

Manual to develop and implement front-of-pack nutrition labelling

Guidance for countries on the selection and testing of evidence-informed front-of-pack nutrition labelling systems in the WHO European Region



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EXECUTIVE SUMMARY

Unhealthy diets are one of the most important risk factors for non-communicable diseases (NCDs) in the WHO European Region. They are associated with an increased risk of overweight and obesity, cardiovascular disease, diabetes and some types of cancer. As a result, one of the major challenges for countries is to promote healthier diets among the population. Although many governments develop and disseminate food-based dietary guidelines, consumers often struggle to translate the guidance into their day-to-day dietary behaviour. Diets in the European region typically include a large share of manufactured foods, and consumers have a low understanding of their nutritional quality and struggle to discriminate between products based on their relative healthfulness. Back-of-pack nutritional information is usually available to consumers in the WHO European Region, but the detailed numerical information is considered to be difficult to understand and requires high cognitive workload to interpret.

Front-of-pack nutrition labelling (FOPL), and more specifically interpretative FOPL providing simplified nutritional information in the form of symbols, colours or words, is seen as a cost-effective measure to help consumers understand the nutritional quality of foods, and orient them towards healthier food choices at the point of purchase. WHO recommends the implementation of FOPL as one of the ‘best-buy’ measures to help prevent NCDs. FOPL aligns with the policy tools recommended in the WHO European Food and Nutrition Action Plan 2015–2020 to create healthier food environments.

Some countries in the WHO European region have implemented FOPL but this has taken different forms, with various degrees of interpretation of the nutritional composition of foods. Research provides evidence as to the effectiveness of the various schemes, as well as a theoretical framework for countries to use in order to develop or adapt a FOPL scheme that is evidence-based and suited to the national context.

In this context, this manual was developed to provide guidance to countries wishing to implement an effective FOPL scheme to support consumers to identify healthier food choices.

This document outlines a five-step approach that countries can follow to develop and implement an evidence-based FOPL scheme:

1. Select the specific strategy: what is expected from a FOPL
2. Select the type of the FOPL graphical design
3. Determine the underlying nutrient profiling system
4. Define studies to be performed to select the final format
5. Establish monitoring procedures

Key to developing an evidence-based model, suited to the national context, is the process of conducting formative research studies that support the selection and refinement of the scheme. Comparative studies enable countries to select the most effective scheme that performs best among consumers. Guidance for each step and examples from previous research are provided to support countries to implement valid formative research methods.

BACKGROUND TO FRONT-OF-PACK LABELLING

In order to tackle the growing burden of nutrition-related non-communicable diseases (NCDs), government-led strategies and policies have been introduced to improve the diet in the population¹². Among the variety of possible interventions, front-of-pack nutrition labels (FOPLs) have received growing attention from public authorities, and are now considered one of the key policies to tackle NCDs^{3,4}. In the European region, FOPL are recommended in the WHO European Food and Nutrition Action Plan, as a key lever to help consumers make healthier choices, drive reformulation and thereby promote healthier diets⁵.

A back-of-pack nutrient declaration – usually a table providing detailed numerical information on the nutritional composition of the food – is a mandatory requirement in most countries in the WHO European Region^{6,7}. However, studies have shown that back-of-pack nutrient declarations are rarely used in purchasing situations⁸, and consumers report that they are difficult to understand, in particular by those with lower levels of education or nutrition knowledge.

Conversely, FOPL refers to nutrition labelling systems that are presented on the front of food packages with the aim of supporting consumers to make healthier food choices at the point of purchase by delivering simplified and at-a-glance nutritional information^{9–11}. More specifically, interpretative schemes are considered the most helpful for consumers – i.e. those FOPLs that convey some form of evaluative judgement on the nutritional quality of a food, through the use of symbols, words or colours. FOPLs need to be easily and quickly interpreted, given that the average time spent selecting a product in a purchasing environment is an estimated 35 seconds⁸. Moreover, FOPLs can act as an incentive for manufacturers to reformulate their products towards healthier composition. Twin motivations operate, where manufacturers aim to avoid having to make unfavourable declarations and are incentivised by the possibility to communicate healthier composition – evidence of which would materialize on the FOP label^{12,13}.

Many countries, globally and in the WHO European region, have implemented some form of FOPL in recent decades, with a clear acceleration in the past five years, and the development of new types of FOPL schemes⁷.

FOPL was initially introduced in 1989 by Sweden (“Keyhole logo”¹⁴, implemented in three further three Nordic countries since) and in the 2000s in the Netherlands (“Choices logo”, since abandoned in 2006¹⁵) and the United Kingdom (“colour coded % RNI”, widely referred to as traffic light labelling¹⁶)ⁱ. In 2014, New Zealand and Australia introduced the “Health Star Rating System”¹⁷. In 2016, Chile adopted warning symbols for key negative nutrients, displayed when the content is considered too high in foods. Israel has adopted similar legislation for the use of warning labels on foods high in sugar, saturated fat and salt, with full implementation expected in 2020. Multiple countries in South America are also considering adopting similar warning labels. Finally, in 2017, France adopted “Nutri-Score”, a summary graded and colour-coded indicator of the overall nutritional quality of foods, from A/dark green to E/dark orange. Spain and Belgium adopted the Nutri-Score in 2018, followed in 2019 by Germany, Luxembourg and Switzerland, and expected to be adopted in the Netherlands in 2021. Parallel to these government-endorsed schemes, FoodDrinkEurope (representing the European food and drink industry) developed the Percentage Guideline Daily Amounts (%GDA) scheme, recently modified as the % Reference Intakes scheme. This scheme was introduced in 2006 as a voluntary initiative from manufacturers and appears as an FOP nutrition label in numerous countries¹⁸. Initiatives from industry in the EU region also include the Evolved Nutrition Label, supported initially by a consortium of 6 multinational food companies (Mars, Mondelez, Nestlé, PepsiCo, Coca-Cola and Unilever). The Evolved Nutrition Label is a variation of the British traffic lights system, but with a colour allocation based on portion rather than on 100g/100ml, which has been shown to modify the way that food products are categorised¹⁹. After the withdrawal of Mars in March 2018, the consortium announced in November 2018 that the development of the ENL system would be suspended in the EU, and Nestlé also withdrew from the scheme.

The various formats of FOP nutrition labelling currently in use throughout the world can be organized depending on the level of interpretation of the nutritional composition that they provide to the consumer: some schemes are considered purely informative if they only reproduce part of the information already available on the back of the pack without additional interpretation (as the % Reference Intakes label) while other schemes may vary in the degree of interpretation that they provide. For these interpretative schemes, the nature of the information, either can be nutrient-based (nutrient specific systems) or provide an overall assessment of the nutritional quality of the food (summary indicator systems) (see Table 1). In the nutrient-specific category, two main formats appear in practice: colour-coded

ⁱ While most research studies identify the Keyhole and Choices endorsement logos as a form of FOPL, hence the inclusion here, logos that identify better-for-you products may be considered claims under Codex Alimentarius guidelines and corresponding EU regulation.

(such as the traffic lights format) and warning labels (affixed on foods depending on their levels of certain nutrients). Summary labels can also be subdivided into two main categories: endorsement schemes (such as the Choices or Green Keyhole schemes), which are applied only to products with higher nutritional quality, and graded indicators, which appear on all products and provide a graded information on the nutritional quality of the product (such as the Nutri-Score or the Health Star Rating System).

| | |
|--|---|
| Endorsement logos (e.g. Keyhole, Choices) | <ul style="list-style-type: none"> • nutrient levels combined to give an overall assessment of absolute healthfulness; • positive evaluative judgement only (on better-for-you foods); • products are eligible to carry the endorsement symbol only if a nutrition standard is met • nutrient cut-off points binary (i.e. if a product meets the standard it can carry the label) |
| Summary indicator systems (e.g. Health Star Rating, Nutri-Score) | <ul style="list-style-type: none"> • nutrient levels combined to give an overall assessment of relative healthfulness; • both positive and negative evaluative judgements (graded directive assessment of food overall); • can appear on all eligible products; • nutrient cut-off points graded (e.g. high, medium, low) |
| Nutrient-specific warning labels (e.g. Chilean warning label) | <ul style="list-style-type: none"> • information on individual nutrients kept separate; • products that exceed a nutrition standard identified (negative judgements of worse-for-you foods); • nutrient cut-off points binary (i.e. if a product exceeds the threshold, it must carry the label) |
| Nutrient-specific interpretive label | <ul style="list-style-type: none"> • information on individual nutrients kept separate; • both positive and negative evaluative judgements (graded directive assessment of nutrients); • nutrient cut-off points graded (e.g. high, medium and low) |

TABLE 1 MAJOR TYPES OF FOPL SYSTEM THAT INCLUDE EVALUATIVE JUDGEMENTS ABOUT THE NUTRITIONAL QUALITY OF FOOD PRODUCTS

Interpretative schemes appear to be the most useful to consumers, as they provide some indication as to the nutritional quality of a product and simplify the nutritional information available at the back of the pack (see Figure 1).

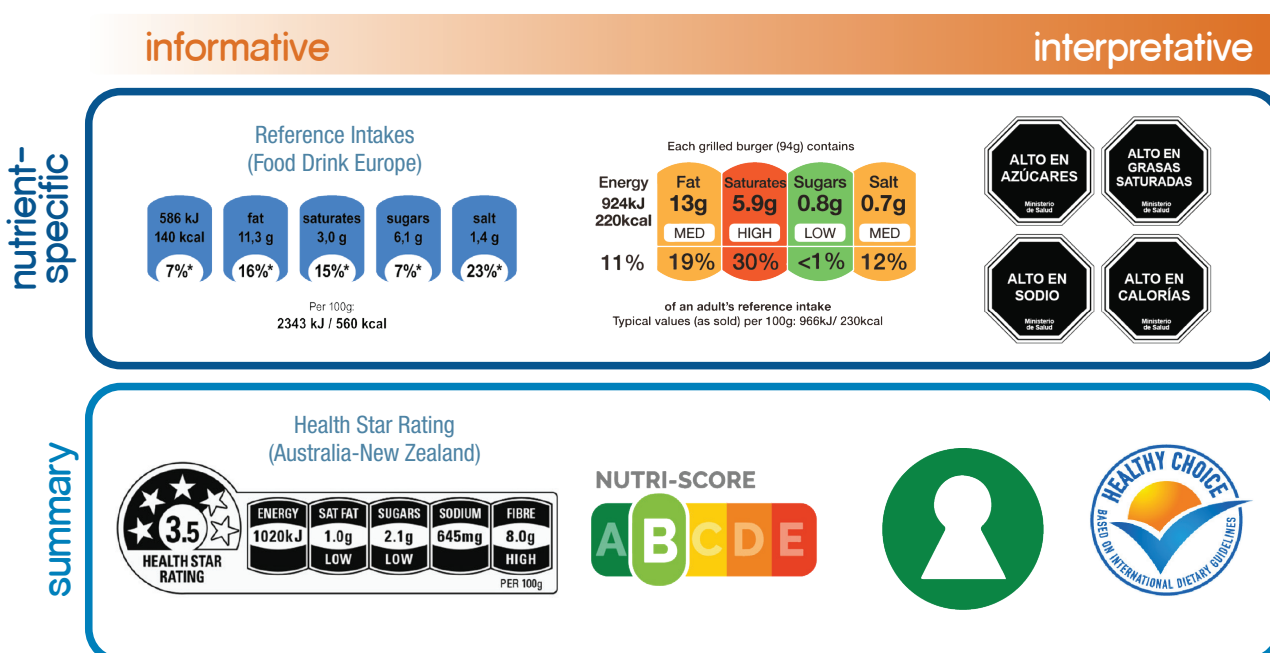


FIGURE 1 TYPES OF LABELLING SYSTEMS AND EXAMPLES OF GOVERNMENT ENDORSED SCHEMES

PURPOSE OF THE PRESENT MANUAL

The manual aims to support countries in the WHO European Region in the development of FOPL schemes and key conceptual thinking about selection and design of the specific scheme. It aims to highlight the different steps countries might go through and the policy-relevant research that might be conducted to inform each step. The manual aims to support WHO European countries implement the recently published WHO Guiding Principles and Framework Manual for Front-of-Pack Labelling for Promoting Healthy Diets.

The scope has been kept broad to include different formats of interpretative labelling currently on the market. However, it is evidence informed in the guidance it provides and applies as a foundation the strong evidence that consumers require interpretative elements⁷.

This manual includes a presentation of the steps that appear necessary for any country wishing to implement an effective FOPL scheme, but includes in an appendix a detailed description of all the research studies that may be conducted to support a given scheme.

Other aspects of the policy development process, such as needs assessments, consultation and stakeholder engagement, are out of scope of this manual. However, many of these issues have been considered in a recent WHO Europe Health Evidence Network synthesis report on the policy development and specifications for FOPL⁷.

DETAILED STEPS AND CONSIDERATIONS WHEN SELECTING AND VALIDATING A FRONT-OF-PACK LABELLING SYSTEM

ESTABLISHING GENERAL OBJECTIVE OF FOPL

Front-of-pack labelling can respond to a number of objectives that may differ in their ambition, from simply informing the consumer on the nutrient content of foods to larger objectives relating to communicating evaluative judgements about foods in order to improve the nutritional quality of consumer purchases. Moreover, in the framework of a more comprehensive nutritional program, a labelling system may be used to shape consistent rules for other policies, such as advertising regulations, regulation of the content of vending machines, etc.

An additional aspect of FOPL that needs to be kept in mind by policy makers is the incentive it can provide to reformulate food products. Indeed, FOPLs can be a potential incentive for reformulation and innovation for manufacturers. However, FOPL schemes impact differentially on reformulation, depending both on their format and their underlying nutrient profiling system. Depending on the government's objective, reformulation may be more or less of a policy priority, and included in the selection process of a FOPL.

For FOPL to support consumers to make informed food purchases and healthier eating choices, consumers must be aware of, and recognise the FOPL, understand what it means and 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 when the format promotes visibility, such as being large in size, placed in a consistent position on the front of packages (e.g. top right hand side) and using contrasting colours. Consumers' ability to use FOPL is assisted by labels that contain interpretive elements (e.g. meaningful colours), while motivation to use FOPL may be supported by systems that are quick to interpret and that apply across foods of all prices.

In the selection of a FOPL strategy, policy-makers should first review the regulatory environment in which the implementation of FOPL policy would fall and the FOPL scheme that may already be in place in neighbouring countries. Policy-makers can then build on previous experience and evidence to select a FOPL adapted to their environment.

STEP 1. SELECT THE LABELLING OBJECTIVES

In terms of strategies, different options can be discussed:

1. Promoting choice of healthier foods
2. Promoting the avoidance of less healthy foods
3. Comparing the nutritional quality of foods

The definition of healthy, healthier, unhealthy, less healthy (or some other indicator of the nutritional quality of foods) can be determined based on nutrient profiling approaches that take into account either (i) specific nutrients contents (sugar, salt, calories, etc.) or (ii) the overall nutritional quality of foods, using an algorithm score.

If incentivizing reformulation is an important secondary outcome of the labelling scheme, this should be factored into the decision-making process when selecting graphical design and thresholds set in the nutrient profiling system. If for example thresholds to define healthier foods are very stringent in terms of nutrient content, they may appear unreachable for a large number of food manufacturers. In this case, the inclusion of multiple thresholds (or a sufficient number of healthiness categories) may provide more scope to encourage reformulation. For example, for a biscuit, if the threshold for sugar is set at a 50% level below its current content, there is little incentive for reformulation, while a 10-20% threshold may appear more reachable in the scope of reformulation. However this needs to be weighed up against the potential risk that the FOPL may encourage consumers to perceive that food as “healthy” or “healthier” than is actually the case.

Once a main objective is set for labelling, the options for FOPL, the graphical designs and nutrient profiling systems are somewhat already pre-determined. The graphical designs that may be selected based on the main objective of the FOPL are outlined below.



FIGURE 2 DECISION TREE FOR FOP SYSTEMS DEPENDING ON THE LABELLING OBJECTIVES. NUTRI-SCORE (FRANCE), MULTIPLE TRAFFIC LIGHTS (UNITED KINGDOM), WARNING LABELS (ISRAEL), KEYHOLE (NORDIC COUNTRIES) AND CHOICES (CZECH REPUBLIC, NETHERLANDS –DISCONTINUED) LOGOS ARE IMPLEMENTED IN THE WHO EUROPEAN REGION

STEP 2. SELECT THE FOPL GRAPHICAL DESIGN

The previous figure highlights some possible graphical designs depending on the main objective that has been selected.

Graphical designs should be considered as having CORE dimensions and VARIANTS within core elements. Only CORE elements are a priority, the VARIANTS being secondary.

Core dimensions correspond to the orientation of the label (e.g. graded vs. warning), level of detail (e.g. nutrient-specific vs. summary) and core graphical elements detailed below (as presence vs. absence). Variants correspond to secondary aspects of these core elements, and might be addressed through marketing research (type of shape selected, variants to a graded colour-scale).

Interpretative FOPL schemes rely on the use of graphical elements to convey to the consumer the intended simplified nutritional information through symbols, colours or words:

1. The use of **colours**: several studies have shown that FOPLs including colours are more salient to consumers, and easier to understand. However, not all colour-coded schemes have the same salience. Indeed, given the specific neurobiological aspects of colour-recognition in humans, green/red cues are considered as the most easily differentiated colours²⁰. Moreover, green/red cues are widely used and therefore a readily interpreted signals in humans²¹, and the colour red reduces food impulsivity towards unhealthy foods²². However, policy-makers need to bear in mind the prevalence of green/red colour blindness in the population (considered to be around 8% in Causasian men and 0.4% in Caucasian women²³), to devise strategies for a FOPL to be salient and understandable for all. A combination of colours and words/letters/numbers may be used to overcome this limitation, as used in the French NutriScore scheme. The inclusion of an overall scale from healthier to less healthy (or high to low) may also help consumers anchoring their interpretation of the label.
2. The use of **words**: Two types of words need to be assessed in the case of FOPLs:
 - a. Names of nutrients: in the case of nutrient-specific FOPLs, the terms used to name nutrients need to be carefully assessed, in order for the terms to be clearly understood in the population (e.g. sodium vs. salt). This is of particular importance in lower health literacy individuals, which are less likely to understand the terms used, or their implication for their health. Studies investigating the understanding of the various terms used need to be conducted within the population to ascertain that the final graphical design used is clearly understood, else it may lead to adverse effects, with a potential increase in health inequalities. The choice of wording should be consistent with international guidance and relevant regulations, and consistent with what is used on the back of pack nutrient declaration.
 - b. Interpretive terms: Some words may be useful to reinforce the message delivered by the FOPL. For example, some studies have highlighted that the inclusion of terms as 'High' 'Medium' and 'Low' within the Multiple Traffic Lights system were associated with a higher salience and understanding of the FOPL²⁴. However, the recourse to words should take into account the potential circulation of goods outside of the country, in neighboring countries with other languages. In this case, the use of words could be viewed as a barrier to trade. In such a case, the use of symbols or letters/numbers could be preferable, to ensure a wider understanding of the content of the FOPL.
3. The use of **symbols**: symbols may be used either to represent nutrients (e.g. salt shaker for salt) or to convey specific messages related to the nutritional quality of foods. Symbols need to relate to consumers to be directly interpreted. They can be derived from traffic signs (e.g. octagons as stop signs – the basis for the Warning labels) or other readily interpretable symbols (e.g. EU energy labels – basis for the Nutri-Score – or star rating for hotels – basis for the Health Star Rating System).

Some other elements of the graphical design need to be considered in the selection and development of a scheme, but relate either to operational aspects that impact the effectiveness of the implementation of a FOPL, and to specific forms of FOPLs.

Overall Scale display: for summary labels providing a graded evaluation of the nutritional quality of a food, it appears important to include the overall scale along with the specific evaluation of the food within the graphical design. For example, the Nutri-Score and the Healthy Star graphical designs include the entire scale within its graphical design, with a specific highlight to indicate the nutritional quality of the specific food being evaluated. The inclusion of the entire scale is of importance for consumers to see and understand the range of possible ways in which a food could be ‘ranked’ and the evaluation that the particular food has received within this scale. In the case where only the “score” of the specific food were given, consumers may not be able to understand the relative ranking of the food within the scale, and would require further educational tools to understand the FOPL.

Operational aspects: Specific aspects of the final graphical design of the FOPL need to be considered during FOPL policy development. These include:

- a. **Minimal size** of the FOPL. This is of particular importance for FOPLs including numeric information, to ensure that all figures are easily readable for consumers. The EU regulation on consumer information specifies a minimal font size of 1.2mm for the nutritional declaration at the back of the pack²⁵. However, this limited size may not be considered sufficient to ensure visibility for a FOPL.
- b. **Position** of the FOPL. Whenever possible, the location of the FOPL within the packaging needs to be defined, in order for consumers to anchor their label search on the packaging.
- c. **Salience** of the FOPL. Given the large amount of information present on food packaging (nutritional and otherwise), it appears of importance to devise ways for the FOPL to keep salient whatever the form or colour of the packaging. This may be performed using a white surrounding of the FOPL or with specific colours within the FOPL.

When selecting a specific graphical design for a FOPL, it appears necessary to test several options together. Indeed, although policy-makers may have a preference at the outset towards a specific type of FOPL, the response from consumers – and more specifically their understanding of the measure – may be different from expectations. Therefore, the preferred scheme should always be tested against multiple options.

Information box n°1: Importance of undertaking comparative studies

Testing a single format of FOPL has several limitations.

The implementation of mandatory back-of-pack information has been useful to ensure consumers are provided with accurate and complete nutritional information, and to hold manufactures accountable. The back-of-pack declaration is also important for consumers with specific dietary requirements – food allergies, specific diets etc. However, there is a consensus that back-of-pack nutrition information alone is of limited help for most consumers in purchasing situations where consumers need to select among a very large variety of products in a very limited amount of time. For this reason, FOPL is an important additional tool.

Studies on both attitudes and understanding have shown any form of FOPL improves the current situation when compared to back-of-pack alone. For attitudes, this leads to very positive ratings of any format of front-of-pack label – generally around 80% favourable responses from consumers. This finding also applies to minimally informative FOPL such a % Reference Intakes (i.e. % Reference Intakes do help somewhat when directly compared to a back of pack label alone).

However, studies investigating a single FOPL alone may – misleadingly – conclude that the FOPL is most effective, while other formats would be more useful. For example, % Reference Intakes routinely perform much worse when compared to other interpretative FOPL¹⁹. The main issue therefore at this point is not only to determine if a FOP system is efficient but which one, out of a multiple possible schemes, can be considered as the most efficient for consumers in a given context.

Comparative studies need to test various CORE dimensions of labelling systems rather than being merely variants of a given graphical format. For example, if a warning system is considered, it should be compared to a graded label (e.g. nutrient-based, such as multiple Traffic Lights, or summary, such as the Health Star Rating System or the Nutri-Score) and vice versa. It must be noted that this type of study should be carried out very early on, as the results might modify the intended objective of a label if the pre-selected format should not be the most helpful to consumers.

STEP 3. DETERMINE THE UNDERLYING NUTRIENT PROFILING SYSTEM

FOPL systems must each be underpinned by a specific “nutrient profiling” method. Nutrient profiling is the science of classifying or ranking foods according to their nutritional composition. The approach taken for nutrient profiling depends on the FOPL system selected, and this may vary between:

- 1) setting threshold amounts for nutrients that meet a certain level (used in interpretive nutrient-based systems);
- 2) applying algorithms for food products’ overall nutrition profile (used in interpretive summary indicator systems).

The development of a nutrient profiling system involves several steps, all of which need to be analyzed in the light of the main objective that is being pursued, and the graphical formats selected. Indeed, nutrient-specific graphical designs need to define nutrient profiles for each nutrient, while summary designs need to use a nutrient profiling system that conveys an overall evaluation of the nutritional quality of a food.

Nutrient profiling systems can be described succinctly using a framework developed by Verhagen et al. in 2008. This framework describes the various elements of a nutrient profiling system and allows classifying them easily.

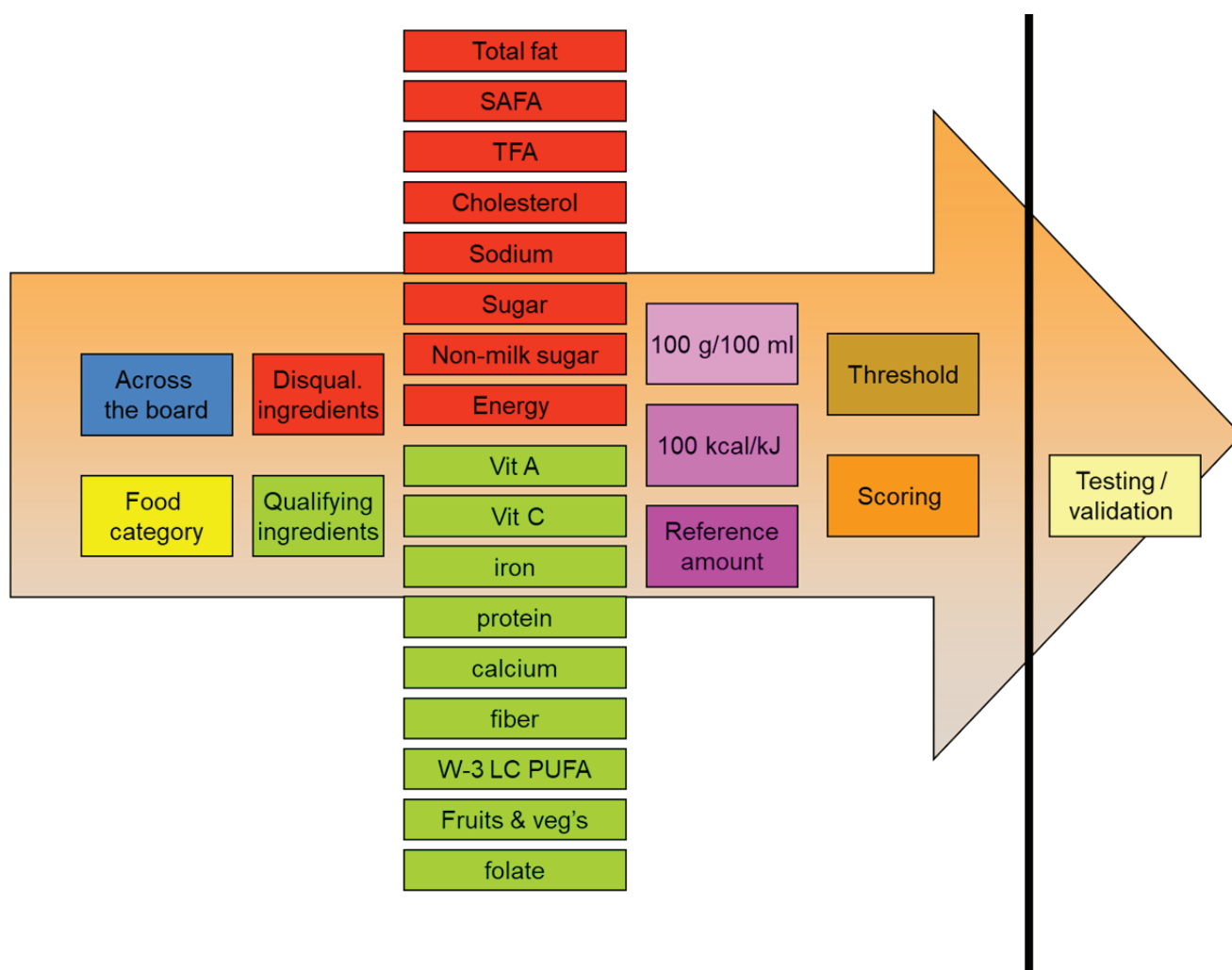


FIGURE 3 STEPS IN THE DEVELOPMENT OR SELECTION OF A NUTRIENT PROFILING SYSTEM. FROM VERHAGEN ET AL. 2008 ²⁶

The first element of the diagram corresponds to the number of food categories for which the algorithm may differ. An across-the board approach entails that the algorithm is calculated in the same way whichever the food considered. Conversely, a category-based approach will have an adapted algorithm depending on the category of food considered.

The second element corresponds to the nutrients/ingredients that are incorporated in the nutrient profiling system, which can include both favourable (qualifying ingredients) and unfavourable elements (disqualifying ingredients).

The third element corresponds to the reference used to compute the algorithm, either on 100g, 100kJ or per serving size. Reference amounts of 100g are recommended, in order to standardize the comparison across foods, in particular as serving sizes are not standardized.

Finally, the last element corresponds to the type of algorithm used: either setting thresholds for each of the elements included for their content to be qualifying/disqualifying, or using a scoring procedure, allocating points for each of the elements in the algorithm which then will be associated with the labelling system.

Many nutrient profiling systems have already been developed worldwide, with some having been designed for an application in food labelling. For the purpose of designing a FOPL, it appears more useful and operational to build from an existing nutrient profiling system, rather than developing a novel system. This is of particular interest, as the validation of nutrient profiling systems may require multiple complex studies, and several years of research, while the use of a previously developed and validated system may build on existing evidence and allow countries to proceed much faster. The various nutrient profiles having been developed in the world have recently been reviewed²⁷.

Overall, nutrient profiling systems can be described using the various elements highlighted in the Figure 3. The involvement of nutrition experts and a feedback from the developers of a given nutrient profile may be of interest, to help understanding the profile and its potential application to FOPL.

STEP 4. DEFINE STUDIES TO BE PERFORMED TO SELECT THE FINAL FORMAT AND NUTRIENT PROFILE MODEL

Various study methodologies are available in order to validate a FOPL and select the most appropriate system in a given context.

Validation builds on the two dimensions of FOPLS: their underlying nutrient profiling systems and their graphical format. For each dimension, a published theoretical framework may serve as reference, and highlight the various steps involved in the validation, each of which can be associated with a specific methodology and study. The theoretical frameworks have been adapted and expanded for the purpose of the present brief, in order to cover the various areas of research that have emerged since their publication (see Figure 4).

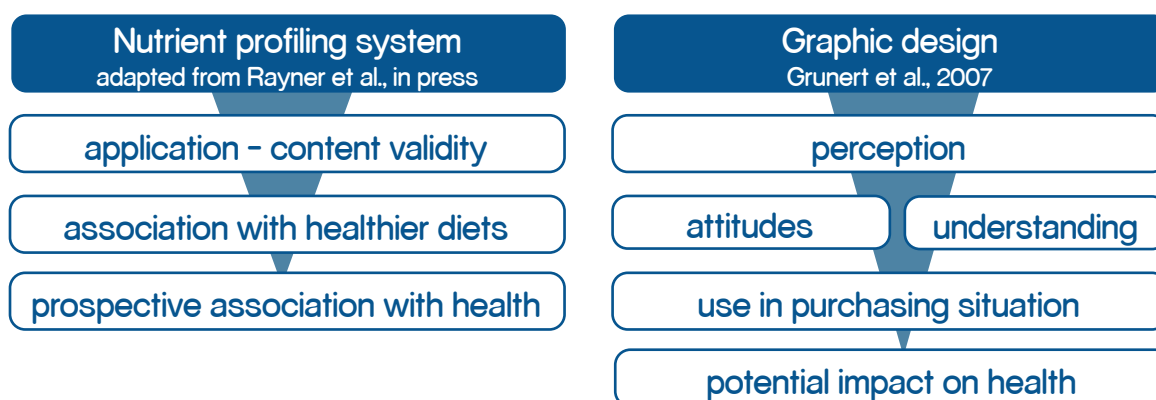


FIGURE 4 ELEMENTS OF VALIDATION OF A FOPL – ADAPTED FROM TOWNSEND ET AL. AND GRUNERT ET AL. ^{28,29}

Some of them appear key and necessary to support the implementation of an effective scheme (i.e core studies). These are presented here in the main body of the manual. Others are considered additional elements to support a scheme, and are therefore presented in the appendix as a package of more expanded methods that might be considered. Moreover, if the FOPL that is considered has already been validated in other settings, some findings from previous studies may be adopted and do not need to be repeated.

Indeed, in the case of the selection of a FOPL already implemented in a neighboring country and supported by scientific evidence, if the cultural backgrounds of the countries are similar, it is reasonable to infer that the scientific evidence from this country would apply. In such a case, the requirement for developing specific studies would be less important but consumer testing might still be considered to secure political buy-in.

The studies that appear necessary include one for the validation of the nutrient profiling system (in particular for summary labels and graded nutrient based systems) and one for the validation of the graphical format.

1. The validation of the application of the nutrient profiling system to foods. The alignment between the nutrient profile and the relevant food-based dietary guidelines should be investigated, so that at the moment of implementation, consumers will not observe inconsistencies that might undermine the acceptability and trust consumers have in the FOPL system.
2. The validation of the objective understanding of the graphical format, comparing several FOPLs should be investigated, so that the format selected is the most efficient for the country.

All the various elements of validation of a FOPL are described below and each study's methodology is detailed. Specific concerns in terms of protocol development are highlighted, as well as ways to overcome challenges.

4.1. VALIDATION STUDY OF THE UNDERLYING NUTRIENT PROFILING SYSTEM: ALIGNMENT WITH RECOMMENDATIONS

One of the most important studies to consider prior to the implementation of a label is the validation of the way the nutrient profiling system would classify foods and whether this classification aligns globally with the most relevant national and/or regional food-based dietary guidelines as well as the overarching objectives of the labelling policy that the government has set itself. This type of study does not investigate consumer response to the FOPL, but rather tests the potential implementation of the FOPL on the market.

Using a food composition database, the application of the nutrient profiling system can be assessed using food-based dietary guidelines (FBDG) as a reference point. The purpose of such a study is to assess:

- whether the FBDG and FOPL classification align globally (e.g. food groups for which FBDG recommend increasing consumption should have better score, grade or ranking with the FOPL, and conversely food groups for which a reduction in consumption is recommended should have lower score, grading or ranking in the FOPL),
- and whether the criteria of FOPLs (e.g. criteria for high/low nutrient levels or for A/E grading) allows for the discrimination of foods (high variability) within categories of foods according to dietary guidelines ^{30,31}.

In the case of a FOPL that may be applied in a region rather than in a specific country, international food-based dietary guidelines may be used.

The food composition database that may be used in this type of study may be either a general database (including the average nutritional composition of foods commonly consumed in the country) or a branded database of foods as sold in the market.

General databases of the nutritional composition of foods usually consumed in the country are available from food safety agencies for surveillance purposes. In the European region the EUROFIR association³² maintains a database including the nutritional composition of foods from several countries that is available for research purposes.

For a more thorough investigation of the validity of a nutrient profiling system, using the nutritional composition of foods as sold in the market would be more operational, as FOPLs are usually targeting pre-packaged foods, rather than foods as consumed. However, databases of the nutritional composition of foods as sold are less frequently available. In France, the OQALI database (Observatoire de la Qualité de l'Alimentation) was established for surveillance purposes and is managed by a research team and the French food safety agency, and it collects branded data from industry on the nutritional composition of their foods³³. More easily available, the database managed by the participative website Open Food Facts is based on information collected from consumers, who participate by photographing and providing the nutritional composition of the foods they purchase³⁴. The Open Food Facts database is an open-data and open-source project, available internationally (based on a wiki-like interface). However, the data available for foods somewhat depends on the number and type of consumers who participate in the collection of nutritional composition data. Researchers may however complete the database by participating in data collection using standardized procedures.

Such methodologies, involving the systematic collection of data from supermarkets by a research group that is then supplemented by user-generated content, is the one followed by the George Institute in Australia for the FoodSwitch application, compiling the nutritional composition of foods from in-store surveys in supermarkets representative of the market³⁵.

To investigate the alignment between the nutrient profiling system and dietary guidelines, the method used is the comparison of the relative classification of foods based on the nutrient profiling system and food-based dietary guidelines. Usually, food-based dietary guidelines identify food groups for which consumption is encouraged (e.g. fruit and vegetables or whole-grain foods) and food groups for which consumption should be limited (e.g. sugary, salty or fatty foods). In some cases, dietary guidelines classify foods as 'core' and 'discretionary' foods. The comparison needs to address whether the different classification systems align globally, e.g. whether food groups for which consumption is encouraged are classified as having a higher nutritional quality, and foods which consumption should be limited are classified as having a lower nutritional quality. However, given the large variability in food composition for both food groups that are recommended and food groups that need to be reduced, and even more so when considering the available range of industrial foods, alignment can only be considered globally and should not be expected to reach 100% agreement.

Testing the classification according to a nutrient profiling system against a reference classification (i.e. FBDG) allows researchers and policy makers to investigate the consistency of the classification and identify any misclassification which may entail a modification to the nutrient profiling systemⁱⁱ. Given the complementary nature of FBDGs and FOPLs, communication material can be used to provide information on how each of them operates.

Given that the underlying rationale for these two classifications are different, researchers should be aware that some inconsistencies for specific products are bound to appear. However, if they are in small numbers, and correspond to specific foods that are not widely consumed, these inconsistencies may not be considered as disqualifying a nutrient profiling system or requiring adaptations. Modifications of a nutrient profile to correct inconsistencies should only be conducted if a large core food group is entirely misclassified (e.g. dairy products).

Additionally, this type of study may investigate the potential of the FOPL to help consumers select healthier options within food categories (e.g. how the FOPL discriminates within breakfast cereals) or even within similar foods from different brands (e.g. how the FOPL discriminates within chocolate puffed cereals). This discriminating power of a FOPL may be considered as one of the key features to help consumers select healthier choices at the point of purchase, as it facilitates substitutions within food categories.

Further validation of a nutrient profiling system does not appear necessary, in particular in the case of the use of an already existing nutrient profiling system, for which such validation studies have been published in other contexts. For further information on validation studies of a nutrient profiling system, please refer to the Appendix.

4.2. VALIDATION STUDY OF THE GRAPHICAL FORMAT: COMPARATIVE UNDERSTANDING OF FOPLS

The validation of the graphical format the FOPL is a crucial element in the selection of the most appropriate scheme. The theoretical framework for this dimension of the validation has been described by Grunert et al.²⁸. Among the various dimensions of the framework, investigating understanding of the information provided by the FOP label is one of the core studies to be performed while selecting a FOPL.

It is necessary however to distinguish two dimensions of understanding:

- subjective understanding (what the consumer thinks he/she has understood from the labelling system) and
- objective understanding (what the consumer actually understood, and whether this aligns with what was intended by the designers of the system).

Subjective understanding in this case relates more to the attitude of the consumer to the FOPL, and should be investigated with dimensions of acceptability and perception of FOPLs (see prior paragraphs and the appendix).

The key study to conduct is the investigation of consumers' objective understanding. Hereafter, objective understanding of a FOPL will relate to the investigation of the understanding of the information that is provided (and intended) by a FOPL by the consumer. In the case of FOPLs, the information that is provided pertains to the nutritional quality of a food (as a FOPL simplifies the nutritional composition of a food).

Objective understanding is generally evaluated by testing the ability of consumers to rank food products according to their nutritional quality, in the presence or absence of a label or comparing across different label systems. Sets of two or three products are presented to participants, in the absence or presence of FOPLs, and the differences in the ranking ability of the participant between the label situations is then compared.

As mentioned before, comparative studies across various types of labelling systems (core characteristics of labels) are necessary in order to reach a valid conclusion as to the most efficient FOPL in a given population.

ⁱⁱ Modifications to an already existing nutrient profiling system need to be performed with caution, in particular if further analyses validating the profile are not available, and the nutrient profiling system needs to be supported by earlier research.

Information box n°2: Methodological issues in comparing FOPLs

FOPLs provide various levels of information on the nutritional quality of foods, depending on their format. Thus, studies comparing across formats need to take into account these inherent differences, and allow a fair – or neutral – comparison across FOPLs.

In the case of studies on objective understanding, this means that the FOPLs tested need to visibly discriminate across products (with a gradation), and with a ranking in the same order whichever the label investigated.

For example, when testing both MTL and warning systems, the food products that are ranked need to have an increasing number of warnings, or an increasing number of 'red'-labelled nutrients. In the case of nutrient-specific labels in particular, it appears necessary to avoid asking to rank two products with the same gradation (i.e. same number of warnings or reds) but in different nutrients. Indeed, this would require that the consumer should be able to prioritize between nutrients, which is not accessible to all consumers, and in particular to consumers with lower levels of education or nutritional knowledge.

This requirement is only necessary in the scope of comparing various types of labels, in order to avoid situations in which a label would be discarded upfront based directly on the methodology that is used. However, given that in real-life situations consumers may encounter products that have the same number of reds or warning labels but for different nutrients, this specific aspect (i.e. how consumers respond to these scenarios) would need to be addressed in further independent research.

Moreover, in order to avoid the effects associated with qualities of a food other than its nutritional quality, other properties of the foods need to be neutralized (e.g. organic labelling, branding, etc.).

This principle of neutrality needs to be taken into account also in the framing of the questions, in order to avoid biases in the comparison of the various labels. For example, when comparing summary and nutrient-based FOPLs, asking respondents which product is higher in a given nutrient inherently disqualifies the use of a summary system. When asking respondents to select the product that has a better nutritional quality overall, it is important for nutrient-specific systems that the number of reds/greens can be used as a proxy of overall nutritional quality and for warning systems the number of warnings.

The products presented to the study participants need to reflect realistic tasks consumers may face in purchasing situations and in which the presence of a FOPL is considered most helpful. Indeed, FOPLs are designed to help consumers making healthier choices of pre-packaged foods, and more particularly within a group of foods. In this case, when asking consumers to make a choice between foods based on the FOPL in a study environment, it appears necessary to use foods from the same category of foods, from a sufficiently narrow category for the ranking task to reflect actual purchasing situations, and with sufficient variability across foods to allow the ranking task to be feasible also in the absence of a label. Categories of foods typically corresponding to these requirements may be pizzas or breakfast cereals, in which nutritional quality is highly variable.

Study participants may be exposed to either actual food packages, from branded products, or 'mock' packages, created for the purpose of the study. Methods allow for participants to view all the labels tested (within-subject comparison) or be randomly assigned to one of the options selected (between-subject comparison). Methods to ascertain that other aspects of the food (brand, nutrition claims, organic products etc.) do not influence responses are necessary (using foods from the same brand and range for example or removing other claims from study packages).

The difference between classification without a label and with a label is considered a measure of the participant's objective understanding of a label.

Prior research suggests that the odds associated with correctly ranking products in the presence of a label may be very high (high magnitude of effect), with mean odd ratios around 3 or 4 for certain types of labels, and up to 20 times higher than in a control situation in specific sub-groups of the population. Given this magnitude of expected effects, study samples around 1000 participants may be sufficient to generate interpretable results.

Objective understanding has been investigated in several studies, and the methods used may be replicated in other contexts ^{19,36–39}.

STEP 5. ESTABLISH MONITORING PROCEDURES TO ASSESS IMPLEMENTATION

Establishing monitoring procedures to assess implementation is a key component of the policy cycle, as it ensures that policy-makers have sufficient information regarding the impact of a given measure, and are in a position to take corrective measures should specific limitations be highlighted during the follow-up. Such information will help policy-makers explore ways to overcome issues with uptake of the FOPL system in the marketplace, including through calls for mandatory implementationⁱⁱⁱ.

Evaluation procedures should always aim at providing baseline measurements before the implementation of the scheme – thus having an initial evaluation and follow-up measurements. The time-scale for the various evaluations should be set as much as possible very early in the process, so that key milestones are anticipated and provided for by policy-makers.

Moreover, though most schemes currently implemented across the world have relied on consumer self-reported data on awareness and use, it appears of importance to obtain objective assessments of the performance of a scheme, as self-reported data may be somewhat biased by familiarity to a scheme once implemented, and desirability bias.

Finally, evaluation should take into account both the impact on demand (consumer behavior) but also the offer (uptake and reformulation by manufacturers) so that both are monitored over time.

In its forthcoming Guiding Principles and Framework Manual for FOPL, WHO has recommended that countries consider the following dimensions in their monitoring exercises⁷:

1. The extent and fidelity of implementation of the FOPL policy
2. The effect of the FOPL policy on changes to consumer understanding of the FOPL system
3. The effect of the FOPL policy on changes to product purchases
4. The effect of the FOPL policy on changes to food product reformulation
5. The effect of the FOPL policy on changes to population dietary intakes

Although all of these dimensions are of interest to evaluate the impact of the FOPL, some of them are outside of the scope of government evaluation. Consideration may be given to ways in which the government can work with or commission academia to study the impact in more depth. The core studies that should be part of government evaluation are reported below; other expanded studies which may require the involvement of academics are detailed in the Appendix.

Policy-makers should also be encouraged to assess the feasibility of trademark registration of a FOPL, which would protect the FOPL and enforce conditions of use by manufacturers. Additionally, it provides a useful tool to monitor industry partners using the trademark.

5.1. EXTENT OF IMPLEMENTATION

Monitoring of the implementation of the FOPL appears of utmost importance, to assess the degree of uptake of the scheme by manufacturers, the extent coverage of food products on the market and the potential exposure of consumers to it, which in turn affects the final impact of the measure. This aspect is key in particular for voluntary schemes, for which the engagement of industry is necessary for the FOPL to appear visible in food retail settings.

Given that the regulatory environment in which the FOPL is implemented – mandatory or voluntary – highly impacts the presence of a FOPL on actual packages, the monitoring procedures may be adapted depending on the context.

Implementation may be measured at two levels:

1. Number of industry partners engaging in the scheme (for voluntary measures exclusively) – and associated overall market share
2. Number of food packages actually presenting the FOPL (and associated percentage compared to all foods in the market) and nutritional quality of the labelled foods

ⁱⁱⁱ Many Member States of the WHO European Region are also Members of the European Union. European Union legislation currently does not permit countries to make their national FOPL schemes mandatory. As such, should a FOPL scheme be implemented as voluntary scheme and experience low level of uptake from manufacturers and retailers, monitoring of implementation (e.g. after two years) can be used to hold industry to account and push for wider adoption. The results of monitoring can also be used to call for steps to convert the measure into a mandatory scheme.

INDUSTRY PARTNERS ENGAGING IN THE SCHEME

In settings where the labelling scheme is implemented on a voluntary basis, it may be relatively easy to track the number of industry partners that have committed to implement the FOPL through a commitment procedure (perhaps in the form of an industry pledge, platform or “charter”). Where such commitments or agreements have been signed, it is vital that they should be fully leveraged to ensure that implementation of the FOPL applies to all foods sold by the brand/manufacturer, and not only on a selection of foods operated by the manufacturer. Countries are encouraged to set this as a condition for use of the label. A timeframe may be specified (e.g. two years), allowing for manufacturers to modify their packages, taking into account the natural rotation of existing packages. Indeed, early monitoring studies from the voluntary implementation of the Health Star Ratings show that companies are picking and choosing where to apply the label, and the majority of foods displaying the label are those that are healthier (i.e. those that perform well and display a higher number of stars)⁴⁰. This challenge is not unique to Australia and is something that all countries implementing voluntary schemes would need to work on and explore solutions.

However, the number of industry partners engaging in the scheme may not always provide a full picture of the actual implementation of the scheme. This is the case in particular for systems in which only a fraction of foods may apply the FOPL (endorsement schemes, or schemes in which industry may be allowed to select the foods which will present the scheme).

NUMBER OF FOOD PACKAGES PRESENTING THE FOPL

Tracking the number of food products actually presenting the FOPL is the primary indicator of the uptake of a scheme in a given market. Ideally, this indicator should be as detailed as possible, compiling data on the individual food products presenting the label. Tracking these elements at the food level may also serve to monitor the efforts of reformulation by manufacturers during the follow-up of the scheme.

Tracking the foods presenting the label requires the implementation of strong monitoring procedures that may rely either on industry disclosure or on real-life surveys of supermarkets.

Policy-makers may require from industrial partners that they disclose the nutritional composition of the foods from their portfolio (all foods) and the foods which present the label at regular intervals. For example, in France, the charter of commitment of industry partners requires that they provide the list and composition of foods to the OQALI, with the date of implementation of the Nutri-Score for every food. This list is required to be regularly updated, to track the uptake of the scheme in stores⁴¹. Such a system however needs to rely also on the monitoring of the nutritional quality of foods overall, so that the proportion of products bearing the FOPL may be calculated for the overall market.

Alternatively, monitoring procedures may rely on regular surveys performed in-store, listing all the foods present and those presenting the label at a given time point. Such surveys have been conducted in Australia⁴⁰. Using the FoodSwitch monitoring database, regular surveys are performed in store – representative of the market – collecting data on the foods present in store, their nutritional composition and the presence of a label. The limitation of such a system is that it requires that the supermarkets targeted for data collection are representative of the food supply in a given country. Indeed, the number of foods available in Western markets is particularly high, several hundred thousand food products, while the selection available in a given supermarket is more likely around several thousands.

Such surveys allow tracking the overall number of foods presenting the FOPL, but also the distribution of the products bearing the FOPL in terms of food categories more represented, and the nutritional quality of the foods. For example, the survey using FoodSwitch in Australia showed that the Health Star Rating System was present on 28% of eligible foods after three years of implementation. However, among the labelled foods, 76.4% displayed a HSR >3.5 stars, therefore a majority of healthier food products, which is not an accurate reflection of actual distribution of food composition available on the market⁴⁰.

Monitoring of the implementation of the FOPL may also be used to monitor food reformulation across the food supply.

5.2. IMPACT ON CONSUMERS' ATTITUDES AND UNDERSTANDING

Investigating consumer perception, understanding and use of the FOPL once implemented is a key step to monitor the consumer response to the FOPL. Studies are similar to those that are proposed to select the label, but testing only the implemented FOPL.

However, preference studies should be conducted with caution, as once a label is implemented, consumers may be biased towards positive ratings for it, due to desirability biases, perhaps more important than in the pre-selection phase (see Box n°1 on the biases of preference studies).

In the case of perception studies, for example, it may be preferable to ask whether the FOPL is recognized, without prompting. Monitoring studies performed in Australia in the review of the Health Star Rating system may be used as examples⁴².

Finally, while self-reported awareness and use are expected to increase over time in the population, objective understanding might not change. Indeed, should a system be well understood from the start, the margin of improvement in consumers' understanding may be limited.

5.3. IMPACT ON CONSUMERS' PURCHASES

The impact of a label on consumers' purchases represents the most useful criteria to evaluate the effect of a FOPL. This type of study requires extensive data on two elements:

1. Purchases: data can be obtained either through scan data from panel studies (e.g. Kantar Worldpanel, GfK ConsumerScan) or by partnerships with retailers. Panel studies usually include a large sample of the population, who are required to scan all their purchases prospectively, to track consumer behavior and preferences. The access to this type of panel data is generally costly, as panel providers work essentially with industry. The quality of the data may vary, but some providers can offer relatively reliable purchase data⁴³. Partnerships with retailers may also be an option, as they have access directly to purchases data in particular for costumers on loyalty programmes. These allow having access to a wide number of participants with real-life purchases. However, these studies only take into account the purchases in a specific supermarket setting, and may not allow capturing the overall effect on consumer behavior (in particular switch from manufactured pre-packaged food to raw non-labelled foods). Finally, market research companies may be a direct source of purchase data accessed from the producers without the use of panels (e.g. Euromonitor International). Alternatively, smaller size studies, auditing for example vending machines may be available. However, these studies only assess a specific type of consumer behavior, and may not be entirely extrapolated to the overall population⁴⁴.
The data collected needs to be detailed (i.e. detailed information on the reference of the food purchased) in order to allow investigating effects of a FOPL. Finally, data may be evaluated as overall sales (i.e. data on the purchase of individual foods) or as individual consumer purchases (i.e. data measured at the individual level, with detailed product data linked to a single individual or household).
2. Food composition and FOPL presence: the purchases data need to be linked to detailed food composition and FOPL presence data in order to investigate the impact of the FOPL on the overall nutritional quality of the foods purchased. This requires to have available data on the food composition of all foods sold on the market, as well as information as to which foods have the FOPL affixed. This relates to considerations mentioned in point 5.1 and point 4.1).

A number of issues need to be taken into account when considering evaluating the effect of a FOPL on individual consumer purchasing behavior. First, the overall effect of a FOPL should be considered in the context of the various determinants of purchasing behavior that enter into consumer decision-making at the point of purchase (price, taste preferences, promotions, etc.). Therefore, the individual effect of a FOPL may be low. This low level of impact may also depend on the type of scheme that is considered, as penetration of a voluntary scheme may be slower than a mandatory scheme and certain labelling formats (because of their design and objectives) may not be present on a large number of products. Therefore, at the start of the implementation, it is very likely that consumers may not integrate the FOPL into their decision making. Studies suggest that the effects of FOPLs tend to increase over time, as consumers get more aware of the existence of the FOPL^{45,46}. Finally, recent studies tend to show that the impact of FOPLs may differ depending on the food category, with effects clustered in a few food groups rather than across all categories⁴⁷.

As such, it may be preferable to conduct studies on the impact of FOPLs on purchases after a few years of implementation (2 to 3 years appear necessary for a significant effect to appear, in particular for voluntary schemes), and expect rather low levels of impact on consumers' purchasing behavior overall, with differential effects depending on the food category. However, a small effect size on a very large population may yield important benefits in terms of public health. For examples of such studies, see [44-48](#).

5.4. IMPACT ON PRODUCT REFORMULATION

A key element in the potential effects of FOPLs is the incentive for food manufacturers to reformulate and innovate towards foods with higher nutritional quality. However, the incentive for reformulation may depend on the FOPL and more specifically on the nutrient profile and nutrient criteria used for FOPL definition. Reformulation efforts may be concentrated only in foods that are close to a threshold (e.g. red to amber colour), so the number of thresholds and their position is crucial.

Some limitations appear in the investigation of the impact of a FOPL on reformulation:

1. Industry usually anticipates the implementation of a FOPL, and reformulation efforts may largely occur before a FOPL is implemented. This requires of countries to collect data on the nutritional composition of food products ahead of the implementation, which may be complex to obtain, in particular if food composition data is collected on a regular basis.
2. Reformulation efforts occur continuously, and an underlying trend of improvement in the nutritional quality of foods needs to be taken into account in investigating to which extent FOPL implementation drives reformulation.

Obtaining data on the nutritional composition of foods from industry through a survey may be a complex endeavor, in particular as not all manufacturers keep historic data on the nutritional composition of their foods and of their changes over time. So retrospective data collection may not be possible. Moreover, voluntary participation of industry may provide a biased assessment of the engagement in reformulation, as selection bias may interfere, with only the most interested manufacturers participating in the survey. This would lead to an overestimation of the level of reformulation underway. Some surveys in industry partners tend to suggest that FOPLs have a positive effect on reformulation and innovation strategies from industry¹².

Monitoring changes in the nutritional composition of foods ideally requires repeated data collection, on large portions of the market, so that the effect of the FOPL may be separated from the underlying reformulation effort of the industry. Databases such as the OQALI or the Open Food Facts databases may be used to track changes in the food supply generally.

Importantly, the analysis of reformulation should not be limited to foods bearing the label, as more global trends of reformulation may be underway in the food industry. Therefore, tracking reformulation in both labelled and non-labelled foods is important to investigate whether the reformulation is driven by the introduction of a FOPL.

For examples of studies performed on the effects of reformulation, see [12,13](#).

CONCLUSION

The five steps presented in this manual aim to provide guidance to Member States for the successful selection and implementation of a FOPL scheme. A limited number of research studies, requiring limited resources can be easily set up to facilitate the process and ensure that the final FOPL selected is adapted to the context of the specific country.

However, policy-makers should be careful to consider the regional context before introducing a FOPL, as validated options in neighboring countries may provide both an opportunity for some homogenization in a given region, and scientific evidence applicable from a neighboring country.

Additional research – highlighted in the Appendix – can provide further support for the FOPL, but should not be considered as a pre-requisite for implementation, as they require extensive additional resources.

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