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Structural responses to the obesity and non-communicable diseases epidemic: the Chilean Law of Food Labeling and Advertising

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Summary

In 12 July 2012, the Chilean Senate approved the Law of Food Labeling and Advertising, resulting from the joint efforts of a group of health professionals, researchers and legislators who proposed a regulatory framework in support of healthy diets and active living. Its goal was to curb the ongoing epidemic increase of obesity and non-communicable diseases. Two actions included: (i) improving point of food purchase consumer information by incorporating easy-to-understand front-of-packages labeling and specific messages addressing critical nutrients, and (ii) decreasing children's exposure to unhealthy foods by restricting marketing, advertising and sales. We summarize the work related to the law's release and discuss the conclusions reached by the various expert committees that were convened by the Ministry of Health to guide the development of the regulatory norms. Throughout the process, the food industry has overtly expressed its disagreement with the regulatory effort. The final content of the regulatory norms is still pending; however there are suggestions that its implementation will be delayed and might be modified based on the industry lobbying actions. These lessons should contribute to show the need of anticipating and addressing potential barriers to obesity-prevention policy implementation, particularly with respect to the role of the private sector.

Keywords: Food labeling and advertising, nutrition policy, obesity and noncommunicable diseases (NCDs) prevention.

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Introduction

Chile has recently passed a law that regulates food labeling and advertising with the aim of helping all Chileans achieve a healthy lifestyle while decreasing obesity and obesity-associated non-communicable diseases (NCDs). In the following sections, we provide the rationale for legislative actions, such as this law, and briefly present its structure and main mandates. We then summarize the conclusions of the expert committees that have reviewed the evidence for implementation of food labeling (which include a definition of critical nutrients and limits and specific labeling conditions such as size, location, and color) and advertisement aspects of the law for the Ministry of Health. We conclude by examining the role of industry in this process, providing an update of what is presently taking place in Chile and discussing what could have been done better to facilitate implementation, as well as the potential for success of this policy.

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The Chilean Law of Food Labeling and Advertising: how did we get there?

In recent decades, Chile has experienced rapid socioeconomic improvements reflected in almost a doubling of the Internal Gross Product and in a high Human Development Index (1,2). The corresponding demographic, epidemiological and nutritional transitions have successfully contributed in virtually eradicating under-nutrition but concomitantly have contributed to a rising prevalence of obesity and related comorbidities; presently, excess weight is among the highest of the world, reaching 67% in adults and 46% in first-grade children (3-5). The Chilean diet has also changed drastically over the past two decades, mainly with a decrease in the consumption of whole grains, legumes, vegetables and fruits and an increase in the consumption of energy dense foods (e.g. in 2007, expenditure in processed food represented 57% of total food expenditure) (6). Similarly, due to a shift from more physically demanding forms of employment to those more sedentary, along with improvements in access to transportation, Chileans have become far less active. In 2009, less than 10% of adult Chileans reported 30 min of physical activity three times per week in their leisure time (4).

In 2002, an expert meeting between the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO), resulted in a call for action to tackle NCDs summarized in the 'TRS 916 Diet, Nutrition and the Prevention of Chronic Disease' report, which raised awareness and concern about this growing epidemic worldwide. In Chile, this motivated a group of Chilean researchers led by Dr. R Uauy to discuss with the senate the potential policy actions that could be implemented to address the ongoing obesity and NCD epidemic (7,8). As a result, legislators from all parties start to discuss with the national scientific community and other policymakers the need for action at the legislative level. This was taken up by Chilean Senate Health Committee, and in March 2007, a bill was introduced to the Chilean National Congress with the aim of promoting healthier food environments (9). Specifically, this project proposed to define unhealthy foods that could not be: (i) sold in or within 100 m of schools, (ii) distributed or sold to children less than 14 years of age, and (iii) promoted by using toys or any other promotional item. It also mandated that the population be informed on the risks associated with excessive consumption of these foods by appropriate labeling and front-of-pack messages. In the initial project, unhealthy foods were defined based on the traffic light food labeling system developed by the Food Standards Authority in the United Kingdom (10). The President of the Republic at that time, Michelle Bachelet, not only supported the bill, but expanded it by incorporating articles that banned infant formula advertisement and made mandatory physical activity (three times per week) and nutrition education at schools.

The discussion of the bill started in the senate with lobbyists from both food companies and public organizations. In the public media, representatives of industry and Chief Executive Officer (CEOs) of food companies warn the public and the government about the risks of taking any regulatory action on the food sector and declare their full opposition. In order to widen the support of the proposed legislation the Chilean Senate in March 2008 assembled the First International Summit on Health and Nutrition. The Summit convened national and international experts, academics and citizens to discuss the implications and feasibility of implementing this law. At the same time, the Ministry of Health started to negotiate the structure of a front of package labeling system with the national food companies; however, despite these conversations, companies decided unilaterally to incorporate Guideline Daily Amounts (GDA) onto food labels and launched a mass media campaign to promote their use. In October 2011, the Second International Summit on Health and Nutrition took place, once again convened by the Chilean Senate. National and international researchers met again with legislators and civil society to discuss topics related directly or indirectly to the implementation of the law (11).

Finally, in 2012, after several discussions and negotiations between political parties, the Chilean Ministry of Health, and players from the food industry, the law was approved by the Chilean Senate. In order to pass the law, some aspects of the original proposal had to be removed: using traffic light food labeling system as the method to define 'unhealthy' foods, banning on infant formula advertising and the prohibition of selling unhealthy foods in universities. The amount of physical education classes was also left unregulated because the recommendation was difficult to implement under the current legislative framework under which the Ministry of Education bears the responsibility for the school curricula; thus any change on allocation of time for physical activity needs approval by the Ministry of Education.

Nutritional profiling scheme in the context of the Chilean Law of Food Labeling and Advertising: how to define 'unhealthy'?

The version of the law approved by the Senate specified that the development of the regulatory norms required for the final implementation of the law would be in charge of the Ministry of Health. The approved version of the law specified that the Ministry of Health was in charge of developing the regulatory norms to finally implement the law. The most critical aspect of the law was how to define 'unhealthy' foods because this definition implied modifying the Chilean Sanitary Regulatory Code and because the

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Table 1 Advantages and disadvantages of different nutrient profiling schemes

Scheme type	Alternatives	Strength	Weakness
Reference amount	Per 100 g	Simple Widely used in profiling schemes, therefore useful for comparisons between schemes	Weak rationale Too permissive for food consumed in large serving sizes
	Per 100 kcal	Allows 'fair comparisons' between foods	 Difficult to use and regulate Not massively utilized in profiling schemes nor even food labeling
	Per serving	 Consider 'real' consumption conditions Allows 'fair comparisons' between foods 	 Difficult to use and regulate Too permissive for food consumed in small serving sizes Needs an additional regulation on serving size Difficult comparison among schemes since serving sizes may vary Serving sizes do not necessarily reflect 'real' consumption conditions
Food categories declination	Category-wise scheme	Takes into account intrinsic differences between food categories	Difficult to use and regulate
	Across the board	Simple Allows for the clear discrimination of 'healthy' and 'unhealthy' food categories	 Not that sensitive Penalization of certain categories Do not discriminate between the 'less unhealthy' among 'unhealthy categories'
Cutoffs	Thresholds values	Simple	Low sensitivity Minimal food reformulation may allow a category switch
	Allocating scores	The overall quality is taken into account Sensitive	 Difficult to use and regulate Difficult for providing a rationale to the score (lacking scientific data)

other two aspects of the law - how to label and how to restrict advertisement - were linked to this definition. Unfortunately, this mandate found the Ministry of Health and its Nutrition Department in the midst of a restructuration with limited technical capacity to define the regulatory norms. In facilitating this decision, the Ministry of Health convened a group of researchers, mainly from the Institute of Nutrition and Food Technology (INTA) of the University of Chile, to review evidence regarding nutrient profiling (i.e. characterization of foods based on scientific and pragmatic principles that define their nutrient composition) (12) and provide a recommendation that would be suitable for the Chilean population (13).

The process of defining the nutrient profiling scheme was extremely complex mainly because of the lack of evidence that could inform the decisions. In Table 1, we summarize some of the nutrient profiling schemes that are available with their corresponding advantages and weaknesses. The expert committee reviewed all the information available and taking into account Chilean context based their work on the following basic principles:

1. Nutrients that had to be regulated (i.e. 'critical nutrients') were defined by the Law of Labeling and Advertising and included: sugar, saturated fat and sodium; energy was also mandated to be regulated. For the purposes of this article, hereafter, we will consider energy, sugar, saturated fat and sodium 'critical nutrients'; trans fatty acids have already been reduced by specific Ministry of Health regulations.

- 2. Nutrient reference values (NRV) had to be defined according to Codex Alimentarius principles (14).
- 3. The proposed profiling scheme had to agree with Chilean Food Sanitary Regulations and did not have to contradict previous efforts on terms of nutritional educational of the population (15).
- 4. The proposed profiling scheme had to be as simple as possible (i.e. the fewer food categories the better).

Following these basic principles, the committee then had to propose specific cutoffs for each of the critical nutrients. These cutoffs could be defined for a fixed amount of food (i.e. per 100 g) or for a specific serving size. The expert committee decided for the latter because they considered it more in line with Chilean Food Sanitary Regulations and with the Chilean dietary guidelines, though there was concern that serving sizes could be altered to avoid the application of the law.

The considerations that were taking into account for defining the cutoffs per serving size included the following:

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Type of simple sugars	Quantity	Source of sugar
Intrinsic sugars, from foods based on the dietary guidelines	45–50 g/day approx.	Sugars in fruits, vegetables and dairy products (estimations based on amount of sugar reported in food composition tables and usual number of portions)
Added sugars	<40 g/day	Sugars added during the elaboration and processing of foods (8% of total energy)
Total sugars reference values	<90 g/day	Total amount of sugars: intrinsic + added

Figure 1 Total sugars: reference values for Chile

- Updated NRV recommendations for energy and critical nutrients: 2000 kcal for energy, 90 g for total sugars (18% total energy), 22 g for saturated fat (10% total energy), and 2,000 mg for sodium. In Figure 1, we present as an example of the rationale for defining 90 g as the ideal total amount of sugars; similar rationale was used for the rest of the nutrients.
- · Chilean dietary guidelines recommend that an adult should eat 15-20 servings of a variety of foods per day, throughout different meals. It was decided that NRV and serving sizes for adults would be used because they represent the vast majority of the population. This decision was criticized by those who argued the law should mainly protect children, and therefore the NRV and the serving sizes should be based on what is recommended for children.
- NRV were divided by the theoretical number of servings that could contain a significant amount of each nutrient, considering that approximately 50% of servings correspond to the non-processed food (i.e. natural food) promoted by the dietary guidelines (fruit, vegetables and dairy). Thus, in critical nutrients that could be more present in foods (i.e. energy), NRV was divided by a greater number of serving sizes (i.e. 10), while NRV of nutrients that were less common were divided by a smaller number of serving sizes (i.e. five for sugars). Final numbers were as
 - o Energy: 2,000 kcal/10 = 200 kcal per serving size
 - \circ Sodium: 2,000 mg/7–8 = 300 mg per serving size
 - o Total sugars: 90 g/5 = 18 g per serving size
 - \circ Saturated fat: 22 g/7 = 3 g per serving size.

Exceptions to these cutoffs were proposed for foods with intrinsic differences in nutritional content, such as the amount of energy in vegetable oils or nuts, or in foods in which critical nutrients had to be included because of technological feasibility (i.e. sodium in sausages or bread). On the other hand, lower cutoffs (i.e. more strict values) were considered for food categories specifically targeted to groups considered to be more vulnerable, such as children (i.e. sugar and energy among candies and breakfast cereals). The Chilean legislation does not mandate serving sizes; thus, servings vary between food production companies. For the purposes of this law, it was decided that cutoffs should be applied in serving sizes of 50 g or greater; thus, in the case of foods with serving sizes smaller than 50 g, cutoffs would be applied based on a 50 g serving size even if the serving size of the package was smaller.

Front of the package food labeling warning in the context of the Chilean Law of Food Labeling and Advertising: how to label 'unhealthy' foods?

The next step on the implementation of the law was defining a warning label to be used in the packaging of foods that exceeded the cutoffs proposed for critical nutrients. An expert committee consisting of epidemiologists, nutritionists and marketing experts was in charge of reviewing the evidence and providing the Ministry of Health with alternatives for warning labels (11). During the first phase, the expert committee reviewed literature and used qualitative techniques (metaplan and an expert panel) to define potential alternatives of labeling. New label designs and content were to be tested in a secondary quantitative phase. The literature review showed that nutritional warning messages were almost non-existent, except in Finland, in which a warning message had been included in foods with high levels of salt (16,17) and in the United Kingdom with the traffic light effort (18). Studies from behavioural sciences and evidence from smoking and alcohol campaigns suggest that warning messages are more effective when they do the following: provide information beyond the warning, such as an explanation of the consequences of excessive consumption and any expected behavioural or health changes should one not comply; are simple in their wording; are big enough to be rapidly seen on the package; include a logo/ figure; and are supported by reputable institutions (i.e. Ministry of Health or University of Chile) (19-22). In Chile, the qualitative studies (metaplan and the panel of experts in nutrition, social marketing, public health, Codex Alimentarius, consumer associations and legislators) suggested that the warning message had to be the as simple as

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Figure 2 Proposal of the Expert Committee for the Front of the Package Food Labeling Warning Message to be implemented as part of The Chilean Law of Food Labeling and Advertising.

possible, and it should be complemented by an easily identifiable figure such as a stop sign. There was no agreement regarding the colors or the need to secure support from a reputable institution on the label.

On a second stage, the information collected was used to design 15 alternative warning messages that combined colors, figures, and types of messages. These messages were tested in a yogurt container. From a nutritional point of view, Chileans do not consider yogurt to be an unhealthy food. The different alternatives of warning messages were evaluated for visibility, comprehension and change of the intention-to-buy in a convenience sample of 1,300 head-ofthe-household women (18-59 years) of low-middle socioeconomic status (SES) of the Metropolitan Region of Chile (in Chile head-of-the-household women of low-middle SES conduct a vast majority of the food purchase, ~70%). These quantitative analyses showed that a white and black octagon with the message 'Excess of -' had the best performance in terms of visibility, comprehension and change in intention-to-buy even after adjusting for educational level (Fig. 2); the analyses also demonstrated that in order to have some impact, the size of the warning message had to be at least 10% of the front surface of the package of the product. Note pilot testing showed this figure should be in color and it will be when implemented. Testing was also done in potentially vulnerable groups (low SES women and adolescents) to assess potential unintended consequences. These analyses showed that a small proportion of women (~7%) and adolescents (~9%) misinterpreted the message and/or declared to be more prone to consume the product after reading the warning message, emphasizing the need to also consider educational campaigns when implementing this type of messaging on labels.

Regulation of food marketing in the context of the Chilean Law of Food Labeling and Advertising: what do we know?

In 2010, WHO recommended restricting food marketing to children in all its forms (1). Based on this recommendation, the third and final component of the Chilean Law of Food Labeling and Advertising pertains to marketing regulation, particularly for children. An expert committee of dietitians and social scientists from the School of Dietetics at the University of Chile was in charge of providing the recommendations for the implementation of this section of the law (23).

After an extensive review the expert committee concluded that the evidence linking marketing strategies to nutrition status was scarce due to the complexity and multidimensional effects the publicity may have on consumer behavior. Note, however, that it has long been established from evidence regarding the tobacco industry that marketing strategies promoting positive attitudes, beliefs and expectations increase the likelihood of consumption of that product, as seen with an increase in smoking initiation (18). There is also consistent evidence showing TV exposure increases the risk of childhood obesity and some suggestion that it would also increase lipid blood levels; however, it is difficult to disentangle how much of this detrimental effect is due to marketing exposure versus other factors. Evidence suggests that food marketing to children influences their decisions directly but also indirectly by changing food perceptions, socially desired behaviors, cultural patterns, family decisions and more. There is also agreement that children and adolescents correspond to a vulnerable group in terms of marketing because they are still unable to fully

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understand the messages and do not clearly identify the persuasive intention of the strategies implemented. Therefore, the committee agreed that there was an urgent need of developing a strong regulative framework for ensuring that the advertisement component of the law was achieved.

Similarly, the expert committee decided that some basic principles should be agreed upon to guide the implementation of the advertisement component of the law. The committee suggested a comprehensive approach in which not only advertisement, but all food marketing strategies, such as package design, promotions and places of display, be regulated. It was also suggested that the law address not only infant and childhood environments (schools, day care center, playgrounds), but also family environments (malls, TV shows, etc.), given that a significant amount of the children's exposure to advertising takes place in these environments. Finally, in terms of specific places for advertisement regulation, the committee suggested that the norms should, in order of importance, focus on: (i) television; (ii) schools (directly and indirectly through advertisements within textbooks and educational materials); (iii) visual or audio placement in films, music videos, video games, the Internet and so on.

Based on these assumptions, the committee suggested 16 norms that applied to the marketing of foods classified as having high levels of critical nutrients and that aimed to: (i) restrict children's exposure to advertisements; (ii) restrict the extent and composition of advertising targeted to children; (iii) regulate school environments; and (iv) restrict such marketing within schools (Table 2). Generally, the committee suggested adding to the food regulatory code the following statement: 'Food advertising should not stimulate or justify unregulated, excessive, or compulsive consumption of foods or beverages; portion sizes suggested in the advertisements should be concordant with the portion sizes normally consumed by the targeted population in the corresponding meal time'.

Implementation of the law of food labeling and advertising: where are we now?

Implementation of the Law of Food Labeling and Advertising is taking place right now. In January 2013, the Ministry of Health published the proposed regulatory norms for public opinion. These norms have followed the recommendations from the expert committees on how to define unhealthy foods, providing a table with mandatory serving sizes based on which the total amount of energy and nutrients of a food product will be calculated. As for the warning message that should be used to label unhealthy foods (i.e. those foods that exceed the levels proposed of critical nutrients), the Ministry of Health has decided to use a black-and-white octagon that will take up at least 10% of the front cover of the package of the product. The label

differs from what was recommended in terms of the wording used ('Alto en'), and it remains unclear how the label will address an excess of more than one critical nutrient (i.e. high in energy and high in salt). Finally, the regulatory norms consider most of the recommendations of the expert committee in terms of advertisement but did not decide to take a more comprehensive approach; thus, other marketing strategies were left unregulated. Also, the proposed norms do not consider the school environment as a particular environment in which more regulation should be in place. In March 2013, the phase for public comments was closed, during which several observations from national and international academia, industry, and a few from community organizations were received. The comments are not publicly available but there is unofficial information that the World Trade Union (WTU) was one the strongest opponents to the proposed regulatory norms. Food companies and some politicians have publicly argued that this law violates freedom of expression, disregards the principle of self-responsibility and does not grasp the complexity of food advertising; lobbyists and public mass media have also spread this idea among the community. Also, there is information that both food industry and other academic sectors proposed alternatives for defining 'unhealthy' foods (based on 100 g per food) along with other options for warning messages (positive messages such as 'consume with moderation'). The Ministry of Health will take all of these comments into consideration and define the final content of the regulatory norms; in order to implement the law the sanitary regulatory norm will have to be updated based on the new regulatory norms established. The law was expected to be in place in July 2013; however, the Ministry of Health has already declared that the implementation will be delayed until all the controversies with the WTU are resolved. Thus, the extent to which the law will be implemented is yet to be seen.

Conclusions regarding the design and implementation of the law of food labeling and advertising: what actions would have made the process faster, more efficient and more successful?

In this section, we examine ways the research and development of this law could have been faster, more efficient and therefore more successful.

Sound evidence that can be translated into actions

Regulatory actions that affect nutrients and foods should be supported by evidence gathered in a setting that reassembles real-life conditions rather than conditions that are so restricted they are only applicable in research settings. In order to translate evidence into preventive or regulatory

rable 2 Regulatory norms suggested by the expert committee on children's marketing for the implementation of the Chilean Law of Food Labeling and Advertising

Restrictions of the children's exposure to advertising of foods with high levels of critical nutrients

1. Advertisement will be banned in:

- malls, fast food centers, as well as in public and private transports (outside and inside the vehicles). Also, all promotional activities of these foods will be forbidden in public events with children swimming pools, hospitals, community centers, cinemas, theaters, parks, cultural centers, gymnasiums, beaches, Public places commonly used by children and adolescents such as daycares, or adolescent participation such as sports, cultural or fan events.
- TV and radio between 6 a.m. and 10 p.m.
- Media targeted to children or adolescents such as textbooks, books, magazines and pamphlets.
- Websites targeted to children or adolescents or in those without age restrictions.
- etc.). Food stores, including Point of Purchase (POP) materials (special shelves, signals, products,
 - Places outside the production, distribution and sales area.
- Accounts in social networks will be not allowed for foods high in critical nutrients; also, web sites of this type of food will not be allowed to provide free access to internet games, awards, interactive applications of any type. ςi

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- Mobile advertising will be also banned; text messaging, awards, applications of all types will be forbidden რ
- Delivery of written publicity, POP materials or any type of marketing product will be forbidden for children younger than 14 years of age
 - Finally, advertising will be not allowed in any form; thus, redirection to sites not explicitly mentioned in these norms will be also banned.

Restrictions of the extent and content of the advertising of foods high in critical nutrients targeted to children 9

a. Will provide product information such as origin, composition, production techniques, and recommendations of consumption. The message 'high in' should be clearly presented on the front by the previous articles: Advertising not forbidden

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- = b. Will be not allowed to include marketing strategies to children.
 - Food packages and labeling of foods high in critical nutrients will be only allowed to have the image of the product, the warning message and the information allowed by the sanitary code; marketing strategies of these products directed to children will be banned. ۲.
- radio, magazines, films and videos directed to children, adolescents and family, Placement of foods high in critical nutrients will be not allowed in TV shows, 6

Marketing products and activities such as awards, prizes, contests and toys will be not allowed for increasing the sales of foods directed to children.

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- critical nutrients will be not allowed to sponsor activities, events and products targeted to children or adolescents. Foods high in 9
- Food machines will not be allowed to have images or pictures or any promotional figure of foods high in critical nutrients; the message 'high in' should be displayed next to the food name at a

Regulations for the school environment

- 12. Sales, distribution, and promotion of foods high in critical nutrients will be not allowed in day cares, preschools, elementary schools, junior high schools or high schools. 13. Marketing activities of foods high in critical nutrients will be not allowed in day cares. preschools. elementary schools innior high schools or high schools or high schools or high schools or high schools.

 - The distribution of free samples or POP materials related to foods high in critical nutrients will be forbidden during educational visits to companies.

Restrictions to food marketing to children

- Foods high in critical nutrients will be not sold or distributed free to children younger than 14 years of age. 15.
 - For foods high in critical nutrients it is forbidden to have:
- Forms that will attract the children's attention, such as childhood heroes or characters, stars, hearts, animals, vegetables, vehicles, toys, etc.; effects such as staining or exploding in the mouth. purposes such as being cups, toys, blocks, etc. Packages that will attract the children's attention (see above for examples); also, these packages will not be allowed to have other ъ.
 - Sale promotions such as two-for-one, increased portion size, or combos.

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policies, researchers need to go beyond the health effects of different nutrients. It is essential when characterizing the risks (or benefits) of food consumption patterns (rather than only nutrients) to consider combinations of quantities, frequencies and forms of delivery. From a public health perspective, this information should be ideally available for different age groups (infants, children, pregnant women, adults and elderly), as well as physical activity patterns (sedentary, moderate and active). Some researchers have this awareness; however, much more information is needed - consider that most of this evidence will be context specific given the cultural diversity of food patterns. Knowing the fraction of disease risk that can be attributable to particular food groups will be an important asset for countries facing the challenge of defining policies that involve food regulations, including taxes, labeling and marketing. There is also lack of evidence from the social and behavioural sciences on how people respond to dietary messages and regulations. Still, established research on alcohol and tobacco could be used to inform policies and to estimate the impact of various actions.

In the case of Chile, experts were confronted with the need of providing recommendations in a short time frame and with limited local evidence. In this scenario, systematic and detailed reviews were carried out to identify the best available evidence. These included scientific publications, international consensus and reports, as well as evidence from other fields of study that seemed applicable to the Chilean situation. Despite this effort, there were several aspects of the law in which there was no available evidence, and recommendations were based on arbitrary decisions and/or common sense. In this scenario, the experts' recommendation was that the implementation of the law had to be thought of as a continuous process of evaluations and adaptations in which the impact will become clearer over time.

Active participation of academia and the community throughout the process to counteract the industry pressure

During the evolution of the law, the Chilean Ministry of Health underwent a profound transition as it shifted from 20 years of liberal rule to a more conservative form of governance. The nutrition section of the Ministry of Health was asked to make the application of the law a top priority without having all the professionals and expertise to do so. The strategy taken by the Ministry was to convene several expert committees to provide recommendations; however, the final decision based on those reports and the actual writing of the amendments to the Sanitary Regulatory Code was the sole responsibility of the Ministry of Health, without further consultation from academia, experts or the community. Deadlines were met, but it was an exclusive

process. Experts from the committees and the Ministry of Health did not consider formal participation from community representatives and informal communications have also been sporadic and unorganized; thus, the regulatory code was designed without receiving viable feedback from the intended beneficiaries. Even in terms of communications, the process has been poorly discussed, and as a result, the community remains largely ignorant to the process that has been taking place, as well as its implications. The almost null participation of the civil society contrasts with the active pressure of the food industry to halt this process. There is unofficial information that the food industry made an intensive lobby at the Senate during the 5 years of discussion of the law; these overt attempts to avoid any kind of regulation were then directed to the Ministry of Health during the process of the development of the regulatory norms. Also, throughout this process, most of the news in the radio, TV, and newspapers alerted that food regulation would have a detrimental impact on local and international trade, and more importantly, that it would attempt against the individual freedom; how much of these news were in fact covert messages from industry is difficult to prove, although it is likely to suspect. Whether the government will give up to the industry pressure or will decide to honor the spirit of the law will be unraveled when the regulatory norms are released.

Potential conflicts of interest

None.

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