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Reflections on proposed modifications to the regulation of genetically modified food labeling in Brazil

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Abstract *Given the uncertainty surrounding the safety of genetically modified organisms (GMOs), the precautionary principle and constitution provide that consumers should have the right to access adequate information on the presence of transgenics through food labelling. This article discusses the implications of proposed modifications to GM food labelling in Brazil. Current labelling legislation and the government agencies involved in labelling do not guarantee that food products not bearing GMO labels are free of transgenics. The approval of Chamber of Deputies Bill No. 34/2015 goes against the Consumer Protection Code by undermining consumer autonomy and choice. In addition, it is likely to weaken the country's biosurveillance capabilities to identify and seize products that have a harmful effect on the health of humans, animals and the environment. The proposed changes constitute a retrograde step in the regulation of food labelling in Brazil and violate the individual and collective rights enshrined in the Federal Constitution, Consumer Protection Code, and international agreements signed by Brazil.*

Key words *Genetically modified organisms, Food labeling, Biosurveillance*

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Introduction

The growing of genetically modified (GM) crops and commercialization of products containing or derived from genetically modified organisms (GMOs), also called transgenics, are central issues for the food system, given the negative direct and indirect impact they can have on health, the environment and food sovereignty. Additional questions include the political and economic interests that drive the replacement of staple food crops such as beans, rice and cassava by GM soybeans and maize, most of which is destined for agroindustry and animal feed and biofuel production.

Although there are no official statistics, organizations maintained by the agro-industrial sector report that Brazil is the world's second largest producer of GM crops, planting an area of 51.3 million hectares, which is equivalent to 27% of world production[1] and approximately 70% of the country's arable land area[2]. In Brazil, 97%, 88.9% and 84%, respectively, of the areas planted with soybeans, maize and cotton are planted with GM varieties[1], which is equivalent to virtually the whole area if one considers biological contamination due gene flow and mixture during harvest, transport, storage and processing[3]. Thus it may be assumed that most of the products and subproducts derived from soybeans, maize and cotton in foods consumed by Brazilians and the population of countries that import these foods are derived from GM plants.

Twenty-five years on from the approval of the first species of GM tomato, there is still no consensus within the scientific community about the safety of the use and consumption of GMOs for the health of humans, animals, and the environment, including trophic networks and fundamental ecological relationships[4]. However, robust studies indicate that the consumption of foods produced using GM varieties can have a direct effect on human and animal health, such as food allergies, toxicity and allergenicity[5-8]. In addition, studies have revealed that there is a relationship between the expansion of GM crop area and increased pesticide use[9-11], demonstrating associations between exposure to pesticides used on GM crops, such as glyphosate-based herbicides, and increased incidence of chronic diseases like cancer, Alzheimer's, Parkinson's, asthma, bronchitis, neurological problems, hormonal imbalance, infertility, gastrointestinal disorders, depression, attention deficit hyperactivity disorder, heart disease, autism, celiac disease, diabetes and obesity[12-21]. However, studies sponsored by biotech companies conclude that eating genetically modified foods does not have a harmful effect on the health of humans, animals and the environment.

Given the contradictions between the results of independent studies and intramural research, and the scientific uncertainty about unstudied aspects, giving rise to safety concerns, especially considering the pesticide use associated with the use of GMOs, measures are urgently needed to prevent potential adverse effects. The adoption of the precautionary principle embodied by the Convention on Biological Diversity and Cartagena Protocol on Biosafety is therefore timely and necessary. This principle advocates taking measures to prevent potential risks even when there is lack of scientific certainty due to the current state of scientific knowledge regarding the extent of potential adverse effects[22-24].

Article 5, clause XIV of the Federal Constitution and the Consumer Protection Code[25] guarantee the public the right to access information on foods. Labeling of foods that contain GMOs is therefore essential and an adequate measure for upholding the precautionary principle. This right should be ensured regardless of the certainty about the risks of the product. Food labelling has multiple functions: (i) it ensures the right to be properly informed about the composition of foods, enabling consumers to make informed choices and decisions; (ii) it meets the needs of consumers belonging to risk groups who must avoid certain foods; and (iii) it ensures consumer safety by permitting the tracing and post-sale control of food products, enabling quality control[26] and research on health impacts. Nevertheless, in many cases, the composition of foods containing ingredients derived from GMOs is not clearly stated on the label[27-30].

In view of the above, this article discusses the implications of GM food labelling proposals for consumer choices in Brazil.

The first part outlines current regulations, contextualizing international recommendations and the labelling approach adopted by Brazil. We then go on to present the changes to the regulations proposed by the Chamber of Deputies Bill Nº 34/2015 – CDB Nº 34/2015 – and their impact on food safety and consumer choices.

It is important to mention that this paper is based on the experience of the authors in the fields of agronomy, genetics, economics and nutrition, as well as the experience of members of the National Biosafety Commission (CTNBio).

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Current regulations

Since 1990, through working groups and meetings with representatives from the governments of various countries, the FAO's Codex Committee on Food Labelling has been working to establish a harmonized set of non-binding international guidelines for the evaluation and formulation of recommendations on GM food labelling standards[31,32]. At the last meeting of the Committee in 2003, a consensus on labelling standards was not reached due to the divergent positions of the member states. As a result, a number of countries have adopted internal guidelines, hampering harmonization.

There are two regulatory approaches for labelling GM foods: (i) voluntary labelling, with no legislative requirements to declare the use of GMOs in the production and commercialization of food; and (ii) mandatory labelling, which requires declaration of the use of gene technology in the production and commercialization of foods[31]. Countries like China, Russia, Indonesia and Brazil, and the European Union have adopted mandatory labelling based on the precautionary principle, differing only in relation to tolerance thresholds. In these countries, foods derived from GMOs are not considered substantially equivalent to conventional foods and the consumer's right to access this information is recognized. This is not the case in other countries such as Argentina, Canada and South Africa, which adopt the concept of substantial equivalence and defend voluntary labelling[33]. In Brazil, the dossiers submitted by proponents of GM technologies to the CTNBio contain information supporting substantial equivalence. Despite having no legal basis, theses dossiers are accepted and approved.

Another particularity that distinguishes labelling standards are the different tolerance thresholds adopted for categorizing a food as GM. This categorization is performed to address situations involving unintended contamination. The criteria adopted by different countries vary between zero-tolerance (zero presence, threshold of 0%) and acceptance of presence with threshold levels of 1%, 3% or 5% of the total weight of the product. Thresholds are applied to the quantity of each GM ingredient or the three or five main product ingredients[31].

With regard to international trade agreements, the adoption of different tolerance thresholds for GM food labelling can be a source of dispute over consumer information and the receipt/acceptance of cargo when importing and exporting seeds and foods[31,34].

In Brazil, Article 6, clause III of the Consumer Protection Code (Law Nº 8,078/1990) establishes the right of access "to adequate and clear information on different products and services, correctly specifying the quantity, characteristics, composition, quality, taxes and price, as well as the risks they pose"[25].

GM food labelling in Brazil is currently regulated by the Biosafety Act (Law Nº 11,105/2005), Decree Nº 4,680/2003, and Ministerial Order Nº 2,658/2003[35-37]. Article 40 of the Biosafety Act provides that "Foods and food ingredients destined for human or animal consumption containing or produced from genetically modified organisms or their derivatives shall contain information on their labels, pursuant to this regulation"[36].

However, the law does not describe how GM foods should be labelled. In 2001, before the introduction of the Biosafety Act, the government issued Decree Nº 3,871/2001, which establishes a 4% threshold for mandatory labelling of packaged foods for human consumption[38]. This limit refers to the threshold for adventitious presence of GMOs in a batch of non-GM food as a percentage of weight or volume. The threshold refers not only to the total volume of the product, but also the proportion of the ingredient of GM origin as a percentage of the total weight or volume of that ingredient.

Decree Nº 4,680/2003 sets a 1% threshold for the mandatory labelling of foods and food ingredients destined for human and animal consumption[35]. This percentage is the tolerance threshold for adventitious presence due to unintended contamination in the different stages of the production process. This threshold refers to the total volume of the product, rather than the specific ingredient.

For example, based on Decree Nº 3,871/2001, a food containing 0.4 grams of GM soybeans and 9.6 grams of non-GM soybeans would be labelled regardless of the final volume of the food or other ingredients. However, based on Decree Nº 4,680/2003, the same product would only be labelled if the volume or final weight of the product was less than 40 grams.

Currently in force, Decree Nº 4,680/2003 sets a 1% threshold for the mandatory labelling of packaged and non-prepacked foods. These foods must use one of the following statements on the label to declare their GM origin and content, accompanied by the GMO symbol: "transgenic

(product name)", "contains (name of the transgenic ingredient(s))" or "product made from transgenic (product name)"[35].

The use of the GMO symbol is regulated by Ministerial Order Nº 2,658/2003, which defines the visual elements of the symbol, consisting of the letter "T" (standing for transgenic) in the center of a yellow triangle[37].

Changes to the GM food labelling regulations

Passed by the Chamber of Deputies in 2015, if approved by the Senate, Bill Nº 4,148/2008 (CDB Nº 34/2015) will bring change the rules for mandatory GM food labelling in Brazil. As part of the legislative process, the bill was also approved by the Committee on Agriculture and Agrarian Reform (September 2017) and the Committee on the Environment (April 2018). However, it was rejected by the Committee on Science, Technology, Innovation, Communication and Information Technology (October 2015), the Committee on Social Affairs (March 2018), and the Committee on Transparency, Governance, Oversight and Consumer Control and Protection (November 2019) (Figure 1).

One of the main changes proposed by CDB Nº 34/2015 is the replacement of the "T" symbol by the following statements: "transgenic (product name)" or "contains transgenic (name of the ingredient)", which are already mandatory under the decree that is currently in force. The bill also changes the wording of Article 40 of the Biosafety Act, revoking Presidential Decree Nº 4,680/2003 and Ministerial Order Nº 2,658/2003[39], which makes labelling and the "T" symbol mandatory for all foods and food ingredients containing or made from GMOs.

According to the current legislation, the statements mentioned above should also appear on the fiscal document. Article 2, Clause 3 of the Decree Nº 4,680/2003 provides that this information shall accompany the product or ingredient throughout the entire production chain. This provision was an innovation aimed at avoiding the need for tests, thus facilitating labelling. With the repeal of the decree, the country will cease to have a system for informing the transgenic nature of transported GM products that is cheap, effective and easy to monitor.

Under CDB Nº 34/2015, labelling will be mandatory only when the presence of GMOs in the end product is attested by a specific laboratory analysis[39]. In many cases, this requirement will mean that it is not possible to prove that the product is of GM origin, as it is only possible to determine origin using inserted DNA sequences or GMO-specific proteins. Thus, it is likely that processed or industrialized foods containing ingredients derived from GM soybean, maize or cotton will escape classification as GM foods due to the minimal chance of detecting GM DNA in these products. It is therefore highly likely that the presence of GMOs will not be declared on the labels of foods such as oils, biscuits, margarine and foods for children in their early years, even when they are made exclusively from GM raw materials. Consumers will therefore be denied this information even when the food has ingredients derived from GMOs because of the difficulties in detecting DNA in highly processed foods.

Currently foods are classified as GM foods based on the raw materials used in the product, thus confirming their identity from the beginning of the production process. Thus, foods made from GM varieties should be labelled accordingly, even if the DNA analysis does not permit their detection. Therefore, soybean oil derived from GM soybeans should be labelled as GM, despite the fact that it is not possible to detect the GM DNA and protein. The ease of detecting GMOs in raw materials used at the beginning of the production process and monitoring along the production chain reduces the cost of analysis and dispenses with the need for laboratory testing at retail level.

Besides increasing costs and making the analysis process more complex, the modifications proposed by the CDB Nº 34/2015 is also likely to lead to the labelling of foods made with GM ingredients as "GM-free". This is because the bill allows for "GM-free" labelling for products where testing does not detect the presence of GMOs. As a result, many foods containing ingredients derived from GMOs will be labelled as "GM-free", meaning that consumers will be forced to make uninformed or wrong purchasing decisions and adversely affecting non-GMO farmer and food companies that produce non-GMO products.

A study of food labels on supermarket foods by Cortese[40] revealed that 2,648 (52.5%) of the 5,048 products analyzed contained at least one potentially GM ingredient. However, only 117 (4.3%) of these foods followed the precautionary principle and declared this information on the food label. The authors identified 28 subproducts derived from GM varieties grown in the country (soybeans, maize and cotton, and a yeast product) used by the food industry. These items were

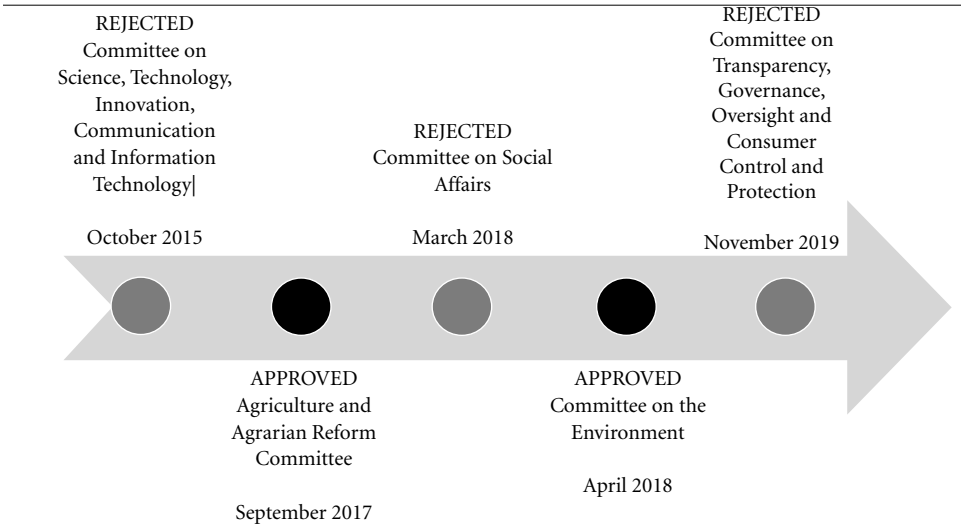

Figure 1. Timeline of the referral of Chamber of Deputies Bill Nº 34/2015 to the house committees, 2019.

Source: Elaborated by the authors.

found under different names and without adequate labelling in 64.5% of the most commonly eaten foods in Brazil. It is worth highlighting here that the threshold for mandatory labelling with this information is 1%.

Thus it can be seen that, if passed, the new bill will make Brazil's GM food labelling legislation ineffectual and misleading, as the GM-free declaration on products cannot be considered safe because it has no scientific basis. Furthermore, in comparison with current labelling laws, the proposed legislation cannot be accepted as valid, as it will require consumers to master scientific nomenclature and a list of potentially genetically modified components to be able to identify them on labels[41].

The scope of this task makes it unrealistic. The abovementioned study identified 101 different terms for potentially GM ingredients derived from maize, soybeans, cotton and the GM yeast strain *Saccharomyces cerevisiae*. Thirty of these terms referred to derivatives of maize, 26 to derivatives of soybeans, three to derivatives of cotton, and one referred to yeast. Thirty-two terms failed to inform the origin of the ingredient, meaning that such ingredients may be common to the three items, such as vegetable fat and vegetable oil, which can be derived from maize, soybeans, cotton or another plant[42]. This illustrates the difficulty consumers will have in knowing if foods contain potentially GM ingredients with the removal of the "T" symbol.

In the state of Santa Catarina, labelling is mandatory for all GM food products and derivatives regardless of quantity. Furthermore, Article 2 of Law Nº 12,128 (15 January 2002) prohibits the industrialization and commercialization of food products without a label stating that genetic engineering techniques were used during the production process. Despite claims by the food industry that the legislation is unconstitutional because it does not set a threshold for mandatory labelling, the courts upheld the legality of the law, which, however, the state fails to comply with.

In August 2012, the Regional Federal Tribunal of the First Region in Brasília determined that food companies should inform consumers about the presence of GMOs in foods, regardless of the percentage or any other condition. The aim of the action, brought by the Public Prosecutor's Office and Brazilian Institute of Consumer Protection, was to ensure the provision of adequate consumer information for all GM products. However, the food industry has yet to comply with this guidance[43].

Decree Nº 4,680/2003 provides that the "T" symbol and name of the gene donor species shall be displayed on the label of foods produced from GMOs or containing more than 1% of GM ingredients. In contrast, the CDB Nº 34/2015 con-

siders that the use of the "T" symbol is inappropriate because it associated with the idea of risk, danger, harm, care and alarm. However, a study by Hakim et al.[44] shows that only 6% of consumers associate the symbol with danger, contradicting one of the key arguments underpinning the bill. The bill also intends to exclude information about the gene donor species in the GM ingredients, arguing that it is hard for consumers to understand[39].

In the study conducted by Cortese[40], 117 foods displayed the "T" symbol, seven provided separate information about the gene donor species, and 114 displayed the symbol together with the name of the gene donor species, meaning that less than 3% of the total complied with the GM food labelling legislation. Although some of the foods analyzed did not display the "T" symbol, they did state the gene donor species, making it possible to identify the product as a GM food. If the CDB Nº 34/2015 is passed, this information will no longer be displayed on food labels, compromising consumer rights set out in the Biosafety Act by denying clear and adequate information about the composition of foods. This constitutes an affront to the Global Strategy on Diet, Physical Activity and Health[45] and the Consumer Protection Code[25].

Furthermore, the declaration of the presence of GMOs on foods containing more than 1% of GMOs only using statements like "transgenic (product name)" or "contains transgenic (name of the ingredient)" may also be criticized because most Brazilians do not have a high level of education (only 16.5% have a degree)[46]. In addition, usually written in small letters and in an inconspicuous place on the label, this information fails to adequately replace a symbol that has been incorporated into the public domain.

A study showed that a large part of products available in mainstream supermarkets containing at least one ingredient potentially derived from GM soybeans and maize fail to declare this information on the label[40]. The approval of CDB Nº 34/2015 would go against the Consumer Protection Code and current labelling proposals aimed at helping consumers make informed choices. Chart 1 shows the main differences between the current legislation and the proposals put forward by CDB Nº 34/2015.

The National Health Surveillance Agency (ANVISA), has proposed the use of symbols (triangles) to inform consumers about the nutritional content of foods, more specifically the sugar, fat and salt content of food products[47], with the aim of making labels easier to understand by providing clear, simple and easy to find information. Although these changes apply to nutrition labeling, they may also be considered for GM food labelling, since they are complementary and have the same aim of informing consumers about food composition, thus enabling people to make informed choices. In contrast, CDB Nº 34/2015 proposes the removal of the very information needed to ensure a constitutionally guaranteed right.

Another point worth highlighting is that, contrary to the provisions of Article 3 of Decree Nº 4,680/2003, CDB Nº 34/2015 proposes to exclude labelling of foods and ingredients produced from animals fed with feed containing GM ingredients. The justification for this exclusion is the lack of regulations governing these foods on the international market. Dinon et al.[48] reported the presence of GM soybeans in six processed meat and soy-based foods out of a sample of 59 products sold between 2007 and 2008; however, only one of these six samples should be labelled according to Brazilian legislation. In addition to the large quantity of GM ingredients added to meats and meat preparations by the food industry, animals fed with feed made with GM maize and/or soybeans are a source of GMOs in human food. This information should be displayed on food labels.

Labelling based on the precautionary principle considers the origin of the raw materials irrespective of detectability in the end product. This includes all highly processed foods derived from transgenic crops that do not contain detectable GM DNA or protein, such as soybean, maize or cotton oil. In addition, the presence of GMOs in the food production process, such as the use of GM yeast in bread for example, is also considered[49,50].

Moreover, the presence of GMOs in the food or production process should always be declared, irrespective of the percentage of GMO in the food. This is because foods derived from soybeans and maize tend to contain pesticide residues, posing risks to human health due to the known effects of these substances.

Brazil's legislation does not require labelling for foods with less than 1% of detectable GMOs, even when they are made from GM grains. Studies have revealed foods with more than 1% of GM ingredients without this information on the label, demonstrating non-compliance with the labelling legislation by the food industry[27,29,40,48].

Greiner and Konistzny[27] found a number of different food products made with ingredients

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derived from GM soy and maize in supermarkets in Brazil. The presence of GM soy in products containing soy rose from 13% in 2000 to 78% in 2005, while around 10% of maize contained in food products was GM, regardless of the year. Another study[29] showed that 68 foods out of a sample of 240 (28.3%) made with soy contained GM soy, while none of the foods made with maize contained GM maize. GM content varied between 0.05 and 1% in 43 samples (63.2%) and was above 1% in 25 samples (36.8%). Despite this, none of the products declared the presence of GMOs on the food label, showing non-compliance with labelling legislation.

It is also important to highlight the lack of studies on a safe threshold (percentage) for the consumption of these foods. In this regard, even when a product contains below 1% of GMOs, its consumption has different impacts depending on the characteristics of consumers. This threshold should therefore be operational and not simply based on risk analyses with families with a history of kidney failure, low immunity, hereditary cancer susceptibility and other illnesses.

According to Recommendation Nº 009/2015 issued by the National Council for Food and Nutritional Security (CONSEA), GM food labelling is an important public health measure that enables the monitoring of products after their introduction into the market and for research on environmental and health impacts[51]. However, there are no plans to include diseases caused by the consumption GM foods on Brazil's national list of notifiable diseases[52] or to identify these diseases on relevant databases, making it impossible to detect the association between consumption and health problems and monitor individuals with conditions related to the consumption of transgenics.

To ensure compliance with the current labelling legislation, inspection and supervision should be shared between the different competent agencies in accordance with their legal roles and responsibilities. According to Regulatory Instrument Nº 1/2004, at federal level, the Ministry of Agriculture, Livestock and Food Supply (MAPA) is responsible for the inspection of fiscal documentation in the field. It falls on ANVISA, which is part of the Ministry of Health, to monitor the food industry and the Ministry of Justice and state and municipal health surveillance agencies are responsible for the inspection and supervision of the supply of products to consumers[53]. With regard to inspection and supervision and carrying out specific analysis set out in CDB Nº 34/2015, it is not clear which authority is responsible for attesting the presence or absence of GM material.

Final considerations

The evidence suggests that mandatory labelling for all products, based on the production process and without stipulating a tolerance threshold, is the only way of ensuring the provision of adequate information so that consumers who do not want to eat genetically modified foods are able to make informed choices. The current GM food labelling system therefore does not allow consumers who reject or understand the harm caused by GMOS to make safe choices. Under the current labelling system, products without GMO labels, and even those with GM-free labels, should not be considered to be totally GM-free. In addition, we did not find any data on the inspection and supervision of compliance with tolerance thresholds for GM ingredients. Thus it is reasonable to assume that the food industry is encouraged to omit this information, not labelling foods that contain more than 1% of genetic material.

If passed, CDB Nº 34/2015 will only worsen this situation, undermining current labelling legislation, opening loopholes and making it even more difficult for consumers to identify products containing transgenic material. The "T" symbol helps consumers identify GM foods and is consistent with ANVISA's proposals on the use of symbols (triangles) to make labels easier to understand. The removal of the symbol and other changes proposed by the bill are not recommended and constitute a retrograde step in the regulation of food labelling in Brazil. Instead, the government should step up efforts to raise awareness about the information contained on food labels, making them more understandable, especially for groups with lower levels of education.

Finally, although GM food labelling legislation in the Mercosur region is not harmonized, the commercialization of GM foods without proper labelling violates the individual and collective rights enshrined in the Federal Constitution, Consumer Protection Code and international agreements signed by Brazil.

It is hoped that this essay will contribute to improving inspection and supervision and to promoting a positive review of Brazil's GM food labelling legislation, increasing the reliability of labels and helping consumers make informed decisions based on the composition of foods, al-

Chart 1. Differences between Decrees Nº 3,871/2001, Nº 4,680/2003 and the Biosafety Act and Bill Nº 4,148/2008 and Chamber of Deputies Bill Nº 34/2015.

Features	Decree/Bill				
	Decree No 3,871/2001 Revoked	**Decree No 4,680/2003 In force**	**Biosafety Act In force**	**Bill No 4,148/2008 Under discussion**	**Bill No 34/2015 Under discussion**
Scope of application	Packaged foods for human consumption	Packaged foods and non-prepacked foods	Foods and food ingredients for human or animal consumption	Packaged foods and non-prepacked foods	Packaged foods and non-prepacked foods
Tolerance threshold	4% (for each ingredient)	1% of product or ingredient weight	0%	1% of product weight	1% of product weight
Statements	- transgenic (type of product) - contains transgenic (type of ingredient)	- transgenic (product name) - contains transgenic (name of the ingredient or ingredients) - product produced from transgenic (product name)	Not mentioned	- transgenic (product name) - contains transgenic (name of the ingredient)	- transgenic (product name) - contains transgenic (name of the ingredient)
Presence of gene donor species	Not mentioned	Information should be displayed in the place where the ingredients are listed	Not mentioned	Information not included	Information not included
Labelling of GM foods for animal consumption	Not mentioned	Foods and ingredients produced from animals fed with feed containing GM ingredients should display the following statement: "(animal name) fed with feed containing transgenic ingredients" or "(name of the ingredient) produced from animals fed with feed containing transgenic ingredients"	Not mentioned	Not mentioned	Applicable
Voluntary labelling of non-GMO foods	Not mentioned	Foods that do not contain GMOs may be labelled as follows: "(product name or ingredient) free of transgenics", provided there are similar transgenic products on the market	Not mentioned	Foods that do not contain GMOs may be labelled as follows: "(product name or ingredient) free of transgenic organisms", provided there are similar transgenic products on the market	Not mentioned
Symbol	Not mentioned	Applicable	Not displayed	Not displayed	Not displayed

Source: Elaborated by the authors.

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lowing conscious consumers to exert pressure on companies through their purchasing decisions.

In conclusion, the adoption of the precautionary principle requires that, in face of uncertainty, products should be labelled based on both the accompanying fiscal document and DNA and protein testing.

Collaborations

RDM Cortese contributed to study conception and drafting and revising the article. RK Fabri, SS Martinelli, L Melgarejo and RO Nodari contributed to critically revising the article. SB Cavalli contributed to study conception and revising the article.

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