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Precautionary labeling: challenges and possibilities for international standards on allergen labeling

Etiquetado de precaución: retos y posibilidades para los estándares internacionales sobre etiquetado de alergénicos

Abstract

Introduction: The treatment of food allergies, which affect 10% of the world's population, is the exclusion diet. The way information on the intentional presence of allergens in labeling is provided is more consensual, but the strategy to warn about the risk of unintended presence (precautionary labeling) is very variable among countries, resulting in a challenge to people living with food allergies. *Objective*: To present the solutions that countries have adopted for precautionary labeling and to highlight the ongoing debate in the *Codex Alimentarius*, proposing an approach that recognizes the duty to comply with human rights protection standards in the context of discussions on guidelines for international trade. *Methods*: A propositional legal method, including comparison of laws, evaluation of *Codex Alimentarius* documentation, as well as international references on the protection and promotion of human rights. *Results*: There are different regulatory strategies, each based on the experience and information available at the time of their approval. The solution under discussion at *Codex* results in a risk of reactions in a number of allergy sufferers without labeling information regarding the potential unintended presence of allergens, which violates the precautionary principle and human rights regulations. *Conclusions*: Consumer health should be the lens for the design of regulations and guidelines. In case of uncertainties, the policy that provides the highest level of protection must be adopted.

Keywords: Food Allergy. Precautionary principle. International commerce. Human rights.

Resumen

Introducción: El tratamiento de las alergias alimentarias, que afectan un 10% de población mundial, es la dieta de exclusión. La manera de informar sobre la presencia intencional de alérgenos en los etiquetados está más consensuada, pero la estrategia para advertir sobre el riesgo (etiquetado de precaución) varía mucho de un país a otro, lo que resulta en un reto para las personas que conviven con alergias alimentarias. *Objetivo*: Presentar las soluciones que los países hanadoptado para el etiquetado de precaución y

subrayar el debate en curso en el *Codex Alimentarius*, proponiendo una mirada que reconozca el deber de observancia de la normativa de protección a los derechos humanos en el contexto de las discusiones sobre directrices destinadas al comercio internacional. ***Métodos***: Método jurídico propositivo, que incluyó la comparación de leyes, la evaluación de la documentación del *Codex Alimentarius*, así como referencias internacionales sobre la protección y promoción de los DDHH. ***Resultados***: Hay estrategias regulatorias diferentes, cada cual basada en la experiencia e información disponible cuando de su aprobación. La solución que está en discusión en el *Codex* resulta en riesgo de reacciones en una parcela de los alérgicos sin que haya información en el etiquetado, loque viola el principio de la precaución y la normativa de derechos humanos. ***Conclusiones***: La salud de los consumidores debe ser la lente para el diseño de normativas y directrices. En caso de incertidumbres, se debe adoptar la política que viabilice el mayor nivel de protección.

Palabras clave: Alergia alimentaria. Principio de la precaución. Comercio internacional. Derechos humanos.

INTRODUCTION

A food allergy is an adverse immunological reaction that a person suffers as a result of contact with one or more foods. The Food and Agriculture Organization of the United Nations (FAO)[1] estimates that food allergy affects ten percent of the global population, significantly impacting the quality of life and the development of individuals with allergies and their social environment.[2]

The standard approach to treatment is to eliminate the food in question from thediet. In the case of processed food, according to Chaddad,[3] compliance depends on providing information in plain language and in an accessible location. Similarly, where there is a risk of unintentional contamination, it is important to include this information on the label.

Since 1999, the international guidelines on food labeling of the Codex Alimentarius[4] Commission have highlighted the foods that are most likely to cause allergic reactions when they are among the ingredients of a product. However, at the time, there was no guidance on the most appropriate way to provide information on the risk of unintended presence.

Several countries regulate the labeling of allergens, but with different approaches to the disclosure of risk information. This has led to an environment of uncertainty characterized by inconsistencies in the wording used to describe the risk of reactions, with no technical basis, and/or information related to only a subset of allergens, omitting the risk associated with others. Countries that have recently passed allergen labeling laws, such as Brazil and other Latin American countries, are experimenting with more detailed ways to communicate risk.

The international guidelines on food allergen labeling under the Codex Alimentarius are being revised,[5] including aspects related to information on the risk of unintended presence of allergens in food.

Discussions in the context of the Codex Committee on Food Labeling (CCFL) usually adopt the rules applicable to the World Trade Organization (WTO) as a parameter, but rarely consider rules related to the duty to promote and protect human rights in their debates.

However, when it comes to risk assessment and beacons for communicating - or omitting - such risks, having only trade regulations as a compass to guide countries can lead to solutions that violate human rights regulations and World Health Organization (WHO) guidance.

Therefore, the present research aims to present the solutions adopted by countries to inform consumers with allergies about the risk of unintended presence of allergens in food, to present the current debate in the Codex Alimentarius, and to evaluate the compliance with human rights protection standards in the discussions on guidelines for international trade.

Allergen information on food labeling

Since the 1980s, the previously mentioned international guideline known as the General Standard for the Labeling of Prepackaged Foods (GSLPF) has stipulated that the right to information must be guaranteed to consumers.

The prohibition of labeling that leads to confusion, error and/or deception is also found in the food legislation of the United States (Code of Federal Regulations, Sec. 101.14), Canada *(Food and Drugs Act, Sec*. 4, item 5), Australia and New Zealand (Australian Consumer Law), the European Union (art. 16 of Regulation

(EC) No. 178/2002), as well as in the context of Mercosur (Mercosur Technical Regulation for Labeling of Packaged Foods, Resolution GMC No. 26/03, item 3).

Over time, the GSLFP was found to be inefficient for people with food allergies, either because of the use of technical terminology, such as casein and albumin, or because of problems with the legibility of the ingredient list. This difficulty was recognized in the 1990s when experts were convened to seek information on the prevalence of food allergies and strategies for reporting the presence of allergens in products, taking into account the necessary balance between health aspects and technological limitations.[6] The revision was approved in 1999 and added guidelines for prepackaged foods to include labeling for the major allergy-causing foods.[7]

Several countries have passed legislation to regulate this issue, such as Australia and New Zealand in 2002, the United States in 2004, the European Union in 2003, Canada in 2011, as well as in South America, where there are regulations for allergen labeling in foods in Chile since 2010, Brazil since 2015, Argentina since 2017, and Paraguay since 2018. The standards listed include as allergens the foods indicated on the GSLPF (in bold), and some of these standards include foods that are not listed (Table 1)..

Table 1. List of foods that should be underlined in the labeling. 2023

Food	Australia/ New Zealand	USA	EU	Canada	Chile	Brazil	Paraguay	Argentina
Milk	X	X	X	X	X	X	X	X
Soy	X	X	X	X	X	X	X	X
Eggs	X	X	X	X	X	X	X	X
Wheat / cereals containing gluten	X	X	X	X	X	X	X	X
Crustacean shellfish	X	X	X	X	X	X	X	X
Peanuts	X	X	X	X	X	X	X	X
Tree nuts	X	X	X	X	X	X	X	X
Fish	X	X	X	X	X	X	X	X
Celery			X					
Mustard			X	X				
Sesame	X	X	X	X				
Sulfites (≥ 10ppm)	X	X	X	X	X		X	X
Lupines	X		X					
Molluscan shellfish	X		X	X				

There was consensus on the need to indicate the presence of major allergens, but not on the manner and conditions of risk communication (precautionary labeling).

The lack of clear guidelines resulted in challenges for consumers: (i) variety of risk warning phrases, such as "may contain", "may contain traces", "contains traces", "packed in an environment where X may be present", with no justification for the use of one or another warning phrase; (ii) inconsistency among warnings depending on the allergen (more precautionary labeling for peanuts and tree nuts than for eggs and soybeans).[3,8]

As a consequence of this situation - and not as a cause, it is important to emphasize - consumers who live with food allergies feel insecure regarding these warnings, as highlighted by Dunn Galvin[9] and, sometimes, try to make a risk assessment based on the sentence used,[10] which does not make sense given what has been previously mentioned.

In addition, Roses notes that sometimes people suffer reactions after contact with the allergenic food whose risk of presence was not warned on the label because they mistakenly understood that the absence of precautionary information would represent safety.[11]

On the other hand, the countries that have approved their regulations in recent years adopted a different, precautionary strategy to provide consumers with more reliable information on the risk of unintentional contamination.

Precautionary labeling: an evolving issue

Although countries in the first wave of regulation recognized the relevance of risk information, at that time they did not have enough data and studies to evaluate the best approach to the issue of precautionary labeling.

The issue was brought back to the spotlight a few years later during the Canadian public consultations to investigate the opinion of stakeholders on the issue of precautionary labeling,[12] with the aim of improving the strategy adopted on this issue between 2009 and 2010. It was found that consumers were not supported by the current preventive risk labeling system, since (i) there was an excessive use of preventive labels, with no effective risk for consumers and (ii) consumers had difficulty in interpreting the level of risk linked to the preventive label, since they did not know the criteria for the inclusion or omission of such warnings. The conclusion was that there should be limits to the permitted warning sentences, which would have to be based on good manufacturing practices. The drafting of a guide with standardized criteria for assessing the risk of unintentional contamination was recommended, as was the creation of educational programs for consumers and industry.

In December 2012, the Canadian government approved the recommendation that, where precautionary labeling is adopted, only the warning "may contain [X]" could be used on labels, in order to avoid the use of different warnings without technical justification for this.[13]

Around the same time, in 2010, Chile approved the resolution on the labeling of food allergens, the first regulation to introduce the need to communicate the risk of unintentional presence of allergens in a food, when the product is at risk of being contaminated, in which case any of the following phrases should be included after the list of ingredients: "May contain ...", 'Contains small amounts of ...', 'Contains traces of ...' or "Processed on lines that also process ..." (art. 107, h).While progress has been made by making precautionary

labeling mandatory, the proliferation of warnings without a basis for their adoption has created risk and confusion.

Years later, Brazil began the process that would result in the approval, in 2015, of its regulation on allergen labeling in food. The Chilean experience served as an inspiration, but the criticisms and expectations regarding the precautionary warning were taken into account, adopting the premise of using a single warning: "may contain".

To ensure that the use of precautionary labeling was not trivialized, the Brazilian health regulatory agency, Anvisa, conditioned the inclusion of precautionary labeling to the existence of an allergen control program, aligned with good manufacturing practices.

Argentina and Paraguay passed their legislations in 2017 and 2018, respectively, which largely mirror the resolution that Brazil passed, including with regard to precautionary labeling. However, these regulations included the submission of an affidavit to the competent authority stating the reasons for the risk of non-voluntary presence.

In the case of Argentina, the inclusion of the warning would be subject to the submission of an affidavit to the health authority; the warning should only be used after a risk assessment has been carried out and when it is considered that there may be a real risk to theconsumer,[14] a different solution from the strategies previously evaluated and which may result in a more delayed and costly process.

The regulatory strategies adopted are systematized in Table 2.

Table 2. Summary of evaluated precautionary labeling strategies. 2023

Strategy	Australia / New Zealand	USA	EU	Canada	Chile	Brazil	Argentina	Paraguay
Optional	X	X	X					
Optional, with regulated text				X				
Mandatory, with multiple sentences					X			
Mandatory, with regulated text						X		X
Subject to prior approval							X	

It is correct to say that precautionary labeling is an important measure for people with higher susceptibility, and that providing a single sentence to warn about the risk reduces uncertainty, as it prevents the false interpretation of risk gradation. Furthermore, conditioning the warning to an allergen control program is an innovative strategy compared to previous approaches. The question remains as to whether this solution does not end up being more costly for both the manufacturer and the public administration, and whether the manufacturer can choose not to communicate the risk, even if it exists, in order to avoid this administrative stage and the cost it entails. The debate must be broadened so that it is possible to reach a solution that best favors consumers with food allergy, from a perspective that considers the duty to promote and protect their rights to health and adequate food.

Precautionary Labeling on the Codex Alimentarius Agenda

In 2019, the CCFL approved the selection of an expert committee to (i) validate and update the GSLPF list of foods and ingredients, (ii) establish tolerance levels for priority allergens, and (iii) evaluate the evidence for precautionary labeling.[15]

One of the issues included in the call was to identify thresholds for priority allergens below which most allergic consumers would not suffer an adverse reaction - the work of the committee to be formed would not begin to cover the entire allergic population. This was confirmed by the recommendations presented.

In its first report,[16] the Committee relied on data from studies reporting double-blind, placebo-controlled provocation tests, typically at the diagnostic stage, conducted in a controlled environment to ensure the absence of risk factors such as viral illness or discomfort of the patient being tested. This type of testing is only suitable for IgE-mediated allergy situations and therefore does not reflect the most common allergy cases in the breastfeeding infant population, cases of eosinophilic esophagitis and cases of food protein-induced enterocolitis syndrome. The test is most commonly used with children and, thus, there is little data on the young and adult population. In addition, it is not usually performed in cases where the patient has previously had a very severe reaction or in people under 2 years of age due to ethical restrictions, as noted by the U.S. agency in 2008.[17]

In the aforementioned document, the experts considered data based on objective symptoms resulting from oral tests, that is, those of a serious nature, externally observable, such as tachycardia, hypotension, chest retractions, coughing, sneezing, convulsions, diarrhea, urticaria, swelling of the lips and/or oral mucosa.

Based on the data evaluated and the conditions described, it is not clear whether the data evaluated could be transposed to the general population, in an everyday situation, regardless of their age, medical condition and food consumption pattern. The Committee's report notes that there are no data from double-blind, placebo-controlled provocation tests in all countries and for all foods, which results in some “grey areas”.

Based on these premises and data, they arrived, in their second report,[18] at a reference dose (ED05), a parameter at which 95% of allergic individuals would not suffer an objectively verifiable adverse reaction, which are the most severe.

The Committee recommended that precautionary labeling should only be implemented in cases where the test showed presence above the reference dose (ED05). In the case of lower occurrence, the label should not include precautionary information.

An additional concern is that analytical testing in industrial environments is performed sporadically, by sampling, and results may not be consistent.

The third report of the Committee[19] warned that the stated reference doses could not be a benchmark for an allergen-free (“free from”) claim. The approach would be to provide less protection and restriction for less sensitive people with food allergies, although the possibility of some risk to a more sensitive group was acknowledged in that document. For this group, more work would be needed on how to provide adequate information to make informed choices about food safety.

As it is not intended for general health protection, the use of the reference doses indicated by the Committee (ED05) would result in (i) risk of objective reactions in approximately 5% of the allergic population with IgE-mediated reactions; (ii) risk of subjective reactions in the allergic population with IgE-mediated reactions; and (iii) risk of allergic reactions in people with non-IgE-mediated food allergies, with mostly

gastrointestinal symptoms and, specifically with regard to infants, a group whose development is significantly impacted.[20,21]

At this point, it is important to evaluate whether the Committee's working premises and its understanding of risk analysis consider the perspective of the current applicable international treaties, including those dealing with the duty to protect human rights.

Coexistence of international trade regulations with those of human rights

Information is one of the most important consumer rights and this concept is present in the Codex Alimentarius references, in the European Regulation and in the current legislation of Mercosur, all of which deal with measures to prevent practices that may mislead consumers.

The duty to inform consumers and to prevent misleading practices, as well as the duty to protect health, as expressed in these instruments, must be interpreted together with the duty expressed in the international instruments for the protection and promotion of human rights, in order to promote what is known as a common policy framework, applicable to the entire structure of the United Nations and other international organizations, and conducive to the coherence of the policies of all United Nations institutions.[22]

Therefore, the interpreter must make treaties consistent in order to enable their mutual accommodation, acknowledging the human rights based approach, whereby treaties that protect fundamental rights, such as the Charter of the United Nations, are, in the words of Chaddad,[23] the beacons to guide the drafting and interpretation of others, including international trade policies.

The modern concept of human rights emerged in the aftermath of the Second World War, when it became imperative for humanity to establish norms for the protection of individual rights to prevent a recurrence of the grave violations that had occurred during the war. In this scenario, several international instruments for the protection of human rights were created, namely the Universal Declaration of Human Rights (UDHR) of 1948 and the International Bill of Human Rights of 1966, consisting of the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR).

The right to health is protected in the UDHR (article 25, paragraph 1) and in the ICESCR (article 11), both of which expressly indicate aspects of well-being and the right to food. This protection includes not only the right to have access to health services and health promotion measures aimed at disease prevention, but also the right to demand that the government and third parties refrain from acts that could harm someone's health, including the safety and quality of food available for consumption.

On the protection of the right to food, there are three aspects that must be observed: (i) availability; (ii) adequacy; and (iii) accessibility (General Comment No. 12 of the Committee on Economic, Social and Cultural Rights of the United Nations).[24]

Therefore, when developing a policy for consumers with food allergies, it should be considered that a food is suitable for these people as long as it is free of allergenic ingredients, and that for prepackaged foods there is clear information about the intentional presence or risk of unintentional presence of allergenic ingredients. As Chaddad[3] emphasizes, this is a crucial aspect for these individuals to be able to exercise their rights to health and adequate food.

The importance of having a policy on risk communication is a result of the precautionary principle, an inherent element of risk analysis. Taking into account the duty to protect health and the impact of food on

people's health (positive or negative), the design of a policy that seeks to make risk management feasible must consider whether an action or omission may cause unnecessary and avoidable harm to people, taking into account the provisions of health protection instruments, which include the aspect of well-being.

Regarding food, there is a concern that protectionist policies for national products may be masked by the precautionary argument. However, there are instances in which the implementation of strategies to prevent potential health impacts is legitimate, particularly when there are potential risks that have not yet been fully investigated by scientific research and analysis. This is particularly relevant in cases where there is scientific doubt surrounding the safety of consumers' health, as Shaw and Schwartz have highlighted.[25]

Article XX of the General Agreement on Tariffs and Trade allows governments to act on trade to protect human, animal or plant life or health, provided they do not discriminate or use this as disguised protectionism. Similarly, the Agreement on the Application of Sanitary and Phytosanitary Measures admits that, in case of scientific uncertainty, higher standards may be set based on an appropriate risk assessment, provided that the approach is consistent and not arbitrary (Article 5.7). This is a clear hypothesis of correct application of the precautionary principle.

Because of its role in international law and its duty to provide high levels of protection for human health, consumers and the environment, the European Union adopts the precautionary principle as a filter for policy-making, such as the aforementioned Regulation (EC) No. 178/2002, which establishes the precautionary principle as an inherent element in risk analysis for human health.

In 2003, Canada[26] published a guide to support the implementation of precautionary measures, namely:(i) they must be subject to reconsideration as science, technology and the protection level chosen by society evolves;(ii) they must be proportional to the potential gravity of the risk being addressed and the level of protection chosen by society; (iii) they must not be discriminatory, and must be consistent with measures taken in similar circumstances; (iv) They must be cost-effective, with the aim of achieving an overall net benefit for society at the lowest cost and with efficient choice of measures.; and (v)where more than one option reasonably meets the criteria listed above, the least trade-restrictive measure should be applied.

Specifically in the Codex Alimentarius, one of the practical principles for risk analysis and its application states that when there is evidence of risk to human health but the scientific data are insufficient or incomplete, the Commission should not develop a normative guideline; in such a situation, it should consider the advisability of developing a text similar to a code of practice supported by the available scientific data (item 10).

The same document calls for risk assessments to be based on realistic exposure scenarios, to consider vulnerable or high-risk populations, and to consider acute, chronic (including long-term), cumulative and/or combined adverse health effects (item 24).

The Codex Alimentarius must take into account its primary purpose of promoting consumer health protection, and thus avoid unjustified differences in the degree of consumer health protection when dealing with similar risks in different situations (item 27).

Under item 34, where there is a a choice between several risk management options that are equally effective in protecting the health of consumers, they should seek to consider the impact that such measures might have on trade among their Member States and choose measures that are no more trade-restrictive than necessary.

It is clear that the Codex Alimentarius must use consumer health as a lens for developing its standards, guidelines and directives, including in relation to vulnerable populations. Moreover, when faced with a

universe of more than one possible action, the choice of one of several options is valid only if all options are equally effective in protecting consumer health. *A contrario sensu*, it can be said that there is no possibility of choosing a measure that is not equally effective in protecting health, nor of choosing a measure that results in insufficient protection.

This conclusion is consistent with the precautionary principle, which states that where there is uncertainty about health effects, the policy should be one that provides the highest level of consumer health protection to avoid or at least reduce the possibility of harm.

Thus, while there is no such thing as zero risk, it is not possible to adopt a policy that knowingly harms people in a discriminatory manner in terms of the level of consumer protection, or to maintain a policy without scientific consensus on its consequences for consumer health.

These are the premises and pillars that make it possible to evaluate the adequacy of the different approaches to the issue of communicating the risk of unintentional presence of allergens in packaged foods.

CONCLUSIONS

Accidental ingestion of an amount of allergen can cause reactions that affect health, including well-being. Depending on sensitivity and the amount of allergen consumed, a person may have an immediate reaction - which may be severe, depending on sensitivity or health status at the time of exposure - or a slower reaction that may affect growth, nutrient absorption, and quality of life in the medium and long term. For this reason, food labeling legislation recognizes the need to clearly inform allergic consumers of the presence of the most common food allergens.

There is less consensus on how and under what conditions to communicate the risk of unintended presence, a situation where the allergen is not an ingredient but may be present due to unintentional contamination. The absence and inconsistency of information on the risk of unintended presence of allergens creates a dangerous situation for the allergic population.

So far, as noted above, there are 5 different regulatory approaches in force in the countries studied: (i) voluntary use of the warning; (ii) voluntary use, but with indication of the recommended warning text, if any; (iii) mandatory use, but without indication of the warning text; (iv) mandatory use, with indication of the warning text in the regulation; and (v) use of the warning subject to prior approval by the health authority.

In the framework of Codex Alimentarius, the Expert Committee proposed that the inclusion of risk information should be limited to cases where the analytical tests carried out show the presence of allergens above the reference dose (ED05). If the presence is below the parameter, even if the allergen is present, the labeling should omit the existence of risk, despite the impact that this omission would have on the allergic population, especially the most sensitive.

Another noteworthy point in this debate is that the proposed approach aims to prevent severe reactions in the majority of the population with food allergy, thus neglecting moderate reactions and leaving the cases of the most sensitive people uncovered, without providing them with any information about the risk.

Thus, even if it has been assessed that a significant proportion of the allergic population can tolerate a certain amount of allergen without serious reactions, this data should not be used to justify the omission of information on the existence of a risk, since this constitutes unequal treatment in terms of guaranteeing the information necessary to protect health, including the aspect of well-being.

One option would be to add a general warning about the possibility of unintended presence to the label, along with the information that the risk is less for allergy sufferers with a higher tolerance tested by a health professional.

According to the precautionary principle, where there is uncertainty about health effects, the policy to be adopted should be the one that provides the highest level of protection of human health without discrimination in order to avoid or at least reduce the possibility of harm. If there is more than one possible regulatory approach with the same level of protection, priority should be given to the one that has the least impact on international trade, but health protection is non-negotiable.

Thus, when a health risk is identified, the measure that provides the highest level of protection should be adopted, a conclusion that is based both on the regulations applicable to international trade and on those that consider the internationally accepted commitments to promote and protect human rights, including the right to health and to adequate food. Therefore, precautionary labeling must be guaranteed to all consumers, informing them in a clear, unequivocal and consistent manner of the risk of the unintended presence of allergens.

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