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Review Article

**RECENT ADVANCES IN REGULATIONS FOR LABELING
AND ADVERTISING IN USA****K. PRAVALIKA*, DR. D. VARUN.**DEPARTMENT OF PHARMACEUTICAL A REGULATORY AFFAIRS, SRI INDU
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501510**Abstract:**

Single cigarettes, which are sold without warning labels and often evade taxes, can serve as a gateway for youth smoking. The Family Smoking Prevention and Tobacco Control Act of 2009 gives the US Food and Drug Administration (FDA) authority to regulate the manufacture, distribution, and marketing of tobacco products, including prohibiting the sale of single cigarettes. To enforce these regulations, the FDA conducted over 335 661 inspections between 2010 and September 30, 2014, and allocated over \$115 million toward state inspections contracts. To examine differences in single cigarette violations across states and determine if likely correlates of single cigarette sales predict single cigarette violations at the state level. There are striking differences in the number of single cigarette violations found by state, with 38 states producing no warning letters for selling single cigarettes even as state policymakers developed legislation to address retailer sales of single cigarettes. The state proportion of warning letters issued for single cigarettes is not predicted by state cigarette tax, youth smoking, poverty, or tobacco production, $P = .12$. Substantial, unexplained variation exists in violations of single cigarette sales among states. These data suggest the possibility of differences in implementation of FDA inspections and the need for stronger quality monitoring processes across states implementing FDA inspections.

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INTRODUCTION:

The most prevalent causes of mortality and morbidity in Chile relate to non-communicable diseases (NCD), with one third of the population classified as obese ¹. The high consumption of energy and nutrients of concern based on foods high in sugars, sodium and saturated fats is the most important risk factor associated with diet-related NCD ². Furthermore, 28.6% of total energy intake of the Chilean diet is derived from ultra-processed foods ³.

International organizations, such as the World Health Organization (WHO), the Pan American Health Organization (PAHO) and the Organization for Economic Co-operation and Development (OECD) have encouraged countries to prioritize prevention of overweight and obesity in public health policies, calling for policies focused on market regulation and policies to revert tendencies of increased consumption of unhealthy foods. In addition, policies on the restriction of sales of processed foods, sugary drinks and the poor nutritional content of fast food and its relation to NCD are encouraged ⁴⁻⁶.

In this context, Chile has implemented several strategies to decrease the burden of obesity and chronic diseases, including specific laws, plans, and programs ⁷. A pioneer in the region, one of the most important was the Food Labelling and Advertising Law (Law 20.606); An innovative policy that implemented a nutritional profile limit for energy and nutrients of concern (total sugars, saturated fats, sodium) for incorporating a front-of-package (FoP) “high in” warning label. Moreover, this same regulation restricts the marketing of “high in” foods to children under 14y and prohibited the sale of these products at schools. The implementation of the Law 20.606 occurred in three periods: 2016 (less restrictive limits), 2018 (more restrictive limits) and 2019 (final limits for energy and nutrients of concern). The primary focus of this regulation was to inform consumers about the high content of energy, total sugar, saturated fat and sodium in processed foods and to improve the food environment for children, restricting their exposure to excessive advertising and sales of unhealthy foods ^{8,9}. Another objective of this regulation was to support the reformulation of processed foods, decreasing total sugars, saturated fats and sodium content or replacing ingredients that improve the nutrient profile.

The presence of FoP warning labels on products improve consumer comprehension of nutritional facts, help consumers identify products high in nutrients of concern, and discourage consumers from purchasing these products ^{10,11}. An Australian study showed that FoP labels could reduce intended

sugar-sweetened beverages purchases independent of type, with the magnitude of effect greatest for graphic warning labels (OR: 0.22; 95% CI: 0.14–0.35) ¹².

Researchers compared the Chilean FoP warning label with the traffic light system among children in grades 4 to 6, and showed a positive effect of the Chilean model in the choices of processed foods (wafer cookies and orange juice), demonstrating a possible impact on the consumption of nutrients of concern ¹³. The availability of unhealthy foods in school kiosks in the capital, Santiago, was analysed in 2014 and six months before the law came into force in 2016. The authors found a reduction in availability of 75.4% of these products and a reduction in energy, total sugar, saturated fat and sodium in the nutrient content of solid products ¹⁴, demonstrating an overall positive outcome of the Law, related to an improvement of the school food environment.

Few studies have established the relationship between FoP warning label implementation and product reformulation. In a simulation study, Ares and cols (2018) found that FoP warning labels could improve consumer intention to select more healthful foods, decreasing intake of nutrients of concern ¹⁵. Another simulation study investigated consumer willingness to pay for a reformulated product and found that this condition was affected by the brand type and sodium and fat reductions in sausages samples ¹⁶. These results demonstrate that implementation of a FoP warning label system could be followed by a reduction in consumption of unhealthy foods after reformulation, which, in turn, could reduce the exposure to this diet-related risk factor for NCD.

Demonstrated a minimal impact of product reformulation before Law 20.606 implementation in Chile, with few reductions in energy content and increases in some nutrients of concern by food groups ¹⁷. There have been no studies considering the latest implementation period (June 2019) of the law. Thus, the purpose of this study was to evaluate the impact of Law 20.606 in energy, total sugar, saturated fat and sodium declaration of packaged foods commercialized in Chile, comparing nutrient content information prior to the law implementation (2013) and after the last implementation stage (2019). We hypothesized that companies reformulated products to adapt to the new regulation, reducing energy and the content of nutrients of concern.

In recent decades, consumption of sugar-sweetened beverages (SSBs) has rapidly increased across the globe ^{18,19}. Excess intake of these beverages has been linked to increased weight gain, glucose

deregulation, and development of non communicable diseases such as type 2 diabetes²⁰⁻²⁴. Compared to foods, SSBs are uniquely harmful because they contain large amounts of calories, which can be rapidly absorbed and are less satiating, leading to inadequate caloric compensation at other eating occasions and contributing to overall positive energy balance²⁵. Around the world, public policies are an important and increasingly common strategy being used to reduce consumption of these beverages and prevent continued increases in obesity and related diseases²⁶⁻²⁹. Recently, fiscal policies such as taxes on SSBs have been the predominant approach for reducing intake³⁰. Over 42 countries and six United States cities have implemented SSB taxes or increased an existing SSB tax, with most of these implemented in the last decade³¹. Although impact on SSB purchases depends on tax design and rates, these policies have generally led to reductions in SSB purchases equivalent to the price increase on SSBs³²⁻³⁶. Evidence also suggests that SSB taxes affect low-income groups and high-SSB consumers the most³⁷.

Additional policy strategies to reduce SSB consumption include mandatory front-of-package (FOP) warning labels, governmental restrictions on marketing SSBs, and bans on SSB sales and promotion in schools³⁸. In particular, FOP warning labels have become the focus of many health scholars and advocates, gaining favour over the heretofore more common positive FOP labels (e.g., a health seal or stamp) and other voluntary FOP systems such as traffic-light labels³⁹⁻⁴⁴. Despite global momentum behind FOP warning-label policies, virtually no evidence exists yet on changes in SSB purchases following implementation of a warning-label policy⁴⁵. Similarly, little is known about the effects of national school sales bans or mandatory restrictions on unhealthy food marketing to children and subsequent changes in food and beverage purchases⁴⁶. Finally, despite calls for implementation of more comprehensive “packages” of obesity prevention policies the joint impact of a set of policies on SSB purchases is unclear, as most national-level food and beverage policies been implemented one at a time.

Chile, a high-income country with high levels of SSB intake, has implemented a uniquely comprehensive set of obesity prevention policies regulating how SSBs and other energy-dense, nonessential foods are packaged, marketed, and sold. The first of these regulations, implemented October 2014, increased Chile’s existing tax on SSBs from 13% to 18% for high-sugar beverages and decreased the tax from 13% to 10% for low-sugar beverages. One evaluation found that in the first year post implementation, this modification resulted in only small price increases and 3.4%

declines in SSB purchases⁴⁷. In June 2016, Chile implemented the Law of Food Labelling and Advertising, which included the first national system of mandatory FOP warning labels for SSBs and energy-dense, nonessential foods⁴⁸. Similar warning-label policies have since been adopted in Peru, Uruguay, and Israel in 2018, and policies are currently under public review/potential finalization phases in Brazil and Mexico, among others. Chile’s Law of Food Labelling and Advertising also exacts comprehensive restrictions on child-directed marketing of SSBs and nonessential, energy-dense foods to children under 14 years of age, as well as restrictions on the promotion and sales of these products in schools⁴⁹. Chile’s marketing regulation, in particular, is more comprehensive than other countries’ in that it restricts unhealthy food marketing on more products across a wider range of media, and it prohibits use of more marketing techniques. Understanding how Chile’s policies on labelling and marketing—and, to a lesser extent, the school sales ban—are linked to changes in household purchases is critical for developing evidence-based obesity prevention policies across the globe.

AIM AND OBJECTIVE

To evaluate the impact of a national law banning sales of competitive food and beverages (CF&B) in schools on the availability of CF&B sold at school kiosks. This study aims to evaluate the impact of Law 20.606 on the ENC declaration of packaged foods in Chile, before and after the law implementation. We analyzed food nutritional labeling declarations from 70% of the most consumed packaged foods in Chile.

DISCUSSION

This impact evaluation of the Chilean Food Labelling and Advertising Law on nutrient declaration showed an extensive decrease in energy, total sugar and sodium content for the most consumed packaged food products (period 2013–2019). The highest reduction was observed in total sugar content, while few changes were observed in saturated fat content. This could indicate an industry reformulation on some products groups during this period. Our analysis was based on food labels declaration and in Chile; compliance with food label regulation is around 70% to 80%.

An important effect found in our study was that the FoP “high in” labelling implemented in Chile has induced a change in nutrient declarations of products, in food groups highly consumed by the population and especially among children, such as cereals, dairy and sugary beverages. On the other hand, very little changes were observed in pastry and desserts and ice creams products, in which reformulation is more complex. These changes

represent positive advances in creating a healthier food environment. In addition, it is important to remember that the most relevant objective of FoP “high in” labels is to provide clear, simple and truthful information regarding the nutritional quality of food, so that consumers can make informed purchases.

The first evaluations of the impact of the Law 20.606 (2018) showed that the population recognizes, supports, and understands the regulation and around 50% are using FoP “high in” labels when purchasing foods. Moreover, according to food-producing companies, food reformulation has occurred in about 18% of package foods. Analysed changes in ENC declaration of packaged food in Chile in 2015 and 2016 (n = 5241 and n = 5479) and found few changes (less than 5%), reinforcing that there was minimal reformulation prior to the implementation of the Law. Nonetheless and considering this minimal reformulation, these changes in nutrient content are reflected in the fact that many products that would have had a FoP “high in” label for energy and nutrients of concern, when food law came into effect (June 2016) did not have one.

With the implementation of the law occurring in stages and the final change happening in 2019, the results of our study imply that consumers can now find products with fewer FoP “high in” warning labels and, as a result, be exposed to lower levels of energy, total sugar, saturated fat and sodium in some food groups such as, dairy, sugary beverages, and flour-based foods. It is important to mention that food producers that decrease the content of nutrients of concern can avoid marketing restrictions and continue with sales in school environments, making reformulation very attractive for food industry. A review of experimental studies of FoP warning labels on sugary beverages and processed food conclude that the strategy was easy to understand and allowed consumers to identify and purchase foods with a lower content of energy and nutrients of concern, which, in turn, helps consumers to rank healthier products. Other models of FoP warning labels implemented in Holland (“Choices”) and in New Zealand (“Health Star Rating”) have been associated with a decrease in sodium content, saturated fat, added sugar, energy and an increase in fiber content on reformulated and in new products. According to our data, dairy presented a high decrease in total sugars (liquid and solid) and energy (liquid). These results could impact the intake of energy and nutrients of concern among children, considering that these products are highly consumed among this age group. One limitation in the dairy group is that each food producer is allowed to define the consistency of the product as either a solid or liquid and indeed this could mask compliance with

the regulation. Observed that in the period after implementation of Law 20.606 this food group increased in availability, with respect to total products, in school kiosks of Santiago (1.7% in 2014 to 5.4% in 2016). This could be mainly due to a reformulation process that was going on in this period and changes in its food matrix, principally focused on decreasing total sugar content and replacing sugars to non-caloric sweeteners. With this strategy, products could be sold at school kiosks since they did not have any FoP “high in” labels. Dairy are widely consumed by preschool and schoolchildren in Chile (e.g., milk, cheese, yogurt, and milk-based desserts) complying with 68.8% (preschool) and 37.8% (school children) of the dairy recommendations intake of the Food Based Dietary Guidelines according to ENCA.

The consumption of flour-based foods is widespread in the Chilean population. According to ENCA, 100% of Chileans consume bread daily (median 151 g/per day), with this product being the principal source of sodium intake in the population (9.5 g per day). Evaluation of sodium content of the most consumed bread in Chile results in an average of 630.2 ± 112.0 mg/100 g. Since 2010, the Chilean government has encouraged a voluntary reduction in the sodium content of bread, following international recommendations. The positive results of this reformulation process could influence the results of sodium content in flour-based foods in our baseline assessment (2013), however, over the study period, we observed a significant decrease in energy and sodium content in this food group.

Fats and oils presented a strong reduction in sodium content, but no changes were observed in saturated fat. This food group has a median consumption of 12.7 g-mL/day and 14.0 g-mL/day among adolescents and young adults, respectively, according to ENCA. Decreasing the amount of saturated fat in this food group and others (e.g., confectionary and similar or desserts and ice creams) require changes in technological process and/or the use of other ingredients capable of maintaining sensorial aspects and food matrix structure, considering that increasing the amount of trans-saturated fatty acids in processed foods is not possible, as it is regulated in Chile since 2010.

Sugary drinks presented a strong reduction in energy and total sugar content and these results could relate to two important Chilean regulations recently implemented: one that increased taxation of sugary drinks (2014) and the Law 20.606 (2016). A recent study analysed sugar-sweetened beverages purchased before implementation of Law 20.606 (2015) and after the first limit of implementation (2017), the authors found a decrease in the volume purchased of beverages with FoP “high in” label of

22.8 mL/capita/day (95% CI: -22.9 to -22.7; $p < 0.001$) and a consequent decline in calories purchased from these products of 11.9 kcal/capita/day (95%CI: -12.0 to -11.9; $p < 0.001$).

Recent meta-analysis support warning labels on sugary drinks as a population-level strategy for reducing sugary drink purchases. Based on simulation studies, authors conclude that reducing sugary drink intake by as little as 15–30 calories per day could reduce obesity prevalence by 1.5% to 7.8% and type 2 diabetes prevalence by up to 6.8%, with effects on behavioural outcomes of smaller magnitude. Interestingly, in some food groups, the absence of different product brands in 2019 compared with 2013 was pronounced (more than 20%). In the meat and derivatives group, this non-presence reached 41.4%, especially due to the absence of processed turkey meat products. The most important change in this food group was the decrease in sodium content in 13.0%. The meat food group is highly accepted by children and includes products like ham and sausages (hot-dog). While product reformulation supports a reduction in sodium intake, no decrease in saturated fat content was observed for this food group.

Although it is important to consider the significant changes in the nutrient content in the food groups, the presence or absence of FoP labels between the analysed period becomes more relevant. For example, there was a reduction of products with FoP “high in” total sugar labels in canned foods, dairy (liquid) and in sugary beverages groups in different proportions (-45.0%, -32.1%, -15.4% and -49.3%, respectively). These reductions suggest important changes in the availability of products and could impact in the population choices and consumption.

There are still many questions to be answered in terms of the effects of the Law 20.606. For example: how has reformulation affected the number of ingredients per product? has food consumption and nutritional status changed in Chile? Are Chileans eating more natural foods since the implementation of the law? Some of these questions will take time to answer. For now, studies such as ours show that the food environment has changed and today there are fewer foods with FoP warning labels in some food groups like dairy (especially liquid products) and, as a result, consumers have more alternatives to purchase products with a lower levels of energy and nutrients of concern. On the other hand, these same products may be higher in artificial sweeteners and additives used to improve the sensorial characteristics of the products.

To date, Chile has conducted only one National Food Consumption Survey, which was carried out in 2009-2010. The behaviour of purchasing and

consuming food of the population can change and can be influenced by many factors like the food environment and advertising. Updated and representative data from population, considering this new scenario is necessary to further evaluate the impact of market changes in patterns of consumption.

During the initial implementation of the food law, no massive campaigns to discourage the consumption of foods with a FoP “high in” label were carried out. It is important to mention that healthy eating messages, based on Dietary Food Guidelines, that recommend increasing the consumption of fruits, vegetables, legumes, fish and low fat dairy products (in their natural state) and reducing the consumption of salt, sugar, and products with FoP “high in” warning labels, are part of counselling strategy used permanently in the primary health care system to promote healthy eating and discourage the consumption of products with FoP “high in” labels.

These results should be evaluated while considering the limitations of this study. One of these relates to the limited number of products evaluated, as we included only the most consumed products according to ENCA. However, consumption patterns could have changed and it is possible that the selected and analysed products in this study do not represent the same proportion of products currently consumed. Some food groups presented low sample, which may have negatively influenced statistical power to show changes. It is important to reinforce that our study design did not consider the replacement of the brand products, only the replacement of product type of the same brand. Another limitation refers to the fact that we simulated the presence or absence of FoP “high in” warning labels, without confirming the real presence of the label on the products.

The findings of this study could stimulate food industry to work on product reformulation and to develop more healthy products by decreasing the content of total sugar, saturated fat and sodium without the addition of chemical replacements. Understanding the impact of Law 20.606 can help in the planning and development of new policies to protect and improve healthy food environments. Future studies should further analyse ingredient modifications of the most consumed products in the country.

The main finding of this study is that following implementation of the Chilean Law of Food Labelling and Advertising, household purchases of high-in beverages decreased 23.7% compared to the counterfactual, or what would have been expected based on preregulation trends. This translates into

roughly 12 fewer calories and 2.7 fewer grams of sugar purchased per capita per day from high-in beverages. In contrast, volume of not-high-in beverage purchases increased by 4.8%, translating into 5.7 calories and 0.7 grams of sugar purchased per capita per day. This increase in not-high-in beverage purchases was not commensurate with the decrease in high-in beverage purchases. Indeed, there was a relative decline in total beverage purchases of 2.2% for volume, translating into a decrease of 7.4 calories and 1.7 g sugar of beverage purchases per capita per day. Among beverage subcategories, we found the largest reductions in consumption among high-in fruit drinks and dairy (42.9% and 28.8% percentage point reductions in the percent of households consuming these drinks, respectively).

Households with higher educational attainment had larger relative reductions in high-in beverage purchases than did households with less education. This may be because higher-educated household had lower baseline purchases of high-in beverage purchases than did low educated households, creating a larger relative difference compared to the counterfactual in the postregulation period. However, the interaction term for education, regulation period, and time was also statistically significant for high-educated households versus low-educated households, suggesting higher-education households had a differential response to the regulation. This is consistent with previous literature finding that higher-educated individuals have higher levels of health literacy and may be more likely to use and understand nutrition labels. Absolute reductions were similar in amount between highest- and lowest-educated households. These results may be concerning, since similar absolute reductions in high-in beverage purchases could lead to an increase in the relative differences in SSB consumption between high- and low-educated households, since low-educated groups had higher baseline consumption levels. This potential for an increasing disparity in SSB consumption is problematic considering that in Chile, individuals with less education already have higher levels of obesity. Future research will be needed to further understand whether these policies increase or reduce disparities in diet and health by educational attainment. Additional research will also be needed to examine changes in purchases among those who were top consumers of high-in beverages prior to the regulation, since previous SSB policy evaluations have found top consumers typically reduce purchases more than do low consumers.

Although the Chilean law included a package of policies implemented at once, it is interesting to consider how the effects observed here compare to

results from evaluations of previous Latin American policies focused on SSB reduction, primarily SSB taxes. Compared to their respective counterfactuals, SSB purchases in Chile declined by 23.7% under the Chilean Law of Food Labelling and Advertising (22.8 mL/capita/day). This relative decline is larger than or similar to previous estimates of reductions in SSBs after Chile's earlier SSB tax modification, which raised the tax on high-sugar drinks from 13% to 18% (one SSB tax evaluation study found a 3.4% decline in SSB purchases, whereas a second study found a 21.6% decline, though both studies found only an approximately 2% increase on paid price for SSBs, making the latter study's large drop in SSBs unlikely based on price elasticity). The absolute and relative decline in SSB purchases after the Chilean Law of Food Labelling and Advertising was also larger than the declines in SSB purchases observed after Mexico's 10% SSB tax, which was associated with an average 7.6% post tax reduction in SSB purchases (12 mL/capita/day) 2 years after the tax. The observed decline in the present study was also larger than the average decline in SSB purchases after a 10% SSB tax, as estimated by a recent meta-analysis.

On the other hand, it is unclear how these results will compare to larger SSB taxes, which, as expected, are likely to have larger effects on purchases, as indicated by recent evaluations of Philadelphia's beverage tax. More generally, it is complex to draw comparisons between SSB policies implemented in different settings and times and with different study designs, at least in part because these real-world evaluations rely on pre-post observational data and cannot assess causality. Based on available evidence, however, the changes in SSB purchases relative to counterfactual estimates following implementation of Chile's Law of Food Labelling and Advertising are larger than those observed after most Latin American SSB taxes. The relatively large effect observed here is not surprising, given that the Chilean Law of Food Labelling and Advertising included a package of policies targeting different aspects of consumer behaviour, whereas most SSB taxes have been implemented as standalone policies. These results suggest that policymakers and public health advocates should consider a package of policies, including FOP warning labels, marketing restrictions, and school sales policies alongside SSB taxes as important strategies for reducing population-level purchase and intake of SSBs.

Although there have not yet been any evaluations of a real-world mandatory FOP warning label policy, the estimated decline in high-in beverage purchases relative to the counterfactual is also larger than what might be expected based on recent meta-analyses of food labelling policies. For example, Shan guan and

colleagues found that labelling was only associated with a 6.6% decline in calories purchased, whereas Crockett and colleagues largely found a null effect of labelling interventions across outcomes. However, these studies examined a diverse array of labelling systems, including voluntary FOP systems, such as the Guideline Daily Amounts (GDAs) and traffic-light labelling, as well as back-of-package nutritional labelling, in a variety of settings (stores, schools, vending machines, cafeterias, and restaurants). Recent experimental studies in Latin American populations have found that the style of FOP warning labels used in Chile is easier to understand and more likely to discourage consumption than other types of FOP labels, such as the GDAs or traffic-light labels. In addition, a recent US-based randomized experiment found that nutrient-based FOP warning labels reduced SSB purchases by 31 calories per interaction, or 22%, which is similar to the effect observed in this study. In addition, along with the warning-label component, the Chilean law includes marketing and school sales restrictions, which likely contributed to the larger effect found here. A recent evaluation found that schools reduced the percent of products that were high-in from 90.4% before implementation to 15.0% after implementation, which may have influenced children's preferences and the subsequent household purchase made by their parents. Indeed, a separate qualitative study found that schools were a key promoter of behavioural change relating to the labelling component of the law: children learned about the regulation at school and then encouraged their mothers to purchase non labelled foods and beverages for them. In addition, an evaluation of Chile's food marketing regulations found that children and adolescents' exposure to unhealthy food and beverage advertisements on television was reduced by 44% and 58%, respectively, in the year following implementation of the law, although it is unclear how reductions in exposure translate to changes in purchasing behaviour. Another consideration is that as these regulations were being enforced, the Chilean Ministry of Health launched a mass media campaign to inform consumers about the meaning of the warning labels and encourage them to choose products with fewer labels, potentially further strengthening the effect of the law. Unfortunately, we are unable to disentangle the effects of each of the labelling, marketing, and school sales ban components of the law, here. Future research will be needed to understand the individual impact of each policy as well as how the policies and media coverage and promotion interacted to lead to reductions in high-in beverage purchases. This study has important limitations. As previously mentioned, the main limitation is that this is an observational pre-post study and thus unable to assess the causal impact of the law or disentangle

the drivers of the observed reductions in high-in beverage purchases. The reductions in purchases of high-in SSBs found in this study likely reflect a combination of changes in consumer behaviour (e.g., consumers choosing not to purchase a high-in beverage) and industry behaviour (e.g., product reformulations that could shift products from high-in to nothing-in status, or other industry actions such as changes in marketing strategy or pricing changes). For example, after the policy, we observed that there was a large decline in the percent of households who purchased high-in fruit drinks and a sizeable increase in the percent who purchased high-in fruit drinks after the policy. Currently, it is not clear whether this is because consumers were choosing to switch from high-in fruit drinks to not-high-in fruit drinks or whether they purchased the same or similar beverages, but these beverages were reformulated under the nutrient thresholds and thus no longer subject to the regulation (and thus no longer classified as "high-in"). Future research to understand the mechanisms of how this regulation changed beverage purchases will be important for designing future policies. For example, regulations intended to incentivize reformulation may be quite different than those designed to influence consumer behaviour.

It is also important to note how different analytical approaches may have affected results. For example, the difference between observed and expected purchase amount depends on a comparison of the slope of the preregulation trend with the slope of the postregulation trend. Underestimating the preregulation trend could, therefore, lead to an underestimated counterfactual and, ultimately, an overestimation of the difference between slopes in the post regulation period.

Similarly, the specified length of the pre regulation period can affect the pre regulation trend, thereby affecting the counterfactual comparison. One potential limitation of this study is that we have a relatively short pre regulation time period (January 2015 to June 2016). Notably, results were consistent even in sensitivity analyses in which we expanded the pre regulation period to January 2014 to account for Chile's October 2014 SSB tax modification (i.e., we account for the fact that there may have been a steeper pre regulation trend between October 2014 and June 2016 due to the change in SSB tax). It will be important for future policy research to consider the effects of including different pre regulation time periods on results, especially in countries where multiple policies are implemented over time.

Our analyses also included only a year and a half of post implementation data. The results show a significant reduction in purchases of high-in beverages immediately after the regulation was

implemented, with no change in the post regulation trend (i.e., there was no attenuation or increase in effect over time). These results could be due to the relatively short post implementation period. Over time, we might expect to see an increase in the effect as social norms shift and as people learn more about the health harms of high-in beverages. Alternately, we could see the effect decrease if consumers grow accustomed to the warning labels and the “novelty effect” wears off, as has been shown in tobacco labelling. Moreover, the nutrient thresholds became stricter (i.e., more products became high-in and were subject to the warning label and marketing and school restrictions) in June of 2018. Longer-term analyses will be needed to understand the effects of the law as it gets stricter over time, as well as to understand whether purchases of high-in beverages remain low, continue to decline, or rebound over time.

Another limitation is that our work evaluates changes in high-in beverages without regard for which specific nutrient(s) exceeded thresholds (sugar, saturated fat, sodium, and/or calories). Although for beverages, the vast majority were regulated as high-in because of excess sugar content, future research should explore potential differences in purchasing according to specific high-in nutrient or the number of high-in nutrients, since the more nutrients that are regulated, the more warning labels a product will carry.

The study also has several limitations relating to generalizability. For example, the sample is limited to only urban-dwelling households. However, 90% of Chile’s population is urban, suggesting that the results are generalizable to most Chilean households. Regardless, it will be important for future research to understand whether policies affect purchases differently in rural areas versus urban cities, as well as by geographical region. Similarly, the study only includes beverage purchases made at stores, including supermarkets, grocery stores, and convenience stores. Store bought beverages account for roughly 88% of non-alcoholic beverage sales in Chile, and this proportion has remained consistent before and after the regulation. However, future research should examine whether there have been any changes in the type or quantity of beverages purchased from other sources (e.g., in restaurants, schools, or homemade), as well as whether actual dietary quality of beverages across sources has changed. For example, if the healthfulness of store bought beverages improved, but the healthfulness of restaurant beverages declined, this could offset improvements in diet quality and blunt any subsequent health gains. Additional work will also be needed to understand changes in food purchases and food intake after these regulations, as well as how consumers potentially substituted between

foods and beverages. Examining the effects of these regulations across total purchases and diet will be essential for understanding whether this package of policies is likely to achieve its goal of obesity prevention.

It is also important to note that this study evaluated beverage purchases only after the first phase of implementation in 2016. In July 2018, the second phase was implemented, including stricter nutrient thresholds as well as a new marketing law that restricts from 6:00 AM to 10:00 PM all television and cinema advertising for high-in foods and beverages and requires health promotion messages to be included when products are advertised outside those hours. This 6:00 AM–10:00 PM restriction is considered to be the most comprehensive marketing restriction on unhealthy foods and beverages implemented to date. In July 2019, the third and final phase of the regulation was implemented with the most stringent nutrient thresholds. Future research on both foods and beverages will be needed examine the impact of the Chilean regulation following implementation of the new marketing law and the final set of nutritional thresholds in 2019 and whether the effects of these regulations wear off or accelerate over time.

This evaluation has important policy implications. Three other countries (Israel, Uruguay, and Peru) have adopted FOP mandatory warning labels, and Mexico and Brazil are among countries considering warning labels and are in consultative stages. However, the majority of these adopted or proposed regulations focus on warning labels only and do not include other components of the Chilean regulation, such as the restrictions on marketing or school sales and promotions. Multi country evaluations may be helpful to disentangle the effects of each of these regulations, as well as to understand how the regulations work in different populations.

In conclusion, this study describes changes in SSB purchases following introduction of Chile’s policy package that includes FOP warning labels, child-directed marketing restrictions, and restrictions on sales in schools of unhealthy foods and beverages. After implementation of this policy package, purchases of high-in beverages declined by nearly 24%; these reductions are larger than those observed after standalone SSB reduction policies in Latin America, such as taxes. Future research should examine the differential effects of the labelling, marketing, and school policies; whether changes in purchases were driven by industry or consumer behaviour; and the effects of these policies on SSB intake.

In this qualitative study, we explored how Chilean mothers of young children understand and perceive

the new regulation of food labelling and advertising. We found that mothers were aware that the more stop signs, the healthier the product and that many of them declare using FOP labels, particularly when purchasing new products. We also found that mothers perceive that school environments have become healthier as a result of the implementation of the law, although other aspects of the marketing restrictions are rarely perceived or noticed. Interestingly, the mothers' discourses reflect that the effects of the different aspects of the law (FOP, school environments and marketing regulation) are all interrelated and operate in coordination to promote healthier behaviours. They also show that children, particularly young children from lower- and middle- SES, have become key disseminators of the messages underlying this regulatory effort.

FOP labels have been indicated as a key measure for the prevention of obesity. Evidence suggests that the simpler the message, the higher the impact on consumer's behaviour. Furthermore, research has also found that warning monochromatic FOP labels that flag products high in key critical nutrients improve consumers' abilities to identify unhealthy food compared to Guideline Daily Amounts (GDA) and traffic-light systems. The results of this study are in line with this evidence. Chile has implemented a simple warning message (i.e., directive FOP) that aims to decrease the consumption of unhealthy foods. We found that mothers of different SES understand well the intended message (i.e., the more stop signs, the healthier the product), although one potential risk is that they understand that a product with one label corresponds to a healthy product. Mothers did not comprehend the underlying principles that explain in which cases a certain product should be labelled. Given that the process of purchase takes place in seconds, this is an intended outcome of a directive FOP like the one implemented in Chile.

We also found that the implementation of the logo allowed "uncovering" some products. That is, it has helped in clarifying the lack of healthiness of some food products that had been traditionally advertised as healthy food. Oatmeal cookies, breakfast cereals, cereal bars, among other food categories have traditionally use healthiness as their marketing strategy and mothers were surprised when they found that the products had warning labels. In addition, the level of attention and use was gradational: mothers reported that the presence of warning labels influenced their purchase decision mostly when deciding about new food products. This result is in line with current FOP label research, which suggests that the impact on behaviours is less strong for products in which there is a consumer loyalty. Finally, regarding FOP labels, mothers' discourses also revealed that they sometimes felt

that the pervasive presence of them was overwhelming and may not end up contributing to better decision making. Although it is not possible to rule out this possibility in the short term, future research could explore whether the omnipresence of warning labels may desensitize people in the long run.

Regulation at schools established restrictions in terms of promotion and selling of unhealthy foods and this was clearly perceived by mothers who participated in the focus groups. Many of them declared that these restrictions are "forcing" healthier children's behaviour because they do not have the option of buying unhealthy food products, particularly in the case of adolescents that bring money to the school; some mothers thought this was something desirable for shaping individual's behaviours but other mothers, particularly those from low SES, declared that they found restrictions were unwarranted. From the mothers' accounts, the analyses also revealed that the schools are going beyond the regulation because teachers are promoting that children should bring healthier snacks from home. Promoting healthier food environments at schools has also been identified as a key area of action in obesity prevention because there is evidence that shows how influential the food environment is, particularly among young children. This environment has a very important impact on their food routine behaviour, considering that about one third of their total daily energy is consumed at educational establishments. This is why some governments have decided to take responsibility by becoming stricter with dietary routines within schools and banning HEFSS food from being sold inside the schools.

The online food retail environment is of increasing relevance for influencing nutrition and health. This is true for both overall and health equity, given the expansion of online SNAP sales to almost every state in the nation. US federal regulations require specific nutrition, ingredient and allergen information to be disclosed on food labels with precise size, location and legibility requirements to protect consumers and create consistency across products and brands. However, our study identified that even with a limited scan of ten popular products across nine major retailers, there was inadequate disclosure of such information to consumers in online environments. Similar to a study conducted in 2018 which assessed the availability, accessibility and legibility of nutrition information for 26 products across 12 online retailers, we likewise found that the required Nutrition Facts Panel and ingredient information were not universally available for packaged food items and this information was not always easily accessed or legible. We also found differences in the provision

of required information even among similar products. Notably, in our study, allergen warnings were the least consistently provided in the online retail environments, rendering it potentially unclear whether the information is missing (e.g. Honey Nut Cheerios) or not required due to lack of a common allergen (Cheerios). In addition, we found that health and nutrition-related claims, which are used to promote products, were most commonly provided conspicuously and legibly, and retailers' web pages provided an additional location to display such claims.

Our findings raise several key questions for future research. Why is nutritional information not sufficiently available, and why do differences exist across both products and retailers? How does lack of legally mandated information influence consumer purchasing decisions? Does the variation by product and retailer lead to consumer confusion to determine whether key information (e.g. allergens) is missing or not applicable to that specific product? And, are these deficiencies and differences merely random waypoints in a still-evolving online landscape, or do they reflect strategic differences in how companies wish to present different products (e.g. perhaps failing to clearly show information for less healthy products) or distinguish themselves from competitors.

Congress enacted the Fair Packaging and Labelling Act based on the rationale that informed consumers 'are essential to the fair and efficient functioning of a free market economy'. What has fundamentally changed is not the rationale, necessity or requirements for mandatory labelling, but rather the effective regulated party: the retailer, rather than the manufacturer.

Our legal research reveals that each of the three federal agencies evaluated likely have the authority to address the online provision of nutritional information in their own way. Regulatory definitions and case law provide compelling indications that the display of food packaging for online retail falls into the definition of 'labelling' under the purview of FDA's regulatory authority and that online viewing is a 'customary condition of purchase'. The FDA may be able to use existing authority to engage in rulemaking to explicitly require the provision of required nutrition information to be highlighted for prominent and conspicuous viewing online. For the FTC, it is arguably the case that all missing or difficult to find required information in online food retail is an unfair and deceptive act or practice, based on consumers' inability to identify this information, and the broad potential for harm and for consumers to choose differently if they had this information. The FDA and FTC could independently or in

tandem engage in enforcement actions or issue guidance documents to ensure online food retail meets current regulatory requirements for food labelling.

For online retailers wishing to accept SNAP, the USDA's authority may be even more compelling due to the risk of losing SNAP contracts. Congress's allowance for the USDA to regulate SNAP retail food establishments indicates that the USDA could amend its regulations to require retail platforms that accept SNAP benefits ensure all required labelling is immediately visible, and conspicuously and legibly displayed. Current SNAP retailers include all of the largest food retailers in the country, including the major players online. Such requirements would benefit SNAP participants and the broader community of consumers shopping for food online.

Whether these federal agencies will take meaningful action, or an act of Congress will be needed, remains to be seen. Congress could legislate requirements that online sale of food products must disclose all required information legibly, prominently and conspicuously. There is precedent for Congress to expand the application of labelling requirements to additional entities. In 2010, Congress extended FDA's food labelling authority to include overseeing the provision of nutrition information by chain restaurants. Congress can likewise amend the definition of labelling for the FDA to explicitly include online food sales. In addition, Congress could grant the FTC explicit authority, through Administrative Procedures Act rulemaking, to address online sale of food products or amend definitions related to SNAP to require online SNAP retailers disclose all required nutritional information.

Limitations of this study include that we examined a limited number of food product categories and foods, because the online coding portion of the research did not intend to be comprehensive. We, thus, may have missed additional deficiencies or strengths (e.g. disclosure of nutrition information when not required in the provision of nutritional information by online retailers. Moreover, we did not examine smaller, regional or local online retailers, which may have garnered different findings. Nonetheless, we did find information was not consistently available, and when available, it was not always conspicuous or readily legible across ten major products sold by the nine largest online retailers in the US, informing and supporting the need to examine federal regulatory authority to address these inconsistencies. This research did not identify which entity in the supply chain created product pages used for coding. The legal research did not examine state options to address the issues

identified, such as options for the State Attorneys General to bring litigation, state retail requirements or state regulation of online disclosure requirements. Moreover, this research did not evaluate unregulated labelling strategies such as interpretive labels voluntarily provided by manufacturers on the front of packages. These are additional areas ripe for future research.

To our knowledge, this is the first study to evaluate changes in the amount of energy and nutrients of concern in packaged foods and beverages available in the market after the initial implementation of the Chilean Law of Food Labelling and Advertising. Our results indicate that, in the cross-sectional analysis, compared to the pre implementation period, after <1 year of the law (i.e., June 2016 to January-February 2017) the proportion of any “high in” product decreased from 51% to 44%, mostly in food and beverage groups in which the regulatory cut offs were below the 75th percentile of the nutrient or energy distribution. Decreases in the proportion of products “high in” were higher in sugars (6 out of the 16 food and beverage groups) and sodium (5 out of the 16 groups), whereas the proportion of “high in” saturated fats and “high in” energy decreased only in 1 and 2 food groups, respectively. In most cases, the energy and nutrient of concern distribution of the food and beverage food groups in which we observed decreases moved just below the regulatory cut off. Several findings were confirmed in the longitudinal analysis.

Although food and beverage reformulation has been suggested as a key strategy for obesity prevention, there is scarce evidence on how real-life initiatives can encourage reformulation. In Australia and New Zealand, significant improvements were seen in the amount of energy (1.5% decrease) and sodium (6.7% decrease) of products that adopted the Health Star Ratings (HSR) FOP label, and reformulation may have been even higher among food products targeted to children. However, HSR was a voluntary initiative implemented by less than 5% of local food suppliers. The nutritional quality of children’s menus in fast food restaurants was reported to have improved after the implementation of an ordinance prohibiting toy incentives to children together with food of low nutritional quality in one county of California, United States. There are also reports of improvement in the nutritional quality of foods driven by other kinds of voluntary actions. However, the overall impact of these initiatives on the whole food supply has not been well characterized.

In the Chilean law, regulatory cutoffs were defined based on natural foods and liquids considered gold standards of a healthy diet. Therefore, the same cutoffs were used for all food and beverage groups,

only considering differences for liquids and solids. Regulatory policies that are more oriented to promoting reformulation might prefer considering specific cutoffs for each of the food and beverage groups. Our results suggest that setting up cutoffs that are below the 75th percentile of the nutrient distribution would allow to achieve the change looked for; conversely, cutoffs defined on the top end of the distribution would not promote significant changes on the food supply. The Chilean law had 2 other phases of implementation in which regulatory cutoffs became increasingly stricter; therefore, further analyses of changes on the food supply throughout the implementation of these phases will allow to test this hypothesis. Several bodies have also claimed that using cutoffs that are too strict (i.e., that leave most of a food category as regulated) would not incentivize food industry reformulation; interestingly, we did not find that this was the case in Chile because we observed significant changes in food categories in which cutoffs were below the 25th percentile (i.e., regulation affected 75% of the products of that category) such as sugars in sweet baked products, energy in breakfast cereals, and sodium in sausages and soups.

We believe our results suggest that industrial production of several packaged foods and beverages was affected by the initial implementation of the Chilean law. Although our design does not allow us to test causality, we do not believe the observed changes are due to previous trends of food reformulation because we have formerly shown that in the years prior to the implementation of the law there were no relevant changes on the amount of nutrients of concern of the food supply and in the current analyses we do not observe significant changes in food categories in which cutoffs are at the top end of nutrient distribution. Moreover, the fact that most of the changes in the amount of energy or any nutrient of concern were around the first phase cutoffs is also suggestive of a promoting role of the regulatory process. The mandatory nature of the Chilean law and the fact that the regulation considered a set of diverse regulatory measures (i.e., FOP warning labels, marketing restrictions to children, and the healthy school food environment) may have resulted in this fast and significant reformulation of packaged food and beverage products. We believe our results show that food industry has the ability to reduce sugars and sodium amounts in major food and beverage groups, and therefore, efforts should be made to achieve these improvements as recently suggested. At the same time, it is clear that the current efforts are limited in their effect on shifting the food supply from unhealthy saturated fats to healthier fats. In fact, the amount of saturated fats has increased in several food and beverage groups, which could reflect the

technical challenges associated to replacement by, i.e., polyunsaturated fats that have a lower melting point and are less stable to oxidation, among other factors. Implication of this finding in population's health need to be elucidated and could depend on the source of the saturated fats involved.

These results can be useful to other countries that are on their way to implementing or have already implemented the use of warning labels for unhealthy packaged foods to prevent obesity, such as Peru, Uruguay, Israel, Mexico, Canada, and Brazil. A comparative study of the healthiness of packaged foods and beverages from 12 countries reported a poor HSR score for the packaged food supply in Chile in 2015 (only Hong Kong and India had poorer scores), suggesting the external validity of our findings could vary from country to country.

Recent reports indicate that food reformulation has a profound impact on diet quality; although this may be an area of debate. In the case of Chile, according to the National Dietary Survey (2010), beverages, milks and milk-based drinks, breakfast cereals, sweet baked products, and sweet spreads represent approximately 15% of the calories and approximately 40% of the added sugars consumed daily by the Chilean population, whereas savoury spreads and sausages account for 22% and 8% of sodium intake, respectively. Therefore, the observed decrease in median amount of energy and sugars have the potential to help mitigate the excessive dietary intakes in added sugars. Moreover, in a sample of Chilean pre schoolers, it has been described that desserts, dairy products, and beverages cover approximately 23% to 30% of the intake of calories, therefore suggesting that the impact could even be higher among children. In the case of sodium, no information is available on the share of the sodium intake represented by the food groups in the study in the Chilean diet; thus, we cannot estimate the potential dietary impact of these changes on sodium intake.

There are limitations in this study. We cannot truly show a direct linkage between the initial implementation of the law and the changes in the amount of energy and nutrients of concern of packaged foods; however, the fact that most left shifts of the distributions were around the first phase cut offs suggest the regulation might be a relevant driver. Also, we cannot disentangle the effect on reformulation of the different policies implemented simultaneously. Other limitations are that our results are not sales-weighted nor consider the dietary share in Chilean diets. However, our analytical sample included only foods and beverages representing $\geq 1\%$ of the sales of the specific category in order to obtain more meaningful results. We primarily conducted cross-sectional analyses in which best-selling products were compared before and after the

implementation of the law. However, by taking this approach, we were unable to differentiate whether changes are due to reformulation of existing products or to exit of old products or entry of new products; moreover, we are unable to fully exclude sampling differences between years. Therefore, we also conducted longitudinal analyses including only food and beverage products that were available before and after the implementation of the law, which allows us to assess reformulation. We believe consistency between cross-sectional and longitudinal analyses increases the validity of our findings. Also, our analysis did not include confounders or modifiers such as manufacturer company. Finally, our analyses rely on the nutrient amount reported by the food manufacturer on the nutrition facts panel printed on the package and is not based on laboratory assessment. A major strength of our study, however, is that all study data were collected prospectively versus one that could be obtained retrospectively from food industry or retailers' databases, therefore decreasing its error.

In conclusion, our results show that several food and beverage groups available in the Chilean market decreased the proportion of products "high in" after a short-time period (<1 year) of implementing a mandatory set of regulations including simple FOP warning labels for energy, sodium, total sugars, and saturated fats. These changes happened mainly for sugars and sodium and were reflected in significant decrease in the amount of such nutrients close to the initial cutoff for defining unhealthy foods and beverages. It remains to be seen how consumers react to these food composition changes and whether this short-term reformulation is sustained over time, especially with the complete implementation of the law. Also, future studies should investigate whether the reported reformulation either positively or negatively impacted the quality of the food supply more broadly, considering, i.e., other nutrients or food components, such as nonnutritive sweeteners. More importantly, future studies need to focus on whether the improvements in sugars or sodium observed among foods and beverages ultimately impacts the quality of the overall Chilean diet.

CONCLUSION:

We conclude that the Chilean Food Labelling and Advertising Law had an impact in the market and in the nutritional content of packaged foods. A great percentage of foods "high in" total sugar, saturated fat, sodium, and energy were withdrawn from the market. Also, a considerable number of products were reformulated, especially in the dairy (liquid), solid fats, sugary drinks, and flour-based food groups. The natural impact of this reformulation is the reduction in the expected number of products with a FoP "high in" label, which are exempt from the sales and advertising restrictions indicated by

the law. It is important to mention that sugary beverages had a strong reduction in energy and total sugar content. This result may relate to the convergence of two recent regulations: the increase in taxation on sugary drinks (2014) and Law 20.606 (2016). It is necessary to continue developing public policies to protect and improve healthy food environments.

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