyle habits”.
Specific requirements
<p>The amount of lycopene contained in the portion of the product ready for consumption, must be declared on the label next to the claim.</p> <p>For products in the form of capsules, pills, tablets and other similar forms, it must be declared the lycopene amount in the daily intake recommendation of the product ready for consumption, according to the manufacturers.</p> <p>The detailed process of the substance obtaining and standardization must be present, including solvents and other compounds used.</p> <p>Present report of the content of residue(s) of solvent(s) used.</p> <p>Present report with the purity of the product.</p>

LUTEIN
Claim
“Lutein has antioxidant action that protects cells against free radicals. Its consumption should be associated with a balanced diet and healthy lifestyle”.
Specific requirements
<p>The amount of lutein contained in the portion of the product ready for consumption, must be declared on the label next to the claim.</p> <p>For products in the form of capsules, pills, tablets and other similar forms, it must be declared the lutein amount in the daily intake recommendation of the product ready for consumption, according to the manufacturers.</p> <p>The detailed process of the substance obtaining and standardization must be present, including solvents and other compounds used.</p> <p>Present report of the content of residue(s) of solvent(s) used.</p> <p>Present report with the purity of the product.</p>

ZEAXANTHIN
Claim
“Zeaxanthin has antioxidant properties that protects cells against free radicals. Its consumption should be associated with a balanced diet and healthy lifestyle”.
Specific requirements
<p>The amount of zeaxanthin, contained in the portion of the product ready for consumption, must be declared on the label next to the claim.</p> <p>For products in the form of capsules, pills, tablets and other similar forms, it must be declared the zeaxanthin amount in the daily intake recommendation of the product ready for consumption, according to the manufacturers.</p> <p>The detailed process of the substance obtaining and standardization must be present,</p>

including solvents and other compounds used.
 Present report of the content of residue(s) of solvent(s) used.
 Present report with the purity of the product.

Table 3. CAROTENOIDS

DIETARY FIBERS
Claim
"The dietary fibers assist in the functioning of the intestine. Its consumption should be associated with a balanced diet and healthy lifestyle".
Specific requirements
<p>This claim may be used provided that the portion of the product ready for consumption provide at least 3g of fiber if the food is solid or 1.5g fiber if the food is liquid.</p> <p>In the nutrition facts table shall be declared the amount of dietary fiber.</p> <p>For products in the form of capsules, tablets, pills and other similar forms, the above requirements must be met in the daily intake recommendation of the product ready for consumption, according to the manufacturers.</p> <p>When presented single in capsules, tablets, pills, powders and other similar forms, the following information, in highlighted bold type, shall appear on the product label:</p> <p>"Consumption of this product should be accompanied by fluid intake".</p>
BETA-GLUCAN
Claim
"The beta-glucan (dietary fiber) assists in reducing cholesterol absorption. Its consumption should be associated with a balanced diet and healthy lifestyle".
Specific requirements
<p>This claim may be used provided that the portion of the product ready for consumption provide at least 3g of beta-glucan if the food is solid or 1.5g beta-glucan if the food is liquid.</p> <p>This claim is approved for beta-glucan present in oats.</p> <p>In the nutrition facts table it shall be declared the amount of beta glucan below the dietary fiber amount.</p> <p>When presented single in capsules, tablets, pills, powders and other similar forms, the following information, in highlighted bold type, shall appear on the product label:</p> <p>"Consumption of this product should be accompanied by fluid intake".</p>
RESISTANT DEXTRIN
Claim
"The dietary fibers assist in the functioning of the intestine. Its consumption should be associated with a balanced diet and healthy lifestyle".

Specific requirements

This claim may be used provided that the portion of the product ready for consumption provide at least 3g of resistant dextrin if the food is solid or 1.5g of resistant dextrin if the food is liquid.

For products in the form of capsules, tablets, pills and other similar forms, the above requirements must be met in the daily intake recommendation of the product ready for consumption, according to the manufacturers.

The use of the ingredient shall not exceed the 30g recommended daily intake of the product ready for consumption, as indicated by the manufacturer

In the nutrition facts table it shall be declared the amount of resistant dextrin below the dietary fiber amount.

When presented single in capsules, tablets, pills, powders and other similar forms, the following information, in highlighted bold type, shall appear on the product label:

"Consumption of this product should be accompanied by fluid intake".

FRUCTOOLIGOSACCHARIDES – FOS**Claim**

"The fructooligosaccharides - FOS contribute to the balance of intestinal flora. Its consumption should be associated with a balanced diet and healthy lifestyle".

Specific requirements

This claim may be used provided that the portion of the product ready for consumption provide at least 3g of FOS if the food is solid or 1.5g of FOS if the food is liquid.

For products in the form of capsules, tablets, pills and other similar forms, the above requirements must be met in the daily intake recommendation of the product ready for consumption, according to the manufacturers.

In the nutrition facts table it shall be declared the amount of **fructooligosaccharides** below the dietary fiber amount.

The consumption of the ingredient shall not exceed the 30g recommended daily intake of the product ready for consumption, as indicated by the manufacturer.

When presented single in capsules, tablets, pills, powders and other similar forms, the following information, in highlighted bold type, shall appear on the product label:

"Consumption of this product should be accompanied by fluid intake".

PARTIALLY HYDROLYZED GUAR GUM**Claim**

"The dietary fibers assist in the functioning of the intestine. Its consumption should be associated with a balanced diet and healthy lifestyle".

Specific requirements

This claim may be used provided that the portion of the product ready for consumption provide at least 3g of guar gum if the food is solid or 1.5g of guar gum if the food is liquid.

For products in the form of capsules, tablets, pills and other similar forms, the above

requirements must be met in the daily intake recommendation of the product ready for consumption, according to the manufacturers.

This claim is approved for the partially hydrolyzed guar gum obtained from the plant species.

In the nutrition facts table it shall be declared the amount of partially hydrolyzed guar gum below the dietary fiber amount.

If the product is in isolated form, in sachets or powder, for example, the company must inform in the label, the amount of liquid in which the product must be dissolved.

When presented single in capsules, tablets, pills, powders and other similar forms, the following information, in highlighted bold type, shall appear on the product label: "Consumption of this product should be accompanied by fluid intake".

INULIN

Claim

"Inulin contributes to the balance of intestinal flora. Its consumption should be associated with a balanced diet and healthy lifestyle".

Specific requirements

This claim may be used provided that the portion of the product ready for consumption provide at least 3g of inulin if the food is solid or 1.5g inulin if the food is liquid.

For products in the form of capsules, tablets, pills and other similar forms, the above requirements must be met in the daily intake recommendation of the product ready for consumption, according to the manufacturers.

In the nutrition facts table it shall be declared the amount of **inulin** below the dietary fiber amount.

The consumption of the ingredient shall not exceed the 30g recommended daily intake of the product ready for consumption, as indicated by the manufacturer

When presented single in capsules, tablets, pills, powders and other similar forms, the following information, in highlighted bold type, shall appear on the product label: "Consumption of this product should be accompanied by fluid intake".

LACTULOSE

Claim

"Lactulose assists in the functioning of the intestine. Its consumption should be associated with a balanced diet and healthy lifestyle".

Specific requirements

This claim may be used provided that the portion of the product ready for consumption provide at least 3g of lactulose if the food is solid or 1.5g of lactulose if the food is liquid.

For products in the form of capsules, tablets, pills and other similar forms, the above requirements must be met in the daily intake recommendation of the product ready for consumption, according to the manufacturers.

In the nutrition facts table it shall be declared the amount of **lactulose** below the dietary fiber amount.

When presented single in capsules, tablets, pills, powders and other similar forms, the following information, in highlighted bold type, shall appear on the product label:
 “Consumption of this product should be accompanied by fluid intake”.

POLYDEXTROSE

Claim

“Polydextrose assists in the functioning of the intestine. Its consumption should be associated with a balanced diet and healthy lifestyle”.

Specific requirements

This claim may be used provided that the portion of the product ready for consumption provide at least 3g of Polydextrose if the food is solid or 1.5g of Polydextrose if the food is liquid.

For products in the form of capsules, tablets, pills and other similar forms, the above requirements must be met in the daily intake recommendation of the product ready for consumption, according to the manufacturers.

In the nutrition facts table it shall be declared the amount of **polydextrose** below the dietary fiber amount.

When presented single in capsules, tablets, pills, powders and other similar forms, the following information, in highlighted bold type, shall appear on the product label:
 “Consumption of this product should be accompanied by fluid intake”.

PSILLIUM OR PSYLLIUM

Claim

“*psillium* (dietary fiber) assist in the reduction of fat absorption. Its consumption should be associated with a balanced diet and healthy lifestyle”.

Specific requirements

This claim may be used provided that the portion of the product ready for consumption provide at least 3g of *psillium* if the food is solid or 1.5 g if the food is liquid.

For products in the form of capsules, tablets, pills and other similar forms, the above requirements must be met in the daily intake recommendation of the product ready for consumption, according to the manufacturers.

The only species to be evaluated was *Plantago ovata*. Any other species should be evaluated for safety in use.

In the nutrition facts table it shall be declared the amount of *Psillium* below the dietary fiber amount.

When presented single in capsules, tablets, pills, powders and other similar forms, the following information, in highlighted bold type, shall appear on the product label:
 “Consumption of this product should be accompanied by fluid intake”.

CHITOSAN
Claim
" <i>Chitosan</i> assists in the reduction of fat and cholesterol absorption. Its consumption should be associated with a balanced diet and healthy lifestyle".
Specific requirements
<p>This claim may be used provided that the portion of the product ready for consumption provide at least 3g of chitosan if the food is solid or 1.5g of if the food is liquid.</p> <p>For products in the form of capsules, tablets, pills and other similar forms, the above requirements must be met in the daily intake recommendation of the product ready for consumption, according to the manufacturers.</p> <p>The processes must present analysis report, using recognized methodology, presenting the content of inorganic contaminants in ppm: Mercury, Lead, Cadmium and Arsenic. Use as a reference the Decree 55871/65, category of other foods.</p> <p>It must be submitted analysis report with physical chemical composition, including the fiber and ash amount.</p> <p>In the nutrition facts table it shall be declared the amount of <i>chitosan</i> below dietary fiber amount.</p> <p>In the label it must contain the warning phrase highlighted and in bold: "Peoples allergic to fish and shellfish should avoid consumption of this product".</p> <p>When presented single in capsules, tablets, pills, powders and other similar forms, the following information, in highlighted bold type, shall appear on the product label: "Consumption of this product should be accompanied by fluid intake".</p>

Table 4. DIETARY FIBERS

PHYTOSTEROLS
Claim
"Phytosterols assist in reducing cholesterol absorption. Their consumption should be associated with a balanced diet and healthy lifestyle".
Specific requirements
<p>The portion of the product ready for consumption should provide at least 0.8g of free phytosterols. Lower amounts may be used provided that proved in the food matrix.</p> <p>The daily intake recommendation of the product, which should be between 1-3 portions/day must ensure the ingestion of 1-3 grams of free phytosterols per day.</p> <p>In the description of the product information should be included "... with phytosterols".</p> <p>The amount of phytosterols contained in the portion of the product ready for consumption, must be declared on the label next to the claim.</p> <p>Phytosterols refer to sterols both as stanols, as well as to esterified.</p> <p>It must present the detailed process of obtaining and standardization of substance, including solvents and other compounds used.</p> <p>Present report with the content(s) of residue(s) of employed solvent(s).</p>

Present report with the product purity and the characterization of the phytosterols/phytostanols present.
The label must contain the following warning phrases highlighted in bold:
"People with high cholesterol level should seek for medical advice."
"Phytosterols do not provide additional benefits when consumed over 3 g/day."
"The product is not suitable for children under five, pregnant women and milk feeding babies."

Table 5. PHYTOSTEROLS

Mannitol/Xylitol/Sorbitol
Claim
“Mannitol/Xylitol/Sorbitol does not produce acids that damage teeth. The consumption of the product does not replace proper oral hygiene habits and feeding”
Specific requirements
Claims approved only for sugar-free chewing gum.

Table 6. POLYOLS

<i>Lactobacillus acidophilus</i> <i>Lactobacillus casei shirota</i> <i>Lactobacillus casei variedade rhamnosus</i> <i>Lactobacillus casei variedade defensis</i> <i>Lactobacillus paracasei</i> <i>Lactococcus lactis</i> <i>Bifidobacterium bifidum</i> <i>Bifidobacterium animallis</i> (including <i>B. lactis</i> subspecies) <i>Bifidobacterium longum</i> <i>Enterococcus faecium</i>
Claim
“The (indicates the microorganism species) (probiotic) contributes to the balance of intestinal flora. Its consumption should be associated with a balanced diet and healthy lifestyle”.
Specific requirements
The minimum viable amount of probiotics must be in the range of 1x10 ⁸ to 1x10 ⁹ colony forming units (CFU) in the daily recommendation of the product ready for consumption, as indicated by the manufacturer. Smaller values may be accepted, since the company proves its effectiveness. The documentation relating to proof of efficacy should include: Report of the product analysis that prove the amount of the minimum viable microorganism until the end of shelf life.

Resistance test of the culture employed in product against the gastric acidity and bile salts. The amount of probiotics in CFU, contained in the daily recommendation intake in the product ready for consumption, must be declared on the label next to the claim. The microorganisms *Lactobacillus delbrueckii* (bulgaricus subspecies) and *Streptococcus salivarius* (thermophilus subspecies) were removed from the list, given that in addition of being species necessary for yoghurt production, they do not have probiotic scientifically proven effect.

Table 7. PROBIOTICS

SOY PROTEIN
Claim
"Daily consumption of at least 25 of soy protein can help to lower cholesterol. Its consumption should be associated with a balanced diet and healthy lifestyle".
Specific requirements
The amount of soy protein contained in the portion of the product ready for consumption, must be declared on the label next to the claim. In the case of products in the form of capsules, tablets, pills and the similar forms, it should be declared the amount of soy protein in the daily intake recommendation of the product Ready for consumption, as indicated by the manufacturer. "The wording on the labeling and on the advertising of products based on soy can not present any claim on the basis of isoflavones, regarding the amount ("contains"), functional, health and therapeutic properties (prevention, treatment and cure of diseases)"

Table 8. SOY PROTEIN

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