

Building momentum: lessons on implementing a robust front-of-pack food label

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About World Cancer Research Fund International

World Cancer Research Fund International leads and unifies a network of cancer prevention charities with a global reach in Europe, the Americas and Asia. We are a leading authority on the links between diet, nutrition, physical activity and cancer. We work collaboratively with organisations around the world to encourage governments to implement policies to prevent cancer and other non-communicable diseases.

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Key Messages

- Front-of-pack food labelling (FOPL) can help consumers to select healthier food products and can also help consumers to understand what is in their food products.
- FOPL that shows judgement or recommendation (interpretive FOPL), the focus of this report, can help to create healthier food environments because they are more easily understood by consumers at all levels of literacy and also indirectly motivate companies to put healthier products on the market.
- Many organisations call for governments to introduce FOPL as part of a comprehensive policy approach needed to promote healthy diets and reduce overweight, obesity and diet-related NCDs, including cancer.
- Governments should consider the mandatory implementation of FOPL to help overcome issues with limited uptake of voluntary systems.
- Understanding the pathways of effect through which FOPL works is important in informing the design, development, implementation, defence and monitoring and evaluation of the label.
- A vast amount of research exists on FOPL in experimental settings; however less is available on the effects of FOPL implemented in real world settings. This is a complex and challenging area to research given the number of different types of FOPL and the number of potential outcomes.
- Academics can provide policymakers with the evidence needed to set clear policy objectives, to support robust label design and to help defend a government's proposal from opposition.
- Lessons can be drawn from governments who have led the development or implementation of FOPL around the world. This report outlines common elements that are important in order to develop and implement a robust front-of-pack food label that can withstand opposition, such as challenges related to domestic, international trade and investment law. These elements include:
 - Considering the local context;
 - Using evidence as a foundation;
 - Setting clear policy objectives;
 - Carefully designing the label;
 - Finding how best to engage with stakeholders; and
 - Including monitoring and evaluation early on in planning.
- Governments can be challenged by third parties, most frequently industry, on the introduction of FOPL. Common tactics used by industry to challenge FOPL can be categorised into four main types: delay, divide, deflect and deny. The experiences of countries who defended their FOPL against challenges can help prepare other countries currently proposing FOPL.
- The development and implementation of FOPL is a political process, one influenced by many factors and actors.
- The evaluation of implemented FOPL systems is important in continuing to build an evidence base to support action nationally, regionally and globally.

Introduction

This is the second report in our Building Momentum series^a that provides advice to policymakers on designing and implementing nutrition policies in the face of various challenges caused by lack of political will and industry interference. The focus of this second report is front-of-pack food labelling (FOPL), specifically FOPL that shows judgement or recommendation (interpretive FOPL).

Nutrition labelling is important as it can help consumers to select healthier foods. It can also support consumers in knowing what is in the food products they consume. Consequently, it is a requirement that nutrition information is printed on pre-packaged food products in many countries.(1) Nutrient declarations, often in table format, are found on the back or side of pre-packaged food products.

Information about the nutritional content of products can also be provided in a variety of formats on the front of pre-packaged food products. This supplementary information can help increase consumers' understanding of the nutritional content of a product and has been found to be more effective than the information provided on the side or back of packages, depending on its format and design.(2) In particular, interpretive FOPL can help create healthier food environments because they are more easily understood by consumers at all levels of literacy and also indirectly motivate companies to put healthier products on the market.(3) FOPL should not replace the nutrient declaration mandated by the Codex Alimentarius.

FOPL is used by governments, civil society organisations and the private sector. There are many ways to categorise FOPL. Generally, FOPL can be divided into two main categories: nutrient-specific systems and summary indicator systems (see Figure 1).

Definitions

Front-of-pack labelling (FOPL):

- Nutrient-specific systems:
 - **Interpretive:** Provides nutrition information for one or more nutrients as guidance rather than specific facts, and shows judgement or recommendation (eg, UK traffic light label, warning labels, 'high in' symbols).(4)
 - **Non-interpretive**: Shows information only, with no specific judgement or recommendation (eg, %GDA (Guideline Daily Amount) system, US Facts Up Front system).

• **Summary indicator systems:** Combines several criteria to establish one indication of the healthiness of a product and shows judgement or recommendation (eg, star-based systems, Nutri-Score, and health logos such as Choices, Keyhole, Healthier Choice symbols). (4)

Nutrient declaration: Information supplied on the back or side of the pack for the purpose of providing consumers with a suitable profile of nutrients contained in a food and considered to be of nutritional importance.(5)

Nutrient profiling: The science of classifying or ranking foods according to their nutritional composition for reasons related to preventing disease and promoting health.(6)



^a wcrf.org/buildingmomentum

Figure 1: Types of FOPL



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Methods

A review of the literature was undertaken, using relevant key search terms, on the implementation and associated challenges governments have encountered when developing, designing and implementing FOPL.

Twenty-three semi-structured interviews were carried out with policymakers, academics and advocates from different countries. A thematic analysis of the interviews was undertaken as part of the qualitative research to inform the report.

This report is aimed primarily at policymakers seeking to implement interpretive FOPL as a way to provide information to consumers that is quick and easy to access, understand and use. It does not focus on non-interpretive FOPL or FOPL introduced by industry or civil society organisations. The scope of this report reflects the evidence base demonstrating that FOPL that shows judgement or recommendation is more effective than non-interpretive FOPL.(2,7,8) **From this point forward, FOPL is used to mean FOPL that shows judgement or recommendation.**

This report provides a framework for designing a robust front-of-pack food label, including core elements to consider in its development and implementation, and advice on how to defend it from opposition. It addresses how to combat common tactics, grouped under four main types (delay, divide, deflect and deny), used to challenge FOPL.



Why FOPL is important in tackling NCDs

Rates of overweight, obesity and diet-related non-communicable diseases (NCDs), including cancer, are increasing globally. In 2016, 40.5 million, or 71 per cent of global deaths were due to NCDs; over three-quarters of these deaths occurred in low- and middle-income countries.(9) Food systems and food environments are changing rapidly, with pre-packaged foods and beverages more readily available in all parts of the world. Leading international organisations recommend diets rich in wholegrains, vegetables, fruit and legumes and low in energy-dense, micronutrient poor foods.(10,11) Many pre-packaged processed products are high in free sugars^b, sodium and saturated fats. These nutrients of concern are linked to increased risk of overweight, obesity and diet-related NCDs.(11)

Today's food environment offers many choices. FOPL can help to inform consumers and help them to make healthier choices. FOPL is also more effective at attracting the attention of consumers than nutrition information presented on the side or back of pack.(12) Accordingly, FOPL is part of creating a healthy food environment and recommended by the World Health Organization (WHO) as part of a comprehensive approach to promote healthy diets, and reduce overweight, obesity and diet-related NCDs.(13–16)

Where we are now

Some governments have implemented mandatory FOPL, while others have established voluntary FOPL or supported FOPL developed by a third party. To date, more than 30 governments have led the implementation of, or supported the development of FOPL, with more action taking place in recent years.(1) Close to 60 per cent of government-led or government-supported FOPL systems captured in World Cancer Research Fund (WCRF) International's NOURISHING database have been implemented since 2010.(1)



WCRF International's NOURISHING policy database holds examples of implemented government policy actions from around the world. It is used globally by policymakers, civil society organisations and researchers as a resource to inform policy action, advocacy efforts and research. www.wcrf.org/NOURISHING



^b 'Free sugars' are defined by the WHO as "monosaccharides and disaccharides added to foods and beverages by the manufacturer, cook or consumer, and sugars naturally present in honey, syrups, fruit juices and fruit juice concentrates. Throughout this report, 'sugar' or 'sugars' refers to 'free sugars'.

Timeline of implemented government-led (mandatory and voluntary) or government-supported FOPL systems from around the world (including non-interpretive FOPL systems) ^{c,d}



cylinder format (total energy and % Recommended Energy and Nutrient Intake) [V]



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[M] = Mandatory, implemented by government; [V] = Voluntary, established by government; [S] = supported, but not mandated by government.

A number of countries are currently in the process of developing and implementing FOPL: Israel, Peru and Uruguay have passed legislation, and Argentina, Belgium, Brazil, Canada, Guatemala, Portugal and Spain are in the process of developing and consulting on FOPL.

^c For a helpful overview of the characteristics of FOPL systems implemented globally, see Kanter et al. (2018) in Public Health Nutrition (4)

^d However, the focus of this report is on government-led FOPL, either mandatory or voluntary, that shows judgement or recommendation.

International context

Recommendations for FOPL

Several organisations recommend FOPL, though there is no consensus on one specific type and design of label. The following documents call for governments to introduce FOPL as part of a comprehensive policy approach to promote healthy diets.

• WHO Global Strategy on Diet, Physical Activity and Health (2004)(15)

 Institute of Medicine (IOM) Front-of-Package Rating Systems and Symbols: Phase I Report (2010)(17)

• Institute of Medicine (IOM) Front-of-Package Rating Systems and Symbols: Promoting Healthier Choices (Phase II Report) (2011)(18)

• WHO NCD Global Action Plan for the Prevention and Control of NCDs 2013-2025 (2013)(16), including the updated Appendix 3 (2017)(13)

• Second International Conference on Nutrition – ICN2 Framework for Action (2014)(19)

• WHO Regional Office NCD Action Plans eg, The WHO Regional Office for Europe European Food and Nutrition Action Plan 2015-2020 (2014)(20)

• WHO Commission on Ending Childhood Obesity Report (2016) and implementation plan (2017) (14,21)

• Health Evidence Network Synthesis Report by the WHO Regional Office for Europe (2018)(22)

A recent Health Evidence Network Synthesis Report by the WHO Regional Office for Europe identified a number of considerations for the adoption or review of FOPL policies, that align with WCRF International's research findings. Two of the most important findings include (22):

• utilise a system of interpretive FOPL that can provide evaluative judgements about product unhealthfulness, which appears to be a more effective way to support consumers to choose nutritionally favourable products; and

• explore ways to overcome issues with uptake of the FOPL system in the marketplace, including through mandatory implementation.

France and **Australia** are convening the first Action Network on nutrition labelling under the United Nations Decade of Action on Nutrition with the first meeting expected to take place in early 2019.(23) This Action Network will provide an opportunity for countries to share experiences, lessons learned, obstacles and challenges faced in the development of nutrition labelling to support more countries in their label design and development.







Codex

The Codex Alimentarius is a collection of internationally adopted food standards, guidelines and related texts, which are often used in national policy development. The mandate of Codex is to both protect consumer health and promote fair trade practices. For more information on how Codex is important for labels and trade, see **Addressing legal challenges**.

Codex guidelines exist on nutrition labelling, but provide limited guidance on FOPL. Existing Codex guidelines state that presentation of 'supplementary nutrition information' is 'optional'. A process is under way by Codex to develop further guidance on FOPL. The process is intended to produce guidelines that will include a definition of FOPL, general principles for FOPL and aspects to consider in the development of FOPL systems.(24) The intention of the work is to provide some consistency to FOPL approaches globally, not to establish a specific global FOPL system.(25) Public health advocates are concerned by the significant imbalance on the working group developing the guidelines, with industry overrepresented and the public health community underrepresented, as there is a potential conflict between public health priorities and industry objectives to promote trade and consumption.(25) It is, therefore, essential that potential conflicts of interest are acknowledged and managed during the FOPL guideline development. It is also important to ensure government health ministries and departments feed into Codex FOPL discussions.(26)

Effects of FOPL

Pathways of effect

A main aim of FOPL is to help consumers make healthier choices, to improve dietary intake and reduce diet-related NCDs. An additional aim is for FOPL to stimulate healthier food production and product reformulation.

Understanding the pathways of effect through which FOPL systems work is important in the development, design, implementation, defence and monitoring and evaluation of the label. Figure 2 illustrates the overarching pathways of effect for FOPL, including short-, medium- and longer-term outcomes. It is important to monitor short- and medium-term outcomes along the pathways since longer-term outcomes are affected by many other factors. More detailed and specific pathways of effect can be developed for different types of FOPL (eg, mandatory versus voluntary; nutrient-specific versus summary indicator systems), highlighting additional outcomes that need monitoring. For example, level of uptake is an important outcome for voluntary FOPL, as it can have a significant impact on consumer awareness and subsequent outcomes in the pathways. Limited uptake limits the effectiveness of FOPL. Governments should consider mandatory implementation of FOPL systems to overcome issues with uptake.

In **Australia**, three years postimplementation, the Health Star Rating (HSR) system appeared on 28 per cent of eligible products.(27) In **New Zealand**, four years post-implementation, the HSR system had a 20.9 per cent uptake level.(28) The ministries in charge of the HSR development agreed in 2013 that if voluntary implementation by industry was found to be inadequate, a mandatory approach would be considered. (29) As such, the low levels of uptake have raised questions as to whether Australia and New Zealand should make the HSR mandatory following the five-year review.(27)





Figure 2: Pathways of effect for FOPL



Source: World Cancer Research Fund International (2019). Building momentum: lessons on implementing a robust front-of-pack food label. Available at wcrf.org/frontofpack

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Research on the effects of FOPL

A vast amount of research exists on FOPL in experimental settings, however less is available on the effects of FOPL implemented in the real world. This is a complex and challenging area to research given the number of different types of FOPL systems and the number of potential outcomes.(30)

Systematic reviews have shown that FOPL that shows judgement or recommendation increases comprehension and understanding of nutrition content, increases the selection of healthier products, and is better understood than noninterpretive FOPL.(2,7)

There has been significant innovation in FOPL in recent years, for example the implementation of **Chile's** 'high in' warning labels and **France's** Nutri-Score summary indicator system. Implementation of new types of FOPL is an opportunity to evaluate and understand their impact on consumer and industry behaviour.

"I think innovation is really enabling stronger labelling."

.....

Dr Anne Marie Thow, Menzies Centre for Health Policy, The University of Sydney, Australia

.....

Many studies have compared different types of FOPL within a single country (31–36) on consumers' perceptions and purchase intentions, and other studies have compared different types of FOPL in different countries.(37–39)

Effects of implemented FOPL

There is a need for real world studies that assess sales data and consumer behaviour in response to FOPL, comparing them before and after implementation.(8)

Evaluations of implemented FOPL systems have shown effects on consumers' use and understanding, purchasing behaviour and product reformulation. For example, in **Ecuador**, one-year post implementation, the traffic light label was widely recognised and understood by consumers and thought to provide useful and important information. Research also found that people consumed fewer products with 'high' labels and more often chose products with 'medium' and 'low' labels.(40) In Chile, six months after implementation, public support for the warning label was strong, it affected purchasing behaviour and had a positive impact on product reformulation.(41) Long-term evaluations of the warning label are under way to understand the health impacts.(42) In New Zealand, implementation of the HSR system resulted in healthier reformulations of some products.(43) In **Singapore**, consumption of products with the Healthier Choice Symbol was associated with better diet quality.(44)



For a summary of what is known to date on the effects of implemented FOPL systems, see WCRF International's evidence table, available online at **wcrf.org/frontofpack**



Context

Economic, political, social and cultural factors all shape the process of developing and implementing FOPL systems. It is, therefore, important for approaches to be context-specific to increase the likelihood of successful and sustained implementation. FOPL must meet the needs of the population of a given country, taking into account education levels, nutrition and health literacy levels, communication barriers, local culture, food patterns and specific needs of disadvantaged populations.



"The ones who benefit the most from front-of-pack labelling are the people with poorer health literacy, and vulnerable populations who are at higher risk of diet-related NCDs."

Prof Mary L'Abbé, Department of Nutrition Sciences, Faculty of Medicine, University of Toronto, Canada However, common elements exist for developing and implementing FOPL across countries and regions. The lessons learned from different countries show that FOPL is often, but not always, met with significant opposition and interference from stakeholders whose interests conflict with the introduction of FOPL.(45,46) Therefore, robust policy design is crucial in order to ensure the development and implementation of FOPL that can withstand strong opposition. Designing FOPL based on lessons learned from other countries can increase the chance of successful implementation. See more in Lessons Learned.

In general there is strong public support for FOPL – people are in favour of having more information about the nutritional content of their food in a more accessible manner, in order to help them make healthier choices, and ultimately reduce their risk of diet-related NCDs.(4,47) The concept of FOPL is also supported by the private sector and government, but there is disagreement about 'how'— for example, whether to take a mandatory or voluntary approach, what type of label to implement or how to set nutrient thresholds. The following section outlines the different aspects governments need to take into consideration when developing and designing an FOPL system.



Evidence

Independent evidence should be at the heart of policy design and is necessary at every part of the policy process.

In order to build a case for, design and implement FOPL that is fit-for-purpose and context appropriate, policymakers can draw on the following types of evidence:

Burden of NCDs

- The rates of overweight, obesity and diet-related NCDs in the country
- The cost of overweight, obesity and dietrelated NCDs to the healthcare system
- Indirect costs of overweight, obesity and diet-related NCDs to society

Nutrients and health

- The links between nutrition and health, including evidence of the link between sugars, saturated fat, salt consumption, dietary fibre and weight gain, overweight, obesity and diet-related NCDs
- Guidelines on specific nutrients:
 - WHO Guideline on sugars intake for adults and children(48)
 - WHO Guideline on sodium intake for adults and children(49)
 - Food and Agricultural Organization of the United Nations Report of an expert consultation on fats and fatty acids in human nutrition(50)
 - Global, regional and national recommendations for dietary fibre intake(51)
- National and regional dietary guidelines

Nutrition and health literacy

- Level of consumer nutrition and health literacy across the population
- Awareness, understanding and use of dietary guidelines

FOPL design

- Evidence that FOPL is recommended at an international level, eg, by the WHO (see updated Appendix 3 of the WHO NCD Global Action Plan (13)) and other international reports and plans
- Nutrient profiling models (52,53)
 - Regional Nutrient Profile Models in some cases can be adapted to be used for FOPL (54–56)
- Evidence that FOPL is effective at influencing outcomes along the pathways of effect (eg, consumer understanding, purchasing behaviour and consumption of foods high in sugars or saturated fat or salt)
- Label characteristics (eg, salience, size, colour and placement)
 - This type of evidence is extremely important for policymakers in drafting regulations for FOPL requirements or guidelines for use of voluntary labels
 - Lessons can be learned from tobacco, where warning label characteristics were studied extensively (57)
- Consumer testing of different label formats on perception, understanding and impact in purchasing situations, including all socioeconomic groups

France: Multiple studies were conducted assessing perception, understanding and use of the Nutri-Score label in purchasing situations, demonstrating a positive impact, including sub-analyses in disadvantaged populations.(58)

In **Chile**, the warning label was developed based on quantitative and qualitative studies conducted with different groups in the population. The warning label performed the best in terms of visibility, understanding and intention to purchase. The research sought to determine which label people understood best, not which label people liked.

 Health and nutrition literacy evaluation of the proposed label (to ensure the proposed label catches all levels of health and nutrition literacy)

FOPL implementation

- Estimated costs and benefits of implementing FOPL (eg, resulting from reduction in direct and indirect health costs)
- Modelling effects of FOPL on health outcomes [eg, WHO Choice Analysis (13,59)]

France investigated prospective associations between the UK Food Standards Agency (FSA) nutrient profiling model dietary index (the FSA nutrient profile model underpins the Nutri-Score label) and health outcomes in two large French cohorts and found poorer diets (as expressed by the FSA nutrient profiling model dietary index) were associated with a higher risk of NCDs.(58)

Evidence needs will vary by country. This is partly due to the level of opposition to the proposed label, what other labels exist in the country's region, the size of the country, what evidence generated elsewhere can be applied to the country, and whether the proposed label is mandatory or voluntary. Chile has been open and willing to share their experience of developing a warning label with other countries seeking to implement a similar type of warning label, for example, supporting Brazil, Canada, Israel and **Peru.** Funding is often a significant barrier to developing country-specific evidence. In some cases, grants and funding from philanthropic organisations have been instrumental in developing the necessary evidence base for FOPL.



"For smaller countries you can use evidence generated elsewhere. But for bigger countries you should also have your own evidence."

Ana Paula Bortoletto, Leader of the Healthy Diets Program at the Brazilian Institute of Consumer Defense (Idec), Brazil

The importance of having robust evidence to support every element in the development of FOPL will be discussed in further sections (see Policy Objectives, Defending FOPL and Lessons Learned). Evidence underpins the overall objectives of the policy and helps governments to defend against challenges to FOPL.

Policy objectives

Before designing an FOPL system, governments need to set clear policy objectives for what the labelling system would attempt to do and how it would operate. Setting clear policy objectives makes it easier to make subsequent decisions.

Typically, there are two main policy objectives of FOPL (4,60):

- to provide additional information that is visible and easy to understand to help consumers make healthier food choices; and
- ii. to stimulate healthier food production and product reformulation.

It is important to set clear and specific objectives in order to defend the label against potential trade issues and legal arguments (see Defending FOPL). It is essential that the objectives clearly identify how FOPL will help address a particular problem (eg, burden of NCDs), by linking the objectives to short-term outcomes in the pathways of effect (see Pathways of Effect). If the objective is too broad, for example 'to prevent NCDs', it weakens the necessity of the label, as other measures besides FOPL can help prevent NCDs.(61) It is important to specify that FOPL is part of a comprehensive policy package to improve nutrition and prevent NCDs.(62)

Once the policy objectives are established the label design can be developed.

Example policy objectives

Australia's FOPL scheme's Project Committee summarised the objective as (63):

'To provide convenient, relevant and readily understood nutrition information and/or guidance on food packs to assist consumers to make informed food purchases and healthier eating choices.' **Canada**: The FOPL-related objective of the proposed amendments to the Canadian Food and Drug Regulation is to (64):

'Help reduce risks to health by providing consumers with quick and easy-to-use information on foods high in sodium, sugars and/or saturated fat to help reduce consumption of these nutrients.'

Chile: The main objectives of Law 20.606, which is the first law to simultaneously regulate a front-ofpack warning label, restrictions to food marketing to children under 14 years of age, and restrictions to the school food environment, are to:

- Protect children
- Promote informed selection of food and decrease consumption of food with excessive amounts of sugars, salt and saturated fat

Brazil: The overall objective set by the Ministry of Health is to facilitate the use of nutritional labelling for the selection of foods by Brazilian consumers. To achieve this objective, six sub-objectives are outlined:

- To improve the visibility and readability of the nutritional information
- To facilitate the understanding of key nutritional attributes of food
- To reduce situations that generate misleading information of the nutrition composition
- To facilitate the nutritional comparison of foods
- To improve the accuracy of the stated nutritional values, and
- To expand the scope of nutrition information

Key decisions regarding the development of the label

The main considerations in developing an FOPL system fall into three categories:

- 1. Legislative context and framework
- 2. Choice of nutrient profile model
- 3. Choice of label format

1. What is the legislative context and framework?

It is important to design a label that works within a given legislative context and framework, and consideration must be given to certain key questions, such as: is the implementation of a mandatory FOPL system possible legally? In other words, is there any law or constitutional provision that restricts the government from introducing a mandatory label? If a mandatory FOPL system is not legally possible, then a voluntary FOPL system can be pursued.

Governments also need to consider the legislative framework it is working under to identify what legislative mechanisms are available to it. For example, is the legislation for nutrition or food labelling dealt with under consumer protection law or health and safety law? It is important to know the relevant legislative framework to understand what evidence is needed and what the overall objectives of the policy need to be. It is also relevant to know which government departments should be encouraged to work together on the design of the label to ensure policy coherence (health departments, trade departments, food security departments, etc).

It is particularly important to engage the government's trade department in a multi-sectoral approach when considering the legislative context in order to ensure all trade and investment requirements are considered and adhered to when designing and implementing FOPL (see more in Defending FOPL). In **Canada**, the legislative framework governing food safety and the nutritional quality of food is the Food and Drugs Act, which falls under criminal law. This means a clear demonstration to the risk to health is needed in order to introduce regulations mandating FOPL, which narrowed down the available label options. A decision was made for the label to focus on saturated fat, sodium and sugars as there is clear evidence on the association of excessive consumption of these nutrients and risk to health. To make the link to health risk, it was decided the label should target foods that are 'high' in these nutrients as a public health concern because the consumption of these foods increases the risks of excess intakes associated with adverse health outcomes.

2. Which nutrient profile model should underpin the label?

"Most of the discussion on frontof-pack labelling revolves around label design. In order for the policy to be effective, the same amount of attention must be devoted to the discussion of an adequate and effective nutrient profiling model."

Dr Ana Clara Duran, Research Scientist, University of Campinas, Brazil

FOPL needs to be based on a credible nutrient profile model. A nutrient profile model classifies or ranks foods according to their nutritional composition. Some countries or regions have nutrient profile models that could be used or adapted when deciding on the particular aspects of a label.(52,54–56) However, not all nutrient profile models can be used for all types of FOPL, especially if they have been created for a different purpose (eg, to identify food and beverages that are sufficiently 'healthy' to be marketed to children).(52) Where countries are developing a new nutrient profile model, it may be beneficial to draw on an existing and appropriate nutrient profile model from a neighbouring country or region in order to avoid unnecessary duplication, especially where resource and capacity is limited.(65) However, the specific context of the implementing country must be given appropriate consideration. The nutrient profile should take into account food composition and dietary patterns of a country. It will also be important to assess how the nutrient profile will impact foods present on the market (eg, will it encourage reformulation? And if yes, what kind of reformulation?).

France, adapted the UK FSA nutrient profiling model (66) for the Nutri-Score label. Research was conducted to assess its applicability to the French food environment. Overall, the FSA score classified foods consistently with French food-based dietary recommendations and displayed a large variability within food groups.(65,67) The FSA nutrient profiling model algorithm was modified for cheese, added fats and beverages, following research showing the Nutri-Score five categories of nutritional quality (green to red) did not align well with nutritional recommendations for these food groups. Final thresholds for the Nutri-Score were defined by the French High Council of Public Health.(68)

In some cases, countries have drawn on existing regulations to help guide the development of FOPL and the underpinning nutrient profile. For example, **New Zealand** and **Australia** agreed that any FOPL system should align with the nutrient profile scoring criteria developed for displaying health claims.

Countries also need to consider which products will be exempt from FOPL, regardless of nutrient levels or score/rating. For example, in Canada, some foods (fruits and vegetables without added sugar, salt or saturated fat, and non-flavoured whole and partly skimmed milk) are exempt from their proposed warning labels.(64) France exempts aromatic herbs, tea, coffee, yeast and alcoholic beverages. Exemptions must be carefully considered to ensure they are not discriminatory. See Addressing Legal Challenges.

"

"Most effective labels bring in a strong nutrient profiling system and strong elements of design."

Prof Mary L'Abbé, Department of Nutrition Sciences, Faculty of Medicine, University of Toronto, Canada

Some specific considerations for deciding on the Nutrient Profile model underpinning the FOPL system are outlined below.

I. Which nutrients should be analysed?

A key question to consider is whether FOPL will focus on 'nutrients of concern' or the nutritional value of the food as a whole (eg, 'positive' nutrients as well as 'negative' nutrients).

The majority of FOPL systems implemented across the world to date focus on fat and/or saturated fat, sugars and salt or sodium ('nutrients of concern'), because of evidence linking these nutrients to obesity and diet-related NCDs (see Evidence). The Institute of Medicine reports concluded that the most critical nutritional components to include in FOPL are energy (as calories), saturated fat, trans fat, sodium and sugars.(17,18) However, some countries also include dietary fibre, total carbohydrates, protein and micronutrients.

For example, Chile's warning labels consider energy, sugars, saturated fat and sodium, the Nordic Keyhole analyses sugars, total fat, saturated fat, salt, dietary fibre and wholegrain, France's Nutri-Score analyses nutrients to limit: energy, sugars, saturated fatty acids, sodium and elements to increase: fruits, vegetables, legumes, nuts, fibres and proteins.(58)

II. What will be used as the reference?

The three main references used by countries that have developed FOPL include: per serving, per 100g or per 100ml, or per 100kJ. Governments find that the per 100g or per 100kJ is easier to regulate. FOPL systems that use per 100g or per 100ml include: **Chile's** warning label, **Nordic** Keyhole, **Singapore's** Healthier Choice Logo, **France's** Nutri-Score, **Australia** and **New Zealand's** Health Star Rating system, **Ecuador's** traffic light label, **UK's** traffic light label and **Sri Lanka's** high sugar warning label. For the **UK** traffic light label, in cases where the portion or serving size of the product is larger than 100g or 150ml, the amounts of fat, saturated fat, sugars and salt per portion are required, with predetermined thresholds set for green, amber and red.(53) Using per 100g or per 100ml allows for easier comparison between products, but it requires numeracy skills to calculate the amount per portion (if not stated).

Canada's proposed FOPL regulations are based, for the most part, on the reference amount. The reference amount is the average amount of food typically consumed at one sitting and forms the basis of serving size declared on the label. Some adjustments are made to take into account foods that are usually consumed in small amounts but can be concentrated sources of nutrients of concern, such as sauces and dressings. Linking the regulations to amounts of food consumed that drive excess intakes of nutrients of concern and associated health risks is necessary to justify the regulation.

Another important decision is whether the references used will be across or within categories of food. **Chile** decided to use references across food categories only and did not establish them within food categories, to enable people to compare not only within categories but also across categories. **Chile** chose to use cut-off values per 100g instead of per serving because research found the Chilean population was not aware of the definition of serving size, and therefore using this reference would make the label more difficult to interpret. Using a per 100g reference allows for a standard measure for all foods, as it describes food based on the nutritional quality of the food, not the way it is consumed, and allows comparison both within and between categories.





"We chose to have a label that compares between food categories. It is not easy to understand when you have for example, french-fried potatoes without a label and yoghurt with a label. If there is a different system for different foods, or different thresholds for different categories, it's very confusing to the population for example, to think that french-fried potatoes are healthier than yoghurt."

Dr Lorena Rodríguez, Osiac University of Chile, Chile



III. What thresholds or scoring will be used?

Thresholds or scoring systems need to be set for the FOPL system. Thresholds are common for nutrient-specific systems, and in some cases will determine which products will display FOPL (eg, warning labels). Summary indicator systems use scoring or rating systems (eg, the Health Star Rating algorithm generates a star rating from 0.5 to 5.0 stars and the Nutri-Score allocates points for different nutrients resulting in a final score that ranges between -15 and +40).



"A robust front-of-pack label has clear rules around which foods are covered. and a wellvalidated underlying scoring mechanism. If both are in place, it shouldn't matter what the food is, or whether it's commonly perceived as healthy or unhealthy - whatever score it gets, that's what has to go on the label. **Expect media and consumers** to be interested in 'anomalies', and design complementary communications to keep front-ofpack labelling in perspective – it's a useful tool, but not a complete source of dietary advice."

Alexandra Jones, Research Fellow (Food Policy and Law), The George Institute for Global Health, UNSW, Australia

France's Nutri-Score is underpinned by a nutrient profiling system derived from the UK Food Standards Agency nutrient profiling model. The Nutri-Score's nutrient profiling system allocates positive points for 'unfavourable' content: energy (kJ, 0-10 points), total sugar (g, 0-10 points), saturated fatty acids (g, 0-10 points) and sodium (mg, 0-10 points) and allocates negative points for 'favourable' content: fruits, vegetables, nuts (0-5 points), fibres (0-5 points), and proteins (0-5 points). The resulting final score ranges between -15 and +40 (most healthy foods to less healthy foods). Therefore, the lower the score the healthier the food. The Nutri-Score defines five categories of nutritional quality ranging from 'green' to 'red' and letters A to E (eg, plain yoghurt = A, chocolate biscuits = E). The entire scale appears on the label.(58)

Canada's thresholds are based on modelling Canadian dietary intake data that shows that intakes of sugars, sodium or saturated fat will exceed recommended limits when present in levels at or above the specified thresholds.

Chile defined limits for each nutrient instead of using a scoring system. All food and beverages that exceed these limits are required to have a front-of-pack black and white warning message inside a stop sign that reads "HIGH IN" followed by the nutrient exceeding the limit, as well as 'Ministry of Health'. A warning label is added to the product for each nutrient exceeding the limit.



Some countries set thresholds or scoring systems that are applicable across the food system while others set thresholds specific to product groups or product categories. For example, the Health Promotion Board in **Singapore** created 14 food categories for the Healthier Choice Symbol with category-specific thresholds for fat, saturated fat, trans fat, sodium, total sugars and added sugars (69) and the **Nordic** Keyhole has specific criteria for 25 categories of food.

Singapore's Healthier Choice Symbol has 14 food categories (beverages, cereals, dairy products, eggs and egg products, fats and oils, fruit and vegetables, legumes, nuts and seeds, meat and poultry, seafood, sauces, soups and recipe mixes, snacks, convenience meals, desserts and miscellaneous). The Healthier Choice Symbol Guidelines were developed with industry to make sure the guidelines are feasible.(69) A 'landscape scan' is conducted for nutrients in each category to find the market median. The guideline is then set to be lower than the median to encourage reformulation. The guidelines are reviewed and tightened over time to further encourage product reformulation.

3. What label format will be chosen?

The third consideration when designing FOPL is how the label will look.

I. Type of label

Labels can use symbols, colours or numbers and words to display information. Simplicity is a major consideration, so that at a glance, or very quickly, consumers can use a label to determine if it is a healthier product or not.

The legislative context and framework and decisions on which nutrient profile model underpins the label narrow down what type of FOPL system is available to governments. Figure 1 highlights the two main categories of FOPL – nutrient-specific systems and summary indicator systems, and the types of labels that currently exist within these categories. When deciding on the type of label, it is important to base the decision on evidence and, where possible, test different label formats in the country to ensure they are fit for purpose (see Evidence).

> "When conducting research about label design and format, the question shouldn't be 'What symbol do you prefer?', but 'What's going to help you make a better decision?'"

6

Dr Ana Clara Duran, Research Scientist, University of Campinas, Brazil

II. Characteristics of the label (eg, size and location)

There are a number of FOPL characteristics that can help to capture consumers' attention in a cluttered and busy environment, including colour, size and position.(70) The label needs to be simple, consistently displayed on the package, possess a design that maximises its contrast with other package elements, and be sufficiently large to effectively compete with other package elements and attract consumer attention. (8,18,71) Regulations or guidelines should be clear and specific about the size and location of the label. For example, **Chile's** implementing regulations and **Canada's** proposed regulation clearly outline specifications for the size, colour and location of FOPL.

> "It's very important to have the same pattern of size and location on the front of the pack so that people can identify it and use it as a symbol, and not just as information on the package like many, many other images and sentences that are included on the front of packages."

Ana Paula Bortoletto, Leader of the Healthy Diets Program at the Brazilian Institute of Consumer Defense (Idec), Brazil Evidence on label characteristics from other consumer products, like tobacco, can also be drawn upon. Research from tobacco warning labels demonstrates that warnings should be clear, direct and accurate; appear on both the front and back of pack; be large enough to be easily noticed; and that warnings with pictures are more effective than text-only warnings.(57)

Israel's FOPL system is based on the Chilean model, but they wanted to use two colours to represent a positive and negative label. Following consultation with various stakeholders (including industry who were against white on black) and people with visual impairments, red (negative) and green (positive) were selected.

In **France**, Nutri-Score is a voluntary label and it was made into a brand to protect its use. Therefore, in order to use Nutri-Score, companies must adhere to certain requirements, such as size and colour. Industry is not permitted to modify, add or remove any elements of the Nutri-Score logo.(72)

Stakeholder engagement

"Policy development itself needs to be government-led, so that a credible system is developed ultimately. Any consultation with industry should really occur after the principles of the policy, the front of pack labelling system and what it hopes to achieve are already outlined by government."

Associate Professor Bridget Kelly, Early Start, University of Wollongong, Australia

Designing and developing FOPL often involves a multitude of stakeholders, including government officials from various departments, public health experts, technical experts, members of civil society organisations, academics and industry representatives. It is important for government to establish the policy agenda, so that the principles of the labelling system being developed are in place before opening dialogue with other stakeholders about specific format and technical details of the system.(22) The presence of industry representation in the decision-making process is a contentious issue. It is important for government to lead the underlying scoring system for a given FOPL system, and for it to be rigorous, including a comprehensive academic review. Ultimately, it is the government's role to manage stakeholder engagement, deciding on which stakeholders are required to collaborate on the design and development of FOPL, and at what stage.

For best practice, it is advised that all parties involved publicly declare their interests, including previous and current work and their funding, to avoid conflicts of interest.(37) Putting robust and transparent governance mechanisms and reporting measures in place will help governments manage the conflicts of interests that will arise from having industry involved in public health regulation.(73,74)

In 2016 Health Canada implemented a new policy to increase transparency of stakeholder engagement activities related to healthy eating initiatives, including FOPL. Health Canada publishes, on an ongoing basis, a table of all correspondence (other than submissions to formal consultations) and meetings with stakeholders that are relayed with the intent to inform the development of policies, guidance or regulations related to healthy eating initiatives. (75) The table is published on Health Canada's website and includes the date, subject and purpose of the meetings and correspondence. It also includes the title of any document shared during the meetings, which can be accessed by members of the public upon request.

"What we have put in place is a policy whereby all interactions with all stakeholders is made public through a table on our website, where we say who we met with, about what and what documents were shared, and a summary of the meeting or correspondence. The driving force was to basically make sure that government policy is not perceived as unduly influenced by a certain group of stakeholders."

Quote from interview



Advisory boards

Some governments have created advisory boards or technical commissions to help advise on the technical aspects of the label and to carry out the research required to inform FOPL design and development. Advisory boards need to ensure potential conflicts of interests are managed.

Australia

The Forum on Food Regulation established a project committee to design and implement a framework for an interpretive FOPL system. The committee was made up of members of the food industry, civil society organisations and the public sector and chaired by the Secretary of the Department of Health. Two working groups were established with the same stakeholder representation, tasked with providing recommendations to the project committee. The project committee then passed its final recommendation to the Forum on Food Regulation.(76)

New Zealand

The Food Safety Minister created a small advisory group with representation from industry, civil society organisations and the public sector. The advisory group was tasked with establishing a set of principles to guide a FOPL system rather than develop or recommend a specific scheme. It was the government's role to recommend a FOPL system. Once the principles were established, the government decided to support the Australian Health Star Rating system and the Food Safety Minister for New Zealand took part in the Australian stakeholder groups.(76)

UK

The Food Standards Agency and subsequently the Department of Health worked collaboratively with stakeholders such as industry and civil society organisations to develop a voluntary FOPL system. This included one-to-one meetings with stakeholders but also the creation of a larger tripartite stakeholder interest group. The main aim of the collaboration was to create stakeholder commitment to the FOPL system, with a secondary aim of gathering input on the design and content of the FOPL system.(76)



Whole of government approach

Different government departments are encouraged to work together to design and implement FOPL to ensure that the final design is clear, enforceable and effective. In particular, government departments concerned with trade and investment law need to be engaged by health departments to ensure the policy design is consistent with domestic and international trade and investment legal obligations.(61)

In **Ecuador**, the Ministry of Public Health, Ministry of Social Security Development (MCDS) and the National Regulation, Control and Health Surveillance (ARCSA) worked together to develop the FOPL proposal.(40)

Industry engagement

The extent to which industry plays a part in the design and implementation process will vary based on the political climate and context of the country implementing FOPL. Most countries that have implemented FOPL to date have engaged industry at some point during the policy process, largely with the view that they can provide input on the economic impact of implementing the regulations on their business, and the technicalities of the regulatory or voluntary measure, such as label design. Governments need to set clear guidelines for the type and scope of industry engagement, ensuring the engagement follows the normal legislative consultation procedures required under national law.

"I think that all the regulatory actions should be defined by the government and informed by academia. I don't think that industry should be involved in decision making because I don't see clearly how their conflict of interest can be managed at that level. I don't think we are expecting the same outcome from the measures. So, I think that it's the government's role to promote healthier environments and healthier lives for the populations."

Dr Camila Corvalán Director of the Food Environment and Obesity Prevention Research Center (CIAPEC), INTA, University of Chile, Chile

Mobilise civil society organisations

The presence of civil society organisations is particularly important in the FOPL policy process because of the involvement of industry. Civil society organisations can help counter the influence of industry in the political process and provide accountability and transparency in upholding the public health objectives of FOPL.

> "Keep the public informed and keen on the selected label. Engage consumer associations – if they agree with the proposed system, they are really good allies because they stir public opinion and counter the power of industry."

Dr Chantal Julia, Associate Professor in Nutrition, Paris 13 University, France

Different countries have involved civil society organisations in different ways, as they can have a large role to play in FOPL design due to the technical nature of the labels and the need for larger stakeholder engagement.

Australia successfully engaged civil society organisations such as public health and consumer groups in their Health Star Rating policy process. Alliances between public health and consumer groups were strong and coherent and allowed them to have influence at the policy table.(77)

Chile also found the involvement of civil society organisations vital as they provided support when higher limits or restrictions on the label thresholds were proposed, as well as opposing the reduction of limits or requirements.(42)

In **Mexico** civil society organisations did not consider themselves meaningfully involved in the development of the FOPL, which was implemented in 2014. Groups raised serious concerns about conflicts of interest given the lack of transparency and industry involvement in the policy development and design of the label.(74)

In 2018 the Mexican Ministry of Health commissioned the National Institute of Public Health to create a group of independent experts to develop a position statement on FOPL. The position concluded that the existing GDA FOPL system in Mexico needs to be replaced, the underlying nutrient profile of a FOPL should be consistent with international models (eg, Pan American Health Organization), decisions on FOPL should be free from interference from industry and recommends the implementation of a FOPL that provides direct, simple, visible and easily understandable information for the Mexican population.(78) This position is supported by an international expert group of more than 30 scholars from the world and by more than 15 Mexican medical societies.

Support from the research community

Academic partners are crucial at every stage of the policy process as they can support governments by providing the necessary supporting evidence, and often by designing relevant studies in-country. Academics can provide policymakers with the evidence needed to set clear policy objectives, to support robust label design and to help defend a government's proposal from opposition.

Public consultation

As part of the policy process, governments sometimes carry out public consultation. **Canada** carried out two rounds of public consultation allowing a wide range of stakeholders to submit their opinions on the proposed FOPL system. **Chile's** proposed set of food label and regulatory norms underwent multiple rounds of public consultation.(79) In **Mexico**, a consultation process was opened where any person or organisation was entitled to submit recommendations; however no official records of this participatory approach are available to the general public and there are reports that industry was more heavily consulted than academics and civil society organisations.(74)

Public education

Public education campaigns can help support the development of a FOPL system. For example, **Brazil** ran an effective campaign, 'Do you know what's in your food?'. This followed another campaign that raised awareness of diabetes and other problems.

It is important that the introduction of a FOPL system into the market is accompanied by a well-designed public education campaign in order to educate the public and increase use and understanding of the label.(18)

In some cases, governments have provided assistance to industry in the implementation of FOPL.(22) For example, in **Ecuador** the government ran a national campaign directed at industry to explain the FOPL regulation. This included a website that responded to questions and concerns and provided a simulator to help industry visualise how the label would be displayed on their products.(40) **Chile** used an advertising campaign consisting of commercials, videos and downloadable posters to explain the meaning of, and justification for, the "HIGH IN" warning label.(42) The campaign message was to 'Choose food with fewer stop signs and if they don't have a stop sign, it is better' and was promoted via TV, Internet, radio, posters, brochures and social media. (42)

A Health Star Rating public campaign was developed in New Zealand by the Health Promotion Agency. Unpaid media was used to build the integrity of the Health Star Rating (HSR) to increase trust and familiarity through public communications and stakeholder engagement. Paid media was then used to increase momentum and was staged strategically with continued public communications and stakeholder engagement. The main component of the campaign used advertisements of animated breakfast cereal boxes on On-Demand television platforms and YouTube. Visual prompts and messages in supermarkets were utilised and the focus remained on breakfast cereals as this product range had the highest uptake of the HSR.(80)

In **Ecuador** the Ministry of Health launched a public awareness campaign across TV, radio and other media channels to inform the public about the correct use and benefits of the traffic light label.(40)



"Prefer foods with fewer warnings and if there are no warnings, even better." Ministry of Health, Chile

Monitoring and evaluation

It is important to develop a monitoring and evaluation framework for a FOPL system before its implementation.(22) This requires dedicated resources, technical capacity, the availability of baseline data and the opportunity to collect followup data. Establishing clear pathways of effect is important for policy evaluation to ensure the appropriate outcomes are being assessed (see Pathways of Effect). Developing the monitoring and evaluation framework during the policy design phase is helpful to identify how best to measure the effects of the label and monitor compliance, including identifying baseline data requirements. Evaluations should be high quality, independent and free from conflicts of interest.

Policies can have unintended positive, negative or neutral impacts when implemented in the real world. Therefore, it is crucial to monitor and evaluate FOPL to understand if it is having the anticipated effect and adjust the policy if not. Questions that need to be addressed include:

- Is the implemented label understood and being used by all parts of the population or the target population?
- What is the uptake for voluntary FOPL systems and what types of products display the label (eg, healthier versus less healthy products?)
- Is the label affecting reformulation of existing products and development of new products?
- Is the label affecting purchasing decisions?

"Be clear from the beginning about what is considered sufficient uptake – is 20% good enough or is it 50% or 80%? – this will impact evaluation of the system."

Prof Cliona Ni Mhurchu University of Auckland, New Zealand and The George Institute of Global Health, Australia

It is important to continue to monitor and assess the appropriateness of the underlying nutrient profile system.

Australia and **New Zealand** conducted a review two years post-implementation to monitor the implementation of the Health Star Rating (HSR) system (81). A five-year review of the HSR system is planned to consider the impact of the system, whether the objectives of the HSR system have been met, and to consider how the system, including its algorithm, could be improved. The reviews help the governments to understand whether the voluntary labels have been effective, and if the uptake has been consistent and broad enough to justify the HSR continuing to be voluntary or whether it should become mandatory to ensure better uptake.(27,29) **Chile** has an enforcement system in place with sanctions for non-compliance.(42) Evaluations of the warning label are also being conducted by the academic sector to assess attitudes and perceptions of the label and its effect on purchases and consumption, which is being supported by Canada's International Development Research Centre, Bloomberg Philanthropies and the University of North Carolina.(41)

An evaluation of **France's** Nutri-Score label, conducted by the Observatory of Nutritional Food Quality (OQALI), is planned for three years postimplementation.(22) OQALI analyses the nutritional composition of foods with the Nutri-Score label and compares it to foods in the same category without the label. It also compares nutrient content before and after the Nutri-Score is applied for specific products (where possible).(82)

At a global level, WCRF International's NOURISHING policy database can be used to track implemented FOPL systems around the world, with links to published evaluations.(1) The evaluation of implemented FOPL systems is important to continue to build an evidence base to support action nationally, regionally and globally.





Defending FOPL

Governments proposing FOPL can encounter two main types of opposition: legal challenges and nonlegal challenges related to the design of the label.

Addressing legal challenges

FOPL can be subject to legal challenges through domestic, international trade and investment law mechanisms. This section provides an overview of how challenges to FOPL can arise and how best to mitigate their impact. Key learnings are then outlined to explain how governments have defended any challenges to date.



"If FOPL is implemented on a mandatory basis, it will be important to understand, assess and mitigate trade and other legal implications. On the trade side for example, the current WTO rules are very clear that governments have the ability to regulate for the public interest. Governments need to demonstrate that the actual measure is not overly burdensome on trade, and that regulations do not discriminate between domestic and imported products."

Quote from interview (policymaker)



International investment law

International investment law could impact a government's ability to introduce FOPL by giving investors the right to challenge FOPL regulation under:

- International investment agreements comprised of a variety of agreements including bilateral investment treaties;
- Investment chapters in free trade agreements; and
- Investment contracts between the state and investors that aim to promote and protect foreign investment in order to stimulate economic growth and development in a country.

International investment law generally provides protection to investors against expropriation of private property (including intellectual property) without due process and compensation and against unfair and inequitable treatment. Regulatory space generally exists within international investment law for governments to enact legitimate, evidence-based public health measures.

Domestic law

FOPL can be legally challenged by third parties in domestic courts for the following reasons:

- Discriminatory FOPL only applies to certain products and not others (eg, based on country of origin or product type)
- Jurisdictional issues government has no mandate or jurisdiction to introduce FOPL; or
- Unconstitutional FOPL restricts or impinges on rights to trade/commerce/intellectual property.

International trade law

World Trade Organization (WTO) under the Technical Barriers to Trade (TBT) Agreement

WTO Member States may raise 'Specific Trade Concerns', or bring a formal dispute, against FOPL measures before the WTO under the TBT Agreement. The TBT Agreement aims to prevent unnecessary technical barriers to international trade, while enabling WTO Member States to maintain their right to adopt regulations to pursue legitimate objectives such as public health. The TBT Agreement states that technical regulations, such as labelling measures, must not be more trade restrictive than necessary to fulfil a legitimate objective, such as public health.(61) The TBT Agreement also contains provisions prohibiting discrimination against imported products unless there is a legitimate regulatory basis for the focus on imported products. WTO Member States need to ensure that their FOPL requirements do not constitute unnecessary 'technical barriers' to free movement of food products across borders.(61)

Regional trade agreements

Many governments have regional, plurilateral or bilateral trade agreements to comply with, for example the United States-Mexico-Canada Agreement (formerly the North American Free Trade Agreement), the Trans-Pacific Partnership Agreement (TPPA) and the European Union's (EU) trade regulations.

EU regulations restrict Members States from implementing a mandatory FOPL system so free trade between EU Member States is not impacted. In October 2014, the European Commission investigated the UK for its traffic light label, after the legality of the system was challenged by a number of EU Member States. The European Commission said that the UK label needed to be investigated after other EU Member States complained that it would 'negatively affect the marketing of several products'. The European Commission stated, as the guardian of the regional trade treaties, that it (the European Commission) had to look for the most appropriate and less trade restrictive means to achieve the public health objectives. (83,84) The decision on this case is still pending, however the UK still uses the traffic light label. In 2017, the European Commission investigated France's Nutri-Score label, as a number of EU Member States raised objections related to trade concerns. Ultimately, the European Commission approved the use of Nutri-Score, ruling its implementation was justified on public health grounds.(85)

Concerns raised before the WTO's TBT committee in relation to FOPL

While there has been no formal WTO dispute regarding FOPL, several countries have raised Specific Trade Concerns at the WTO'S TBT Committee about proposed FOPL measures from **Thailand, Chile, Indonesia, Peru** and **Ecuador** over the past several years. Most issues raised with the WTO do not progress to become formal disputes and one of the main aims of the TBT Committee is to resolve trade conflicts. Countries have raised concerns over mandatory FOPL seeking justification for the measure that is perceived to have a significant impact on trade.(61)

Summary of concerns raised in cases brought to the WTO TBT Committee to date (61):

- The FOPL system chosen was not proportional to the policy objective being pursued. There were other policies or labels that could be introduced that would reach the same objective but would be less trade restrictive.
- There was insufficient evidence to show the effectiveness of the FOPL system that would 'necessitate' the anticipated significant impact on trade. Countries often asked about the scientific evidence for the nutrient thresholds on which the FOPL system was based.
- Concerns were also raised regarding the utilisation of 'relevant international standards' as the basis of the measure, with reference made to Codex Alimentarius Guidelines. Concerns were raised that the interpretive labelling measure was inconsistent with the Codex guidelines on nutrition labelling which state that the nutrient declaration should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health. Concerns were also raised about not depicting certain foods as negative in accordance with Codex guidelines.
- Evidence was also requested regarding the selection of target foods and food categories and whether certain food groups were discriminated against by the FOPL system.
- Concerns were raised about difficulties faced by exporters in other countries needing to comply with a novel system of food labelling for only one of their export markets and the administration and logistics required to prove conformity with the regulations.



Key learnings to mitigate risk of legal challenge

Under domestic, international trade and investment law there is space for governments to regulate in the interest of public health provided the measures are legitimate and evidence based.(26,61)

Researchers have summarised learnings related to domestic, international trade and investment law to assist governments in mitigating the risk of having legal challenges brought against their nutrition policies. The key learnings are as follows:

- Ensure you have a strong, legitimate public health objective for the measure that is based directly on evidence in relation to the pathways of effect for FOPL;
- FOPL should form part of a comprehensive package of policies aimed at achieving a clear public health objective;
- Ensure your evidence is strong and proves that your measure will help you meet your stated policy objective;
- Do not discriminate against products of different origins – eg, do not require a label to be displayed on products imported from a certain country or region but not on domestic products **and** do not discriminate between foreign investors or investments in 'like' circumstances;

- As much as possible, ensure your measure is based on international consensus, where relevant;
- Engage legal, trade and investment government officials early on in the development of mandatory FOPL to understand the broader legal implications and ensure due process is followed;
- Undertake multisectoral collaboration between health and investment sectors to ensure that public health measures are developed with an understanding of obligations under international investment law, and that investment and trade agreements with investment chapters are negotiated and drafted to ensure regulatory space for public health;
- Ensure due process is observed in any interactions between government and foreign investors in the policy development process in accordance with national law and establish a clear expectation that FOPL will be subject to ongoing regulation. Avoid specific commitments, undertakings or representations to industry that such regulation will remain unchanged. (26,61)

Common industry tactics used to challenge FOPL

Common tactics used by industry to challenge FOPL can be categorised into four main types: delay, divide, deflect and deny.







Opponents will:

- Push for longer consultation periods
- Push for more research and evidence to be collated

In France, the Ministry of Health requested a report on new policy areas that would be more effective in changing the food environment. Multiple policy options were put forward and one of the options chosen was the principle of a simplified interpretive front-of-pack label to help consumers choose their food. The agriculture industry and the Federation of Retailers both publicly came out against the label. They suggested their own labels and required the government to experiment with an array of labels to prove which was the most effective. After experimentation with five labels - including labels proposed by industry and retailers - industry further delayed the decision by suggesting further alternative labels that required testing. The government kept allowing experiments to occur and the researchers carrying out the experiments had known conflicts of interest. Nutri-Score proponents had a multitude of consistent scientific evidence to support each point of the label, which was ultimately adopted by the French Ministry of Health.(86)(85)

- Threaten litigation and/or trade action
- Argue that it is too difficult to implement administratively
- Propose their own FOPL measures as an alternative

>DIVIDE

Opponents will:

 Develop and promote their own labels. These are generally less stringent than the government's proposal and often confusing and uninterpretable.

In response to the introduction of **France's** Nutri-Score label, Mondelez International, Nestle, PepsiCo, The Coca-Cola Company, Mars and Unilever announced in early 2018 they would launch their own FOPL system called the Evolved Nutrition Label (ENL) in some EU countries. The ENL used portion size as a reference amount and measured the nutrients of concern against an adult's daily reference intake. By the end of 2018 all six companies had ceased pursuing the ENL, after the label was heavily criticised, stating there was insufficient consensus around what constituted an average portion size.(87)

In **Canada**, some Canadian food and beverage industry associations proposed either a 'Facts Up Front' (Guideline Daily Amount) label or a hybrid GDA/traffic light label instead of the proposed 'high in' nutrition symbol.(88)

- Argue for labels that are less interpretive
- Argue for voluntary labels over mandatory labels
- Attack every element of the label eg, the choice of format, the thresholds chosen
- Lobby politicians behind closed doors to stop regulation



DEFLECT

Opponents will:

- Claim any of the following:
 - Warning labels scare people
 - Labels are too simple, they will mislead people
 - The nutrient profile model is too strict, all foods, or no foods, are going to have the label (depending on the type of label)
 - Another label would restrict trade less or another policy measure would reach the same objective but restrict trade less
 - Industry self-regulation is working
- Reframe the issue to be about any or all of the following:
 - The impact on business or economy by restrictions on trade or job losses in manufacturing and agriculture
 - Identify physical inactivity or individual responsibility as the central issue
 - Nanny state governments should not interfere with people's food choices

Chile: "The World Trade Union, the food industry and some politicians objected to the law on the basis that it violated freedom of expression, was paternalistic and was naive as it ignored the complexities involved with food advertising."(79)

 Cost of food – costs of changes to packaging could be passed on to consumers, placing greater financial burden on consumers

>DENY

Opponents will:

- Claim there is not enough evidence to make decisions
- Cast doubt on existing evidence of effectiveness
- Argue that there is lack of agreement globally on the 'most effective label'
- Fund research and reports that showcase alternative policy options

In order to address these challenges, the next section outlines lessons learned throughout the policy process, including rebuttals of the arguments outlined above.



"Having advocated for tobacco control for many years, I have the feeling of, "Have I seen this movie before?" it's really strong, particularly in terms of industry interference. Seeing what they are doing in countries proposing warning labels is outrageous, regardless of all the evidence and very strong advocacy."

Paula Johns, Director General, ACT Health Promotion, Brazil



Lessons learned: advice on designing and implementing FOPL

Governments, civil society organisations and researchers all play important roles in the development, defence and implementation of FOPL. Lessons can be learned from experiences of countries that attempted to implement, are in the process of implementing, or have successfully implemented FOPL.

In order to combat common industry tactics and increase the likelihood of implementing an FOPL system, policymakers, advocates and academics from different countries were interviewed to provide lessons learned from their experiences of implementing FOPL.

Be prepared with evidence

- Be ready with sound, robust evidence to underpin the design of your proposed label and nutrient profile model, as well as estimated costs of implementation.
- Get consensus on the evidence from academia before taking action to show a united front against industry.
- Balance what you need and the timing of the scientific studies. Help researchers understand what evidence is needed (and by when) to support the policy process.
- Consider monitoring and evaluation of FOPL from the outset.





"Many arguments were used in opposition to the Nutri-Score, but we could respond easily enough because we had strong scientific data underpinning the label. We have data demonstrating people understand and use Nutri-Score and that it has a positive impact on purchases. It's not difficult to defend Nutri-Score, but perseverance is necessary and you have to be ready to react."

Prof Serge Hercberg, Director of the Nutritional Epidemiology Research Team (EREN), Paris 13 University, France

Carefully consider the local context

• Understand how the country's regulatory process works.



"I think that it is really important to build a relationship with the technicians involved in the process and understand how the process works. This is, I think, the first step. You need to be engaged in the regulatory process even before the main discussion starts. You need to know how the process works, who are the people involved from the private sector, how the private sector is involved, and how much the private sector knows about it. It is really, really important to understand the technical area within the regulatory process."

Ana Paula Bortoletto, Leader of the Healthy Diets Program at the Brazilian Institute of Consumer Defense (Idec), Brazil

• Have a thorough understanding of health literacy levels across the population.



"Locally designed independent studies which actually assess the performance of the label amongst consumers of different socioeconomic groups against a set of performance criteria such as comprehension, accuracy of interpreting whether a product is healthy or not healthy, how fast they're able to make that interpretation are really important to support the design and implementation of a policy."

Dr Modi Mwatsama, Honorary Assistant Professor, London School of Hygiene and Tropical Medicine, UK

Be strategic

 Be able to identify and ready to seize windows of opportunity.

> "Having funding and having people, a few people, people who know the subject, who can do research and can mobilise things quickly both in terms of research and advocacy, already working together, in order for things to go through so quickly."

Dr Ana Clara Duran, Research Scientist, University of Campinas, Brazil

- Governments must lead the policy process in order to counter the power imbalances caused by industry influence. It is a government's responsibility to protect and promote the health of their citizens, including safeguarding against conflicts of interest in the public health policy process.
- Governments must have their own established agenda before involving external stakeholders, so the principles of the labelling system that they want to develop are in place before opening dialogue with industry about specific format and technical details of the system.



"If it's not government-led, if it doesn't have that backing of government and the perceived credibility of the system that goes along with that, then really I think the system will fail ultimately and consumers won't pay attention to it."

Associate Professor Bridget Kelly, Early Start, University of Wollongong, Australia

- Engage with other departments of government, not just the department responsible for the regulatory process but also with other departments that can support the efforts.
- Adopt a transparent approach to stakeholder engagement to reduce any pressure or lobbying

 publish any correspondence received on the matter from external parties and any meeting notes online to allow the public to see the full political process.

Develop a broad base of support

- Map key actors from the beginning and decide how and when best to engage them.
- Engage the public health community in a manner that gives them as much information as possible.
- Engage technical teams of health authorities or relevant groups from academia and get support of international organisations like the World Health Organization, Food and Agriculture Organization and their national offices.
- Engage the media to ensure that the need for FOPL stays on the public's agenda



"We had a lot of support from the media – to the point Nutri-Score became a societal debate. There was an enormous amount of press due to the significant lobbying by industry against Nutri-Score, conflicts of interest, political pressures and the fact that it's a public health issue. We consistently put out press releases following the publication of scientific studies to encourage their uptake in media."

Prof Serge Hercberg, Director of the Nutritional Epidemiology Research Team (EREN), Paris 13 University, France Build and run a public campaign with the support of civil society organisations in order to gain public support for FOPL.

> "We did a lot of work to counter the myths industry were using. We had a comprehensive strategy to address the myths head on, we emailed MPs, we produced open letters and developed op-eds which we had placed in different newspapers, we ran e-advocacy campaigns, placed ads in different publications and used social media."

Manuel Arango, Director, Policy, Advocacy & Engagement, Heart & Stroke, Canada

Scrutinise the label design

 Ensure the label design meets the overall objectives set out and that the objectives are feasible.



"It's that real risk of if you implement a system that's not effective, it's really hard to undo it."

Professor Cliona Ni Mhurchu, University of Auckland and The George Institute for Global Health, New Zealand

- Scrutinise the label design from industry's perspective and from the viewpoint of those responsible for implementation. Locate any loopholes, correct them, and make the policy clear and enforceable.
- For voluntary labels, specify what 'sufficient' uptake is and outline the policy and legal repercussions of insufficient uptake.

Be prepared for push back

 Be prepared with solid arguments. Arguments are often technical, therefore, you need a strong technical team.



"I do not understand why global companies fight so hard against warning labels as they have the technology to reduce much of the sodium and added sugar, and all trans fats. On the one hand it forces enormous reformulation, and it does affect sales of their major products, but they have the technology to reformulate quickly as we found in Chile. However, it does cover 40-55% of the packaged foods and beverages and the Chilean warning label has shown this is extremely impactful in terms of reducing unhealthy food and beverage purchases. When linked with advertising bans it impacts the advertising sector, which then joins the political battles."

Prof Barry Popkin, Gillings School of Global Public Health, University of North Carolina, US

 Raise the issue of diet-related NCDs, including cancer, to help increase political and economic will. There is not a single country that is not facing the burden of diet-related NCDs.

"Governments can familiarise themselves with the tools and ways that industry interferes, the corporate playbook, be prepared to counteract."

Dr Modi Mwatsama, Honorary Assistant Professor, London School of Hygiene and Tropical Medicine, UK

- Prepare public health arguments for different audiences, including: industry, the public, public health professionals and different government departments (eg, finance, foreign affairs, agriculture).
- You also need people with 'soft' skills who have the capacity to negotiate and to convince others to defend public health.

"You need to help people understand by personalising the issue – it affects their families and children too."

Prof Ronit Endevelt, Director, Nutrition Division, Ministry of Health, School of Public Health Haifa University, Israel

 It is a government's role to protect the population's health, and this framing can rebut the arguments that obesity and food consumption is a matter of personal responsibility and not a place for governments to intervene.



"It takes a long time – it's not going to happen overnight. Perseverance is key."

Manuel Arango, Director, Policy, Advocacy & Engagement, Heart & Stroke, Canada

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"Nutri-Score took four years to implement. There were three types of hurdles we had to overcome: scientific, political process and legislative – both at the national and EU level."

Prof Serge Hercberg, Director of the Nutritional Epidemiology Research Team (EREN), Paris 13 University, France

Perfect storm: synergy for success

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The circumstances and series of events that lead to the successful implementation of FOPL are context specific and involve many different factors, however, common elements exist. Many theories of the policy process help explain how certain policies make it onto the political agenda and become implemented.(89–91) The implementation of health policies to prevent and control NCDs is a political process. Therefore, an exploration of the motivations and enablers of various implemented FOPL systems can allow for an analysis of the political process in order to understand the common elements that create synergy for success or a 'perfect storm' of political and public will to successfully introduce and implement FOPL.

Below, the motivations and enablers that supported FOPL implementation in **Chile** (warning label), **France** (Nutri-Score label) and the **UK** (traffic light label) are explored.



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- Increased supply, demand and consumption of processed and ultraprocessed foods
- High rates of overweight and obesity in the population
- Large diet-related NCD
 problem
- Rising healthcare costs stemming from overweight and obesity

- Strong conviction by government and members of parliament, including support from the President, regarding the urgent need to address the growing diet-related NCD problem
 - Political will from the Ministry of Health and some members of parliament
- Strong and influential policy entrepreneur (Senator Guido Girardi)
- Support from stakeholders including universities, civil society organisations and international organisations throughout the policy process
- Strong scientific basis for the proposal, supported by academic sector
- Research demonstrating that regulatory measures would be cost
 effective and help prevent obesity
- · Engagement by civil society organisations in consultation process
- Educational communications campaign on the concept of the warning labels
- Support from public and most stakeholders (in part due to strong public awareness of the warning labels)
- Strong evidence to support the legislation including national and international data to justify the proposed measures, costeffectiveness data, and evidence demonstrating mandatory measures are more effective than voluntary measures
- Framed as an innovative policy for preventing obesity
- Government was prepared to counter arguments brought against them by those opposing the measures
- Government led the regulatory process, and the implementation was an intersectoral process with the participation of food industry



• Minister of Health commissioned a report for new proposals to intensify measures to improve the health status of the French population, searching for innovative policy ideas that looked at wider environmental factors beyond individual responsibility

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- Earlier policy strategies had not had the intended impact
- A report was prepared on policy options by the president of the National Nutrition and Health Programme (PNNS) and the policy idea chosen by the ministry was simplified FOPL, which was subsequently included in the 2016 Health Law

- Multiple independent studies were conducted by the Nutritional Epidemiology Research team at Paris 13 University between 2013 and 2017, validating the nutrient profiling model underlying Nutri-Score and the label format
- Consistent results across studies showing the effectiveness of Nutri-Score held a lot of weight
- Extensive experimentation comparing multiple labels, under the umbrella of the Health Ministry, proved consistently that Nutri-Score was the most effective label
- Media was a strong ally and helped garner public support: articles were published and documentaries produced following the story of the label and highlighting the industry delay tactics
- Mobilisation of civil society organisations, including consumer associations
- French Health Promotion Agency was involved to translate the science behind the label into the label design, including testing the label
- A citizen-led petition on change.org supporting Nutri-Score received >250,000 signatures, which was well received by the Ministry of Health, as it demonstrated strong public support for Nutri-Score

UK

- M 0 T I V A T I 0 N
- Public nutrition emergency due to the BSE crisis (mad cow disease) decreased public's trust in government
- New Labour Party government created political will to improve public health and supported traffic light labels

- History of early research and pilots of FOPL in mid 1980s to 1990s led by civil society organisations and supermarkets working with academics
- Establishment of Food Standards Agency led to commitment to improve nutritional information for consumers
- Government commissioned research into food labels in early 2000s
- Government Action Plan introduced in 2004 committed to introduce FOPL within two years
- Chair of Food Standards Authority (FSA) championed labels
- FSA set up supporter group with civil society organisations and industry in support of traffic light labels that helped defend the traffic light labels
- Large supermarket chains piloted the traffic light labels before implementation
- Public will for more nutrition information on food
- The process was informed by evidence generated independently by academics, which helped with defending the labels against attack
- Supporters of the labels used evidence to show that labels would reduce inequalities, which helped defend arguments against labels
- By the time government changed in 2010, the traffic light labels were well established and could not be removed

Conclusion

FOPL that shows judgement or recommendation can help to create healthier food environments because they are more easily understood by consumers at all levels of literacy and also indirectly motivate companies to put healthier products on the market. FOPL is recommended by the WHO as part of a comprehensive approach to promote healthy diets and to reduce overweight, obesity and diet-related NCDs. Governments should consider the mandatory implementation of FOPL in order to overcome issues with uptake.

More action is urgently needed to reduce diet-related NCDs in order to meet related global targets. The policy process to develop, design and implement FOPL is context specific, non-linear and shaped by many different actors and factors. Governments can learn from the experiences of other countries that have implemented FOPL. Governments seeking to implement FOPL should consider their local context; build a strong evidence base; set clear and specific policy objectives; consider their international, regional, and domestic legal obligations including commitments under trade and investment law; carefully consider the design of the label; implement robust and transparent governance mechanisms to manage stakeholder engagement and potential conflicts of interest; integrate monitoring and evaluation early on in the policy development process and be prepared at every step along the way to defend the label from opposition. In order to increase the effectiveness of FOPL, it is important to protect the development of FOPL from conflicts of interest, to ensure the final design is as robust as possible and is able to meet the policy objectives.

Common barriers and challenges exist to the development and implementation of FOPL that are experienced by countries globally. These are often the result of opposition from industry, including the use of common tactics used to challenge FOPL, that can be categorised into four main types: delay, divide, deflect and deny. Sharing lessons learned from these experiences is extremely useful to other countries seeking to implement FOPL, as well as other public health nutrition policies. The evaluation of implemented FOPL systems is important to continue to build an evidence base to support action locally, regionally and globally.



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