

**Global Health
Advocacy Incubator**

Changing Policies to Save Lives



Key Legal Factors

For Developing
Front-of-Package
Warning Labeling
Regulations



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Introduction

Front-of-package labeling is an important tool that governments can use for addressing diet-related non-communicable diseases (NCD), particularly when they are part of a broader policy package. The World Health Organization (WHO) recommends front-of-packaging warning labeling (FOPWL) as a key policy to promote healthy diets and reduce NCD prevalence worldwide. The use of FOPWL is supported by decades of evidence demonstrating that it can effectively nudge consumers away from food and drinks high in sodium, sugar and saturated fat.

There are many different systems of front-of-package labeling used throughout the world today, and countries continue to innovate when developing front-of-package labeling measures. The Global Health Advocacy Incubator (GHAi) has worked extensively with country, regional and global partners to assess key factors for crafting strong and effective front-of-package labeling measures. Based on our experience and all available research, we strongly recommend the use of mandatory, warning-style labels (FOPWL) that highlight only negative attributes of unhealthy foods such as those with excess sugar, sodium, fat and excessive calories. Therefore, this document focuses on developing this style of front-of-package labeling. We also encourage complementary measures to be pursued in tandem with FOPWL, as its efficacy can increase when it is part of a broader package of food policies aimed at addressing multiple issues within food environments.



"We strongly recommend the use of mandatory, warning-style labels (front-of-package warning labels or FOPWL) that highlight only negative attributes of unhealthy foods such as those with excess sugar, sodium, fat and excessive calories."



Example

Argentina has enacted a mandatory FOPWL Law coupled with complementary regulations that include regulations on:

School environments: Products with at least one label are outlawed from being offered, marketed, advertised, promoted or sponsored in educational establishments of the initial, primary and secondary levels of the National Educational System. It also mandates public authorities to include nutritional and food education at these educational levels to promote healthy eating habits and warn about the harmful effects of inadequate nutrition.

Marketing restrictions: Marketing restrictions on products with at least one warning label are not allowed to be given for free or to contain children's characters, cartoons, celebrities (musicians, social media influencers, etc.), athletes, pets, gifts, contests or any other element that encourages their consumption or purchase. Furthermore, the legislation bans all children-directed advertising, promoting and sponsoring of products with at least one warning label.

Public procurement: The law establishes that the federal state should prioritize the purchase of foods and non-alcoholic beverages without warning labels.

Health/nutritional claims: The law bans products with at least one warning label from having complementary nutritional information and/or logos or phrases sponsored or endorsed by scientific societies or civil associations dedicated to medicine, nutrition and/or sports. Also, these products are prohibited from highlighting complementary nutritional statements that highlight any positive and/or nutritional qualities of the products, to avoid confusion regarding nutritional contributions.



These are the warning labels and warning messages of non-sugar sweeteners and caffeine set in the Argentinian legislation.



These are the warning labels to be included in products whose front side is 10 cm² (1,55 inches) or less. These products will contain a single octagon with the number of labels or warning messages within each product. For example, a number two on an octagon means that the products contain two nutrients of concern/ingredients that are over the cut-off point and/or that carry warning messages.

This document summarizes key factors for developing FOPWL from a legal perspective. It includes:

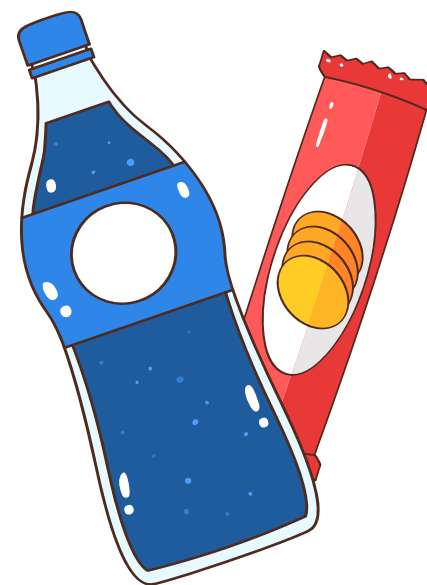
- [**1. Key legal factors for developing FOPWL**](#)
- [**2. References and additional resources**](#)

This is a working document, which GHAI will continue to update as we learn of new innovations and factors for developing strong FOPWL measures. GHAI is available to provide additional support and resources, including on research, communications and advocacy for FOPWL policy-advocacy work.

Key legal factors for developing front-of-package warning labeling (FOPWL)

The list below includes information and legal recommendations related to **15 topics** that GHAI has identified as key legal factors for developing strong FOPWL measures:

- (1). Legal grounds to support the advancement of FOPWL regulations**
- (2). Existing measures regarding labeling and other related issues**
- (3). Definitions**
- (4). Scope of the measure**
- (5). Exclusions**
- (6). The measure's objectives**
- (7). Label design**
- (8). Nutrients of concern**
- (9). Nutrient Profile Model (NPM)**
- (10). Complementary measures**
- (11). Implementation, monitoring and evaluation, and enforcement**
- (12). Due process and notification requirements**
- (13). Implementation schedule**
- (14). Evidence and research**
- (15). Industry**



Details and examples are provided throughout. This document is meant to guide **legal aspects** of developing FOPWL measures. It should be complemented by other specialties, including research and advocacy.

(1). LEGAL GROUNDS TO SUPPORT THE ADVANCEMENT OF FOPWL REGULATIONS

Advocates can leverage different areas of law to support the advancement of FOPWL policies depending on the jurisdiction's laws framing according to local contexts. This could also inform the regulatory objective and the policy goal. These are -but not limited to-the following:

- a. Consumer protection law:** Consumer protection plays a pivotal role in shaping FOPWL regulations by safeguarding the interests and rights of consumers, so they are provided with clear, accurate, transparent and sufficient information about the nutritional content and potential health risks associated with packaged food products. Moreover, FOPWL regulations can prevent, minimize, counteract and dissuade misleading claims and deceptive marketing practices on unhealthy foods and beverages and also trigger enforcement mechanisms and consumer protection authorities' action. For instance, if there is a lack of compliance by companies with FOPWL requirements, this could be deemed deceptive as it could cause confusion on consumers' understanding about the levels of nutrients of concern present in a product, which could open the door for consumer defense measures.
- b. Human Rights Law:** Enacting FOPWL regulations is a manifestation of the government duties to respect, protect and fulfill multiple interconnected human rights:
 - i. Right to Health:** A human rights-based approach recognizes the right to the highest attainable standard of physical and mental health. A robust FOPWL policy furthers the right to health by providing clear, accurate and easily understandable information about the nutritional content of food products. This empowers individuals to make informed choices and contribute to their overall health and well-being, while also improving food environments.
 - ii. Right to Access Information:** The right to access information is a fundamental human right that facilitates informed decision-making. A comprehensive FOPWL policy should guarantee consumers' right to information about the health impact of food products. This includes prominently displaying key nutritional information and utilizing user-friendly symbols or warning labels to indicate the healthiness of a product.
 - iii. Right to Adequate Food & Nutrition:** A human rights-based approach requires considering the



right to adequate food in the development of FOPWL and complementary nutrition policies. Healthy food policies should encourage the availability, accessibility and affordability of healthy food options while discouraging the consumption of unhealthy foods. By promoting healthier choices, FOPWL policies contribute to the realization of the right to adequate food and nutrition and address some of the systemic factors that hinder its fulfillment.

iv. Right to a Healthy and Clean Environment: The substantive elements of this right entail, among many others, the access to healthy and sustainably produced food and safe water. Unhealthy foods and beverages high in nutrients of concern tend to be ultra-processed or processed products linked to unsustainable practices and harms to the environment across their entire supply chain. These include the use of pesticides, monoculture practices linked to biodiversity loss and soil exploitation, abuse of hydric resources and others. Since FOPWL facilitates purchasing decisions decreasing the consumption of these unsustainable products, it is a policy that fulfils this fundamental human rights.

v. Right to Non-Discrimination: FOPWL can advance the right to non-discrimination by ensuring equitable access to information and promoting health equality among diverse communities. It provides easily understandable information about the nutritional content and health risks associated with certain products high in nutrients of concern. FOPWL empowers consumers to make informed choices irrespective of their background, education or socio-economic status. *Please visit [GHAI's Right to Health Hub](#) to review relevant human rights resources to support the development of FOPWL policies.*

c. Public Health Law: Front-of-package labeling regulations are inherently linked to public health objectives related to NCD prevention and health promotion. Public health law serves as a critical foundation for developing and implementing FOPWL regulations linked to public interest law and preventative/precautionary principles applied to regulation of risk.





Example: In Peru, Law No. 30021/ 2013 for the Promotion of Children and Adolescents' Healthy Eating states in its article 1:

Article 1. Objective of the Law

The purpose of this law is the effective promotion and protection of the right to public health, the adequate growth and development of people through educational actions, the strengthening and promotion of physical activity, and the implementation of healthy kiosks and canteens in regular basic education institutions and the supervision of marketing, information and other practices related to food and non-alcoholic beverages aimed at children and adolescents to reduce and eliminate diseases linked to overweight, obesity and chronic illnesses known as non-communicable.



Example: In Argentina, article 1 of the Law 27.642 sets the policy goal for the FOPWL policy package:

This law aims to:

- a.** *Ensure the right to health and adequate nutrition through the promotion of healthy eating, providing simple and understandable nutritional information for packaged foods and non-alcoholic beverages, to encourage assertive and active decision-making and safeguard the rights of consumers.*
- b.** *Warn consumers about excessive components such as sugars, sodium, saturated fats, total fats and calories, based on clear, timely and truthful information in accordance with Articles 4 and 5 of Law 24,240, Consumer Protection.*
- c.** *Promote the prevention of malnutrition in the population and the reduction of non-communicable chronic diseases.*



(2). EVIDENCE AND RESEARCH

In the early stages of planning a FOPWL measure, such as when research studies are developed and evidence is gathered, legal considerations should not be overlooked. These preliminary steps can have legal implications later on, impacting how effectively a measure is eventually implemented, and whether it can withstand legal scrutiny. Therefore, it is important to have multidisciplinary teams involved in early planning phases, including in developing research and gathering evidence.

FOPWL measures should be evidence-based. To the extent possible, local research without conflicts of interest should inform how FOPWL is designed. Global evidence and examples from other countries – particularly when they have regional and other similarities – can further support the measure.

Research is crucial for informing many components of FOPWL, including but not limited to the type of label and its design, the NPM and the measure's objectives.

Throughout the process of developing a FOPWL measure, the government should document the evidence it relies upon. This should include evidence supporting the components of the measure, as well as evidence demonstrating that options it declined to utilize were less appropriate.

(3). EXISTING MEASURES REGARDING NUTRITION LABELING AND OTHER RELATED ISSUES

FOPWL should be drafted by a government authority to fit within existing regulatory systems to the extent possible. This enables regulators to use and build upon existing implementation, monitoring and evaluation, and enforcement structures, which reduces the regulatory burden of FOPWL. It also helps ensure that consumers have consistent and reliable information. However, if existing measures for nutrition labeling contain problematic provisions, such as missing key nutrients, it may be important to amend them before or while establishing FOPWL.

Conducting a preliminary legal analysis is important for understanding what relevant measures exist: if they are strong and evidence-based and if they are being effectively implemented.

- a.** FOPWL is considered supplemental nutrition labeling. It is typically developed after back of pack labeling (BOPL), which lists ingredients and nutritional table/information, has been implemented.
- b.** If existing measures are weak or problematic, you may need to amend them before or while developing FOPWL so that such issues are not incorporated into the FOPWL measures as well. If such measures are strong, then you can incorporate elements of them – such as definitions ([See the Definitions section below for more detail on this topic](#)) – into the FOPWL measure.
- c.** Assessing if and how well related measures are being implemented can help inform how to construct an effective FOPWL measure. For example, if related measures are not being enforced, assess why that is – perhaps there are resource constraints, relevant government bodies do not have appropriate powers or political will, or governments have insufficient access to labs or other resources to effectively implement and enforce the requirements.

Relevant measures to analyze include BOPL; the use of claims such as nutrition and health claims; other aspects of labeling, such as restrictions on imagery on labels, like cartoon characters and fruit; and the use of robust NPM, dietary guidelines, and similar policies.



Example: In Mexico, FOPWL regulations were passed through an amendment to the [General Health Law](#) from 11/29/2019 regarding overweight, obesity and FOPWL for food and non-alcoholic beverages. Accordingly, amendments were incorporated into the [NOM 051 NOM-051-SCFI/ SSA1-2010](#) on the technical aspects of the FOPWL, ensuring consistency with existing regulations.

(4). DEFINITIONS

- a.** Check existing measures for relevant definitions. Many key FOPWL terms are likely defined in existing measures, such as definitions for food, prepackaged or prepacked food, processed and ultra-processed foods, relevant nutrients, nutrients of concern, labeling, front-of-pack, claims and more. It is very important to ensure consistency throughout the regulatory framework to foster policy coherence and avoid confusion or difficulty in interpretation.
- b.** Ensure that existing definitions are strong, clear, enforceable, operative and usable for FOPWL. If they are problematic, consider what steps are needed to amend them. Also, consider lessons learned on FOPWL from other countries to mitigate the industry from leveraging legal loopholes.
- c.** If existing definitions are workable, it can be important to use them for the FOPWL measure. This helps ensure that FOPWL can fit within and build upon the country's existing food regulatory system.



Examples of key definitions to inform the FOPWL measure

Colombia

Sweetener: any substance other than added or free sugars that provide a sweet taste. (Art. 2 (3.19), Resolution No. 2492/2022 which amends Art. 3 of Resolution No. 810/2021)

Ultra-processed food: those elaborated in a technological transformation process, where salt, sugar, fat or other ingredients are added. These have more than five ingredients and/or additives and less than 50% of the ingredients are unprocessed or barely processed food.

Mexico

Main display surface: It is the area of the packaging's labeling, excluding the sealing and splicing areas, where the name and trademark of the product are among others, and its dimensions are calculated according to the NOM-030-SCFI-2006. (Art. 3 (3.49), NOM 051/2020).

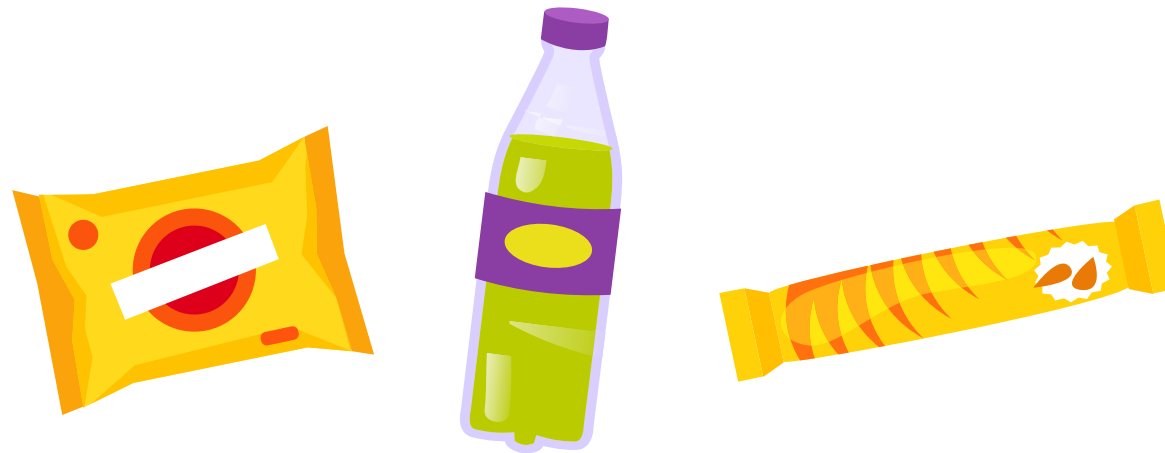
Venezuela

Manufactured products are defined as any food product which has been put under a technological or crafted process in order to transform, modify, preserve and prepare those, which are sold and distributed to people in packages approved by the authorities, with high content of sugar, trans fat or saturated fat.

See [GHAI comparative table of FOPWL regulations around the world](#) to check other relevant definitions.

(5). SCOPE OF THE MEASURE

- a. FOPWL should be mandatory for all applicable products based on a robust NPM. The scope of a FOPWL policy should clearly outline which products are covered, which ones are excluded, which nutrients/additives are considered, and what nutritional thresholds were used to categorize those products, as it will be explained in the following sections.
- b. In order to properly define the policy scope, the specific wording should be tailored to the country's existing regulatory system, if possible; common options include “prepackaged food”, “prepacked food”, “food ready to be consumed”, among others. Ensure that prepackaged drinks are included in the definition.
 - i. Oftentimes, these terms are already defined in existing measures or recommendations, such as BOPL or national dietary guidelines. Unless there are issues with how they are drafted, incorporate these definitions into the front-of-package labeling measure, so that it is well aligned with the existing regulatory system.
- c. Exclusions should be narrow. ***(See point 6 below)***





Examples of measures' scopes

European Union regulations applicable to front-of-package labels

Prepacked food: "Means any single item for presentation as such to the final consumer and to mass caterers, consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, but in any event in such a way that the contents cannot be altered without opening or changing the packaging; 'prepacked food' does not cover foods packed on the sales premises at the consumer's request or prepacked for direct sale".

"This Regulation shall apply to food business operators at all stages of the food chain, where their activities concern the provision of food information to consumers. It shall apply to all foods intended for the final consumer, including foods delivered by mass caterers, and foods intended for supply to **mass caterers**."

Argentina

It defines "**packaged product**" as any food contained in a packaging, regardless of its origin, packaged in the absence of the customer, ready to be offered to the consumer. Moreover, as the law is based on PAHO NPM, according to the PAHO cut-off points set to the nutrients of concern for food and non-alcoholic beverages, the FOPWL shall be applied for products packed in the absence of the consumer, with added sugar, fat, sodium, sweeteners and/or caffeine. (Art 2 (j), Law 27.642; Arts. 2 (j), 4, 6, 8, Annex I, Decree No. 151/2022).

Mexico

"**Prepackaged product**": Non-alcoholic food and beverages packaged in the absence of the consumer, being the amount of product contained in it unmodifiable, without opening the package.

See [GHA1 comparative table of FOPWL regulations around the world](#) to check other relevant definitions under the "covered products" row.

(6). THE MEASURE'S OBJECTIVES

- a. When drafting a FOPWL measure, it is important to identify the public health problem that it is meant to address. This should inform the drafting of objectives, against which the success of the measure can be assessed.
 - i. From a legal perspective, the stated objectives might differ from other research or advocacy documents because their purpose is distinct: they are intended to frame the government's work on FOPWL in a way that could help withstand a legal challenge. Many public health measures are challenged based on how clearly their objectives are defined and linked to the measures' goals and supporting evidence. *(Further information on developing the measure's objectives is available in GHAI's resource, [Legal Issues in the Design and Implementation of Public Health Measures.](#))*
- b. Objectives should be layered and link the measure to a broader public health goal and explain how FOPWL fits within the government's broader and mid-to-long-term efforts to meet that goal.
- c. Objectives should be supported by evidence that is free from conflicts of interest. Governments should document all the evidence they rely upon for developing the FOPWL measure, including the objectives.
- d. The measure's objectives are important from a legal perspective, as they can be relevant for defending against domestic and international legal challenges. With regards to international challenges based on trade law, note that trade law principles allow governments to set their own risk tolerance in relation to their health goals; trade law challenges can only question the measures that countries take to address an articulated public health problem. *(Further information on this issue is available in GHAI's resource, [FOPWL – preparing for and responding to international trade law arguments](#))*



Policy objectives for FOPWL

Note that objectives should be tailored to the country context, including which nutrients of concern are included.



Examples of policy objectives of implemented regulations

Argentina

Guarantee the right to health and to an adequate diet, through the promotion of healthy eating, giving simple and clear nutritional information to consumers, regarding prepackaged food and non-alcoholic beverages, in order for people to make informed and assertive decisions, preserving their rights as consumers to warn consumers about the excess of nutrients of concern in food and non-alcoholic beverages products; and to promote the prevention of malnutrition and NCD. (Art. 1, Law No. 27.642/2021)

Mexico

Establish commercial and sanitary information that any label for prepackaged food must have, and also implement a FOPWL system which must warn in a clear and truthful way about nutrients of concern and the presence of ingredients that may put people's health at risk when consumed in excess. (Art. 1, NOM 051)

Peru

Effective promotion and protection to the right to public health, adequate people's growth and development through actions of education, promotion of physical activity. Also, the implementation of healthy kiosks and canteens in educational centers. It also aims to regulate advertising and information directed to children, regarding food and nonalcoholic beverages containing nutrients of concern, to prevent and mitigate obesity and other NCD. (Art. 1, Law No. 30021)

See GHAI comparative table of [FOPWL regulations around the world](#) to check other relevant definitions under the “policy goal” row.

(7). EXCLUSIONS

- a. The list of product exclusions should be narrow and defined in a way that does not allow for many products to be included under the exclusion.
- b. When considering exclusions, it is important to avoid discrimination, when possible, to decrease trade law concerns. Discrimination means foreign products are treated differently than domestic products, or products from different countries are not treated the same. Discrimination is problematic even if it is inadvertent. If any discrimination is unavoidable, ensure that there is a documented health justification. *(For more detail on this issue, see GHAI's resource, [FOPWL – preparing for and responding to international trade law arguments](#))*
- c. For small packaging, it is preferable to have alternative formatting options rather than categorical exclusions. *(See point 8 below)*



Examples of excluded products from FOPWL

Argentina

Regular sugar, vegetable oil, nuts and regular salt. Also, natural products without any added nutrients of concern. The cut off points are not applicable for food with specific medical purposes, vitamin supplements and baby formula up to 36 months.

Colombia

A) Infant formula for children between 0 and 6 months. B) Infant formula for children between 6 and 12 months. C) Special infant formula. D) Food for Special Medical Purposes (APMES). E) Single ingredient products that do not contain additional additives. F) Iodized and fluorized salt and salt substitutes. G) Foods with the packaging of natural origin materials. H) Herbal and fruit infusions; tea, decaffeinated tea, instant or soluble tea, or tea extract, decaffeinated tea extract: decaffeinated coffee, ground coffee, instant or soluble coffee, or coffee extract, or decaffeinated coffee extract, which do not contain added ingredients. I) Food in bulk. J) Foods used as raw material for the industry and secondary ingredients that are not sold directly to the consumer. K) Packaged foods with no added salt/ sodium and/or fats or sugars. L) Hydrating energy drinks for sportsmen and women. M) Unprocessed foods. N) Minimally processed foods. O) Typical or artisanal foods and beverages.

Israel

Fruits, vegetables, mushrooms and fresh seaweed, meat that has not undergone processing, fresh eggs in their shells, food that has been prepared in an eatery, food that has been prepared at the consumer's request at its time of sale, food that has been prepared in a catering business for the purpose of supplying it for consumption outside the place where it has been prepared and excluding prepackaged food for retail sale; nutritious supplements; infant formulas food that has only one ingredient — except when vitamins or minerals are added under laws requirements or has a flavor/scent added, without changing its intrinsic nutritional value; food packages for major sale -not retailing- some species; alcoholic beverages; salt, vegetal oils without additives; products whose packages are too small; diet soda.

See [GHA comparative table of FOPWL regulations around the world](#) to check other relevant definitions under the "excluded products" row.

(8). LABEL DESIGN

- a. When developing a FOPWL measure, many detailed elements of the labels' design should be carefully selected. Argentina and Mexico's FOPWL measures have detailed specifications of the label design, which can serve as an example for other countries.
- b. There are multiple front-of-package labeling models around the world. Nevertheless, considering that these policies should inform consumers simply and quickly about the content of nutrients of concern in a product while discouraging the purchase of unhealthy packaged food, the **"high in" of "excessive" warnings are the most effective label design to fulfill that objective.** The evidence to date demonstrates that FOPWL **reduces**:
 - i. Consumers' perceptions of healthfulness compared to other front-of-package label types.
 - ii. Consumers' intentions of purchasing products containing high levels of nutrients of concern.
 - iii. The percentage of products on the market with high levels of sugars and sodium, based on Chile's experience within the first year of the policy's implementation.



For more information about the evidence, please review [GHAI's Evidence Sheet on front-of-package labels](#) or this [resource](#) from the University of North Carolina at Chapel Hill's Global Food Research Program. PAHO includes useful information [here](#))

- c. Existing regional and global evidence can add further support for FOPWL design decisions. Sources of such evidence include:
 - i. GHAI strongly recommends focusing efforts on this type of label. It is important for governments to document that they considered other label designs and the evidence they relied upon when choosing warning-style labels.
 - ii. Resources from international institutions, such as the WHO and its regional offices, recommending that governments adopt FOPWL as a tool to promote healthy diets and reduce the prevalence of diet-related NCD.
 - iii. Evidence generated by countries that have implemented FOPWL. Such examples may be particularly useful if there are regional and other similarities among countries. It is also important to note that evidence evolves and regulations must do so as well. (See [GHAI's comparative table of FOPWL systems around the World](#))
 - iv. Global trends in the development of FOPWL systems. (For example, see maps below)
- d. As it has been highlighted, many countries are adopting FOPWL. This labeling scheme highlights excessive amounts of key nutrients of concern.
 - i. GHAI strongly recommends focusing efforts on this type of label. It is important for governments to document that they had considered other label designs and the evidence they relied upon when choosing warning-style labels.
 - ii. **Contact GHAI for additional evidence on the effectiveness of warning-style front-of-package labeling and why this is often the best type of measure for achieving countries' policy objectives.**
- e. Even if the recommended warning is not implemented, it is important to consider the following factors for the FOPWL design more broadly:
 - i. The type of label that will be used. (See example box below for various types of labels)



****Note that GHAI strongly encourages the use of warning-style labels, as there is a large and growing body of evidence supporting that such labels best meet the objectives of the countries where we work.***

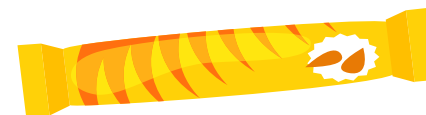
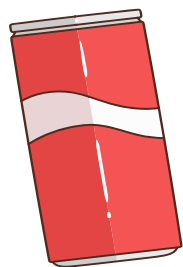
- ii. The nutrients that will be included and the NPM that establishes thresholds for the products to carry labels. *(See [points 9 and 10](#) for more details).*
- iii. The shape(s) that will be used for the type of label selected. Countries may consider using different shapes, such as octagonal warning-style labels for key nutrients of concern for the entire population, along with additional rectangular labels for nutrients that are of particular concern for children – such as caffeine and non-nutritive sweeteners.
- iv. The phrasing and/or symbols that will be used on the labels.
- v. Choice of font for any text on the labels.
- vi. Formatting details for the labels' buffer zone – an area where text is not permitted around the labels – and borders, including their width and positioning.
- vii. Colors of the background, border, text, outlines and any other aspects of FOPWL design.
- viii. Size specifications for the labels, including alternative label designs for small packages. Note that it is preferable to use alternative labels for small packages, rather than exclude such products from FOPWL requirements.
- ix. Inclusion of an endorsement from the government or trusted scientific institution (e.g. Ministry of Health) to increase credibility.
- x. Restrictions on the use of certain colors, shapes or designs near the front-of-package labels on the package. This ensures the front-of-package labels are not obscured and remain clearly visible to consumers.
- xi. For nutrient specific front-of-package label systems, the order in which nutrients are displayed and the possible ways that they can be arranged should be specified to ensure consistency.

xii. Specifications about where on the package the labels are placed should be included according to packages' various shapes, so they are consistently in one area of the package and readily visible (e.g. the top right corner on boxes and bags). Some shapes, such as cylindrical containers, pose unique challenges for ensuring they cannot be displayed in ways that obscure the front-of-package labels. It is important to ensure that labels are on the main display panel of products and that these are displayed at points of sale. It is also important to assure that the warnings are not inserted in a way that once the package is opened, they are stripped away from it.

f. Decisions about these key aspects of the label design should be informed by local evidence as much as possible. However, international evidence can also be used to support advancement of FOPWL policies to support public health.

i. Such evidence should demonstrate that the label design was selected to address the specific public-health problem the government identified and meet its policy objectives. For instance, mandatory front-of-package octagonal warning labels have shown to be the best performers in terms of informing consumers and change purchasing decisions to discourage consumptions of these products.

ii. It is important that the government document this decision-making process, demonstrating that it considered various options and made selections that best meet its objectives.





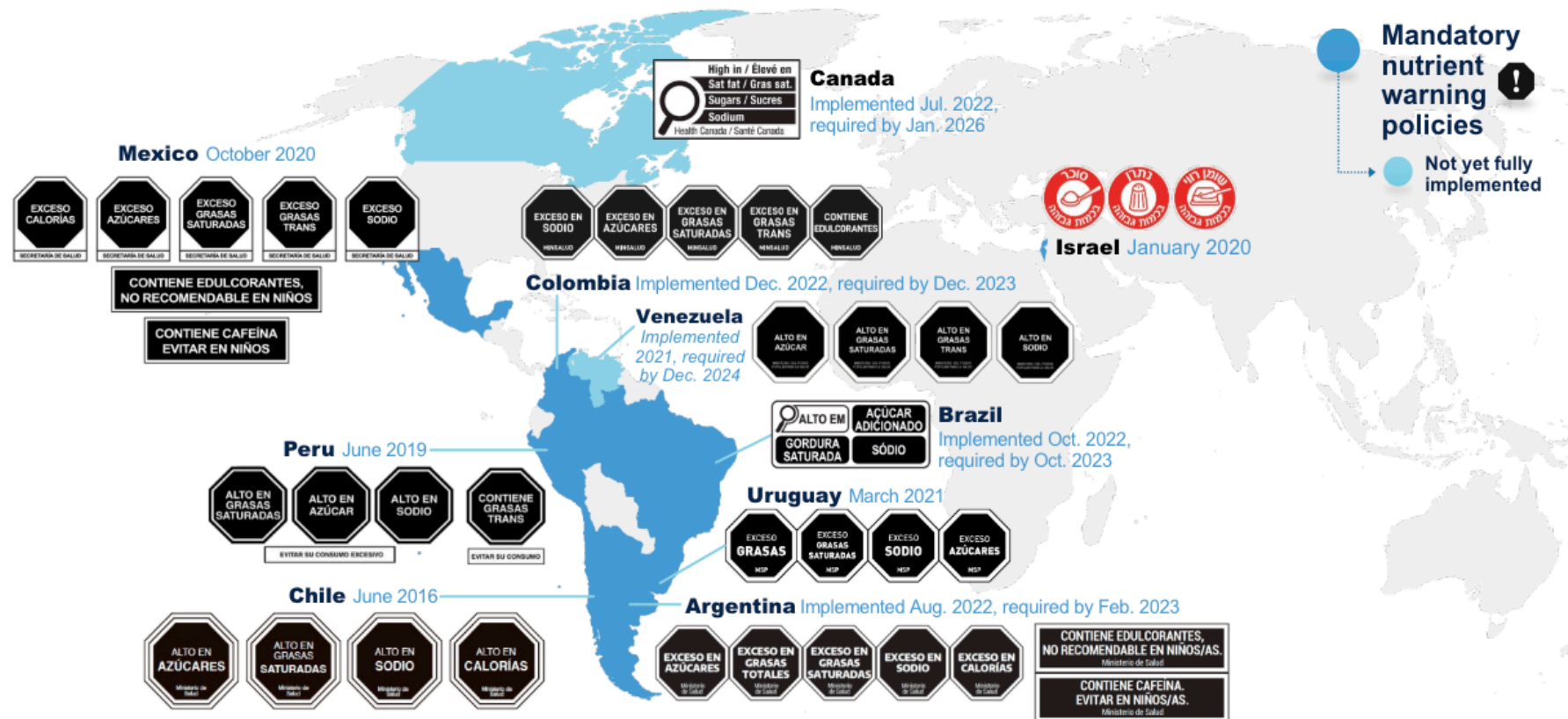
Example: maps illustrating various FOPWL systems around the world and the growing trend to use mandatory warning-style FOPWL

Front-of-package labels around the world

Global Food Research Program
UNC-Chapel Hill



Front-of-package labels: Mandatory nutrient warnings



GLOBAL FOOD RESEARCH PROGRAM at UNC-CHAPEL HILL

Updated March 2024. © Copyright 2024 Global Food Research Program at UNC-Chapel Hill
 Base map copyright © FreeVectorMaps.com

(9). NUTRIENTS OF CONCERN

a. Nutrient-specific FOPWL systems, such as warning-style labels, require selecting which nutrients are to be included. This section provides guidance on selecting key nutrients to include for warning-style labels known as “nutrients of concern.”

b. Local and regional evidence should guide the determination of which nutrients should be included in FOPWL, to the extent that such information is available. The nutrients of concern should be tailored to the measure’s objectives. Typically, such objectives are related to addressing diet-related NCD so it is useful to have evidence about which nutrients are of particular concern in the country.

c. Global evidence about nutrients contributing to diet-related NCD and information learned from countries that have enacted FOPWL offer additional guidance for determining which nutrients should be included in FOPWL.

i. From this perspective, key nutrients to consider are:

- Sodium / salt
- Sugar
- Saturated fat
- Trans fat

ii. Some countries have included warning labels for total energy and total fat. However, these are not priorities, since products high in energy (kcal) are not necessarily unhealthy, and total fat includes healthy fats.

d. Recently, some countries have added additional labels for nutrients, additives, ingredients that are of particular concern to children – caffeine and non-sugar sweeteners. It is important to document evidence supporting the inclusion of such labels. ***GHA’s research team can provide information about what research is currently available and how countries have used the precautionary principle.***

i. Mexico has included these additional labels with the phrasing:

- “contains caffeine, not suitable for children,” and
- “contains sweeteners, not recommended for children.”

- ii. Note that it is important to tailor this terminology to the local context and carefully draft definitions. For example, if the term “sweeteners” is used, it should be clearly defined to encompass non-sugar sweeteners only (if that is the intended meaning).



Example: Mexico’s FOPWL measure includes general nutrients of concern in octagons and rectangular labels for nutrients of particular concern to children




(10). NUTRIENT PROFILE MODEL

- a. For FOPWL, a NPM is needed to determine the thresholds for and definitions guiding which products should be labeled. The WHO defines nutrient profiling as “the science of classifying or ranking foods according to their nutritional composition for reasons related to preventing diseases and promoting health.” [Please see our NPM position paper for more comprehensive information.](#)

- b.** Nutrient profile models help decision-makers implement food policies that promote and protect healthy diets, and subsequently prevent NCD. Implementation of robust and evidence-based NPMs are necessary for public health, as NPM will guide the design, implementation and ultimate impact of multiple healthy food policies.
- c.** A NPM will play a role in determining the scope of the measure. *(See point 5)* Within the broad category of products that may be subject to a FOPWL measure – such as prepackaged products or ultra-processed products – the NPM establishes a subset of products for which FOPWL may be applied.
- d.** Exclusions within the NPM should be narrow and evidence-based. It is important to avoid discrimination whenever possible, to decrease trade law concerns. *(See GHAI's resource, [FOPWL – preparing for and responding to international trade law arguments, for more details on this topic](#))*
- e.** NPMs may be used for other food measures as well, such as marketing restrictions and public procurement.
 - i.** When conducting the preliminary legal analysis (see point 1), it is helpful to check whether there are any existing NPMs used in the country context. If so, these NPMs should be analyzed by nutrition and technical professionals to determine if they are a good fit for FOPWL. If they are not a good fit, then consider whether any existing measures need to be amended when developing FOPWL to ensure that there is a well synchronized food regulatory system.
 - ii.** Consider whether the country is pursuing any complementary measures in tandem with FOPWL, like marketing restrictions or public procurement mandatory guidelines. It can be helpful to assess from the outset whether a potential robust NPM would work well across these measures to harmonize the policies and facilitate implementation and government enforcement.

Based on the best available evidence, GHAI has put together key recommendations for governments to consider when designing NPMs. Governments are encouraged to adopt and implement a NPM based on strong scientific evidence free of conflict of interest. They should also consider the lessons learned in other countries through the following:

- 
- a.** Guarantee that the adoption process remains unaffected by food industries and other corporate stakeholders.
 - b.** Adopt PAHO, SEARO, AFRO regional NPMs to define products excessive in nutrients and ingredients of concern with adaptations to the country context when needed. These established models represent the highest standard to identify food and beverages with excessive amounts of nutrients and ingredients of concern, and their adoption requires fewer resources than the creation of a new NPM as it is less time consuming and is more appropriate for the entire population covering different age groups including children.
 - c.** Include all nutrients and ingredients of concern in a NPM, incorporating sodium, sugar, saturated fat, trans fat and non-sugar sweeteners (NSS).
 - d.** Use a strict criterion of at least 5% for sugar in liquids (5% of total calories).
 - e.** Adopt the NPM only for two categories – solids and liquids - for each nutrient/ingredient of concern so implementation and enforcement are feasible.
 - f.** Monitor the emerging evidence and lessons learned on an ongoing basis to continue improving the standards and the protection the right to adequate food.

(11). COMPLEMENTARY MEASURES

- a.** Leverage the opportunity to advance other complementary food and nutrition measures as well. Such additional initiatives can help support the goals of FOPWL and ensure that consumers are not receiving conflicting information about a product – on the package itself or from other types of marketing.
- b.** Remove health/nutritional claims or declarations and cartoons or other elements that can capture children's attention from all products with warnings to avoid confusion and deception and to restrict/prohibit the marketing of these products. Some complementary labeling requirements should:
 - i.** Prohibit/restrict the use of positive claims – such as nutrition, health and comparative claims – on products that qualify for FOPWL. Such claims are used by industry as a form of marketing and are intended to make a product appealing to consumers. This conflicts with the purposes of



FOPWL which are meant to help consumers clearly and quickly identify when products contain high levels of nutrients of concern.

- Some countries that have implemented this approach; for example, Mexico's FOPWL measure prohibits any claims related to nutrition properties on products that have at least one warning label.
- ii.** Ban the use of cartoons, children's characters, celebrities and other images and messages that are appealing to children – whether they are on the package itself or otherwise visible to consumers, for all products that have at least one FOPWL.
- Argentina's law establishing FOPWL serves as a useful example, prohibiting: "Children characters, animations, cartoons, celebrities, athletes or pets, interactive elements, the delivery or promise of gifts, prizes, presents, accessories, stickers, visual-spatial games, digital downloads, or any other elements, as well as the participation or promise of participation in contests, games, sports, musical, theatrical or cultural events together with the purchase of products with at least one regulated nutrients in excess, that may incite, promote or encourage the consumption, purchase or choice thereof."
 - Avoid loopholes by specifying that the banned images and messages for products with FOPWL may not be visible in any form (beyond the packaging itself) when the product is presented for sale. Industry could use this loophole to present images in other places than the packaging. For example, such images and messages should not be permitted in food displays, price and promotion tags, the clothing or accessories of grocery and food workers or any other components of the environment where such products are sold.
- iii.** Require FOPWL on all panels of a package that are designed in ways that could potentially be used as the primary display panel. This will prevent companies from designing products that can be displayed in a way that occults the FOPWL from consumers at point of sale. Additionally, products could be required to display its FOPWL in manner that is direct and visible to consumers.
- Front-of-package labeling should be coupled with other healthy food policies to reduce the demand of UPPs and provide accessible, affordable, fresh, healthy and nutritious foods.



Example: Mexico's FOPWL measure bans these types of child-appealing images on packages. Companies put cartoons on the food itself, displaying this imagery through clear packaging or in photographs of the product on the package. Companies also put these cartoons on grocery store workers' clothing and accessories.



Please reach out to GHAI for additional information about these complimentary measures, including what is current best-practice and available supporting evidence.

(12). IMPLEMENTATION, MONITORING AND EVALUATION AND ENFORCEMENT

- a. When developing a FOPWL measure, consider implementation, monitoring and evaluation and enforcement from the outset.
 - i. Build these considerations into the measure, as much as possible. For example, consider whether existing government bodies have sufficient authority, personnel, resources, training, and political will to effectuate, monitor and evaluate the measures. If not, determine what gaps need to be filled and whether some of them can be addressed in the measure itself, such as creating a funding stream for ongoing implementation efforts.
 - ii. Identify or generate baseline data. Such data is important for being able to assess the measure's impact and its effectiveness in achieving the policy objectives. *GHA's research team can provide guidance on types of data that can be useful to collect.*
 - iii. Develop metrics that can be used for ongoing assessments of the measure's efficacy. These metrics should also be tied to the policy objectives.
 - iv. Include protections against conflict of interest into implementation, monitoring and evaluation and enforcement mechanisms. For example, the government should ensure that those tasked with evaluation do not have financial conflicts of interest, or any other ties with relevant industries.
 - v. *The WHO's Guiding principles and framework manual for front-of-package labeling for promoting healthy diet provides additional guidance on developing system monitoring and evaluation measures – particularly [Table 1](#) on pages 21-22.*
- b. Establish a strong enforcement system that includes a range of penalties, which accounts for the type of offender, egregiousness of the offense and one-time versus repeat violations.
 - i. Product recalls can be an important deterrent; they can be particularly impactful for large companies that might care less about fines, which they could view as a cost of doing business.
 - ii. Complaint systems (new or building off an existing one) create avenues for consumers and civil-society organizations to raise complaints.
 - iii. Determine if any initial support is needed for small- and medium-size enterprises (SMEs) for compliance. Governments can provide training and/or facilitate information-sharing from large companies to SMEs, to help ensure that all segments of the industry are able to implement the measure.

(13). DUE PROCESS AND NOTIFICATION REQUIREMENTS

- a.** When developing a FOPWL measure, it is important to ensure that all mandatory government processes are followed. This includes domestic due process requirements, as well as regional and international trade and investment law obligations.
- b.** Specific domestic due process requirements vary by country and the type of measure being developed.
 - i.** A common example is the notice-and-comment period, in which a government publishes a draft regulation and specifies a timeframe during which the public can submit comments; typically, the government must then follow specified processes for reviewing those comments and developing a final regulation.
- c.** Countries also have process requirements that derive from regional and international trade and investment law agreements. Such obligations will vary based on the agreements a country has joined.
 - i.** For example, the World Trade Organization (WTO) advises its members to announce new measures that may potentially impact trade. This enables other member states to raise concerns before such measures are enacted. The WTO's Technical Barriers to Trade Agreement, which is relevant for FOPWL, recommends a 60-day comment period.

(14). IMPLEMENTATION SCHEDULE

- a.** When designing a FOPWL measure, it is important to consider implementation from the beginning. The measure should establish an implementation schedule.
- b.** Industry often argues that the implementation schedule should be longer, regardless of the starting point. Thus, it is important to propose an implementation schedule that is reasonable but not protracted.

¹This notification is required by international trade law within the scope of the Technical Barriers to Trade (TBT) Agreement of the WTO. It is worth noting that economic and trade legal arguments are used as discourses linked to potential obstacles to delay and weaken FOPWL policies. GHAI recommends reviewing our [technical document on how to legally respond to those arguments](#) to ensure the policy can securely advance with a public health and human rights-based approach.



Examples: Implementation schedule

Argentina

A gradual implementation schedule was established, considering different thresholds for each stage. Products containing caffeine or sweeteners shall be indicated during both stages.

- a.** The first stage will take place within nine months from the date of entry into force of the Law and within 15 months for small and medium enterprises (SMEs). The possibility of extending this period (for 180 days) will be evaluated in accordance with the provisions of article 20 of the Regulatory Decree, based on justifiable reasons. The cut-off points for this stage are the following:
 - i.** Added sugar: $\geq 20\%$ of added sugar's total energy. • Total fat: $\geq 35\%$ of the total energy coming from total fat.
 - ii.** Saturated fat: $\geq 12\%$ of saturated fat's total energy.
 - iii.** Sodium: ≥ 5 mg of sodium/1 kcal or ≥ 600 mg/100 g. Non-alcoholic beverages without energy intake: ≥ 40 mg of sodium/100 ml. ç
 - iv.** Calories: food, ≥ 300 kcal/100 g; non- alcoholic beverages: ≥ 50 kcal/100 ml.
- b.** *The limit of the second stage is established within a period of no more than 18 months from the date of entry into force of the Law, and 24 months from that date for SMEs. The thresholds are:*
 - i.** *Added sugar: $\geq 10\%$ of added sugar's total energy. • Total fat: $\geq 30\%$ from the total energy coming from total fat.*
 - ii.** *Saturated fat: $\geq 10\%$ of saturated fat's total energy. • Sodium: ≥ 1 mg of sodium/1 kcal or ≥ 300 mg/100 g. Non alcoholic beverages without energy intake: ≥ 40 mg of sodium/100 ml.*
 - iii.** *Calories: food, ≥ 275 kcal/100 g; non- alcoholic beverages: ≥ 25 kcal/100 ml.*

In its article 21, The Law establishes that foods whose production date is prior to the entry into force will not be withdrawn from the market and may remain on sale until their stock is sold out.

(Art. 6, Decree No. 151/2022)

Brazil

- a. 24 months after its publication, the new regulation will go into effect (products manufactured before the regulation may be marketed until its expiration date).*
- b. 12 months after the regulation goes into effect, smaller companies will have the additional time to comply with the new regulation. Smaller companies include small family farmers, rural entrepreneurs, microentrepreneurs, individuals, small-sized agro-industries, artisanal industries or artisanal productions.*
- c. Up to 36 months after the regulation goes into effect for compliance of nonalcoholic beverages in reusable packaging, coming from total fat.*

(Arts. 50 & 51 RDC 429/2020 & Art. 25, ANVISA Instruction 75)

Mexico

Three stages of implementation were considered. In the first two, only the added nutrients of concern will be considered for the front-of-package labeling. From October 1, 2025, added and intrinsic nutrients will be mandatorily considered for the established thresholds. (Arts. 1 to 6, transitional normative of NOM 051/2020)

(15). INDUSTRY

- a.** The food and beverage industry often strongly opposes strong FOPWL measures and works to interfere in the policymaking and implementation stages. The potential for such interference – which can be overt or behind-the-scenes, such as funding research studies that are skewed towards the industry's interests – should be taken into account for all FOPWL policy advocacy work.
- b.** Industry may seek to use domestic and international law to interfere with the enactment and implementation of FOPWL. GHAI has created resources on identifying, accounting for and standing up to industry interference for and food policy, including FOPWL.

- i. Factsheet: FOPWL – preparing for and responding to international trade law arguments
 - ii. Report: Behind the Labels: Big Food’s War on Healthy Food Policies (website)
 - iii. Additional GHAI resources about how industry interferes with the advancement of healthy food policies (website)
- c. Please reach out to GHAI for additional guidance on identifying, protecting against and responding to industry interference.

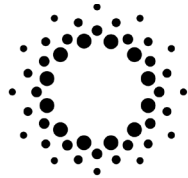
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Available at: <https://advocacyincubator.org/>

Global Health Advocacy Incubator



Changing Policies to Save Lives

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