

**Guiding
principles and
framework
manual for
front-of-pack
labelling for
promoting
healthy diet**



**World Health
Organization**

Table of Contents

List of figures.....	5
List of tables.....	5
List of boxes.....	5
List of appendices.....	5
Abbreviations and acronyms.....	5
Acknowledgements.....	6
Executive summary.....	7
1. Introduction.....	9
1.1 Background.....	9
1.2 Purpose and structure of the document.....	10
2. Aims and scope of FOPL.....	10
2.1 Aims.....	10
2.2 Scope.....	10
3. What is FOPL?.....	11
3.1 Definitions.....	11
3.2 How can FOPL achieve its aims?.....	12
3.3 Who are the stakeholders in FOPL?.....	12
4. Framework for the development, implementation, and monitoring and evaluation of a FOPL system.....	12
4.1 Development of a FOPL system.....	12
Step 1: Contextual analysis (needs assessment).....	14
Step 2: Government to confirm the aims, scope and principles of the FOPL system.....	15
Step 3: Establish a government-led stakeholder engagement process for FOPL system development.....	16
Step 4: Select the FOPL system format.....	17
4.2 Implementation of the FOPL system.....	20
4.3 Monitoring and evaluation of the FOPL system.....	21
5. Governance of the FOPL system.....	23
References.....	24
Appendix 1. The 15 guiding principles for FOPL system development, implementation, and monitoring and evaluation.....	25
Appendix 2. Nutrient profiling for FOPL.....	27
Appendix 3. Monitoring and evaluation framework for FOPL.....	38

List of figures

Fig. 1: Steps in the development of the FOPL system

Fig. A1: Timeline for evaluation stages

List of tables

Table 1. FOPL system monitoring and evaluation measures

List of boxes

Box 1. Overarching principles for FOPL systems

Box 2. Principles for a collaborative approach to FOPL development

Box 3. Principles relating to FOPL system format (i.e. design and content)

Box 4. Principles for the implementation of FOPL systems

List of appendices

Appendix 1. The 15 guiding principles for FOPL system development, implementation, and monitoring and evaluation

Appendix 2. Nutrient profiling for FOPL

Appendix 3. Monitoring and evaluation framework for FOPL

Abbreviations and acronyms

CCFL	Codex Committee on Food Labelling	
FOPL	front-of-pack labelling	
FSA	United Kingdom Food Standards Agency	NCD noncommunicable disease
NGO	nongovernmental organization	
RI	reference intake	
WHO	World Health Organization	

Acknowledgements

This manual was initially developed based on the outcomes of the WHO Technical Meeting on Nutrition Labelling for Promoting Healthy Diets, held in Lisbon, Portugal, on 9–11 December 2015, including various country experiences and lessons learned, and the review of evidence undertaken as background preparation for the technical meeting. The manual was further developed and updated in June 2017 and again in November 2017, taking into consideration the discussions held at the Technical Consultation on Front-of-Pack Labelling of Food and Drink Products organized by the Pan American Health Organization and the WHO Regional Office for the Americas in Washington, DC, United States of America, on 13–15 November 2017, as well as the inputs received from the discussions held at the Regional Workshop on Nutrition Labelling To Promote Healthy Diets, organized by the WHO Regional Office for South-East Asia and the WHO Regional Office for the Western Pacific, held in Bangkok, Thailand, on 17–19 April 2018.

WHO also acknowledges valuable technical inputs and support provided to the development and further elaboration of this manual by Dr Bridget Kelly, Associate Professor, School of Health and Society, University of Wollongong, Australia and Ms Jenny Reid, Manager, Food Science and Risk Assessment in the Regulation and Assurance Branch, Ministry for Primary Industries in New Zealand.

Executive summary

Front-of-pack labelling (FOPL) is an important policy tool for countries to help consumers to make healthier food choices. This document – *WHO guiding principles and framework manual for front-of-pack labelling for promoting healthy diets* – has been developed to support countries to develop, implement, and monitor and evaluate an appropriate FOPL system.

The development, implementation, and monitoring and evaluation of FOPL should be government led, with input from key stakeholder groups. The development of FOPL should be an iterative and collaborative process.

There are some key considerations and steps that need to be taken in developing a FOPL system. Various FOPL systems have already been developed by different countries. Hence, it is important to learn from the experiences of others, adapting approaches where appropriate, taking into consideration the particular needs of the country while recognizing the importance of global consistency. The Codex Alimentarius Commission (Codex) is also in the process of undertaking work on FOPL, and this manual will be an important resource for the Codex.

The first step is a contextual analysis of the country, in which a specific situational analysis is undertaken to provide the rationale for proceeding with the development and implementation of FOPL. This includes assessing the current dietary patterns and nutritional and health-related status of the population; the legal framework under which FOPL would be introduced and the interface with other legislation; and the relevant nutrition policies that FOPL would support.

The aims, scope and overarching and specific principles of the FOPL need to be confirmed by governments at a national and regional level, because they provide the critical framework for developing the specific details of the FOPL system. The **five overarching guiding principles** for FOPL that form the basis of this manual are as follows:

Principle 1: The FOPL system should be aligned with national public health and nutrition policies and food regulations, as well as with relevant WHO guidance and Codex guidelines.

Principle 2: A single system should be developed to improve the impact of the FOPL system.

Principle 3: Mandatory nutrient declarations on food packages are a prerequisite for FOPL systems.

Principle 4: A monitoring and review process should be developed as part of the overall FOPL system for continuing improvements or adjustments, as required.

Principle 5: The aims, scope and principles of the FOPL system should be transparent and easily accessible.

In developing the FOPL system, careful consideration should be given to the process of implementation and the approaches used to evaluate the effectiveness of the nutrition policy. An appropriate governance structure is also necessary to support the FOPL system throughout its development, implementation, and monitoring and evaluation.

Effective implementation of a FOPL system requires a well-resourced and robust consumer education programme that provides key messaging on using FOPL, as part of a wider suite of country nutrition messaging and dietary guidance.

Effective nutrition labelling, including simple-to-use FOPL, has been identified as one of the strategies that countries should use to address the growing global concern of unhealthy dietary patterns. This manual supports effective FOPL development, implementation, and monitoring and evaluation to help improve dietary patterns and reduce the burden of diet-related noncommunicable diseases.

Pre-formatted final draft - May 2019

1. Introduction

1.1 Background

There has been increasing global interest in nutrition labelling as a policy tool through which governments can guide consumers to make informed food purchases and healthier eating choices. This interest comes as countries contend with an emerging epidemic of diet-related noncommunicable diseases (NCDs) and low population compliance with dietary recommendations.

The Codex Alimentarius Commission (Codex) identifies three types of nutrition labelling: nutrient declarations; nutrition and health claims; and supplementary nutrition information, which includes front-of-pack labelling (FOPL) (1). Nutrient declarations are standardized listings of the nutrient content of a food or beverage, usually positioned on the back or side of the package. In 2012, Codex recommended that nutrient declarations be mandatory on food packages (1).

WHO conducted the 2nd Global Nutrition Policy Review in 2016–2017. In that review, 74 countries reported that they are implementing nutrient declarations, and majority of countries (70%) indicated that nutrient declarations were mandatory in their countries. However, these countries which are implementing mandatory nutrient declarations are largely in the WHO Region of the Americas and the WHO European Region. Nutrient declarations provide essential information about the nutrient content of foods, but the complexity of the quantitative information on the back of the pack means that it is not readily accessible and is often poorly understood. FOPL can complement nutrient declarations by providing convenient, relevant and readily understood information on the front of packs. Codex does not define or outline specific principles for FOPL systems.

Nutrition labelling has been considered as a policy implementation tool in various official WHO documents adopted by the World Health Assembly. These include the *Comprehensive Implementation Plan on Maternal, Infant and Young Child Nutrition* (2014) (2), the *Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020* (2013) (3) and, most recently, the *Report of the Commission on Ending Childhood Obesity* (2016) (4). Nutrition labelling was also identified as a tool for creating enabling environments for making informed choices by the 2nd International Conference on Nutrition (ICN2) in 2014, the recommendations and outcomes of which served as the basis for the United Nations Decade of Action on Nutrition (2016–2025).

FOPL was first introduced in the late 1980s by nongovernmental organizations (NGOs) and some government agencies. Today, there are many different types of FOPL, developed not only by government agencies, but also by NGOs, food industries (including retailers) and health experts. Responding to increasing requests by Member States for guidance, WHO held a technical meeting in 2015, to review the available evidence and to compile various country experiences and lessons learned in developing and implementing FOPL systems. The outcomes of that technical meeting and the review of evidence undertaken in preparation for that meeting served as a basis and context for the principles and guidance framework on FOPL presented in this manual.

The Codex Committee on Food Labelling (CCFL) has now agreed to undertake new work for providing additional guidance on “Supplementary nutrition information”, under Section 5 of the Codex Guidelines on Nutrition Labelling (5). This new work will take into consideration the evidence

and recommendations that are now becoming available on FOPL. This document – *WHO guiding principles and framework manual for front-of-pack labelling for promoting healthy diets* – complements the work being undertaken at CCFL.

1.2 Purpose and structure of the document

The purpose of this manual is to assist Member States in developing and implementing FOPL systems, to be used as a tool for promoting healthy diets and preventing obesity and diet-related NCDs. A set of guiding principles for FOPL was established at the WHO technical meeting on FOPL held in December 2015, and was further developed and updated in June 2017. This manual builds on these guiding principles for FOPL by outlining how they can be operationalized in the development, implementation, and monitoring and evaluation of FOPL.

The principles, described below, provide an overall framework for the design of FOPL systems, and for the development, implementation, and monitoring and evaluation of such systems. They should serve as the starting point for countries, which can either confirm them as their own principles or can add to them if necessary.

The guiding principles are separated into steps in the process. The overarching principles are described in the section below on confirming the system aims and scope (Step 2). Principles related to multisectoral engagement are found in the step on applying a collaborative approach to system development (Step 3), and principles related to system design are found in the step on selecting the FOPL system design (Step 4). A full list of the 15 principles for FOPL system development, implementation, and monitoring and evaluation is provided in Appendix 1.

2. Aims and scope of FOPL

2.1 Aims

The principal aim of FOPL is to provide convenient, relevant and readily understood nutrition information or guidance on food packs, to assist all consumers to make informed food purchases and healthier eating choices. An additional benefit is to stimulate favourable compositional changes to food products available in retail outlets.

2.2 Scope

The priority focus or scope of FOPL is packaged, manufactured or processed foods that are required to carry a nutrient declaration, presented as ready for sale to the consumer in the retail sector.

FOPL is **not** appropriate for some packaged foods, including foods specially manufactured for infants and young children, and infant and follow-up formula. Foods for infants and young children have strict compositional criteria; hence, promoting reformulated products is not appropriate. Also, in line with Health Assembly resolutions and WHO policies, products for infants and young children – in particular, infant and follow-up formula – should not be promoted in any way, including using a FOPL.

Packaged foods that are exempt from displaying a nutrient declaration should not display a FOPL. These include foods with very low nutritional contribution such as herbs, spices, tea, coffee and

condiments. Because these foods have minimal nutritional contribution to the diet in terms of both their composition and amounts that are eaten, it is inappropriate for them to carry a FOPL, and a FOPL would not assist the consumer in making better food choices. FOPL should also be excluded from alcoholic beverages.

3. What is FOPL?

3.1 Definitions

Front-of-pack labelling (FOPL) refers to nutrition labelling systems that:

- are presented on the front of food packages (in the principal field of vision) and can be applied across the packaged retail food supply;
- comprise an underpinning nutrient profile model that considers the overall nutrition quality of the product or the nutrients of concern for NCDs (or both); and
- present simple, often graphic information on the nutrient content or nutritional quality of products, to complement the more detailed nutrient declarations usually provided on the back of food packages.

There are two major categories of FOPL: interpretive and non-interpretive systems. Subsystems within these groups include nutrient-based systems, summary indicator systems, endorsement logos and nutrient-based warning labels. Endorsement logos are usually considered to be health claims in international and domestic standards; however, they are included as FOPL in this document because they meet the criteria for FOPL stated above and are a tool for supporting healthier food choices.

FOPL systems differ in the extent to which they provide consumers with nutrient information versus nutrition advice. At one end of this spectrum, non-interpretive nutrient-based systems provide a summary of nutrient information from nutrient declarations for one or more nutrients and no advice or direction on the overall nutritional value of the food to assist with purchasing decisions. At the other end of the spectrum, interpretive systems may provide no nutrient information but only at-a-glance guidance on the relative healthfulness of a product. There is a range of variations between these two extremes.

FOPL systems have specific **nutrient profiling** methods. Nutrient profiling is the science of classifying or ranking foods according to their nutritional composition (5 references missing). The approach taken for nutrient profiling depends on the FOPL system selected, and this may vary between:

- setting threshold amounts that meet a nutrition guideline (used in interpretive nutrient-based systems);
- applying algorithms for food products' overall nutrition profile (used in interpretive summary indicator systems); or
- basing criteria on nutrient reference values (used in non-interpretive nutrient-based systems).

The **format** of FOPL systems refers to their visual appearance or how the nutrition information is actually presented on the label. Examples include the use of coloured indicators; interpretive words, numbers, letters or symbols; or numerical information and percentages.

The **content** of FOPL refers to the actual nature of the information presented. This includes the nutrients and summary nutrition information presented.

3.2 How can FOPL achieve its aims?

For FOPL to support consumers to make informed food purchases and healthier eating choices, consumers must be aware of, and recognize, the FOPL symbol (or symbols), understand what the symbol means, be able to use it correctly and be motivated to use it. Label awareness is facilitated by systems that are widely adopted across the retail supply and by formats that promote visibility; for example, those that are large in size, are placed in a consistent position on the front of packages (e.g. top right-hand side) and use contrasting colours. Consumers' ability to use FOPL is assisted by labels that contain interpretive elements (e.g. meaningful colours), whereas motivation to use FOPL may be supported by systems that are quick to interpret and that apply across foods of all prices.

3.3 Who are the stakeholders in FOPL?

Many different groups of stakeholders have a potential interest in the implementation of FOPL systems. Engagement with all key stakeholders is important for the success of a FOPL system.

Stakeholders include:

- those with a health focus; for example, government departments and ministries; international organizations with a focus on health; health and consumer organizations; and the scientific community, including public health and nutrition experts; and
- those with a wider economic and development interest, including an interest in food industry growth, sales and trade; such stakeholders include:
 - the wider food and agriculture sectors – in particular, food manufacturers and retailers, and the scientific community involved in agriculture and food; and
 - those government departments and ministries responsible for industry development and trade.

4. Framework for the development, implementation, and monitoring and evaluation of a FOPL system

4.1 Development of a FOPL system

The development of a FOPL system should be an iterative process, as shown in Fig. 1. It should be government led, whereby the government first confirms the aims, scope and principles of what is being proposed, and then uses a collaborative approach to determine the specificities of the system (e.g. the content and format) while staying faithful to the overarching principles.

As shown in Fig. 1, FOPL system **development** can be separated into four sequential steps and the following describes each of those steps.

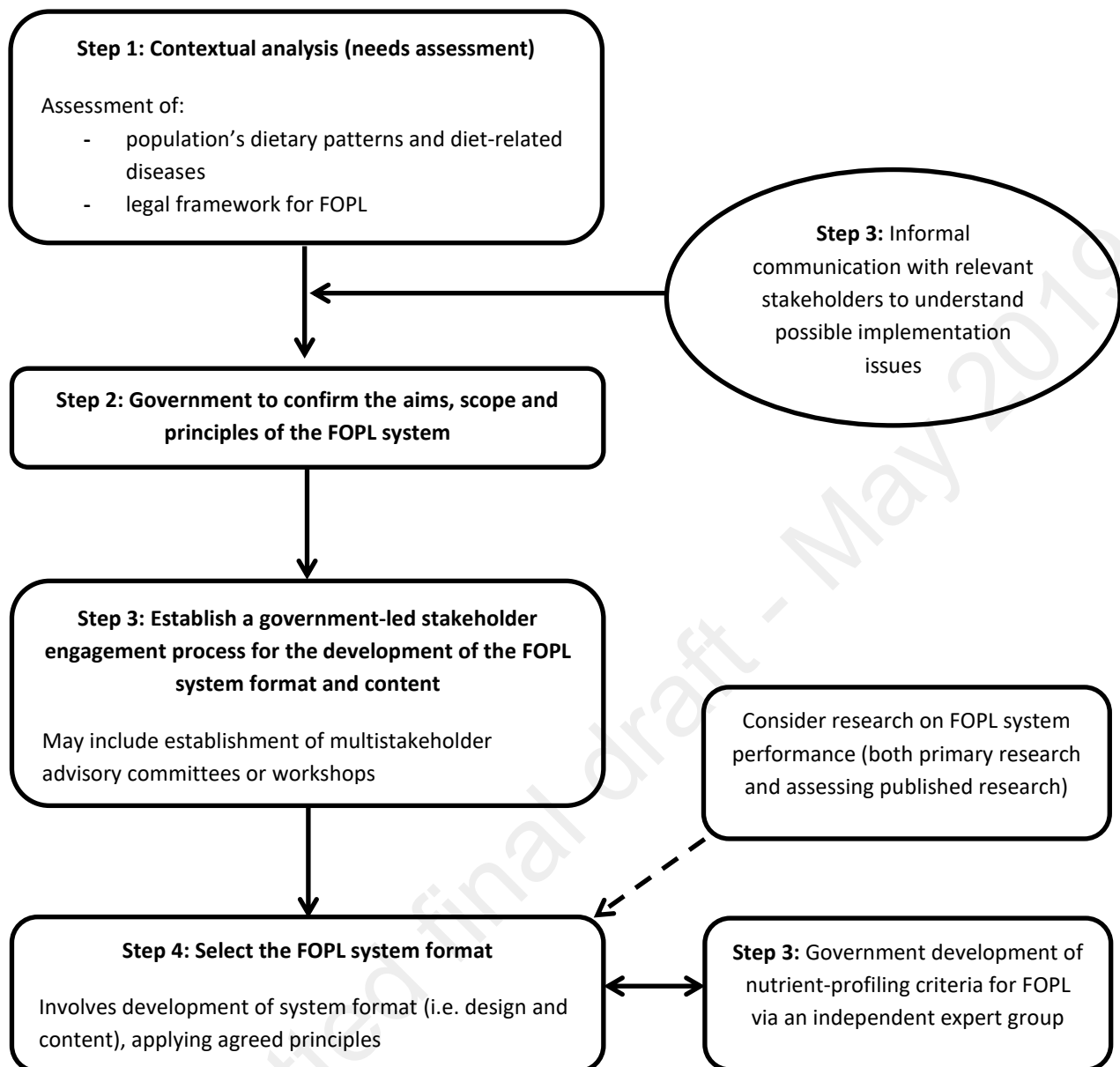


Fig. 1. Steps in the development of the FOPL system

Step 1: Contextual analysis (needs assessment)

The situational country context should first be assessed to identify the rationale for the FOPL intervention, the legal framework for its introduction and the current policy environment that may support or hinder FOPL implementation. The contextual analysis may include the following assessments:

- epidemiological analysis of diet-related NCDs and the population's dietary patterns;
- analysis of the legal framework under which FOPL would be introduced; and
- analysis of relevant national nutrition policies.

Each of these types of assessment is discussed below.

Epidemiological analysis of diet-related NCDs and the population's dietary patterns

This analysis can provide a rationale for intervention with FOPL where diet-related NCDs are increasing and the population's diets are not aligned with national dietary guidelines. Examples of data to be captured include:

- inadequacies in intakes of key positive nutrients, and excess intakes of energy and key nutrients of concern;
- intakes of unhealthy foods and beverages (e.g. sugar-sweetened beverages, and high-fat or salty snacks); and
- prevalence of overweight and obesity and diet-related NCDs.

Data may be cross-sectional or provide evidence of trends over time.

Analysis of the legal framework under which FOPL would be introduced

This analysis can consider the legal framework for nutrition and health claims (e.g. endorsement schemes), or other legal frameworks for FOPL. Because a key role of FOPL is to complement and simplify the nutrient information provided in nutrient declaration panels, mandatory nutrient declaration labelling is a prerequisite for a FOPL system.¹ National, regional and international nutrition legislation may be relevant, as well as other related legislation, such as labelling requirements for international trade.

Analysis of relevant national nutrition policies

This analysis should seek to analyse existing national nutrition recommendations and nutrition policies, to examine the feasibility of implementation and the appropriateness of the timing for development. The implementation of FOPL is more feasible where this is supported by a nutrition policy framework that recognizes the need to promote healthy diets for nutritional well-being and NCD prevention, and where the provision of nutrition information to consumers is identified as one strategy to promote healthy diets.

¹ The Codex Guidelines on Nutrition Labelling (5) note that "The use of supplementary nutrition information on food labels should be optional and should only be given in addition to, and not in place of, the nutrient declaration, except for target populations who have a high illiteracy rate and/or comparatively little knowledge of nutrition. For these, food group symbols or other pictorial or colour presentations may be used without the nutrient declaration."

Step 2: Government to confirm the aims, scope and principles of the FOPL system

Once the decision has been made to progress with the development of a FOPL system based on the outcomes of the contextual analysis, the aims, scope and principles of the FOPL system should be confirmed. The overall aims and scope of FOPL are described in Section 2 above.

The country-specific scope of the FOPL system should also be identified, including what is within the scope and what is outside the scope. It is recommended that the initial focus be on packaged foods that are required to make a nutrient declaration. The FOPL system will supplement national nutrition policies and dietary guidelines. This means that messages about consumption of unpackaged foods – such as the promotion of fresh fruit and vegetables – would continue alongside any FOPL system, even though unpackaged fresh fruit and vegetables would not carry a FOPL.

The five overarching principles for FOPL should be considered at all stages of system development, implementation, and monitoring and evaluation (see Box 1). The overarching principles highlight that country-specific aims, scope and principles of the system may also need to be identified, possibly taking into account the findings from the contextual analysis and the specific food culture or cultures of the population. Specific considerations related to the findings from the contextual analysis may include:

- the health or nutrition issues to be addressed by the labelling, as identified from the epidemiological analysis and the emphasis of current nutrition policies; and
- the legal options for system adoption, which may affect the regulatory framework for the system, including whether the system should be mandatory or voluntary.

Box 1. Overarching principles for FOPL systems

Principle 1: The FOPL system should be aligned with national public health and nutrition policies and food regulations, as well as with relevant WHO guidance and Codex guidelines.

Principle 2: A single system should be developed to improve the impact of the FOPL system.

Principle 3: Mandatory nutrient declarations on food packages are a prerequisite for FOPL systems.

Principle 4: A monitoring and review process should be developed as part of the overall FOPL system for continuing improvements or adjustments as required.

Principle 5: The aims, scope and principles of the FOPL system should be transparent and easily accessible.

Food culture considerations of a population may stipulate the extent to which certain foods can be classified as being more healthful or less healthful, and the food groups or food types that the labelling should focus on or for which special exclusions may apply.

The process of developing country-specific aims, scope and principles of the FOPL system should be transparent and easily accessible for those wishing to follow its development. These principles should be affirmed at the outset of the process for FOPL system development. This process should be government led, but ideally with the support of key stakeholders.

Step 3: Establish a government-led stakeholder engagement process for FOPL system development

There are three main considerations for applying a collaborative approach to FOPL system development:

- initially, informal communication mechanisms should be used to gain insight from relevant stakeholders on possible implementation issues;
- a formal government-led stakeholder engagement process should be used for the development of the system format and content; for example, through multistakeholder advisory committees or workshops and consultation processes; and
- government should have responsibility for setting nutrient profiling criteria, via an independent expert group and reference to information from authoritative scientific sources.

In the initial conceptual stages, informal engagement from a wide group of experts is recommended to gain an understanding of the likely issues and possible opposition to FOPL. These experts may include food scientists, public health and nutrition experts, and consumer behavioural experts.

Following the government's establishment of the overarching aims, scope and principles of the FOPL system (Step 2), government should then establish formal working groups to facilitate a collaborative approach to system development. This part of the process seeks to operationalize the principles that have already been established by government. Engagement of other stakeholder groups is needed for identifying the system's format and content. This collaborative process should be government led to ensure that the process is translated into a FOPL system that is feasible for industry, is credible to consumers, applies evidence from scientific research on nutrition labelling, is consistent in design and is aligned with other national nutrition policies. To strengthen consumer trust in the system, the process of system development and the negotiations between government and stakeholders should be transparent and accessible; this can be achieved by, for example, making meeting reports publicly available, and using a process of public consultation and open public meetings.

Government, including those responsible for food regulations and national health authorities, have the ultimate responsibility and authority for the development, implementation, and monitoring and evaluation of the FOPL system and the nutrient profiling criteria that underpin the system (see Appendix 2). These nutrient profiling criteria should be based on authoritative scientific sources. Government should lead the proposal for the underpinning nutrient profiling criteria, via an expert group. Ideally, these criteria would adopt or adapt existing nutrient profiling approaches but be relevant for the national or regional food supply. The *WHO guiding principles and framework manual for nutrient profiling* can be used as a guide in developing or adapting nutrient profile models (2).

Box 2 outlines a principle for the coordination of a collaborative approach to FOPL system development.

Box 2. Principle for a collaborative approach to FOPL development

Principle 6: Government should lead the multisectoral stakeholder engagement process for the development of trusted systems, including nutrient profiling criteria.

Step 4: Select the FOPL system format

Negotiations with stakeholders on the format (i.e. design and content) of the FOPL system should use the agreed aims and scope, as well as overarching principles (Box 1) and any additional country principles. Principles related to FOPL system format have also been developed (Box 3) to guide the process of designing a FOPL system and to ensure that there is a common understanding among stakeholders on the expectations for the system. These principles outline pre-established criteria to underpin negotiations with stakeholders to determine the exact format of the content (i.e. the information that will be conveyed) and the design (i.e. how information will be portrayed). These specific principles, along with any additional required country-specific principles, will need to be endorsed and agreed on by government.

The principles reflect evidence from scientific reviews of FOPL performance, which is summarized in the background paper that was developed for the WHO technical meeting on FOPL (6). Briefly, interpretive FOPL systems that use interpretational aids and minimize numerical information are most useful for aiding consumer comprehension of FOPL information. The use of meaningful colours to signpost the relative healthfulness of foods performs consistently well in consumer testing of food labels. Numerical-based, non-interpretive systems are less helpful, particularly for population groups with lower levels of food and nutrition literacy, and lower education, and for members of Indigenous or minority ethnic groups.

Much of the available evidence on the performance of FOPL in guiding consumers to identify healthier food products comes from developed countries and has tended to focus on the comparison of interpretive (particularly multiple traffic light labels) and non-interpretive nutrient-based systems. Furthermore, evidence suggests that system performance may be moderated by its familiarity in the marketplace, such that increased familiarity with a system improves its understanding. However, emerging findings of primary research studies, in particular from Latin American countries, provide new evidence on the potential effectiveness of other types of systems, including other interpretive nutrient-based systems, summary indicator systems and hybrid systems. Hence, the generalizability of research findings on a FOPL system's performance across countries may be variable, given differences in prior exposures. It is prudent for countries to undertake consumer testing of proposed FOPL systems to ensure their suitability for the target market.

Box 3. Principles related to FOPL system format (i.e. design and content)

Design

Principle 7: The FOPL system should be interpretive, based on symbols, colours, words or quantifiable elements.

Principle 8: The design of FOPL systems should be understandable to all population subgroups, and should be based on the outcome of consumer testing, evidence of system performance and stakeholder engagement.

Content

Principle 9: Content should encompass nutritional criteria and food components with the aim of informing choice and enabling interpretation of food products against risks for diet-related NCDs, and of promoting healthy diets.

Principle 10: The FOPL system should enable appropriate comparisons between food categories, within a food category, and between foods within a specific food type.

Adapting existing systems, or creating a new system?

Some countries will create their own system, whereas other countries may adapt an existing system. Checklists for guiding both of these pathways are presented below.

Adapting an existing FOPL system

It may be expedient and appropriate to adapt an existing system, which generally takes less time and costs less than developing a new system from scratch. Below is a checklist to assist in selecting between existing systems, and for then adapting the chosen system to the national context.

Checklist for identifying and adapting existing systems:

- Consider the evidence on the effectiveness of existing systems (published evidence or evidence gathered through undertaking primary consumer studies of systems' awareness and performance with the target market).
- Consider the FOPL system that facilitates healthy food choices quickly and easily. Consumers' objective understanding of FOPL systems is the primary performance outcome of relevance.
- Consider the FOPL systems that consumers are familiar with.
- Understand the barriers to making healthy food choices, so that the FOPL system elements can address these.
- Consider systems that would be feasible by seeking input from the food industry, the scientific community, and consumer and health organizations.
- When adapting a FOPL system, ensure that the underpinning nutrient profiling criteria reflect national dietary guidelines and eating habits of the population.
- Where countries do not have standard serving sizes, adopt nutrient criteria based on per 100 g or 100 mL of a food/beverage.

- The focus of the FOPL should be on the mandatory list of nutrients categorized in Codex guidelines (i.e. total fat, saturated fatty acids, total sugars and sodium).

Developing a new FOPL system

The development of a new system may be appropriate where there is strong disagreement about the use of any existing systems, or where these existing systems do not align with the country-specific aims, scope and principles of the FOPL system or the country context.

Checklist for developing a new FOPL system:

- Review the elements of existing systems that are considered to be more effective or less effective in supporting consumers to make informed food purchases and healthier eating choices (using published evidence or primary consumer studies of the usefulness of FOPL system elements, including format such as design and content). The three main categories of systems that can be compared are:
 - interpretive systems such as the multiple traffic light labelling system (United Kingdom), Nutri-Score system (France) and warning system (Chile);
 - non-interpretive systems such as percentage reference intakes (European Union); and
 - hybrid systems such as the Health Star Rating (Australia and New Zealand).
- Understand the barriers for the target group in making healthy food choices, so that the new system elements can address those barriers.
- Consider FOPL systems that would be feasible by seeking input from the food industry, the scientific community, and consumer and health organizations.
- Consider the adaptation of existing nutrient profiling to make these relevant and reflective of national dietary guidelines and eating habits of the population.
- Where countries do not have standard serve sizes, adopt nutrient criteria based on per 100 g or 100 mL of a food and beverage.
- Ensure that the FOPL system focuses on the mandatory list of nutrients categorized in Codex guidelines (i.e. total fat, saturated fatty acids, total sugars and sodium).
- Compare the performance of the proposed new system with existing FOPL systems by undertaking primary research with consumers. Studies may assess consumer perceptions, understanding, acceptability and intended use of FOPL systems.
- Revise the proposed FOPL system based on the outcomes of the consumer studies.
- Engage communications experts to determine the best way to present the proposed FOPL system, using consumer testing for presentation options.

Consumer research on FOPL system performance

When assessing published research or undertaking primary research with consumers on FOPL system performance, a hierarchy of outcomes has been identified (6). These outcomes increase in validity as follows: 1) consumer preferences for FOPL systems and perceived understanding; 2) objective understanding of FOPL systems under experimental conditions; and 3) changes to product sales or changes to dietary intake or health impacts longitudinally in real-world or naturalistic experimental trials applying one or more FOPL systems (see Appendix 3).

4.2 Implementation of the FOPL system

Implementation of the developed FOPL system should be widespread and should apply across the majority of packaged, manufactured or processed foods and beverages in the retail food sector required to carry a nutrient declaration.

Early engagement with the food industry is essential to familiarize the industry with the proposed FOPL system and to ensure that industry can use the nutrient profiling criteria to identify the appropriate FOPL system for their product or products. This is particularly important for smaller businesses that may not have specialist staff to undertake this process.

Well-resourced and targeted public education campaigns and consumer engagement can facilitate understanding and use of FOPL systems. The resourcing for consumer engagement and public education should ideally be fully government funded. For consumer engagement and public education related to the FOPL system, there may be a lag time between system introduction and communication, to allow for penetration of the FOPL system into the marketplace. Engagement with different experts at this stage is important, including experts in communications and consumer engagement. Given population inequities in diet-related NCDs and unequal nutrition literacy across population groups, communication materials should particularly target at-risk groups, as identified in the contextual analysis (Step 1). It is important to also engage with public health and nutrition experts and the media at this early stage when key messages about the FOPL system are made public, because these stakeholders play a critical role in promoting the FOPL system.

Before a FOPL system is implemented, baseline data for impact and outcome evaluation should be collected to support monitoring and evaluation of that system. Baseline data should capture consumer-related outcomes (i.e. FOPL system understanding, trust, use and purchases) and reformulation outcomes (i.e. food product composition) (Appendix 3).

Box 4 presents principles for the implementation of FOPL systems to facilitate uptake by the food industry and use by consumers.

Box 4. Principles for the implementation of FOPL systems

Principle 11: Uptake of the FOPL system should be encouraged across all eligible packaged foods, either through regulatory or voluntary approaches.

Principle 12: Early engagement of industry groups and the development of guidance documents (e.g. a style guide) are necessary in facilitating the implementation of the FOPL system.

Principle 13: Engagement with key opinion leaders (including food and nutrition experts and the media) and consumers are essential, and should be well managed.

Principle 14: Well-resourced public education campaigns and consumer education, with special consideration of techniques to target at-risk groups, are necessary for improving nutrition literacy and consumer understanding and use of the FOPL system.

Principle 15: Baseline data should be collected to support monitoring and evaluation of the impact on consumers and reformulation of food products.

4.3 Monitoring and evaluation of the FOPL system

Once a FOPL system has been introduced, monitoring and evaluation of the system is needed to ensure compliance and enforcement. In government-implemented or regulated systems, government has responsibility for the monitoring of implementation and compliance of the FOPL system. This should be coordinated through either a government agency or an independent group that does not have conflicts of interests. For voluntary systems, government monitoring of compliance with other regulations (e.g. those preventing misleading information on labels and nutrition and health claims) may be useful.

Evaluation of the use and performance of the FOPL system in achieving its aims is an important part of the system design. Measures related to the principal aim and additional benefit of FOPL systems are given in Table 1, together with considerations for data capture and assessment. Unintended consequences of the FOPL system, such as food price changes, may also be assessed. Appendix 3 provides a more detailed framework for monitoring and evaluation of a FOPL system.

The five key elements to be monitored are:

- the extent and fidelity of implementation of the FOPL system;
- the effect of the FOPL system on changes to consumer understanding;
- the effect of the FOPL system on changes to product purchases;
- the effect of the FOPL system on changes to population dietary intakes; and
- the effect of the FOPL system on changes to nutrient compositions of food products (reformulation).

Table 1. FOPL system monitoring and evaluation measures

FOPL aim	Measure	Evaluation activities	Data considerations
<i>Principal aim:</i> To assist all consumers to make informed food purchases and healthier eating choices.	The extent and fidelity of implementation of the FOPL system	Assess: 1) extent of implementation, including the proportion of manufacturers and retailers using the FOPL system, and the number and proportion of products displaying the FOPL system; and 2) fidelity of implementation, by comparing the consistency of labels with the requirements for format and content.	<ul style="list-style-type: none"> - Audit data on FOPL system implementation should be collected and assessed by an independent body or research group. - Photographs of packages should be taken as part of the audit data collection.
	Changes to consumer understanding of the FOPL system	Assess changes to consumer awareness, understanding and trust in the FOPL system.	<ul style="list-style-type: none"> - The same methods and measures should be used at baseline and follow-up. - Study sampling approaches should ensure representation from particular cultural and socioeconomic groups that are known to have poorer food labelling literacy. - Consumers' self-reported understanding of FOPL systems is prone to social desirability bias and objective measures are preferred.
	Changes to product purchases	Assess changes to consumer food purchasing behaviours.	<ul style="list-style-type: none"> - The same methods and measures should be used at baseline and follow-up. - Product sales data are ideal but can be difficult or expensive to source. Alternative approaches can include the collection of supermarket receipts in a sample of consumers over time, or self-reported use of or intention to use the FOPL system for informing food purchases.
	Changes to population dietary intakes	Assess changes to population dietary intakes, including intakes of target nutrients and their food sources.	<ul style="list-style-type: none"> - The same methods and measures should be used at baseline and follow-up. - National food intake data are desirable to model changes in dietary intakes, ideally

			including nutrient contribution to the diet from specific food items. - An alternative approach includes combining information on purchasing patterns (e.g. sales data) and the nutrient content of purchased foods. This provides information on 'nutrients purchased'.
<i>Additional benefit:</i> To stimulate favourable compositional changes to food products.	Changes to nutrient compositions of food products (reformulation)	Assess changes to the nutrient composition of the retail packaged food supply.	- The same methods and measures should be used at baseline and follow-up. - Longitudinal data on the nutritional composition of market products is needed to monitor changes in nutrient content of foods with the FOPL system.

Among the additional elements to include in the overall evaluation of the FOPL system are its general acceptability and its support from consumers, the public health community and food industries. Monitoring media coverage and public comment is a useful addition to the data gathering outlined above. Media commentary may be indicative of areas of the FOPL system that need to be modified. It is important that the system is given a chance to work before modifications are made. A period of 3–5 years is seen as a realistic time frame for considering evaluation of system effectiveness and the need for any modifications.

5. Governance of the FOPL system

For FOPL systems to be effective and sustainable, there must be a commitment to governance and oversight of the system throughout its development, implementation, and monitoring and evaluation. This is especially important for voluntary FOPL systems. A governance group should be government led, but should include members from key stakeholder groups. In the early stages of implementation, as the FOPL system is becoming embedded, there needs to be a process to identify and manage label anomalies, and to oversee the consumer education campaign and monitoring and evaluation processes. Anomalies occur when elements of the FOPL system are inconsistent with national dietary guidelines and nutrition policies, or when elements of the FOPL system used to make comparisons within a food category or across comparable food categories would mislead consumers. If anomalies are not managed, they have the potential to undermine the credibility of the proposed FOPL system. Examples of such governance arrangements include those supporting the Health Star Rating system used in Australia and New Zealand (5, 6). Governance processes and decisions should be transparent and accessible.

References

- 1 Codex Alimentarius Commission. Guidelines on nutrition labelling CAC/GL 2-1985. Geneva: Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO); 2015.
- 2 Comprehensive implementation plan on maternal, infant and young child nutrition. Geneva: World Health Organization; 2014 (<http://apps.who.int/iris/handle/10665/113048>, accessed 10 September 2018).
- 3 Global Action Plan for the Prevention and Control of NCDs 2013–2020. Geneva: World Health Organization; 2013.
- 4 Report of the Commission on Ending Childhood Obesity. Geneva: World Health Organization; 2016 (<http://apps.who.int/iris/handle/10665/204176>, accessed 10 September 2018).
- 5 Codex Alimentarius Commission. Guidelines on nutrition labelling CAC/GL 2-1985. Adopted in 1985. Revised in 1993 and 2011. Amended in 2003, 2006, 2009, 2010, 2012, 2013, 2015, 2016 and 2017. Annex adopted in 2011. Revised in 2013, 2015, 2016 and 2017. Geneva: Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO); 2017 (http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BGL%2B2-1985%252FCXG_002e.pdf, accessed 6 September 2018).
- 6 Kelly B. Background paper on front-of-pack food labelling (FOPL). Geneva: World Health Organization 2015.

Appendix 1. The 15 guiding principles for FOPL system development, implementation, and monitoring and evaluation

A1.1 Overarching principles

Principle 1: The FOPL system should be aligned with national public health and nutrition policies and food regulations as well as with relevant WHO guidance and Code guidelines.

Principle 2: A single system should be developed to improve the impact of the FOPL system.

Principle 3: Mandatory nutrient declarations on food packages are a prerequisite for FOPL systems.

Principle 4: A monitoring and review process should be developed as part of the overall FOPL system for continuing improvements or adjustments as required.

Principle 5: The aims, scope and principles of the FOPL system should be transparent and easily accessible.

A1.2 Principles for a collaborative approach to FOPL development

Principle 6: Government should lead the multisectoral stakeholder engagement process for the development of trusted systems, including nutrient profiling criteria.

A1.3 Principles for FOPL system format

Design

Principle 7: The FOPL system should be interpretive, based on symbols, colours, words and/or quantifiable elements.

Principle 8: The design of FOPL systems should be understandable to all population subgroups and be based on the outcome of consumer testing, evidence of system performance and stakeholder engagement.

Content

Principle 9: Content should encompass nutritional criteria and food components that aim to inform choice and enable interpretation of food products against risks for diet-related noncommunicable diseases (NCDs) and for promoting healthy diets.

Principle 10: The FOPL system should enable appropriate comparisons between food categories, within a food category, and between foods within a specific food type.

A1.4 Principles for the implementation of FOPL systems

Principle 11: Uptake of the FOPL system should be encouraged across all eligible packaged foods, either through regulatory or voluntary approaches.

Principle 12: Early engagement of industry groups and the development of guidance documents (i.e. style guide) are necessary in facilitating the implementation of the FOPL system.

Principle 13: Engagement with key opinion leaders (including food and nutrition experts and the media) and consumers is essential and should be well managed.

Principle 14: Well-resourced public education campaigns and consumer education with special consideration of techniques to target at-risk groups are necessary for improving nutrition literacy and consumer understanding and use of the FOPL system.

Principle 15: Baseline data should be collected to support monitoring and evaluation of the impact on consumers and reformulation of food products.

Pre-formatted final draft - May 2019

Appendix 2. Nutrient profiling for FOPL

Nutrient profiling is the science of classifying or ranking foods according to their nutritional composition, for reasons related to disease prevention and health promotion (5 references missing). Careful formulation of the nutrient profiling criteria is required to ensure that the front-of-pack labelling (FOPL) system is sensitive enough to identify and signpost differences in the healthfulness of products. The classification of products must also align with national dietary guidelines and expectations of the nutritional quality of foods. Testing and monitoring of the criteria are required to avoid labelling anomalies whereby less healthful foods are portrayed as healthful. Such anomalies would undermine the credibility of the FOPL system. This appendix provides an overview of the key considerations in developing or adapting nutrient profile models for FOPL systems. It also outlines the processes of validating and implementing nutrient profile models, and gives examples from countries that have undertaken these processes. This information supplements other WHO publications on nutrient profiling, which outline the process of developing, validating and implementing nutrient profile models, including for FOPL policies.

As highlighted in this manual, government should have the ultimate responsibility and authority for the nutrient profile model that underpins the FOPL system. This government-led process will facilitate the adoption of credible nutrient profiling criteria that is based on authoritative scientific information, reflects national dietary guidelines and eating habits of the population, and is free from commercial and other vested interests.

A2.1 Key considerations in developing or adapting nutrient profile models for FOPL

This section outlines key questions to be posed when determining the criteria for the FOPL nutrient profile model. These questions relate to the nutrients to be included, the food groups to be covered and the approach to be used for applying the criteria. A fundamental first decision is whether to adapt an existing nutrient profile model or to develop a new model.

A2.1.1 Develop a new model or adapt the nutrient profile model

Should a new model be developed or an existing model be adapted?

A large number of nutrient profile models have been developed globally for various policy applications (1). Such models include those that serve to categorize foods based on their relative healthfulness for regulating nutrition and health claims, marketing of foods to children and FOPL. All WHO regional offices have developed nutrient profile models for the purposes of identifying foods that should be precluded from being marketed to children (2-5),¹ while the Pan American Health Organization nutrient profile model is also specified for use for nutrient-based warning labels on the front of food packages among other policy applications (6). These WHO models all dichotomize foods into those that are “permitted” or “not permitted” to be marketed to children (or should or should not carry a warning label).

Within a country, nutrient profile models may also have been developed for other policy or regulatory purposes. An assessment should be undertaken, to identify any models for classifying the healthfulness of foods in use within the country and, if such models are found, to determine their appropriateness for application in policies related to FOPL.

¹ The WHO Regional Office for Africa is currently in the process of finalizing their regional nutrient profile model for release.

It is possible to adapt nutrient profile models that have been originally developed for one policy area for use in a different policy area (7). However, in such cases, some modifications would be required. For example, the binary classification of foods in the models developed by WHO regional offices may be appropriate for some types of FOPL, including endorsement logos and nutrient-specific warning labels. Conversely, these binary criteria would not be appropriate for FOPL where graded levels of healthfulness are given (e.g. summary indicator systems) or where nutrient-specific information is provided (e.g. multiple traffic light labels). Instead, the establishment of additional cut-off points would be required (see Box A2 for an example).

A2.1.2 Nutrients to be incorporated

Should the model encompass nutrients to encourage or nutrients to limit?

Most nutrient profile models that have been developed for the purposes of FOPL tend to focus on the key negative nutrients of concern for diet-related noncommunicable diseases (NCDs) – particularly, saturated and *trans*-fatty acids; sodium (or salt); and free, added or total sugars – as well as energy (calories or kilojoules) (8). The selection of these negative nutrients should be based on authoritative recommendations for nutrients to limit for NCD prevention (9).

The focus on negative nutrients is relevant from a population nutrition perspective, and it potentially improves the accuracy of label interpretation. The presence of information on positive nutrients (e.g. fibre, vitamins and minerals) has been shown to greatly influence health perceptions of a product, suggesting that the display of information about positive nutrients should be excluded on FOPL appearing on less healthful products (10). Research evidence relating to other nutrition labels, including nutrient declarations on the back of the pack, suggests that labels indicating high levels of positive nutrients increase product purchases (11), and that nutrition and health claims about positive nutrients increase consumption of labelled foods (12). Thus, the presence of information about positive nutrients may overinflate the perceived healthfulness of products. A review of FOPL by the United States Institute of Medicine concluded that only negative nutrients should be included on front-of-pack food labels (13). Positive nutrients should be excluded because of (13):

- the lack of an identified critical public health need for micronutrients (in developed countries);
- concerns about overfortification;
- limited space for front-of-pack symbols on food packages, for labels where information on individual nutrients is provided separately; and
- the existence of nutrition claims that already highlight positive nutrients within specific products.(13)

Other non-nutrient food components may also be considered as part of criteria for classifying foods based on their relative healthfulness. Fruit and vegetable content, for example, has been considered in many existing nutrient profile models (14), whereby either:

- positive points are allocated for fruit and vegetable content as part of a product's overall nutritional assessment for summary indicator FOPL systems; or
- minimum fruit and vegetable content criteria are set for some food groups to be eligible to carry endorsement logos.

What are the specific nutrients of concern for the target population?

The contribution of key nutrients (and major contributing food groups) to the overall diet of the population should be considered, to ensure that the nutrient profile model is specific to the nutrient priorities of the target population. Nutrient profile models should be designed or adapted to ensure

that the nutrient and food criteria reflect the key nutrient inadequacies or excesses of the target population, and the cultural dietary patterns within a country (1).

Step 1 of the development of a FOPL system outlines the process for undertaking a country contextual analysis to highlight the need for FOPL policy. Part of this contextual analysis includes an epidemiological analysis of population dietary patterns and comparison with national dietary guidelines. Identified at-risk nutrients should be considered as part of the FOPL nutrient profile model.

What nutrient information is mandatory on back-of-pack labels?

To facilitate labelling implementation, consideration should be given to the nutrients that are already required to be displayed on nutrient declarations within a country. Where mandatory back-of-pack labelling for declaration of nutrients is required, these data will be available for use in the derivation of the FOPL nutrient profiling.

A2.1.3 Food groups to be covered

Which food groups should the FOPL apply to?

As outlined in this manual, the initial focus of FOPL policy should be on packaged foods that are required to make a nutrient declaration. FOPL is intended to complement national nutrition guidelines and other nutrition policies and programmes, which should promote the consumption of unpackaged foods, such as fresh fruit and vegetables. However, there are some examples globally of FOPL policies that extend to unpackaged foods. The Swedish Keyhole logo, for example, is also applied to unpackaged fruit, vegetables, bread, cheese, meat and seafood (15). Applying FOPL to unpackaged foods may be a secondary extension of the FOPL policy.

Consideration should also be given to the food categories for which the FOPL should not be used. Specifically, FOPL should not be applied to foods intended for infants and to alcoholic beverages. Products that are specially manufactured for infants have strict compositional criteria, and reformulation is not appropriate. Corresponding with World Health Assembly resolutions, infant and follow-up formula should not be promoted in any way, including through FOPL. Similarly, for alcohol, FOPL systems that promote “healthier” choices (e.g. endorsement logos and summary indicator systems) are not appropriate, given the association between alcohol and health harms.

Ideally, the FOPL system would apply across most packaged food categories that exist within the marketplace in a country. This helps to ensure greater penetration of the label across products, thus facilitating product comparisons and improving consumer familiarity with the FOPL system. Greater label familiarity has been linked to improved consumer use and comprehension of the label information (8).

In the specific case of endorsement logos, prudent consideration should be given to the food categories that may carry the symbol. There is a tension between allowing endorsement logos on ostensibly less healthful foods and supporting consumers to identify relatively better products across food categories. The Swedish Keyhole logo, for example, is not provisioned for use on snack foods. This eliminates the potential for misclassification of these foods as part of a healthy diet if the endorsement logo were to be displayed on these foods. However, the absence of labelling hinders informed consumer choice and does not encourage product reformulation.

Should nutrient profiling criteria apply across or within food categories?

Nutrient profiling criteria can be arranged to discriminate either between foods within a food category, or across all foods. In the former arrangement, criteria are set that are specific to particular food categories. For example, most endorsement logos in use currently establish discrete criteria for different food groups (e.g. milk and dairy products, beverages, breads and cereals, and meat and fish), which vary in the nutrients considered and the nutrient cut-off points (8). Alternatively, criteria that are set to allow comparisons across all foods establish consistent nutrient cut-off points across major food groupings (e.g. all foods and all beverages).

Each of these arrangements has potential benefits and limitations in supporting the consumer and the reformulation aims of FOPL policies. In relation to product reformulation, food category-specific criteria have the potential to target key nutrients for a particular food group and to drive incremental reformulation. Nutrient criteria that apply to specific food categories are usually informed by the nutrient content of products in the market. This allows criteria to be nuanced to the nutrients of concern for particular foods; it also allows cut-off points to be sensitive to technological advancements and adjustments to taste acceptance of these foods over time. On the other hand, nutrient profiling criteria that apply across broad food groupings could stifle food product reformulation incentives within a category, given that category bands are generally wide and that substantial changes may be required to shift to a healthier band (7).

Related to supporting consumer food choices, the value of each approach to setting nutrient profiling criteria within or across food categories depends on the way in which consumers use the information supplied. Few studies have investigated whether consumers apply nutrition information in choosing products within a category, across categories or both. Some studies suggest that consumers perceive that nutrition labels compare products across food categories rather than just within one category (16, 17). However, research on nutrient declarations has found that consumers tend to make comparisons within a category of products (18). It is recommended that further studies be undertaken, to provide better evidence on the way in which consumers expect to use the FOPL to make food selections, either across or within food categories.

A2.1.4 Application of the nutrient profiling criteria

There are three main approaches for applying nutrient profiling criteria for FOPL, and the choice of approach depends on the FOPL system that is adopted (Box A1).

Box A1 Approach to applying nutrient criteria, by FOPL system type

Typical approach to applying nutrient profiling criteria	FOPL system type
1. Enumerate the nutrient contribution that a food makes to recommended nutrient intakes (e.g. RI). Information on individual nutrients is kept separate.	<ul style="list-style-type: none">• Non-interpretive nutrient-specific systems (e.g. %RI)• Hybrid systems (e.g. colour-coded %RI)
2. Set threshold amounts (i.e. cut-off points) for individual nutrients, which divide nutrient contributions into categories that are either graded (e.g. high, medium and low) or binary (e.g. meet the standard and do not meet the standard). Information on individual	<ul style="list-style-type: none">• Interpretive nutrient-specific systems (e.g. multiple traffic lights)• Endorsement logos (e.g. Keyhole logo)

nutrients is kept separate. For endorsement logos, products only display the logo when all relevant cut-off points for individual nutrients are met.

3. Apply algorithms to derive a consolidated score representing products' overall nutritional profile. Information on individual nutrients is combined.
 - Summary indicator systems (e.g. Nutri-Score)

FOPL, front-of-pack labelling; RI, reference intake.

What information should form the basis of nutrient criteria, cut-off points or scoring algorithms?

Nutrition guidelines form the basis for all nutrient profiling approaches outlined in Box A1; however, these guidelines are applied in different ways. In the first approach, guidelines for individual nutrient requirements (e.g. reference intakes, RI) are used to derive the percentage contribution that a food makes to these requirements. For example, in the European Union, RI are based on an "average" adult, with an estimated energy requirement of 8400 kJ/2000 kcal (19).

The second and third approaches establish cut-off points for individual nutrients or algorithms to combine nutrient information, respectively. Again, these criteria should be based on nutrition guidelines for populations, including national dietary guidelines and RI for nutrients. These approaches differ from above by interpreting the level of nutrient contribution that a food makes to dietary recommendations, going beyond the provision of numeric information. Where nutrient criteria apply to specific food categories, the nutrient composition of products in the marketplace are also considered in setting cut-off points based on practicability and consumer acceptability.

Should criteria be adjusted for product categories that target different population age groups?

Nutrition guidelines, and particularly RI, have large variability between population age groups. As noted above, RI are typically based on an "average" adults' requirements. The presentation of RI information on foods that are specifically designed for, or targeting, children would greatly underestimate the contribution that a food made to energy and nutrient requirements for children (20). For example, %RI label information may state that a food contributes 5% of the RI for saturated fat for an adult, when it may contribute 20% of the RI for children. Such an issue would arise in non-interpretive nutrient-specific systems (e.g. %RI) or in hybrid systems that incorporated %RI information (e.g. colour-coded %RI).

This issue was previously investigated by the United Kingdom Department of Health, which explored the possibility of developing RI for children for the purposes of nutrition labelling. It was determined that the creation of a single set of RI for children would be inappropriate, given the heterogeneity in energy and nutrient requirements across childhood ages and stages of development (21). Rather, the application of RI for adults was recommended to be used with a qualifying statement on labels to indicate that the information was based on adult requirements.

What should be the reference amount of food used in the model?

The reference amount expresses the quantity of a product for which the nutrition information on the label relates. This is different from the RI, which compares the contribution that a food makes to

nutrient recommendations. Reference amounts are usually expressed as either per 100 g or per serving (22). There are other reference amounts that are used less frequently; for example, per 100 mL or nutrients expressed in relation to their energy contribution (e.g. percentage of energy from saturated fat).

Again, the decision on whether to base nutrient criteria on a per 100 g or a per serve basis (or another measure) requires careful consideration of the benefits and limitations of each approach. Presenting nutrient-specific information on a per 100 g basis allows consumers to make direct comparisons between products. For this reason, for nutrient declarations, Codex recommends the provision of nutrient information on a per 100 g basis (23).

Presenting nutrient information on a per serving basis allows consumers to identify the specific amount of a nutrient to be consumed in an eating occasion of a product. However, in most countries, serving sizes on nutrition labels are not regulated; hence, inconsistencies in serving sizes across food products within the same food category are likely. This hinders comparisons across products and can cause consumer confusion. Serving sizes on food packages are often smaller than the amount usually consumed, to make the nutritional content appear more favourable. This would mean that the label would underrepresent the amount of a nutrient in the typical portion that consumers eat.

A2.2 Process for validating nutrient profile models for FOPL

“Validity” broadly refers to the accuracy or truthfulness of a measure. Here, “validation of the nutrient profile model” refers to the assessment of whether the criteria classify the healthfulness of products correctly. There are three major approaches for testing the validity of nutrient profile models, which increase in merit but also in complexity (22).

1. **Content validity** – This form of testing involves classifying food products using the nutrient profile model and assessing the extent to which the model is able to discriminate between products based on healthfulness.
2. **Convergent validity** – Given that there is no available “gold standard” for defining healthy food, this approach to validation seeks to compare the convergence or agreement of product classifications obtained using the model against classifications obtained using other systems (e.g. food-based dietary guidelines) (14). This testing identifies any apparent anomalies in product classifications, and is the approach used in testing of most nutrient profile models to date (22).
3. **Predictive validity** – In this most advanced type of testing, nutrient profiling criteria are applied to population dietary data, and these data are then used to compare health risks across population segments with better or worse diet quality, based on the nutrient profiling criteria.

An example of the testing of the French nutrient profile model used in Nutri-Score FOPL is provided in Box A2, applying all three of these validity assessments.

Box A2 Development and validation of the nutrient profiling algorithm underpinning the French Nutri-Score FOPL

The nutrient profiling algorithm underpinning the French Nutri-Score system (a summary indicator FOPL system) was adapted from the United Kingdom Food Standards Agency (FSA)/Ofcom nutrient profile model. This model was originally developed in the United Kingdom to classify food and beverages that were inappropriate to be marketed to children, classifying them as “permitted” or “not permitted” to be advertised. The adaptation of this model for the purposes of Nutri-Score labelling required the conversion of a binary scoring system into a graded classification, with cut-off points to divide algorithm scores into five bands (24). The Nutri-Score system uses traffic-light colour coding (from dark green to dark red) with corresponding letters (from A to E) to provide a five-level scale of product healthfulness. The nutrient profile model uses an algorithm to derive a consolidated score representing products’ overall nutritional profile.

Developing and testing the adapted model involved three steps:

1. First, the FSA nutrient profile model was applied to a French food composition database containing 3508 foods and non-alcoholic beverages consumed by a French population cohort, to determine its ability to discriminate between products based on healthfulness (25). The model was found to have good ability to differentiate the healthfulness of foods using five scoring categories, which determine the thresholds for the five colour-bandings in the label.
2. Second, convergent validity was assessed in multiple studies, which compared rankings of products using the five-category nutrient profiling criteria against expectations, based on the French dietary guidelines (25, 26). In these studies, the nutrient profile model was applied to a French food composition database containing 3508 foods and non-alcoholic beverages consumed by a French population cohort (25) and, separately, to 777 foods available in the French market (26). The distribution of algorithm scores for products was mostly consistent with the French dietary guidelines. Foods that are encouraged to be consumed were more likely to be in the first quintiles of the FSA score distribution (representing more healthful profiles), whereas food groups for which consumption is recommended to be limited were more likely to be in the last two quintiles. Anomalies were identified for some categories – including nuts and dried fruit, beverages, cheese and added fats – where ranking of these products did not align with consumption recommendations (26). To address these anomalies, the scoring system was adapted. This adaptation included modifying the allocation of points for energy and sugars for beverages, and for saturated fatty acids for added fats; and modification of the overall algorithm for cheese, taking protein into account.
3. Lastly, the nutrient profile model was applied to dietary data for an existing French population cohort (27-30). An aggregated diet quality index for individuals was calculated based on the scoring of foods consumed, using the nutrient profile model. The diet quality index was found to accurately characterize the quality of the diets, in that those with a better diet quality had higher intakes of vitamins commonly associated with healthier diets (beta-carotene and vitamin C) (27). Diet quality was also compared to the incidence of weight gain, metabolic syndrome, cardiovascular disease and cancer over 12 years of follow-up. A higher diet quality index, representing poorer food choices, was associated with greater weight gain (29), and increased risk of metabolic syndrome (30), cardiovascular disease (28) and overall cancer (31) at follow-up.

A2.3 Considerations for implementing nutrient profile models for FOPL

Nutrition epidemiology, nutrition science and food technology are undergoing rapid changes. Thus, nutrient profiling criteria should not remain static, but instead must be periodically reviewed to ensure that criteria reflect contemporary dietary guidelines and scientific evidence on nutrition recommendations, new product formulations and food-processing techniques. Such periodic review may occur every 3–5 years following policy implementation, or in line with regular reviews of national dietary guidelines, to ensure consistency.

More regular assessment should be undertaken to continue to identify any apparent anomalies in product classifications after the FOPL is introduced into the marketplace. As an example of how this process has been managed in other countries, Box A3 outlines the formal process for identifying and managing any apparent anomalies in the classification of food in Australia and New Zealand following the implementation of the Health Star Rating FOPL.

Box A3 Process for identifying and managing apparent anomalies in the classification of foods using the Health Star Rating in Australia and New Zealand

The Health Star Rating includes a summary indicator that provides a consolidated rating for products' overall nutritional profile. This rating is visualized using stars, ranging from half a star (least healthful) to 5 stars (most healthful). With the implementation of the Health Star Rating, the Australian and New Zealand governments established a formal process for identifying and managing apparent anomalies that arose because of incorrect classification of foods using the nutrient profile model.

An apparent anomaly occurs when a star rating for a product is inconsistent with the Australian or New Zealand dietary guidelines, or when comparisons within a food category or across comparable food categories would mislead consumers.

Apparent anomalies are identified through public complaints, submitted using an application form (32). Complaints are then considered by the Health Star Rating Advisory Committee, which includes representatives from governments, industry, and consumer and health organizations. The committee may then refer the complaint on for further technical advice. Technical advice may be sought from either a panel of preselected technical specialists, or an individual technical specialist with expertise relevant to the potential anomaly. Where an anomaly is confirmed, the nutrient profile model is updated to resolve the issue.

Appendix 2 references

- 1 FINUT. Nutrient profiling: scientific aims versus actual impact on public health. FIBUT scientific-technical report 01, 2017 (http://www.finut.org/wp-content/uploads/2017/02/Nutrient_Profiling_Scientific_Aims_versus_Actual_Impact_Public_Health_FINUT_final_180117.pdf, accessed 30 July 2018).
- 2 World Health Organization Regional Office for Europe nutrient profile model. Copenhagen: 2015 (<http://apps.who.int/iris/handle/10665/152779>, accessed 10 July 2018).
- 3 World Health Organization Regional Office for the Eastern Mediterranean, Rayner M, Jewell J, Al Jawaldeh A. Nutrient profile model for the marketing of food and non-alcoholic

- beverages to children in the WHO Eastern Mediterranean Region. Cairo: World Health Organization Regional Office for the Eastern Mediterranean; 2017
(<http://apps.who.int/iris/handle/10665/255260>, accessed 30 July 2018).
- 4 WHO nutrient profile model for South-East Asia Region. New Delhi: World Health Organization Regional Office for South-East Asia; 2016
(<http://www.who.int/iris/handle/10665/253459>, accessed 30 July 2018).
- 5 WHO nutrient profile model for the Western Pacific Region. Manila: World Health Organization Regional Office for the Western Pacific; 2016
(<http://apps.who.int/iris/bitstream/handle/10665/252082/9789290617853-eng.pdf?sequence=1>, accessed 30 July 2018).
- 6 Pan American Health Organization nutrient profile model. Washington DC: Pan American Health Organization; 2016 (<http://iris.paho.org/xmlui/handle/123456789/18621>, accessed 30 July 2018).
- 7 Van Camp DJ, Hooker NH, Souza-Monteiro DM. Adoption of voluntary front of package nutrition schemes in UK food innovations. *Br Food J.* 2010;112(6):580–91.
- 8 Kelly B, Jewell J, Breda J, Wickramasinghe K. WHO Health Evidence Network (HEN) evidence synthesis report on front-of-pack food labelling. World Health Organization Regional Office for Europe; In press.
- 9 Global Action Plan for the Prevention and Control of NCDs 2013–2020. Geneva: World Health Organization; 2013.
- 10 Hawley KL, Roberto CA, Bragg MA, Liu PJ, Schwartz MB, Brownell KD. The science on front-of-package food labels. *Public Health Nutr.* 2013;16(3):430–9
(<http://www.ncbi.nlm.nih.gov/pubmed/22440538>, accessed 9 September 2018).
- 11 Baltas G. The effects of nutrition information on consumer choice. *J Adv Res.* 2001;41(2):57–63 (<http://www.journalofadvertisingresearch.com/content/41/2/57.abstract>, accessed 9 September 2018).
- 12 Belei N, Geyskens K, Goukens C, Ramanathan S, Lemmink J. The best of both worlds? Effects of attribute-induced goal conflict on consumption of healthful indulgences. *J Marketing Res.* 2012;49(6):900–9 (<https://doi.org/10.1509/jmr.10.0155>, accessed 28 January 2018).
- 13 Institute of Medicine. Front-of-package nutrition rating systems and symbols: promoting healthier choices. Washington, DC: The National Academies Press; 2012.
- 14 Nutrient profiling: report of a technical meeting, London, United Kingdom, 4–6 October 2010. Geneva: World Health Organization; 2011
(http://www.who.int/nutrition/publications/profiling/WHO_IASO_report2010/en/, accessed 6 September 2018).
- 15 Swedish National Food Agency, Danish Veterinary and Food Administration, Norwegian Directorate of Health, Norwegian Food Safety Authority. Design manual for the Keyhole logo – prepacked food and generic marketing. 2015
(http://www.nokkelhullsmerket.no/frontpage_en/article640.ece/binary/Design%20manual%20for%20the%20Keyhole%20logo, accessed 1 August 2018).
- 16 Feunekes GI, Gortemaker IA, Willems AA, Lion R, van den Kommer M. Front-of-pack nutrition labelling: testing effectiveness of different nutrition labelling formats front-of-pack in four European countries. *Appetite.* 2008;50(1):57–70
(<http://www.ncbi.nlm.nih.gov/pubmed/17629351>, accessed 9 September 2018).
- 17 Parker G, Souvlis P, Parry-Husbands H. Health star rating system: consumer use and understanding Surrey Hills, NSW, Australia: Pollinate Research; 2015
([http://healthstarrating.gov.au/internet/healthstarrating/publishing.nsf/content/474CBBEC911CFF01CA25803A007E7B2B/\\$File/HSR-Consumer-Use-and-Understanding-Benchmark-report.docx](http://healthstarrating.gov.au/internet/healthstarrating/publishing.nsf/content/474CBBEC911CFF01CA25803A007E7B2B/$File/HSR-Consumer-Use-and-Understanding-Benchmark-report.docx), accessed 31 July 2018).
- 18 Higginson CS, Rayner MF, Draper SW, Kirk TR. The nutrition label – which information is looked at? *Nut Food Sci.* 2002;32(3):92–9.

- 19 European Commission. Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers. Brussels: European Parliament, Council of the European Union; 2011 (<http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32011R1169&from=en>, accessed 9 September 2018).
- 20 Blewett N, Goddard N, Pettigrew S, Reynolds C, Yeatman H. Labelling logic: review of food labelling law and policy. Canberra: Commonwealth of Australia; 2011.
- 21 United Kingdom Department of Health. Update on children's reference intakes. 2013.
- 22 Rayner M, Scarborough P, Kaur A. Nutrient profiling and the regulation of marketing to children. Possibilities and pitfalls. *Appetite*. 2013;62:232–5 (<http://www.sciencedirect.com/science/article/pii/S0195666312002450>, accessed 6 September 2018).
- 23 Codex Alimentarius Commission. Guidelines on nutrition labelling CAC/GL 2-1985. Adopted in 1985. Revised in 1993 and 2011. Amended in 2003, 2006, 2009, 2010, 2012, 2013, 2015, 2016 and 2017. Annex adopted in 2011. Revised in 2013, 2015, 2016 and 2017. Geneva: Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO); 2017 (http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCAC%2BGL%2B2-1985%252FCXG_002e.pdf, accessed 6 September 2018).
- 24 Julia C, Hercberg S. Development of a new front-of-pack nutrition label in France: the five-colour Nutri-Score. *Public Health Panorama*. 2017;3(4):537–820.
- 25 Julia C, Kesse-Guyot E, Touvier M, Méjean C, Fezeu L, Hercberg S. Application of the British Food Standards Agency nutrient profiling system in a French food composition database. *Br J Nutr*. 2014;112(10):1699–705 (<https://www.cambridge.org/core/journals/british-journal-of-nutrition/article/application-of-the-british-food-standards-agency-nutrient-profiling-system-in-a-french-food-composition-database/DC2AB3C0EE6DD7A00E600E25B1A76C4F>, accessed 9 September 2018).
- 26 Julia C, Ducrot P, Péneau S, Deschamps V, Méjean C, Fézeu L et al. Discriminating nutritional quality of foods using the 5-color nutrition label in the French food market: consistency with nutritional recommendations. *Nutr J*. 2015;14(1):100–12 (<https://nutritionj.biomedcentral.com/track/pdf/10.1186/s12937-015-0090-4?site=nutritionj.biomedcentral.com>, accessed 9 September 2018).
- 27 Julia C, Méjean C, Touvier M, Péneau S, Lassale C, Ducrot P et al. Validation of the FSA nutrient profiling system dietary index in French adults—findings from SUVIMAX study. *Eur J Nutr*. 2016;55(5):1901–10 (<https://doi.org/10.1007/s00394-015-1006-y>, accessed 9 September 2018).
- 28 Adriouch S, Julia C, Kesse-Guyot E, Méjean C, Ducrot P, Péneau S et al. Prospective association between a dietary quality index based on a nutrient profiling system and cardiovascular disease risk. *Eur J Prev Cardiol*. 2016;23(15):1669–76 (<https://doi.org/10.1177/2047487316640659>, accessed 31 July 2018).
- 29 Julia C, Ducrot P, Lassale C, Fézeu L, Méjean C, Péneau S et al. Prospective associations between a dietary index based on the British Food Standard Agency nutrient profiling system and 13-year weight gain in the SU.VI.MAX cohort. *Prev Med*. 2015;81:189–94 (<http://www.sciencedirect.com/science/article/pii/S0091743515002741>, accessed 6 September 2018).
- 30 Julia C, Fézeu LK, Ducrot P, Méjean C, Péneau S, Touvier M et al. The nutrient profile of foods consumed using the British Food Standards Agency nutrient profiling system is associated with metabolic syndrome in the SU.VI.MAX cohort. *J Nutr*. 2015;145(10):2355–61 (<http://dx.doi.org/10.3945/jn.115.213629>, accessed 9 September 2018).
- 31 Donnenfeld M, Julia C, Kesse-Guyot E, Méjean C, Ducrot P, Péneau S et al. Prospective association between cancer risk and an individual dietary index based on the British Food

Standards Agency nutrient profiling system. Br J Nutr. 2015;114:1702–10
(<https://www.cambridge.org/core/services/aop-cambridge-core/content/view/S0007114515003384>, accessed 6 September 2018).

- 32 Australian Government Department of Health. Health Star Rating system policy context – what is an anomaly? 2016
([http://healthstarrating.gov.au/internet/healthstarrating/publishing.nsf/Content/873516DC76D23EC2CA257DA500196043/\\$File/Process%20for%20assessing%20a%20potential%20anomaly.pdf](http://healthstarrating.gov.au/internet/healthstarrating/publishing.nsf/Content/873516DC76D23EC2CA257DA500196043/$File/Process%20for%20assessing%20a%20potential%20anomaly.pdf), accessed 1 August 2018).

Pre-formatted final draft - May 2019

Appendix 3. Monitoring and evaluation framework for FOPL

The ultimate goal of the evaluation is to inform continued improvement of the FOPL system. In the early stages of development, evaluation identifies the need for FOPL intervention and the establishment of FOPL system specifications (contextual analysis and formative evaluation). Following implementation, evaluation should monitor the extent and fidelity of the FOPL system delivery (i.e. process evaluation). Later, it should monitor the impact of the FOPL system on changes to consumers' understanding of the FOPL system, and food purchasing and consumption behaviours and the food supply (i.e. impact and outcome evaluation). This framework provides recommended evaluation activities for each stage of the FOPL system development and implementation.

The final design of the monitoring and evaluation framework for a country will depend on a number of factors, including:

- whether the FOPL system is mandatory or voluntary; and
- what resources are available for evaluation, including money, access to databases on packaged foods, access to data on food and nutrient intakes, and access to sales data.

This framework details how these factors may affect the final design and methodologies chosen for monitoring and evaluation.

The monitoring and evaluation framework should refer to the guiding principles presented in this manual. Particularly important is the need for the collection of baseline data to support monitoring and evaluation of the impact of the FOPL system on consumers, and to monitor reformulation of food products (Principle #15). The design of the monitoring and evaluation framework should occur before any implementation of the chosen FOPL system. As with all aspects of FOPL system development and implementation, monitoring and evaluation activities should be government led, but may be carried out by an independent body or research group.

There are five stages to the monitoring and evaluation of a FOPL system, which follow the usual processes of health promotion policy evaluation:

Stage 1: Contextual analysis (needs assessment)

Stage 2: Formative evaluation

Stage 3: Process evaluation

Stage 4: Impact evaluation

Stage 5: Outcome evaluation

Detailed information on each of these stages is outlined below, including the time frame, purpose, recommended activities, methodological and data considerations, resource requirements and engagement with stakeholders.

A3.1 Stage 1: Contextual analysis

Time frame: This is undertaken at the initial phase of FOPL system development.

Purpose: This stage refers to Step 1 of the development of the FOPL system (see Fig. 1), which involves defining the problem to be addressed by the FOPL system and the situational context. It

provides the rationale for the FOPL intervention and the basis for the legal framework in which the implementation of the FOPL system will be situated.

Activities:

- Epidemiological analysis of diet-related NCDs and population dietary patterns.
- Analysis of the legal framework under which the proposed FOPL system would be introduced.
- Analysis of relevant national nutrition policies.
- Assessment of consumer understanding and use of nutrition labelling (including nutrient declarations and any existing FOPL systems).

Methodological and data considerations: Baseline data on consumer understanding and use of nutrition labelling is required, including nutrient declarations and any existing FOPL systems. There may not be awareness of the proposed FOPL system before implementation. Nevertheless, understanding the drivers for consumer choice of packaged foods, and knowledge and use of current nutrition labelling, is important background information in identifying the best FOPL system to meet consumers' needs.

A3.2 Stage 2: Formative evaluation

Time frame: This is undertaken at the initial phase of FOPL system development.

Purpose: This stage refers to Step 4 of the development of the FOPL system (see Fig. 1), which relates to selecting the FOPL system format (including design and content). Formative evaluation involves literature search and pretesting of proposed FOPL systems to identify the preferred FOPL system for adoption.

Activities:

- Review the evidence on the effectiveness of existing FOPL systems in supporting consumers to make informed food purchases and healthier eating choices, as described in the background paper on FOPL developed for the WHO Technical Meeting on Nutrition Labelling for Promoting Healthy Diets (1).
- Where there is a lack of evidence on the effectiveness of FOPL systems for a country, or where a new system is being developed, undertake primary research with consumers to assess the usefulness of system elements, including format and content.

Methodological and data considerations: Study outcomes to be assessed in both literature reviews and primary consumer studies include consumer perceptions, understanding, acceptability and use or intended use of FOPL systems. Studies objectively assessing consumer understanding of FOPL systems are preferred because self-reported understanding is prone to misreporting.

Resource requirements: The adaptation of an existing system takes less time and is less expensive than developing a new FOPL system from scratch. Any newly developed system should be thoroughly pretested with consumers.

Engagement with stakeholders: Seek input from the food industry, the scientific community, and consumer and health organizations to identify FOPL systems that are feasible for adoption or adaptation and any available evidence of their effectiveness.

A3.3 Stage 3: Process evaluation

Time frame: This is undertaken at the initial phases of FOPL system implementation (1–2 years post-implementation)

Purpose: The purpose of process evaluation is to assess the extent and fidelity of implementation of the FOPL system. “Extent” refers to the number and proportion of food manufacturers or retailers using the FOPL system; and the number, proportion of products and type of food products displaying the FOPL. “Fidelity” refers to the accuracy of the label in meeting the policy requirements (format and content); that is, the compliance.

Activities:

- Assess the extent of implementation by measuring the FOPL system uptake by food manufacturers and food retailers. This includes the proportion of manufacturers or retailers using the FOPL system, and the number and proportion of products displaying the FOPL system. For mandatory systems, this information can also be used as a compliance tool.
- Assess the fidelity of implementation by comparing the consistency of labels with the FOPL system’s format (i.e. design and content) requirements, including placement on pack, size, colour contrast and correct use of the nutrient profiling criteria.
- Identify any anomalies that arise. These may be the result of unexpected product healthfulness ratings due to issues with the nutrient profiling criteria. Anomalies occur when elements of the FOPL are inconsistent with the national dietary guidelines and nutrition policies. They also occur when elements of the FOPL used to make comparisons within a food category or across comparable food categories would mislead consumers. Often, these anomalies do not become apparent until the system is operating. Anomalies should be managed under a governance system that will oversee the whole process of implementation, monitoring and evaluation, and enforcement (see Section 5).
- Collect and assess data on media and public comment on the FOPL system. Tracking this over time will form part of the story of the progress and acceptance or success of the FOPL system. It will also assist with public messaging and the focus of consumer education.

Methodological and data considerations: There are two possible approaches for capturing information on the extent and fidelity of FOPL system implementation:

- comprehensive assessment of the FOPL system on retail food products, using audit inspections; and
- industry self-reporting on the uptake of the FOPL system, supplemented with independently conducted partial audits in retail outlets to confirm the self-reported information.

In both cases, it is preferable for audit data to be collected and assessed by an independent body or research group. Photographs of packages should be taken as part of the audit data collection (2). Photographs should include the FOPL logo, the nutrient declaration and the ingredients list (where nutrient profiling criteria use non-nutrient declaration ingredients, such as fruit or vegetable

content). It is worthwhile photographing other nutrition labelling elements such as nutrient content claims and health claims, because these are an important part of the environment surrounding the FOPL system. The photographs can be used to assess fidelity of the FOPL system both in terms of consistency with the nutrient profiling criteria and in terms of the general correct use of the different elements of the label, such as contrast and placement on pack.

Audit data should be as current as possible, using available data sources. Data that are collected on an annual basis work well for longer term monitoring, but do not provide up-to-date data on industry uptake in the short term.

Resource requirements: Comprehensive assessments of the FOPL system on retail food products requires greater time and financial resources. However, photographic data of food labels that are captured for the purpose of assessing the extent and fidelity of the FOPL system (process evaluation) can also be used to assess changes in nutrient compositions of food products as a result of the FOPL system (impact evaluation).

Engagement with stakeholders: Engagement with the scientific community, and with consumer and health organizations is useful for identifying the availability of any existing databases of the retail food supply. Input will be required from the food industry where self-reported information on label uptake is used. Systems for capturing these self-reported data would need to be established.

A3.4 Stage 4: Impact evaluation

Time frame: Baseline measures are assessed at pre-implementation stage; and intermediate-term follow-up is undertaken in 2–3 years post-implementation.

Purpose: The purpose of the impact evaluation is to assess the effect of the FOPL system on changes to consumer understanding of the FOPL system, product purchases and food product reformulation.

Activities:

- Assess changes to consumer awareness of the FOPL system.
- Assess changes to consumer understanding of the FOPL system, in isolation or relative to other FOPL systems.
- Assess changes to consumers' trust in the FOPL system.
- Assess changes to consumer food purchasing behaviours.
- Assess changes to the nutrient composition of the retail packaged food supply.

Methodological and data considerations:

To assess *changes* in consumer-related outcomes (e.g. FOPL system understanding, trust, use and purchases) and reformulation outcomes, the same methods and measures must be used at baseline and follow-up.

It is well documented that there are sociodemographic variations in consumers' understanding and use of FOPL systems. Consumer research should consider sampling approaches, to ensure representation from particular cultural and socioeconomic groups that are known to have poorer nutrition labelling literacy.

Measures of consumers' awareness of the FOPL system may include both unprompted and prompted recognition. Consumers' self-reported understanding of FOPL systems is prone to social desirability bias and objective measures are preferred. Trust in the system is important in supporting consumer use. These consumer data can also help to inform consumer education and social marketing messages during the ongoing implementation of the FOPL system.

In measuring changes to consumer food purchasing behaviours, product sales data are ideal, but can be difficult or expensive to source. Alternative approaches to measuring changes in purchasing patterns can include the collection of supermarket receipts in a sample of consumers over time, or self-reported use or intention to use the FOPL system for informing food purchases.

Data on the nutrient composition of packaged foods can be collected in line with the comprehensive audit procedures outlined in the section on process evaluation. That is, data on nutrition labelling (e.g. FOPL, nutrient declarations and ingredients lists) on packaged foods can be used to identify changes in food product formulations following the introduction of the FOPL system, and to assess the extent and fidelity of implementation as part of process evaluation. Country-specific data collected by an independent body or research group would be ideal. Some of the global food supply monitoring initiatives available may assist with data collection (3). Data collection should ideally include photography of the food package. Important data to be transcribed from photographs into a database include nutrient content per 100 g or 100 mL for nutrients of interest, serving size recommendations, and use of any other nutrition or health claims. Baseline and follow-up data on the nutrient content of packaged foods displaying a FOPL system can be compared to assess reformulation (taking into account any secular changes, such as gradual reductions in sodium in some food categories). New foods entering the market can be identified as well as product lines that have been deleted (perhaps due to unfavourable nutrient compositions).

Resource requirements: Where resources are constrained, impact evaluation measures should focus on consumer-related outcomes (e.g. FOPL system understanding, use and trust), given that the principal aim of FOPL systems is to help all consumers to make informed food purchases and healthier eating choices. Reformulation is an additional benefit and, as such, should be assessed where resources allow or where established systems for data collection are available.

Impact evaluation should *not* occur until there has been sufficient FOPL system implementation (extent and fidelity), as identified through the process evaluation. Premature impact evaluation is a waste of resources.

Engagement with stakeholders: Inputs from the scientific community, and consumer and health organizations may be sought for support in undertaking the consumer research and for identifying the availability of any existing databases of the retail food supply. Food industry supply of sales data is possible but is unlikely due to commercial-in-confidence issues.

A3.5 Stage 5: Outcome evaluation

Time frame: Baseline measures are assessed at pre-implementation stage; and long-term follow-up is undertaken in 3–5 years post-implementation.

Purpose: The purpose of the outcome evaluation is to assess the effect of the FOPL system on changes to population dietary intakes. A positive change in dietary intakes is the ultimate goal of FOPL systems. Implementation of FOPL systems should be one part of a comprehensive suite of activities and policy actions to support and promote healthy diets. Dietary changes that are identified over time from national food consumption surveys may not be wholly attributable to the FOPL system intervention, but rather to the range of policy actions that a country has implemented.

Activities:

- Assess changes to population dietary intakes, including changes to intakes of target nutrients.
- Assess changes to key food sources of target nutrients.

Methodological and data considerations:

To assess *changes* in population dietary intakes, the same methods and measures must be used at baseline and follow-up.

National food intake data are desirable to model changes in dietary intakes, ideally including nutrient contribution to the diet from specific food items. Analyses should consider sociodemographic variations in dietary outcome data. Nutrient status should also be compared to WHO's dietary goal guidelines. These nutrient intake goals were developed by WHO for the consideration of countries in establishing their dietary recommendations for the prevention of diet-related NCDs (4).

An alternative approach for assessing changes to dietary intakes can include combining information on purchasing patterns (e.g. sales data) and the nutrient content of purchased foods. This provides information on "nutrients purchased", and can be a proxy for nutrients consumed.

Although the FOPL system may support the reduction of NCDs, it is not recommended that this end-point be included in the monitoring and evaluation framework because of the lag time between changes to the population's diets and changes to disease outcomes.

Resource requirements: Outcome evaluation should *not* occur until there has been sufficient FOPL system implementation (extent and fidelity), as identified through the process evaluation, and there has been a demonstrable change to consumers' awareness, understanding or use of the FOPL system, as identified through the impact evaluation. Premature outcome evaluation is a waste of resources.

Engagement with stakeholders: Inputs from the scientific community may be sought for support in undertaking analyses of the population's nutrition and food consumption data. Food industry supply of sales data is possible but unlikely due to commercial-in-confidence issues.

A3.6 Time frame for monitoring and evaluation

The Gantt chart at Fig. A1 outlines notional timings for the evaluation stages. The timing for the evaluation of outcomes may differ for mandatory versus voluntary FOPL systems, with shorter

evaluation time frames possible for Stages 3–5 (process, impact and outcome evaluation) for mandatory FOPL systems where implementation targets are established within set time periods.

Pre-formatted final draft - May 2019

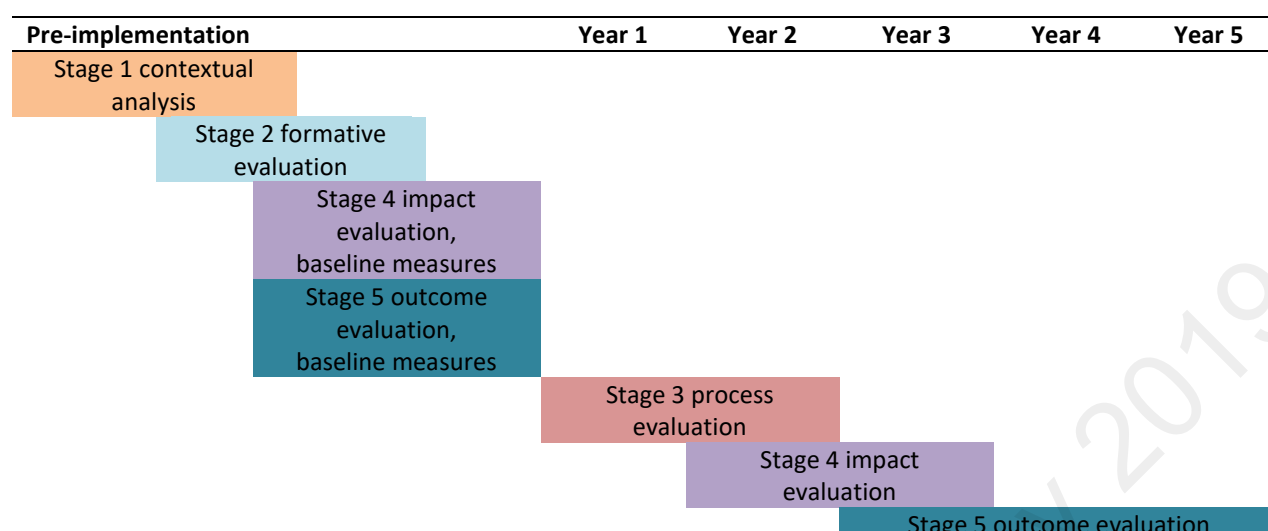


Fig. A1. Timeline for evaluation stages

Appendix 3 references

- 1 Kelly B. Background paper on front-of-pack food labelling (FOPL). Geneva: World Health Organization 2015.
- 2 Nutrient profiling: report of a technical meeting, London, United Kingdom, 4–6 October 2010. Geneva: World Health Organization; 2011 (http://www.who.int/nutrition/publications/profiling/WHO_IASO_report2010/en/, accessed 6 September 2018).
- 3 The George Institute for Global Health Australia. Global Food Monitoring Initiative. 2017 (<http://www.georgeinstitute.org.au/projects/global-food-monitoring-initiative>, accessed 6 September 2018).
- 4 Diet, nutrition and the prevention of chronic diseases: report of the joint WHO/FAO expert consultation. WHO Technical Report Series, No 916 (TRS 916). Geneva: World Health Organization; 2003 (<http://www.who.int/dietphysicalactivity/publications/trs916/en/>, accessed 6 September 2018).

Department of Nutrition for
Health and Development

World Health Organization
20, avenue Appia
CH-1211 Geneva 27

tel: +41 22 791 2111

fax: +41 22 791 3111

www.who.int



**World Health
Organization**