



Analysis of the policy process for the implementation of nutritional warning labels in Uruguay

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Abstract

Objective: To analyse the process for the development and implementation of mandatory nutritional warning labels in Uruguay, in order to inform future nutrition policy making and strategic engagement by public health actors.

Design: The study design drew on policy analysis methodology and case study research methodology. Two main sources of information were selected and analysed for the current study: eighteen official documents from the Uruguayan government and 259 news reports, published between June 2017 and February 2021.

Setting: Uruguay, Latin America.

Results: The Uruguayan Ministry of Public Health led a cross-sectoral working group composed of diverse governmental stakeholders, international organisations and the academia to develop the front-of-package nutrition labelling policy. A robust evidence-based approach, based on rigorous scientific knowledge generated in the country, was followed. However, changes in the systemic governing coalition as a consequence of a change in government led to a delay in the entry into force and changes in the regulation. The food industry was the main opponent to the warning label regulation and relied on widely reported corporate political activities to influence the policy process: information and messaging, legal action, policy substitution, opposition, fragmentation and destabilisation.

Conclusions: Key insights to inform future policy action in Uruguay and other jurisdictions were derived. Results stressed the importance of an evidence-based approach for policy design and the early engagement with actors from all the political system.

Keywords
Front-of-package
nutrition labelling
policy making
regulation
corporate political activity

Although the world has committed to end all forms of malnutrition by 2030, projections indicate that this objective will not be met⁽¹⁾. The double burden of malnutrition remains a threat worldwide, particularly in Latin America and the Caribbean^(1,2). Although the region has achieved the largest reduction in undernutrition worldwide, it shows the highest prevalence of overweight⁽³⁾. High blood pressure, high fasting blood glucose and overweight and obesity are the most important risk factors for mortality and are responsible for the greatest loss of years of healthy life in the region⁽⁴⁾. This situation does not only have health consequences but also have enormous negative consequences to social and economic development^(5,6).

The rise in overweight, obesity and non-communicable diseases (NCD) in Latin America has been linked to major

transformations in the food systems, which have motivated an increase in the consumption of ultra-processed foods with excessive content in sugars, fats and sodium (Na)^(7,8). This situation makes it necessary to implement cost-effective and population-wide strategies to promote healthier eating habits and tackle obesity and NCD⁽⁹⁾. For this purpose, a set of comprehensive policy actions, including front-of-pack (FOP) nutrition labelling, has been recommended by the WHO⁽¹⁰⁾.

FOP nutrition labelling comprises labels positioned on the FOP to provide a simplified summary of the nutritional composition of foods and beverages⁽¹¹⁾. This policy intends to empower citizens to make informed food choices and could serve as a ‘nudge’ to improve the healthfulness of their diet⁽¹²⁾. Several FOP nutrition labelling schemes have

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been developed worldwide, ranging from non-interpretive schemes (e.g. guideline daily amounts system) to interpretive schemes⁽¹³⁾. This last type of scheme comprises nutrient-based schemes (e.g. the traffic light system), summary indicators of overall nutritional quality (e.g. Nutriscore), endorsement logos and nutritional warnings⁽¹³⁾. Research has shown that interpretive FOP nutrition labelling help consumers to distinguish between healthy and less healthy products and has the potential to discourage selection of products with excessive content of nutrients associated with NCD^(14–16).

However, efforts by governments to introduce mandatory FOP nutrition labelling have faced challenges globally, particularly in the form of industry opposition and trade challenges. For example, successful implementation of mandatory nutrition warning labels in Chile and France has faced ongoing opposition from the food industry, including threats of trade challenges in Chile, and delays resulting from changes in government^(17,18). Trade concerns raised in the World Trade Organization over the impact of mandatory FOP nutrition labelling on trade have contributed to the watering down of policies and delays in implementation^(17,19). Trade concerns have also highlighted that there is currently no formal global guidance on interpretive FOP nutrition labelling, although discussions have been underway at the Codex Alimentarius Committee for several years⁽²⁰⁾. The result has been significant regional and national diversity in the approaches taken; this lack of harmonisation at the global level for food labelling can make it hard for countries to implement policies and easier for industry to dispute⁽²¹⁾.

Context and objective of the present work

Uruguay is a small high-income country located in the south-eastern coast of South America, between Argentina and Brazil. It stands out in Latin America for its high human development index and low level of inequality⁽²²⁾. Uruguay shows one of the highest rates of overweight and obesity in the continent in all age groups: 9.8% among children younger than 4 years old, 40% among 5–12 years children and 65% among adults^(23–25).

Uruguay is part a MERCOSUR (acronym for Mercado Común del Sur or Common Market of the South in English), a trade agreement signed by Argentina, Brazil, Paraguay and Uruguay in 1991 to promote business and investment opportunities. The member states have signed trade, political and cooperation agreements, which include efforts to harmonise technical measures applying to traded goods. Drawing on the 2015 MERCOSUR agreement on policy recommendations for obesity prevention and control, Uruguay was the first member State to introduce FOP nutrition labelling⁽²⁶⁾. In August 2018, a presidential decree mandated the inclusion of nutritional warnings on the FOP of products

with added sugar, fat and/or Na if the content of sugar, fat, saturated fat and Na exceeded preestablished thresholds based on an of the nutrient profile model of the PAHO⁽²⁷⁾. Before the approval of the policy, Uruguayan citizens showed a positive attitude towards the policy and stated that nutritional warnings would allow them to make informed choices and to increase the quality of their diet⁽²⁸⁾. The decree set the date for entry into force (full implementation) as the 1st of March 2020⁽²⁷⁾. This date coincided with a change in government, after 15 years, from a left-wing party to a centre-right coalition, characterised by more pro-market economic policies⁽²⁹⁾.

A few days after the implementation of the warnings, high citizen awareness and self-reported use of nutritional warnings were reported⁽³⁰⁾. However, on 11 March 2020, a new decree postponed the entry into force of the original decree by 120 d⁽³¹⁾. On September, another new decree modified the criteria regarding the definition of ‘excessive’ content of sugar, fat, saturated fat and Na and set 1 February 2021 as the date for full implementation⁽³²⁾. A few days before, another decree introduced further modifications in the nutritional criteria⁽³³⁾.

In this context, the objective of the present work was to analyse the process for the development and implementation of mandatory nutritional warning labels highlighting products with excessive content of sugar, fat, saturated fat and Na in Uruguay. The overall aim of the analysis was to improve understanding of experience of FOP nutrition labelling efforts in Uruguay, to inform future nutrition policy making and strategic engagement by public health actors.

Methods

Study design

The study design drew on policy analysis methodology⁽³⁴⁾ and case study research methodology⁽³⁵⁾ to analyse the process of agenda setting, design, implementation, changes and subsequent delay of the warning label policy in Uruguay. Theories of the policy process and policy learning informed the study design – particularly Sabatier’s Advocacy Coalition Framework⁽³⁶⁾ and Hall’s theory of policy learning⁽³⁷⁾. These frameworks emphasise the importance of stakeholder beliefs, coalitions and framing, as well as underlying policy paradigms, in shaping policy decisions. In particular, these theoretical insights guided coding of key actor commentary that revealed beliefs, frames and paradigms regarding the policy, as well as the existence of coalitions or relationships between actors, within media reports and also of text relevant government policy documents that revealed dominant policy frames and paradigms. This enabled the analysis of the key factors shaping decision making, throughout this extended policy process.



Data collection

Two main sources of information were selected and analysed for the current study. Official documents from Uruguayan government were retrieved through the search engine of governmental websites with the term 'labelling' ('etiquetado' and 'rotulado' in Spanish). All relevant websites related to governmental actors involved in FOP nutrition labelling were considered. A total of 18 official documents were analysed, including decrees, documents submitted to the public consultation, governmental responses to the comments submitted during the public consultation, transcripts of parliamentary and committee sittings and legal actions presented against the decrees.

Reports related to FOP nutrition labelling published in Uruguayan newspapers were manually identified and stored from June 2016 to September 2020. In addition, a hand search on Google with the term 'labelling' ('etiquetado' and 'rotulado' in Spanish) was used to identify reports related to FOP labelling published on Uruguayan news websites between June 2016 and February 2021. A snowball approach was used to identify additional reports. Using both approaches, a total of 259 news reports, published between June 2017 and February 2021, were identified.

Data analysis

Following the data collection process, the full text of all data sources was iteratively analysed, and relevant information extracted and organised into themes, using a deductive-inductive approach. Data extraction and coding was performed individually by two of the researchers who authored the research. The final coding was defined by agreement between the two researchers and was informed by the study frameworks.

Data were then triangulated from the different sources to construct a chronological case study of the policy process. This case study formed the basis of analysis to identify key contextual factors, events and stakeholders. Based on the study frameworks, and drawing on data from government reports and media, the key government decisions made regarding labelling were analysed with respect to the dominant arguments and frames evident and the interests and influence of key stakeholders (including government stakeholders). Drawing on Hall's framework for policy learning, focus was also placed on policy design (policy objectives, instrument and settings) and its interplay with actor influence and framing. The framework proposed Mialon *et al.* was used to code the practices of the food industry⁽³⁸⁾.

Results

In 2013, representatives of the government, the food industry and civil society signed a commitment to develop actions to achieve the full realisation of the human right to food in Uruguay, including the implementation of regulatory

measures to promote informed food choices⁽³⁹⁾. In the context of the commitment, the possibility of implementing the traffic-light system as FOP nutrition labelling was discussed between 2013 and 2015. In September 2015, MERCOSUR signed an agreement on policy recommendations for obesity prevention and control, which included FOP nutrition labelling⁽²⁶⁾. The following month, the Uruguayan government launched a participatory process called '*Social dialogue: Uruguay to the future*' to obtain insights to develop a national strategy to achieve the Sustainable Development Goals⁽⁴⁰⁾. FOP nutrition labelling was included within the strategies proposed to address Sustainable Development Goal 2, i.e. to end all forms of hunger and malnutrition by 2030⁽⁴⁰⁾.

The process for the design and implementation of the FOP nutrition labelling policy started in 2016. Based on the official documents, three main periods were identified: design of the regulation (June 2016 – August 2018), implementation of the regulation (August 2018 – March 2020) and delay of the entry into force and revision of the regulation (March 2020 – February 2021). Table 1 presents a timeline of the main events related to Uruguayan regulatory process.

Media coverage of the FOP nutrition labelling policy started right after the public consultation was launched in June 2017 (Table 1). As shown in Table 2, 140 of the 259 news reports corresponded to the last period of the process: the delay of the entry into force and revision of the regulation. The relevance of the different stakeholders in the media reports changed during the process (Table 2): the number of mentions to stakeholders related to the food industry remained constant, whereas references to civil society and political actors markedly increased.

In the following sections, the events in each of the three periods for the design and implementation of the FOP nutrition labelling policy in Uruguay are described. For each period, the dynamics and revealed beliefs of key actors are presented.

Design of the regulation (June 2016 – August 2018)

In June 2016, the Uruguayan Ministry of Public Health created a cross-sector working group to develop a FOPL regulation (Table 3)⁽⁴¹⁾. Based on results from a series of local experimental studies conducted with participants from different age groups and socio-economic status^(42–50), the working group selected nutritional warnings as the FOP nutrition labeling scheme. The working group explicitly considered nutritional, behavioural and economic factors in decision making. The identified advantages of nutritional warnings included: (i) they facilitate the interpretation of nutritional information and clearly identify products with excessive content of sugars, fat and Na; (ii) they do not provide information about low nutrient content, avoiding potential misinterpretations; (iii) they represent a lower cost of implementation compared to the guideline daily amounts or traffic light system as they would only be included on products with excessive content of nutrients associated with NCD⁽⁴¹⁾.

Table 1 Timeline describing the main events related to the design and implementation of nutritional warnings in Uruguay

Period	Date	Event
Design of the regulation	June 2016	Creation of an inter-sectoral working group to design an FOPL regulation
	June 2017	Public consultation of the draft regulation
	November 2017	A final version of the decree is prepared by the inter-sectoral working group
	June 2018	Agreement of the Ministers of Health of MERCOSUR regarding FOPL
Implementation of the regulation	29 August 2018	Decree 272/018 approves nutritional warnings in Uruguay
	September 2018	Trade concerns raised by Argentina and Paraguay at MERCOSUR
	November 2018	Appeals from the food industry presented at the national level
	February 2019	Changes in the administrative process to register food products to be commercialised in the country are introduced to facilitate enforcement of the regulation
	March 2019	Implementation manual is published by the Ministry of Public Health
	May 2019	Mass media campaign about healthy eating from the Ministry of Public Health, including octagonal warning signs with the expression 'Avoid Excess'
	June 2019	Requests to postpone the entry into force are presented by the food industry
Delay of the entry into force	September 2019	Children attending public schools received magnets featuring octagonal warnings signs with the expression 'Avoid Excess'
	1 March 2020	Entry into force of the regulation
	1 March 2020	Change in government
	11 March 2020	Delay of the entry into force (Decree 091/020) and creation of a cross-sector working group to revise the policy
	29 May 2020	The cross-sector working group prepares a report with two different recommendations
	June 2020	Results of studies on citizens' opinions about the decision to delay the entry into force of the policies and the immediate effects of nutritional warnings are published in the media
	18 June 2020	Press conference to announce the continuation of the policy
	2 September 2020	Decree 246/020 introduces changes in the nutritional criteria to define excessive content of critical nutrients
	September 2020	Appeals against the new decree are presented by the food industry
	26 January 2021	Decree 034/021 introduces changes in the nutritional criteria to define excessive content of critical nutrients

Table 2 Key stakeholders identified in Uruguayan news reports (*n* 259) in each of the three main periods of the process for the development and implementation of the front-of-package nutritional labelling policy in Uruguay

Stakeholder type	Most frequently mentioned stakeholders	Total number of mentions in the media reports		
		Design of the regulation	Implementation of the regulation	Delay of the entry into force and revision of the regulation
Government	Ministry of Public Health; Ministry of Industry, Energy and Mining	85	77	142
International organisations	PAHO, FAO, UNICEF, United Nations	18	31	56
Industry	Food Industry Chamber, Uruguayan Industrial Chamber, Association of Importers, specific companies	34	33	26
Civil society	NCD Alliance, Uruguayan Medical Union, Uruguayan Association of Nutritionists	3	6	58
Academia	Interdisciplinary group 'Food and Wellbeing', Observatory on the right to food, Food Science and Technology Department	14	5	37
Political actors	Cristina Lustemberg (deputy), Nibia Reisch (deputy)	0	3	33
Others	Government of Argentina, Government of Paraguay, Dora Szafir (retired judge)	7	11	9
Number of media reports		56	63	140

One year after the creation of the working group, in June 2017, the Ministry of Industry, Energy and Mining launched a national and international public consultation on the draft decree for the labelling, to be signed by the Executive Branch of the Uruguayan government⁽⁴¹⁾. The draft decree

framed FOPL in the context of a series of regulatory measures to promote healthier dietary habits to tackle the increased prevalence of obesity and overweight in the country. Details of the content of the draft are summarised in Table 3.



Table 3 Description of the main contents of the draft regulation and the three decrees approved between 2018 and 2020 on front-of-package warning labels in Uruguay

Decree	Composition of the intersectoral group	Approval date	Planned entry into force	Objective	Scope of the regulation	Type of label	Nutrient profile model*	Additional provisions
Draft regulation	Ministry of Public Health; Ministry of Industry, Energy and Mining; Ministry of Social Development; Ministry of Education and Culture; Ministry of Agriculture, Animal Husbandry, and Fisheries; Ministry of Economy and Finances; the local government of the capital city; the academia (Interdisciplinary research group "Food and Wellbeing" from Universidad de la República), the Honorary Commission for Cardiovascular Health; FAO; UNICEF and PAHO	July 2017	12 months after approval	To provide objective information through a simple and accessible tool that warns consumers about the excessive content of nutrients associated with overweight, obesity and NCD	Packaged foods with added sugar, fat or sodium, when the content of sugars, total fat, saturated fats and/or sodium exceeds the thresholds established in the decree	Octagonal signs with the expression "Excess", followed by the corresponding nutrient and the acronym of the Ministry of Public Health (MSP)	PAHO nutrient profile model	- The inclusion of complementary nutritional information (nutritional claims) for products that were eligible for a nutritional warning (e.g. a reduced fat claim on a product featuring a sodium warning) is banned - Donations of foods with excessive content of nutrients to governmental institutions are banned
272/018		29 August 2018	1 March 2020 (18 months after approval)		Packaged foods with added sugar, fat or sodium, when the content of sugars, total fat, saturated fats and/or sodium exceeds the thresholds established in the decree.		Flexible version of the PAHO nutrient profile model	The regulation would be modified if a regional FOP nutritional labelling regulation was approved at MERCOSUR
246/020†	Ministry of Foreign Affairs; Ministry of Education and Culture; Ministry of Economy and Finances; Ministry of Industry, Energy and Mining; Ministry of Public Health	2 September 2020	1 February 2021 (5 months after approval)		Foods for medicinal uses, foods for partial meal replacement, dietary supplements, sport supplements and tabletop sweeteners are excluded.		Adaptation of the Chilean nutrient profile model	N/A
034/021†		26 January 2021	1 February 2021 (4 d after approval)				Flexible version of the Chilean nutrient profile model	N/A

*Details about the nutritional criteria used to define excessive content of sugars, total fat, saturated fat and sodium are shown in Table 3.

†The decrees only modified Decree 272/01 in terms of the nutrient profile model and the date of full compliance.

Table 4 Nutritional criteria used to define excessive content of sugars, total fat, saturated fat and sodium for the implementation of nutritional warnings in Uruguay according to the draft regulation and the three decrees approved between 2018 and 2020

Decree	Sugars	Total fat*	Saturated fat*	Sodium
Draft	10 % of calories from sugar†	30 % of calories from fat	10 % of calories from fat	1 mg/kcal or 360 mg/100 g
272/018	20 % of calories from sugar or 3 g/100 g‡,§	35 % of calories from fat	12 % of calories from fat	8 mg/kcal or 500 mg/100 g§
246/020	Solids: 10 g or 12 g/100 g for products without non-nutritive sweeteners and energies from sugar < 80 % of total energies and Liquids: 3 g/100 ml or 5 g/100 ml for products without non-nutritive sweeteners or 7 g/100 g for products without non-nutritive sweeteners and energies from sugar < 80 % of total calories	Solids: 9 g/100 g Liquids: 4 g/100 ml	Solids: 4 g/100 g Liquids: 3 g/100 ml	Solids: 400 mg/100 g Liquids: 200 mg/100 ml
034/021	Solids‡: 13 g/100 g Liquids‡: 3 g/100 ml or 5 g/100 ml for products without non-nutritive sweeteners or 7 g/100 g for products without non-nutritive sweeteners and energies from sugar < 80 % of total calories	Solids: 13 g/100 g Liquids: 4 g/100 ml	Solids: 6 g/100 g Liquids: 3 g/100 ml	Solids: 500 mg/100 g Liquids: 200 mg/100 ml

*Fats from whole nuts and seeds used as ingredients in a food are not considered.

†Lactose and sugars from whole fruits and vegetables used as ingredients are not considered.

‡Products complying with the following three criteria are exempted from including a sugar warning: (i) sugar content < 7 g/100 g; (ii) do not contain non-nutritive sweeteners and (iii) calories from sugar < 80 % of total calories.

§If calorie content is <13 kcal/100 g, the criteria is set in 100 mg/100 g.

In an official document, the government noted the main comments or themes arising from the public consultation as industry and foreign country concerns regarding the justification for the regulation, violation of international trade agreements (MERCOSUR and Technical Barrier to Trade Agreement), criticisms to the nutrition labelling scheme and its underlying nutrient profile model and insufficient time for its implementation^(41,51).

The final version of the decree was prepared in November 2017 (Table 1)⁽⁴¹⁾. According to news reports, the Ministry of Foreign Affairs and the Ministry of Economy and Finances raised concerns about the potential negative consequences of the regulation on trade within MERCOSUR, which aligned with public industry criticisms to the regulation.

In June 2018, the Ministers of Health of MERCOSUR agreed on the general principles of FOP nutrition labelling schemes to be implemented in the member States. According to the agreement, schemes should focus on communicating excessive content of nutrients associated with NCD (sugars, Na, total fat, trans fat and saturated fat), rely on Pan American Health Organization (PAHO) recommendations for the definition of excessive nutrient profile model and be implemented on a compulsory basis⁽⁵²⁾. According to the Uruguayan government, the MERCOSUR agreement reduced barriers for the approval of the regulation in the country.

The final decree was approved by the Executive branch of the Uruguayan government on 29 August 2018 (Table 1). The approved regulation introduced a series of the changes to the initial draft, which addressed some of the concerns raised by the food industry (Tables 3 and 4)⁽²⁷⁾.

Key actor dynamics

There were shared beliefs regarding the importance of labelling demonstrated by support from international institutions, academia and civil society actors. PAHO, FAO and UNICEF were part of the cross-sector working group created to design the initial decree, as was an academic research group conducting studies on labelling⁽²⁷⁾. Representatives of the three UN agencies stressed the importance of FOP nutrition labelling as one of the policies that should be implemented in the country for the prevention of obesity and NCD. Academics also played a key role in the design of the regulation, leading all the studies that informed the selection of the FOP nutrition labelling scheme and its graphical design, and employed similar frames^(41–50). The group had an active role in the media, providing several interviews in the media to explain the regulation and its main objectives: promoting healthier eating patterns, promoting informed food choices through the identification of products with excessive content of nutrients associated with NCD, protecting consumers against misleading information and contributing to the prevention of obesity and NCD. In several news reports, the academia provided counterarguments to the criticisms to the regulation raised by food industry representatives.

Civil society had a limited role in the media during the development of the policy (Table 2). During this period, only three media reports described support from civil society organisations (e.g. Uruguayan Association of Nutritionists, Uruguayan Medical Union), who stressed the importance of the policy in the context of the prevention of obesity and NCD. In addition, there was no media commentary by any political actor external to the executive



branch of the government, led by a left-wing party, during the design of the regulation.

The food industry was the main opponent to the warning label regulation. Since the public consultation was launched, representatives of the food industry expressed their opposition to the regulation. During the design of the regulation, industry representatives stated that they were in favour of providing information to consumers but framed the FOP nutrition labelling scheme as an inappropriate solution, as it would stigmatise foods, creating fear and confusion among consumers⁽⁵³⁾. They also questioned the efficacy of the policy to encourage changes in eating habits (e.g. *'The industry is 100 % in agreement with providing information to consumers about which are the foods that help to achieve an adequate diet and the maintenance of good health. However, we do not agree on the use of a black octagon because it tends to stigmatize some foods and can lead to demonizing a flagship brand... It can scare more than it educates'*⁽⁵³⁾). Instead, industry representatives promoted a traffic light system based on their own nutrient profile model as an alternative to the policy and argued it was more informative and *'friendlier with the packaging color and the consumer'*^(54,55).

The nutrient profile model of the regulation was another major point of criticism. Representatives from the food industry stressed that the nutrient profile model included in the draft regulation was too strict, leading to a large percentage of products categorised as having excessive content of nutrients associated with NCD⁽⁵⁶⁾. They also stressed that the profile did not encourage reformulation (although this was not an explicit objective of the policy, as shown in Table 1)⁽⁵⁷⁾.

Industry actors and economically oriented Ministries within the government also argued against the labelling on the basis of lack of harmonisation within MERCOSUR. This was presented as a major barrier for the implementation of the regulation⁽⁵⁸⁾.

The potential economic and administrative burden for industry associated with the regulation was stressed in several news reports. Industry representatives stated that the regulation would cause job losses and price increases due to the reduction in sales and the additional costs created by the labelling (e.g. *'We are afraid that this will generate rejection as the population would not have much information. It generates a stigma over consumption of foods that have a label, and it is a fear of the industry due to the loss of sales, income and jobs'*⁽⁵⁹⁾). In addition, they complained about the lack of labelling in establishments selling unpackaged foods (e.g. *'Why are there no labels in a bar or a delicatessen...?'*⁽⁵⁶⁾).

The industry also intended to promote deregulation by focusing on education and physical inactivity (e.g. *'...physical activity and communication should be the fundamental pillars'*⁽⁶⁰⁾). Threats to use legal action against the policy were also mentioned in the news reports⁽⁵⁸⁾.

According to news reports, the food industry partnered with researchers from the Food Science and Technology Department of the national university (Universidad de la República) and Argentinean consultants and arranged a series of interviews in different media (TV, radio and newspapers). In the interviews, researchers and consultants expressed their opposition to the regulation using the same arguments mentioned by the food industry in the media and the public consultation. These stakeholders also criticised the PAHO nutrient profile model from a technical perspective, arguing that the model incorrectly extrapolates WHO dietary recommendations to individual products⁽⁶¹⁾. In addition, the Uruguayan Association of Food Engineers expressed opposition to the regulation in two media reports, using the same arguments as the food industry.

Implementation of the regulation (August 2018 – March 2020)

Immediately after the approval of the regulation, Uruguay presented a request at MERCOSUR to start the development of a regional technical regulation on FOP nutrition labelling based on nutritional warnings⁽⁶²⁾. Although Argentina and Paraguay agreed with the request, they did not agree with restricting the regulation to nutritional warnings and suggested the consideration of other schemes⁽⁶³⁾. Both countries raised trade concerns over the approval of the Uruguayan FOP nutrition labelling regulation⁽⁶³⁾. Lack of harmonisation within MERCOSUR was the main argument of a legal action against the decree presented at the national level by a group of eight Uruguayan food importers (Table 1)⁽⁶⁴⁾.

Despite national and international concerns, the Uruguayan government continued working on the implementation of the regulation. The Ministry of Public Health made necessary procedural changes to support implementation^(65,66) and included the warning signs as part of a public awareness campaign about healthy eating (Table 1).

Key actor dynamics

After the approval of the regulation, industry criticisms to the policy continued. The policy was regarded as a technical barrier to trade and a violation to international regulations, particularly at MERCOSUR level. In addition, the economic burden of the policy was further stressed. In addition, the food industry initiated two legal actions against the decree at the National Court. One of the actions was presented by a group of eight food importers, who stated that the decree was more restrictive than necessary and violated MERCOSUR regulations⁽⁶⁴⁾. The second action was initiated by a Uruguayan processed meat producer, who argued that the decree limited the right to property, as well as the right to freedom of industry and commerce⁽⁶⁴⁾.

In June 2019, the Uruguayan Food Industry Chamber requested a 1-year delay in the entry into force of the policy to the Ministry of Public Health. The request was justified by

the insufficient time to modify packages and reformulate products, as well as lack of capacity for printing the new packages in the country^(67,68).

When the delay of the entry into force of the regulation was announced, representatives of the food industry stated that the decision was positive and stressed the importance of achieving harmonisation within MERCOSUR: *I think it will be positive for the country and the deadline is correct in order to negotiate with the other MERCOSUR partners*⁽⁶⁹⁾

During the implementation of the regulation, actors related to public health (international organisations, civil society and the academia) stayed active in the media, stressing the importance of the regulation. In addition, once the right-wing party won the elections in November 2019, political actors from the left-wing party became active in the media (Table 2). In a couple of news reports, representatives from the left-wing party stressed the importance of FOP nutrition labelling policy and urged the incoming government to enforce it.

Delay of the entry into force and revision of the regulation (March 2020 – February 2021)

The entry into force of the FOP nutrition labelling regulation coincided with a change in government (Table 1). Ten days after the entry into force, the new government postponed 120 d the date of full compliance and created a new cross-sector working group to review the regulation and to assess harmonisation within MERCOSUR⁽³¹⁾. The new group had a different composition than the original, with relatively more economic representation than public health (Table 3).

According to news reports, after three meetings, the cross-sector working group did not reach an agreement and submitted a report with two different recommendations to the Presidency. The Ministry of Public Health recommended continuing with the existing decree (Decree 272/018, Tables 3 and 4). On the contrary, the other four members of the working group (Ministries of Industry, Energy, and Mining; Economy and Finances; Foreign Affairs and Education and Culture) recommended a new delay in the implementation until July 2021 in an attempt to achieve harmonisation within MERCOSUR.

In June 2020, a few days after results from studies assessing public acceptance of the policy and immediate effects of its implementation were published in Uruguayan media, the Minister of Public Health and the Minister of Industry announced that the government had decided to continue with the nutritional warning policy, although some of the characteristics of the regulation would be reviewed (Table 1).

In September 2020, a new decree introduced changes to the nutrient profile model of the regulation was approved, although the rest of the dispositions remained unchanged (Table 3). As shown in Tables 3 and 4, the new decree moved away from the PAHO nutrient profile model and

expressed the limits per 100 g or 100 ml, established according to the recommendations of technicians from the Ministry of Industry. According to the Minister of Public Health, the change was justified by an attempt to harmonise criteria within MERCOSUR: *The calculations will be better explained by food technologists and engineers, but they have to do with, not only the kilocalories, but the kilocalories in relation to the portion . . . it is the criterion used by Chile and the other MERCOSUR countries. The quantity per 100 g has to do with harmonisation within MERCOSUR. Not the values, but the reasoning*⁽⁷⁰⁾. Particularly throughout this phase of the process, there was an evident belief among varied stakeholders that food technicians were important knowledge holders regarding the appropriate design of the regulation and its implementation.

The criteria included in the new decree were based on the Chilean nutrient profile model and ended up being more stringent than the original decree⁽⁷⁰⁾. The decree approved in September 2020 was supposed to enter into force on 1 February 2021. However, a few days before a new decree introducing further changes to the nutrient profile model was approved (Table 3)⁽³³⁾. As shown in Table 4, the new decree increased the limits for defining solid foods with excessive content of all nutrients and modified the sugar criterion from total sugars to free sugars (as in the original decree)⁽³³⁾. According to the Minister of Public Health, the decree intended to maintain the same percentage of products with nutritional warnings as in the original decree but expressing the criteria per 100 g instead of per calories⁽⁷⁰⁾.

The Minister of Industry regarded the decree approved in September as a mistake, as it would lead to a high proportion of products with warnings: *We transformed the caloric base of Decree No. 272 . . . In reality, we said: "We are going to take the Chilean standard" (Decree 246), but it must be recognized that it was a mistake*⁽⁷⁰⁾. According to the Minister, a very stringent nutrient profile model could undermine industry's reformulation efforts and reduce the potential of the policy to modify consumer behaviour, highlighting a difference in belief from the Ministry of Public Health regarding the primary goal of the policy.

According to the Minister of Public Health, the government planned to start a risk-based enforcement process of the provisions of Decree 034/021, starting with the monitoring of compliance for products frequently consumed by children⁽⁷⁰⁾. Based on the evaluation of the impact of the decree, a gradual change in the nutrient profile model towards stricter values was foreseen, although it was not explicitly indicated in the regulation⁽⁷⁰⁾.

Key actor dynamics

During the period spanning the delay of the entry into force, starting in March 2020, there was an increase in the activity of the external actors supportive of the



regulation (Table 2). In May 2020, after the delay of the entry into force of the regulation, a deputy from the left-wing party (former Secretary of the Ministry of Public Health) issued a request of information at the Parliament about the advances of the cross-sector working group in charge of revising the policy.

In June 2020, PAHO and UNICEF launched a report of studies analysing public acceptance of the policy and changes in citizen purchasing behaviour after the entry into force of the regulation in March 2020. The two UN agencies, together with FAO, provided several interviews to discuss the results and launched a social media campaign based on results from the study. The activity of civil society organisations markedly increased. The Uruguayan NCD Alliance, composed of several associations related to health and nutrition, and the Uruguayan Medical Union became key stakeholders in the media during this period, expressing their concern over the delay in the entry into force of the regulation. FOP nutrition labelling was framed as a significant advance for public health, which would contribute to the control of NCD, expressing concerns over the delay and the subsequent changes to the regulation.

After the press conference held in June 2020 (Table 1), the organisations stressed the importance of implementing the regulation without any modifications, given that it was based on scientific evidence and recommendations from international public health organisations. Similarly, academic groups also stressed that strict enforcement of the policy was necessary to achieve its objectives. During the delay of the entry into force and revision of the regulation, the academia was not part of the cross-sector working group in charge of the design of the policy. However, it was an active stakeholder in the media, stressing the importance of the policy, showing its effects on consumer behaviour, raising concerns about the delay and lack of justification of the changes. In November 2020, the NCD Alliance launched a mass media campaign (TV, radio and street billboards) raising awareness of the regulation and its entry into force on 1 February 2021.

After the approval of the last decree in January 2021, civil society organisations raised concerns over the lack of justification of the changes implemented by the government and questioned the increase in the limits for defining excessive content of nutrients. They stressed that the changes *'reduce the credibility of the policy and the perceived risk of consuming products with excessive content of nutrients'*⁽⁷¹⁾. In addition, they stated that the changes represented a new delay in the entry into force of the policy and benefited the food industry⁽⁷¹⁾. Political actors also became highly active in the media after the approval of the last decree, in January 2021. Deputies and senators from different parties raised concerns about the changes and particularly over the fact that the Ministry of

Industry, Energy and Mining had decided the nutrient profile model. The Minister of Public Health and the Minister of Industry, Energy, and Mining were cited to the Parliament to explain the changes and the process leading to the approval of the last decree. As a consequence of the last decree, a deputy of the left-wing party announced that a law on food environments, including FOP nutrition labelling, marketing restrictions and school environments, would be presented to be discussed in the Chamber of Deputies in 2021.

During the delay of the implementation, representatives of the food industry relied on the same arguments presented during the design and implementation of the regulation: lack of harmonisation within MERCOSUR; criticisms to nutritional warnings and promotion of the traffic light system; economic burden of the policy in terms of prices and the labor market⁽⁷²⁾. During this period, representatives of the food industry criticised results from the experimental studies conducted by the academia, stating that they were biased⁽⁷³⁾.

Industry representatives were not mentioned in the press after Decree 246/020 was approved in September. However, the increased stringency of the nutrient profile model motivated two food companies to initiate legal action at the National Court against the new decree, based on a violation of the legal principles of legitimate confidence and legal certainty. They argued that the new decree harmed them as their reformulation efforts became useless, generating a loss of their investment⁽⁶⁴⁾.

After the last decree introducing a more flexible nutrient profile model was approved, in January 2021, industry representatives expressed their agreement with the changes introduced by the last decree in the nutrient profile model: *'Only few products would have managed to avoid the octagons. The shelves were going to be a sea of octagons'*⁽⁷⁴⁾. However, they expressed that additional time (1 to 6 months) would be needed to modify packages to comply with the last decree or to reformulate products. In addition, industry representatives criticised civil society organisations and positioned themselves as technical knowledge holders, i.e. the most knowledgeable about appropriate design and implementation. When referring to representatives of civil society organisations, a representative of the food industry said: *'All the food geniuses that started working in food now, because they didn't work on the topic before'* or *'Did they really make the calculations to know how many products will feature more warnings and how many products will feature less warnings? I can't believe it... We have a lot of chemical engineers and food engineers and we are still working to evaluate the changes'* (introduced by the new decree)⁽⁷⁴⁾. They also stated that civil society organisations criticised the changes in the policy because of political reasons and their general opposition to the government.



Discussion and Conclusions

The present work analysed the process for the development of implementation of nutritional warnings in Uruguay. Results identified three key strengths of the process. First of all, the Ministry of Public Health led a cross-sectoral working group composed of diverse governmental stakeholders, international organisations and the academia. Engagement of multisectoral stakeholders has been recognised as a key factor underlying successful implementation of health policies⁽⁷⁵⁾. Secondly, the Uruguayan government followed a robust evidence-based approach⁽⁷⁶⁾, based on rigorous scientific knowledge generated in the country^(42–50). Finally, following recommendations for best-practice a public consultation was held to grant access to the content of the policy to relevant stakeholders, such as the food industry, governments from foreign countries and non-governmental organisations. Public consultation has been reported to positively contribute to the legitimacy of the policy⁽⁷⁷⁾.

Changes in the systemic governing coalition as a consequence of a change in government led to a delay in the entry into force of the regulation and changes in the regulation. The new government, led by a centre-right coalition characterised by more pro-market economic policies⁽²⁹⁾, gave more prominence to the Ministry of Industry, Energy and Mining in the policy process, whereas several stakeholders related to public health (e.g. PAHO, UNICEF, academia) lost participation in decision making. However, these stakeholders, together with civil society organisations, played a key role in the media during the delay of the entry into force and revision of the regulation by highlighting the importance of the policy. Their involvement and the strengths of the policy process highlighted in the previous paragraph were identified as key determinants of the governmental decision to maintain the warning label policy with a small number of changes. The role of civil society, i.e. the part of the society distinct from government and commercial for-profit stakeholders, in shaping health policy has been previously acknowledged^(78–80). Interestingly, the features of the regulation that were based on local scientific evidence (type of scheme and graphical design) were not modified during the process, stressing the importance of evidence-based policies⁽⁷⁶⁾.

The food industry was the main opponent to the regulation, in agreement with reports from other countries implementing FOP nutrition labelling regulations^(17,18,38). Results demonstrated the use of corporate political activities that have been documented elsewhere with respect to nutrition policy making, in particular, information and messaging, legal action, policy substitution, opposition, fragmentation and destabilisation^(38,81,82). These mechanisms for influence were used to convey a series of common arguments against the policy, including that it would be better to use a nutrition education approach, that there will be negative impacts on trade and employment

and that consumers will suffer from higher prices. These arguments were made more resonant by the different mandates within government sectors, as previously reported in Chile⁽⁸⁰⁾. This is reflective of the general alignment of economic sectors to neoliberal economic approaches seen globally⁽⁸³⁾. The Ministry of industry was more receptive to the concerns raised by industry, particularly during the government led by the centre-right coalition. This is in agreement with left-wing and right-wing approaches to the market economy⁽⁸⁴⁾.

The analysis also highlighted (sub)Regional Trade Agreements – in this case, MERCOSUR – as both a potential enabler and a potential barrier for FOP nutrition labelling. In particular, there is potential for a strong harmonised approach to underpin effective mandatory policy in MERCOSUR countries. But without agreement, as is currently the case, the ‘lack of consistency’ with other MERCOSUR countries has been used to bolster opposition to the policy. This is reminiscent of the global situation, in which the lack of a global standard from the Codex Alimentarius has been used to contest innovative national approaches to FOP labelling in trade forums⁽⁸⁵⁾, in addition to broader claims of ‘inconsistency’ with International Economic Agreements, for example, in the case of Chile⁽¹⁷⁾.

The nutrient profile model underlying the warning label regulation was an ongoing concern of the food industry and food technologists, particularly the PAHO nutrient profile model. Stakeholders related to public health acknowledged the use of WHO dietary recommendations as a key strength of the PAHO nutrient profile model; food technologists identified this as its main weakness. The debate over the concept of ultra-processed foods may underpin the opposition from food technologists to the PAHO nutrient profile model^(86,87). In this sense, the shift in the policy mandate between the Ministry of Public Health and the Ministry of Industry contributed to the decision to move away from the PAHO nutrient profile model in Uruguay. Results from the present work point towards the need to improve engagement of different disciplines for the definition of nutrient profile models⁽⁸⁸⁾.

Despite reformulation not being an explicit objective of the policy, industry actors nevertheless used it as a key issue for assessing the nutrient profile model. The large percentage of products eligible for a nutrition warning according to the PAHO nutrient profile model was a key barrier for its implementation as such, even when the Ministry of Public Health was leading the policy process. In this sense, gradualness in the implementation was identified as a strategy to motivate stakeholders to support the implementation of the food labelling and marketing law in Chile⁽⁸⁰⁾.

Strengths and limitations of the study

This study has presented a detailed documentary and media analysis of the policy process for FOP labelling in Uruguay. By drawing on multiple documentary data



sources over time, the majority in Spanish, the study was able to examine in detail the changes to the regulation and the nature of stakeholder interests and influence. The limitations of the study include reliance on documentary data that analysed only what is publicly available, assuming stakeholder interests are accurately reflected in public statements. Discrete (non-public) information on lobbying activities by industry and the civil society were not included in the analysis. Another limitation of the present work was the lack of triangulation in the coding process. However, two researchers independently coded the documents, and the final coding was defined by agreement between them. In addition, the present study reports a single case and thus not necessarily generalisable. However, results are consistent with other studies conducted on different policies in different countries worldwide.

Key insights from the process

The process and debate regarding the design and implementation FOP labelling in Uruguay is in line with that of other nutrition policies. Similar politico-economic concerns and challenges in the cross-sectoral dynamic have been previously reported in studies on other policies, such as marketing regulations and fiscal policies^(89–92).

This study suggests that future FOP nutrition labelling policy making could be enhanced by strategic and early engagement with actors from all the political system. Unlike the Uruguayan experience, Chile did not experience changes in the regulation despite political changes in the national government during the implementation of the policy⁽⁸⁰⁾. Engagement of actors from different political parties during the discussion of the Chilean law may have contributed to maintaining the policy unchanged. Although multisectoral action within the government was a strength of the Uruguayan process, over time buy-in varied. This highlights the need for ongoing relationship-building between sectors.

The evidence-based approach for the design of the policy was a key strength of the policy process and may have been a protective factor that contributed to the maintenance of warning labels as FOP nutrition labelling scheme in Uruguay. Results from this study further suggest that WHO recommendations on FOP nutrition labelling need to take into account both the evidence and the political economy of this issue. It is not simply 'health policy' but a trade and industry sector policy issue that is often highly contested. As such, technical support and training for public health nutrition policy makers that supports strategic engagement with economic policy actors early in the process could enhance global action on FOP nutrition labelling and other public policies to promote healthier eating habits and tackle obesity and NCD.

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