

# Information on the presence of allergens on food labels: the state's duty to ensure that people with food allergy have the right to health and adequate food

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## Abstract

People with food allergy, about 8% of children and 3% to 5% of adults, must keep a diet that excludes the presence of allergens, as a way to guarantee their well-being and a decent life. Given the interrelationship between the right to health and right to live, as well as the one between the right to health and the right to adequate food, the availability of dietetically adequate food has to be guaranteed. For those who have food allergy, this requires the guarantee of allergen-free food products. Thus, this paper discusses the State's duty to protect the rights to health and adequate food of such segment of the population, who needs information about the presence of food allergens on food labels.

**Key words:** Fundamental Rights. Social Rights. Right to Health. Right to Adequate Food. Right to Information.

## Introduction

People who suffer from food allergy require special attention from the State because of their condition, particularly the health protection system. The supply of adequate food, with special attention to dietary restrictions, is a duty of the State, and is closely associated with its duty to fulfill the right to health and to proper food. In this context, the State must be concerned with the promotion of measures that provide food allergic consumers with the right to receive information on the presence of allergens on the labels of products.

This paper will bring about the normative foundations that justify the State's duty to protect the rights to health and adequate food of people with food allergy, as well as some sentences from the common justice and higher courts which illustrate how the Judiciary Power has addressed the issue of right to health, adequate food, and information.

## Data on food allergy

In order to increase awareness of the judicial system about the idea that health care and proper food to people with food allergy are relevant, some technical and statistical data will be mentioned, because they underpin the assumptions made in this study.

Food allergy is defined as hypersensitivity of the body to something ingested, inhaled or touched, and a resulting response from the immune system, which sees a given substance as a threat, in this case food (or more).<sup>1</sup> Due to various factors, such as genetics, lifestyle habits, consumption of highly processed food and excessive hygiene, the number of cases of food allergy has increased dramatically around the world.

Despite a notable increase in cases, there is no national compilation of data in Brazil, to date, on the prevalence of food allergy. Therefore, there is no accurate information so far about the number of people with food allergy or about the foods that most often trigger allergic reactions in the Brazilian population.

For this reason, national studies on this topic are based on research conducted with other populations, especially the American population. According to data from the Food Allergy Research & Education, food allergy is an increasing public health problem that affects more than 15 million Americans: nine million adults (approximately 4% of the adult population) and six million children (about 4% of children, considered as people under 18 years old).<sup>2</sup> It is also worth of notice that the National Health Interview Survey indicated a 18% increase in cases of food allergy among people under 18, between 1997 and 2007.<sup>3</sup>

In Europe, data indicate that approximately 17 million Europeans suffer from some kind of food allergy, and 3.5 million out of them are under 25 years old. The data also show that allergy in children 0-5 years has doubled in the last ten years with significant increase in hospitalizations because of severe reactions such as anaphylaxis.<sup>4</sup> In Canada, Health Canada, responsible for protecting the health of the Canadian population, estimated that the prevalence of food allergy affects 5-6% of children and 5-6% of adults.<sup>5</sup>

Because of the recognized importance of the number of people suffering from food allergy in those countries, they have already approved standards for prominent labels informing on the presence of the allergens that most affect the population. In Brazil, where the population tends to follow the same percentage, the deficit of research on the topic, the lack of regulation of mandatory information about the presence of allergens and little information disseminated on the importance of diets cause undeniable injury to the health of people with food allergy.

Most international standards for labeling of allergens on food products determine that labels must highlight the presence of eight allergens that account for 90% of cases of food hypersensitivity, namely: milk, soy, egg, nuts, peanuts, fish, shellfish and gluten containing grains.

The consequences of consumption of allergenic substances by people with food allergy can be better understood when brief explanations are given about the mechanisms involved in allergic reactions and possible reactions that can occur from exposure to allergens.

According to the definition contained in the document prepared by both the Brazilian Society of Pediatrics and the Brazilian Association of Allergy and Immunopathology, called "Brazilian Consensus on Food Allergy" (2007), the intake of food can result in reactions that depend on the susceptibility of each individual person, and may be classified as: not immune-mediated (food intolerance) or immune-mediated (food allergy or food hypersensitivity).<sup>6</sup>

In non-immune-mediated reactions, which are typical of food intolerance, there is an enzyme deficiency that hinders the absorption of a given element (e.g., lactase, the enzyme that processes lactose, name of the sugar present in cow's milk). In turn, food allergy manifests when there is a response from the immune system of the body, caused by the action of immunoglobulin (mediated IgE) or not (non-IgE mediated), with a consequent release of histamine.

In IgE-mediated reactions, sensitization to food allergens occurs by formation of specific IgE antibodies, leading to immediate sensitization. For this group, these are the most common manifestations, according to the Brazilian Consensus on Food Allergy (2007): cutaneous reactions (atopic dermatitis, urticaria, angioedema), gastrointestinal reactions (swelling and itching of the lips, tongue or palate, vomiting and diarrhea), respiratory reactions (asthma, rhinitis) and systemic reactions (anaphylaxis with hypotension and shock).<sup>6</sup>

Some reactions are classified as mixed, as they are mediated by IgE and cells (T lymphocytes and proinflammatory cytokines). In this group, the following clinical manifestations occur: eosinophilic oesophagitis, eosinophilic gastritis, eosinophilic gastroenteritis, atopic dermatitis, asthma, and hemosiderosis, according to the Consensus above-mentioned.

The last group, which belongs to the class of non-IgE mediated manifestations, is composed of people whose allergic reactions are not as immediate; they may occur hours or days after ingestion of an allergen. In this group, according to the Brazilian Consensus on Food Allergy above-mentioned, the following clinical manifestations occur: proctitis, food protein-induced enteropathy and food protein-induced enterocolitis.

Thus, responses of the body when exposed to an allergenic substance vary from person to person. Some people have immediate reactions while others react just a few hours or even days later. In some cases, the reactions are not necessarily triggered by actual intake of food, but simply when a sensitized individual touches or inhales a given allergen.

Regardless of this mechanism, according to the Brazilian Consensus on Food Allergy, treatment of food allergy depends on the absolute exclusion of allergen, which is the *only treatment* recommended to date for food allergies.

## Right to health

Social rights, aimed at improving people's living conditions and material equality, cover both positive benefits relative to health, housing, leisure, education and food, as well as the rights to defense, especially labor rights, e.g., strike, bonus pay for night work and hazardous work, and social security rights.

If life is assumed to precede the exercise of all other rights, the protection of the right to life demands the defense of the right to health. This implies the need for the State to take measures for the prevention and treatment of health ailments.

Lenir Santos explains that the protection of the right to health requires the consideration "of the conditions surrounding the individual and the community", because the right to health should not be assessed only in the individual perspective; aspects of diffuse, collective, individual and homogeneous interest must also be protected.<sup>7</sup> José Afonso da Silva believes that health is a right and duty of the State, "which must ensure it through social and economic policies aimed at reducing the risk of diseases and other health problems".<sup>8</sup>

Because of its undeniable importance, the right to health is protected both in the international context and in the domestic sphere of Brazilian law. Internationally, the Universal Declaration of Human Rights protects such right to well-being, providing in Article XXV, paragraph 1, which

reads “everyone has the right to a standard of living adequate for the health and well-being of himself and of his family”.<sup>9</sup>

In turn, the International Covenant on Economic, Social and Cultural Rights (ICESCR) provides, in Article 12, “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”. It is the duty of the State, in accordance with item c, to focus on “the prevention, treatment and control of epidemic, endemic, occupational and other diseases.”<sup>10</sup>

In Inter-American normative sphere, the theme is protected under the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, concluded on November 17, 1988, (“Protocol of San Salvador”). It provides, in Article 10, that the implementation of the right to health requires, among other measures: (i) the prevention and treatment of endemic diseases; (ii) education of the population on the prevention and treatment of health problems; and (iii) satisfaction of the health needs of the highest risk groups and of those whose poverty makes them the most vulnerable.<sup>11</sup>

The World Health Organization (“WHO”), in turn, states that health is not merely the absence of disease, but also comprises complete physical, mental and social well-being.<sup>12</sup>

It is noted from the foregoing discussion that the protection of the right to health, which includes physical, mental and, within the Americas, social welfare, is a duty assumed and reaffirmed by Brazil internationally. Therefore, the Brazilian government should take all measures within its power to safeguard this right, which implies the duty to protect the health of people with food allergy that require special dietary care in order to prevent damage to their well-being.

In Brazil, the right to health gained a particular constitutional status after promulgation of the Federal Constitution of 1988, which did not merely address the issue through the perspective of the division of legislative (article 24, XII) and administrative (Article 23, II) powers.<sup>13</sup> Rather, the Constitution of 1988 provided the right to health as a social right (Article 6) and also established a number of rules and principles.

Indeed, at the constitutional level, in the Social Security section, it included a chapter devoted specifically to the right to health (Title VIII, Section II), in which it states that, for this right to be guaranteed, it is the duty of the State, under Article 196, to promote social and economic policies with a view to (i) reducing risk of diseases and other health problems and (ii) ensuring universal and equal access to actions and services for the promotion, protection and recovery of health.

Stating that everyone has the right to health, as guaranteed by the Constitution, means that quality of life must be ensured to everyone. That is, the State is given the duty to affirm universal and equal access to actions and services to promote, protect and recover health, in order to prevent the risk of diseases or their aggravation.

At this point, it is worth noting that the Federal Supreme Court (STF) understands that the right to health is an inseparable consequence of the constitutional right to life, and the guarantee of its protection by the State is relevant.<sup>14</sup>

There is no doubt that the right to health is covered by the list of fundamental rights, not only by the topological question (Article 6 of the Federal Constitution of 1988, which addresses the right to health, is contained in the title of fundamental rights and guarantees) but especially in view of content which is of such a right. The objective is to safeguard the well-being and quality of life, which ultimately means to preserve the dignified existence of everyone.

Furthermore, when addressing the right to health in particular, the constitution aimed, in Article 197, to take into consideration health care services, as well as health-promoting actions, by providing that **health services** and **actions services** are of public importance” (emphasis added). Thus, the State is supposed to regulate, supervise and control actions aimed at ensuring everything that is relative to health.

On the one hand, the normative protection of the right to health has a positive side, relative to the right to measures taken by the State with the aim of preventing diseases and treating them; on the other hand, a negative side is that one can require that the State and third parties should refrain from acts that could harm someone’s health.

Moreover, “standards that define fundamental rights and guarantees have immediate application”, under § 1 of Article 5 of the Federal Constitution of 1988, which is why the right to health is expected to be safeguarded when analyzed from the perspective of treatment, and implemented, if viewed from the perspective of prevention.

## Right to adequate food

There is a clear correlation between the right to health and the right to food, and this is the view of the Economic, Social and Cultural Rights Committee in its General Comment No. 14, whereby such committee expressly links the right to health to the right to food.<sup>15</sup> In this sense, Alessandra Gotti Bontempo highlights that “the right to health encompasses various socioeconomic factors that promote conditions which people can enjoy for a lifetime (with) health, such as food”.<sup>16</sup>

In the Brazilian normative scenario, Law no. 8.080, of September 19, 1990, provides for the conditions for the promotion, protection and recovery of health, a “fundamental human right”, resulting in the State’s duty to “provide the necessary conditions for its full achievement”. In accordance with Article 2, the law above-mentioned also provides, in Article 3, that a determinant of health is nutrition.<sup>17</sup>

At this point, we must emphasize that the proper nutrition of an individual - which goes far beyond the provision of a meal - is an important condition for the preservation of his health and, consequently, for the enjoyment of his right to life.

The report submitted by Brazil at the World Food Summit (WFS) in Rome, in 1996, contained the following statement:

*[...] Access to food is a human right in itself, in that food is the right to life itself. Denying this right is, above all, denying the first condition for citizenship, which is life itself.*<sup>18</sup>

In this respect, doctor Luiz Flavio Schieck Valente contends that adequate food is a right that assumes the exercise of the right to life, *verbis*: “Without adequate food, both in terms of quantity and quality, there is no right to life”.<sup>19</sup>

In this perspective, Ana Elizabeth Lapa Wanderley Cavalcanti highlights: “We found that the right to food is not only the right to ‘kill’ hunger, but also to nourish, to have food security and enable the maintenance of life and health in a dignified manner”.<sup>20</sup>

When considering the protection of the right to food, one must resort to the same regulations already mentioned in the item above. The Universal Declaration of Human Rights considers the right to food as something inherent in the right to health and wellness by providing, in Article XXV, that “everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food.”<sup>9</sup>

In turn, the International Covenant on Economic, Social and Cultural Rights (ICESCR) provides for the right to food in Article 11, which prescribes the food is a *sine qua non* condition for a person to have an adequate standard of living, which includes the duty of the member States to adopt measures to improve methods of production, conservation and distribution of food, among other issues, by making full use of technical and scientific knowledge and disseminating the principles of nutrition, which is closely associated with the proposal presented here.<sup>10</sup>

Under the Protocol of San Salvador, the theme is safeguarded in Article 12, which states that “everyone has the right to adequate nutrition which guarantees the possibility of enjoying the highest level of physical, emotional and intellectual development.”<sup>21</sup>

According to the current understanding of the topic, present in General Comment no. 12 of UN Committee on Economic, Social and Cultural Rights, the right to food encompasses three elements: (i) availability; (ii) adequacy; and (iii) accessibility.<sup>22</sup> Availability relates to the existence of sufficient amount of food for the world population today and provision to feed future generations.

Adequacy is associated with compliance with the dietary needs of each individual, not only with regard to nutrients, but also with regard to cultural needs and other specific needs of every citizen, that in the case of those who have food allergies, would guarantee food free of allergenic ingredients, observing people's specificities.

Finally, accessibility is subdivided into two categories: (i) economic accessibility, whereby the cost to purchase food may not result in the impossibility of realization of other rights, such as housing, health and education; and (ii) physical accessibility, which includes consideration of physically vulnerable people, including children, adolescents, the elderly, people with walking difficulties and also people with persistent medical problems.

At this point, it is worth exploring the guidelines set out in comment no. 12, made by the UN Committee on Economic, Social and Cultural Rights in 1999, which deals specifically with the right to food, and associates it with human dignity, and considers it essential, according to the comment in question, for the exercise of other rights.<sup>22</sup>

According to what can be gleaned from the comment no.12, what is sought is to ensure access to adequate food, which would be more than a package of calories, proteins and other nutrients (item 6). It is indispensable to consider not only the amount of food, but also its quality in order to ensure the dietary needs of a given population (item 8), thus advocating for the adoption of measures to maintain, adapt and strengthen dietary diversity (item 9). The available food should also be free of adverse substances, including those resulting from improper handling along the production chain (item 10), and be suitable for vulnerable people (item 13). It is the duty of the member States to take the necessary measures to respect, protect and fulfill the right to food (item 15), given that failure to regulate such right effectively is seen as a violation of the Universal Declaration of Human Rights (Item 19).

In line with the international context, the enactment of Constitutional Amendment. 64, approved on February 4, 2010, the Federal Constitution of 1988 gave the right to food the status of fundamental right, and included it in the list of social rights provided in Article 6, thus a right to be respected, protected and implemented by the State.<sup>23</sup>

At the infra-constitutional level, the National Food and Nutrition Policy (PNAN), approved by the National Health Council through Ordinance No. 710, of June 10, 1999, aimed to bring together all government policies aimed at understanding the universal human right to food and nutrition. One of its objectives was the prevention and control of nutritional disorders and diseases relative to food and nutrition, as regards health care provision for those who depend on their diet as a way to prevent or avoid disease progression.<sup>24</sup> On November 17, 2011, Ordinance No. 2715 was approved. It repealed Ordinance No. 710, providing for a new National Food and Nutrition Policy (PNAN).<sup>25</sup>



It should also be noted that on September 15, 2006, Law no. 11.346 was approved, then regulated by Decree. 7.272, of August 25, 2010, which created the National System of Food and Nutritional Security (SISAN), in order to ensure the human right to adequate food. In Article 2, in line with what is set out in comment. 12, made by the Committee on Economic, Social and Cultural Rights, it provided that the right to “adequate food is a fundamental human right, inherent dignity of humans and essential to the realization of the rights enshrined in the Federal Constitution”. It is the State’s duty to adopt policies and actions required to promote and ensure food and nutritional security for the population.<sup>26, 27</sup>

There are some important facets of the right to adequate food, provided by the legislation that created SISAN: ensuring food safety and considering the specific needs that involve access to quality food in sufficient quantity. Some other issues should also be considered: (i) “promotion of health, nutrition and feeding of the population, including specific groups and populations in a vulnerable social situation” (Article 4, section III); (ii) “assurance of technical quality [...] of food”(Article 4, Paragraph IV); and, (iii) the “production of knowledge and access to information”, topics closely associated with the object of this article.

From the above, it can be seen that proper nutrition is a prerequisite for the enjoyment of other rights of great importance, such as the right to health, given that food can only be seen as adequate if it meets the special dietary needs of a given population. Indeed, PNAN should take into account special dietary needs, observing the specificities of people with metabolic or physiological changes that require different biological use of nutrients or food consumption path (enteral or parenteral), whether temporary or permanent .

In this scenario, it is understood that the right to health of the population with food allergy goes hand in hand with the right to adequate food. In other words, if the diet of people with allergies is correct from the nutritional point of view, with due exclusion of allergens in food, health is safeguarded; whereas, if the diet is inadequate, health is noticeably shaken (sometimes immediately and harshly).

If the diet plays a crucial role in life (considering also existence and quality), it is the State’s duty to ensure that dietary needs of people with food allergy are catered for, with the corresponding provision of safe options to citizens that have food allergies; thus, there has to be a standard imposing the duty to highlight allergens on food labels.

## Responsibility of the state as regards social rights

To Flavia Piovesan, inspired by the lessons of Hannah Arendt, human rights are not data, but a historical construct; the result of long-term work by society.<sup>28</sup>

Human rights, which can be defined as moral claims, arise when there is space and context for such, which confirms their historicity in that they are the result of processes of construction and reconstruction. In this sense, Norberto Bobbio, in the Introduction of his book *The Age of Rights*, teaches a lesson.<sup>29</sup>

The contemporary conception of human rights gained momentum after the end of World War II, when humanity was forced to normatively protect people's rights in order to avoid repetition of gross violations of rights that took place during the war. In this scenario, there emerged several international instruments protecting the rights of the human person, especially the Universal Declaration of Human Rights of 1948; and, in 1966, the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR).<sup>10,30,31</sup>

While social rights do not usually have the same status of civil and political rights (as a rule, with full effect, regardless of a standard regulating its exercise), such rules, even if applied progressively, are binding. That is, they are mandatory, although some regulation is required to enforce them.

Thus, with standards that deal with social rights, the State must adopt effective measures with well-defined objectives in order to enforce these rights, which takes place with respect, protection and implementation.

The realization of constitutionally provided social rights depends on a series of actions by the State, including normative production and adoption of public policies; According to Alessandra Gotti Bontempo, they are:

*[the] complex set of rules and actions aimed at achieving public purposes enshrined in the Constitution of 1988, whose structural elements are: the program (material dimension of public policy), the action-coordination (coordination of the State for the achievement of certain results), the process (sequence of acts tending to an end, which are essential at this point of popular participation).<sup>32</sup>*

An important feature of social rights, previously mentioned, is that they are rights whose implementation happens gradually; i.e., the state is obliged to take as many measures as necessary to ensure that, in practice, these rights can be enjoyed by their recipients.

If, on the one hand, it is understood that the implementation of these rights occurs gradually, because it is limited to the capacity of resource available at a given time; on the other hand, the social backlash and the omission of the State are avoided.

In regard to the legal impact of the failure of the State to protect the fundamental rights, the doctrine has held that this inaction can breach the legal system, in that it would offend the principle which forbids both the standards that go beyond, and those that fall short of what the constituent longed because proportionality, in the strict sense, it prevents not only the excess but also the lack of standards.

Especially on the issue of omission of the State in health issues, Luis Roberto Barroso states that the Government “cannot prove indifferent to the problem of the population’s health, under penalty of incurring, even if for culpable omission, in serious unconstitutional behavior “. <sup>33</sup>

Thus, the State’s failure to require clear labels with regard to the presence of allergens violates the legal system.

### **The state’s duty to protect the rights to health and nutrition**

As previously mentioned, the right to health is a social right under Article 6 of the Federal Constitution of 1988, whose protection deserves special attention from the State in view of the undeniable relevance of a person’s life, and it shall, pursuant to Article 196 the Federal Constitution of 1988, ensure it “through social and economic policies aimed at reducing the risk of disease and other health problems and the universal and equal access to actions and services for its promotion, protection and recovery”. <sup>34</sup>

At the infra-constitutional level, Law no. 8.080/90, which regulates the Unified Health System (SUS), provides that health is “a fundamental human right and the State shall provide the conditions required for its full realization” (our emphasis). <sup>17</sup> One of the objectives of the SUS, in accordance with Paragraph III of Article 5 of the Law, is to “assist people through promotion and restoration of health by means of integrated care provision actions and preventive activities”.

Furthermore, Article 7 of the Law under review, while scrutinizing what the article 198 of the Constitution of 1988 provides, brings a list of principles that should guide the actions and public health services that are part of the SUS, particularly the need for “full assistance, understood as a cohesive and continuous set of preventive and curative, individual and collective actions and services required for each case at all levels of complexity of the system”.

Particularly with regard to children and adolescents, it is worth stressing that, under Article 227 of the Federal Constitution of 1988, the State must ensure this group of people, with absolute priority, the rights to life, health, food, among others, and the State shall promote comprehensive health care provision programs for children, adolescents and youth in accordance with the first paragraph of the legal provision under discussion.<sup>34</sup>

Also as regards children at the infra-constitutional level, Law no. 8.069/90, which provides for the Child and Adolescent Statute (ECA), states that “children and adolescents have the right to life and health through effective implementation of public social policies that allow birth and healthy and harmonious development, under conditions of dignified existence”.<sup>35</sup>

Because the rights to health and adequate food are important and it is essential for those who suffer from food allergies to have access to food free of ingredients that cause their allergic reactions, it is clear it is the duty of the State, in all spheres, and it is a duty shared between the federal government, the states, the Federal District and municipalities (Article 23, item II of the Federal Constitution of 1988), to provide all actions aimed at preventing health problems, which necessarily involve providing adequate food, with safe options for those who have food allergy.

The assurance of the rights to health and adequate nutrition of the population with food allergy depends on direct access to information about the presence of allergens, and it is the duty of the State, as responsible for the implementation of actions aimed at guaranteeing constitutionally provided social rights, to promote appropriate measures to ensure the effective realization of the right to information under the Consumer Protection Code (CPC), approved by Federal law no. 8.078/90.<sup>36</sup>

## Duty to guarantee the right to information about the presence of allergens

Assuming that the right to information is safeguarded not only in order to protect (and enable) citizens against the State, but also to allow the exercise of full citizenship, it can be seen that the right to information is expressed in section XIV of Article 5 of the Federal Constitution of 1988.

Under this perspective, Alexandre David Malfatti argues that the constitutional right to information, as regards consumer relations, has three consequences: (i) the supplier’s right to inform consumers about the products and/or services that they want to sell; (ii) the supplier’s duty to inform consumers about the characteristics of the products and/or services; and (iii) the consumer’s right to be informed.<sup>37</sup>

For Malfatti, “the Federal Constitution of 1988 imposed a duty on individuals to report when their activities - business or otherwise - involved directly or indirectly human dignity and other

fundamental rights,” which results in the duty of compliance with social responsibility.<sup>37</sup> In this line, Flavia Piovesan emphasizes that the human rights agenda should also guide the actions of the private sector, and highlights the need for companies to have social responsibility, while the State should monitor private companies' compliance with social rights.<sup>38</sup>

It is this part of the right to information, which defines it as enforceable against the economic order, in view of the need for the private sector to guide its activities based on social responsibility in their duty to respect fundamental rights, that will underpin the duty to highlight the presence of allergens in products available to consumers. In this respect, Sueli Alves da Costa notes that

*[...] social responsibility is seen as a set of other responsibilities that have some points in common: they are derived from social movements, and dissemination of conviction or imposition of alternative and ethical standards outlined in reaction to a crisis of values.*<sup>39</sup>

Still on social responsibility, Maria da Conceição Maranhão Pfeiffer argues that private companies should fulfill their social function, which includes the duty to provide information to consumers.<sup>40</sup>

Specifically at the infra-constitutional level, the CPC establishes standards of consumer protection, public order and social interest, and in the words of Claudia Lima Marques, “a liberal and individualistic view of civil law” shifts to “a social view, which values the role of law as an active guarantor of balance, as protector of the trust and of legitimate expectations in consumer relations on the market.”<sup>41</sup>

The CPC stipulates the national policy of consumer relations, whose “objective is to meet the needs of consumers, respect their dignity, health and safety, protect their economic interests, improve their quality of life as well as promote the transparency and harmony of consumer relations”<sup>36</sup>

One can only think of effective protection of consumer rights when there is respect for consumers' dignity, health and safety by some of the stakeholders involved in consumer relations. It should be noted that in order to achieve this goal, the CPC expressly stated that government measures must be taken “in order to effectively protect the consumer,” also with regard to ensuring adequate quality and safety standards, features which are more closely associated with the object of the present work (item “d” of section II of Article 4 of the CPC).<sup>36</sup>

According to the provisions of section V of article 4 of the CPC, one of the principles of the national policy of consumer relations is “to encourage the creation by suppliers of efficient means of quality control and safety of products and services.”<sup>36</sup> Moreover, a *basic* consumer right is

“*proper and clear information on different products and services, with correct specification of quantity, characteristics, composition, quality as well as the risks posed*” (item III, Article 6, emphasis added).<sup>36</sup>

In turn, Article 31 of the CPC, regarding the conditions for the provision and presentation of products or services, states that one must grant “correct, clear, precise, and overt information in Portuguese about their features, quality, quantity, *composition*, price, warranty, expiry dates and origin, among other data, as well as the risks posed to health and safety of consumers “(emphasis added).<sup>36</sup>

Particularly about consumer products (such as food, medicines, toiletries and beauty), it should be noted that, for quality control, one must understand the ability of the supplier to identify, without any omission or failure, all components of a product, even when the percentage of a component is low. This becomes especially relevant in the case of people with food hypersensitivity, because an allergic reaction can often be triggered regardless of the amount of exposure to the allergen. Suffice it that it is present, albeit in the form of small amounts of allergens unintentionally added to the product in the production line (the “features”).

There is no other reason to sustain the need to control not only the ingredients of a product, but also the features arising from the production process, transport or storage of the product, thus protecting consumers’ full right to information.

The proposal for regulations on allergen labeling and the requirement to control the management of allergenic substances aims to protect the diffuse rights of people with food allergies who need to ensure a allergen-free diet to have their health preserved.

Precisely because of the need to ensure the protection of the health of this group of people (and their carers, in a broad sense, encompassing not only the family but the health professionals involved in the treatment and monitoring of the development of food allergy), it is argued that there is the need to ensure adequate food supply to individuals with food hypersensitivity, which is to occur through proper labeling of allergens on food products, as well as the availability of such information from the customer service channels, whether online or by phone.

Because health protection is of the basic rights of consumers, all necessary measures must be taken to ensure the enjoyment of such a right, which, in the case of the allergic population, demands the availability of information about the presence of allergens. Frederico da Costa Carvalho Neto points out that “information is arguably one of the most important, if not the most important, rights of consumers.”<sup>42</sup> Along the same lines, Claudia Lima Marques emphasizes that the duty to inform is “truly an essential duty, a basic duty (art. 6, section III) for harmony and transparency of consumer relations”; it is a “true burden attributed to suppliers”.<sup>43</sup> The duty to inform appropriately and clearly is justified by the fact that only suppliers hold information about

the items that make up a given product, as they are the ones who manipulate the product, and consumers are thus vulnerable, which is even more delicate when taking into account the risks that exposure to allergens can cause on a person's health.

Particularly on the duty to inform on product composition, Alexandre Malfatti states that this right arises from the possibility that the consumer has “unique characteristics - health, creed, religion, etc. - which may be incompatible with the product or service offered.”<sup>37</sup> This is the premise taken here: there is a segment of the population that needs, for purposes of protection of their right to health, accurate information about the contents of food products.

It is known that the consumer is at the mercy of what is mentioned on the product label, in unquestioned position of vulnerability (Article 4, paragraph I of the CPC), thus unable to imagine that the content of the label does not represent the whole composition of the product. In the case of people with allergies, as above-mentioned, lack of such information can result in serious damage to consumers' health, given that, in the case of people with food allergies, the information is especially relevant in the pre-contractual phase, relative to reading the information on the labels. In this respect, Fátima Nancy Andrichi points out:

*[...] Information provided in the pre-contractual stage is essential for consumers to have their own conviction, because only after full awareness of quantity, quality and risks of the service offered will consumers be able to decide whether or not to close the deal.*<sup>44</sup>

Only suppliers are able to minimize what Roberto Augusto Castellanos Pfeiffer calls “information asymmetry”, by consolidating and transmitting precise data about the presence of allergens in a product, whether added voluntarily, or involuntarily arising from the production process.<sup>45</sup> In this sense, the search for the correct identification (and display) of all components of a product is closely associated with the concern of the CPC (and the national policy of consumer relations) with consumer safety, which is clear in the case of allergy.

Also on the issue of informational vulnerability, Claudia Lima Marques points out that this is “the greatest factor of imbalance in the *vis-à-vis* relationship with suppliers, who, more than *experts*, are the only true holders of information”.<sup>46</sup>

It is precisely because of the informative vulnerability of consumers that suppliers are expected to be always based on the principle of objective good faith, which results in the obligation of the supplier to give all the information of the product or service as a way to balance the consumption relationship. Ana Elizabeth Lapa Wanderley Cavalcanti says that “the duty to inform can be understood as a norm of behavior that demonstrates the good faith required to balance the consumption relationship”.<sup>20</sup>

The principle of objective good faith is particularly important when one considers the need of people with food allergies to have access to accurate information about the content of products available on the market. It is known that the CPC, as a rule, prohibits the sale of products or services that may be harmful to consumers. This is addressed by Articles 8 and 9 of the CPC, which provide the rules applicable to products and services that are potentially harmful or dangerous.<sup>36</sup>

According to these standards, all products and services available for consumption shall contain necessary and appropriate information, and in the event that a product or service, by nature or use, may pose risks to consumers' health or safety, such information, although considered as normal and predictable, in addition to generic information about the ingredients and functionality, must conspicuously and appropriately highlight the risks involved in order to enable consumers to protect against them.

It should also be noted that, under Article 10, it is forbidden to trade products or services whose supplier knows or should know are heavily harmful or hazardous to health or safety. Thus, when by nature or enjoyment there is any risk of impairment of health or safety, the supplier shall provide such information conspicuously and appropriately.

Decree No. 2181 of March 20, 1997, which provides for the organization of the National System of Consumer Protection, establishes that it is an offense to make available in the consumer market, product or service "that entails risks to the health or safety of consumers and lacks overt and appropriate information "(art. 12, IX," b "). Moreover, the same Decree provides as infringing practice the offer of products or services "without correct, clear, precise and overt information, in Portuguese, on their features, quality, quantity, composition, price, payment terms, interest, costs, warranty, expiry dates and origin, among other relevant data "(art. 13, I).<sup>47</sup>

For products containing allergens, even if they are not potentially harmful or dangerous to all consumers, contact with such substances expose people with food allergies to a number of risks, given that prevention would depend solely on the correct labeling of food products. Thus, in order to meet the provisions of Article 9 of the CPC, one should sustain the duty of the supplier to "inform, conspicuously and appropriately, on its harmfulness or dangerousness".<sup>36</sup> It should be noted that the indication of the presence or absence of allergens must be accurate, under penalty of accountability by the disparity information indicated in the product, in accordance with Article 18 of the CPC.

Addressing what he calls "information addiction", Alexandre David Malfatti is quite incisive towards duty liability of the supplier in case of inaccurate information. He believes that, if there is defective information, lack of security stems from legitimate consumer expectations being frustrated



by the lack of accurate information from the supplier on product use or service enjoyment or on the risks involved.<sup>37</sup>

It is worth mentioning a lesson by Antonio Herman V. Benjamin, for whom absent or defective information results in ill quality stemming from insecurity.<sup>48</sup> Thus, even though a food product available for consumption is not, *a priori*, a harmful or dangerous product to health, the lack of information makes it a threat to the segment of the population with restrictions on the consumption of certain ingredients, as such food can trigger allergic reactions when consumed.

Particularly with regard to food products, Luciano Custodio Teixeira says that, because of the importance that food represents to humanity, it would be reasonable to set strict liability for damage caused by defective information.<sup>49</sup>

The Court of the State of São Paulo, when analyzing a lawsuit where punitive damages were pleaded due to the consumption of spicy stick containing wheat, decided that the package should contain clear information about product content. It determined the duty to indemnify, in this case, because there was no specific information on the product label on the presence of wheat flour in the composition of the product. In the case above, the consumer reaction occurred after the consumption of the product, which contained no reference to the presence of wheat in the ingredient list, making it impossible for the consumer to know that the consumption of that product could cause damage to their health.<sup>50</sup>

To the same effect was the decision of the Regional Court of the 3rd Region, which claimed as reasonable to suspend the sale of products that do not indicate the presence of soybean oil. It reinforced the thesis that packages should include information concerning product composition.<sup>51</sup>

If the consumer protection is a right guaranteed by the Constitution and access to information on product composition is the tool to control public health, it is reasonable to support the need for suppliers to provide information about the presence of allergens, even if as features, since even small amounts of allergens can trigger allergic reactions in people.

It is also worth highlighting the Court of Justice of Rio Grande do Sul in a case of allergic reaction arising from consumption of a product that did not contain the allergen (milk) among its ingredients, but had traces of milk because of shared machinery in the production process. In this case, confirming the decision rendered by the court of Porto Alegre, the court held that the liability of the manufacturer of the product was objective, and therefore could only be set aside if proven that the supplier had not introduced the product on the market, that the defect did not exist, or that the harmful event was derived solely from the fault of the consumer, situations that did not apply to the case under discussion.

Based on the right to consumer information, it was decided that, although at the time of purchase of the product there were no specific regulations of ANVISA about the need to warn against the existence of allergenic products, there was offense against the CPC because of the lack of accurate information on the contents of the product sold. The decision makes it clear that the lack of information about the presence of allergens (regardless of amount) is a matter of strict liability, because the legislation that supports the consumer rights reiterates throughout the whole standard that consumers have the right to clear and accurate information and that the supplier has a duty to inform it.<sup>52</sup>

It should be noted that in the event of damage to the health of someone with food allergy, who ingested allergens not mentioned on the package of the product, there would be no room for any defense from the food industry based on development risk. Currently, although the issue is not settled in Brazil, industries already have full knowledge of the existence of a considerable percentage of people with food allergies and are thus subject to liability in case of accidents arising from consumption when information on the presence of allergens is missing.

For these reasons, safeguarding the right to accurate information on the presence of allergens is essential measure for the protection of the rights of the allergic population in order to ensure their fundamental rights to health and adequate food, provided in international treaties and the Brazilian Constitution, especially the Universal Declaration of Human rights and the International Covenant on Economic, Social and Cultural rights.

As an example, it should be noted that there is an evolutionary process in the legislation of many countries as regards the obligation to indicate the presence of allergens on the labels of food products. In Europe, United States, Australia and New Zealand, it has been debated for over a decade, and it is constantly revisited in order to maintain the necessary update for meeting the demands of the allergic population and the advances of science. In such nations, whenever a product contains any allergen included in its composition, this fact shall be highlighted on the package, either in bold, with information in parentheses or apart at the end of the list of ingredients list so that consumers can easily identify whether the ingredient that causes an allergic reaction in them is present in the product.

## Conclusions

Although the subject matter has been addressed worldwide for over a decade, this reality has not been implemented in Brazilian standards so far, thus harming people with food allergies, their carers and health professionals, who are left wondering what foods would be safe for this segment of the population.

There is a great percentage of people with food allergies, and the percentage of interest in the regulation of labeling grows significantly when one considers the number of caregivers of allergic children who needs accurate information to feed them.

Laura E. Derr warns that, for every allergic person, there are about ten non-allergic people involved in the purchase of food, which reinforces the importance of correct labeling.<sup>53</sup>

Given the demands of the population, ANVISA decided to focus more attention on the issue of labeling of allergens in packaged foods. On May 29, 2014, the Board of the Agency decided to open public consultation for a proposed rulemaking on the subject in Brazil so that, for a period of 60 days from June 16, 2014, interested parties can express themselves about the theme.<sup>54</sup> In less than three days of public consultation, there were over 700 comments, with the massive part arising from families of children with food allergies who were favorable to the proposed rule, in so far as the health of their sons and daughters would be better supported by the adoption of a rule for mandatory allergen labeling.<sup>55</sup>

The approval of a rule imposing a duty to highlight the presence of allergens will certainly benefit the population with food allergy, who are currently exposed to the risk of accidental consumption because it is difficult to identify the presence of allergenic ingredients in products.

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