

Appendix

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



Document number: WHO/EURO:2020-1570-41321-56235

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Suggested citation. Appendix. Manual to develop and implement front-of-pack nutrition labelling: detailed description of additional validation studies that may be considered to select and evaluate a front-of-pack labelling scheme. Copenhagen: WHO Regional Office for Europe; 2020. Licence: CC BY-NC-SA 3.0 IGO.

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1. VALIDATION OF THE UNDERLYING NUTRIENT PROFILING SYSTEM

The validation of a nutrient profiling system involves several steps. The first step of validation is required to ensure that the application of the nutrient profiling system is consistent with the predefined objectives of the FOPL; methods for assessing this appear in the main body of the report. Further possible validation studies described here may require more complex dietary data, and may not be able to be performed in the absence of detailed dietary surveys. In addition, these studies may be best led by or commissioned to academics. In the absence of detailed dietary surveys or suitable academic partners, the reliance on already validated nutrient profiling system may be helpful to support a FOPL proposal. The validation of the nutrient profile may follow the various steps identified in Townsend et al. Please note, the list of studies described below does not attempt or claim to be a fully comprehensive overview of all possible methods for validating nutrient profiling systems.

1.1. APPLICATION TO FOODS

Given that no gold standard has been established at the international level as to the nutritional quality of foods, several approaches may be used to analyze the validity of the application of the nutrient profiling system. The investigation of the alignment with food-based dietary guidelines appears as the most important study to perform, other forms of validation may be available.

ALIGNMENT WITH FOOD-BASED DIETARY GUIDELINES (CORE STUDY)

This type of study is detailed in the first part of the report.

CONSISTENCY WITH EXPERT CLASSIFICATION

For a small number (N=100-200) of foods with a 'generic' composition (i.e. a composition averaged across different foods), the method consists in asking several experts in the field of nutrition to rate the products from healthier to less healthy. The list of products may correspond to commonly consumed foods. The number of classes in which the experts are asked to rate the foods may be directly linked to the final graphical design of the FOPL. For example, for a three-category summary indicator FOPL (e.g. 'green', 'amber' and 'red'), the experts may be asked to rate foods in three categories (as for example 'higher', 'intermediate' or 'lower' nutritional quality). For a warning label, the experts may be asked to categorise foods as to whether they would expect the food to carry a warning logo or not. The task may therefore be adapted for any type of FOPL, using outcomes as overall nutritional quality for summary labels, or by nutrient content for nutrient-specific foods. The experts may be provided only with an overall descriptor of the food, and not its actual nutritional composition. Indeed, the objective is to test the algorithm against expert attitude.

Given the small amount of foods included in the survey compared to the very high number of foods on a country's market, the foods selected need to be representative of highly consumed foods within the population. Moreover, they need to represent the range of products that may be impacted by the FOPL. In the case of a FOPL that would only be applied on pre-packaged foods, however, it is useful to include raw products, in order to also validate the capacity of the algorithm and the expert rating to discriminate between raw and processed products. The nutritional composition of the foods selected needs to appear as a 'generic' nutritional quality. Indeed, as the nutritional composition of foods is highly variable, the experts may only be expected to be able to rank 'average' foods.

The consistency with the classification by experts and the algorithm is then compared, to yield an estimate of the efficiency of the algorithm. This type of study is quite easy to perform, provided a group of experts agrees to the task. See Azais-Breasco or for an example of such a study². The limitation of such a study pertains to the potential biases in the experts selected for the task, who may put specific focuses on certain aspects of the nutritional quality of foods (key nutrients, etc.) depending on their research and expertise area.

DISCRIMINATORY CAPACITY

In the case of a FOPL that would have the objective of comparing the nutritional quality of foods (e.g. the Nutri-Score or Health Star Rating System), another dimension of the nutrient profiling system that may be investigated is its discriminatory capacity, i.e. its capacity of differentiating foods across food groups, within a food group and for similar foods from different brands.

Using data from foods as sold (using the Open Food Facts database for example) application of the nutrient profiling system and the thresholds for the FOPL can be used to ascertain whether the classification of foods may help consumers make healthier choices: i.e. compute for each food group the number of categories of the FOPL are available for the choice of the consumer. This type of study investigated whether the FOPL allows discriminating foods during purchases, and could be used as a basis for food substitutions. For an example, see ³⁻⁵

1.2. CHARACTERIZATION OF THE DIET

One of the key steps to further validate a nutrient profiling system is the transposition from specific foods to individual diets. This step allows investigating the public health interest of a given nutrient profiling system, and to go beyond the mere question of foods, towards impact on dietary intakes. This step is key to all subsequent validation studies.

For this step, it is necessary to use a survey of dietary behavior, with detailed data on food consumption. Additionally, the generalizability of the results to the overall population may be improved with the use of data from a representative sample of the population at the national level.

The most robust method of data collection for this purpose is the use of repeated 24h dietary records or dietary recalls. Indeed, given the high number of foods available for subjects, and their very high nutritional variability, the transposition from specific foods to individual diets needs to be based on very detailed data. The use of food frequency questionnaires, given the smaller number of foods assessed may lead to lower differences between subjects at the individual level, and therefore lower power to investigate associations.

The objective of such a study is to investigate whether the nutrient profiling system can accurately describe the nutritional quality of the diet at the individual level.

The transposition from specific foods to individual diets needs to rely on a dietary index based on the nutrient profiling system of the foods consumed. Two approaches can be devised:

- 1. **Thresholds**: using thresholds to identify 'healthier' or 'less healthy' foods, depending on the objective of the FOPL, and developing an indicator as a proportion of the foods consumed.
- 2. **Continuous**: if the nutrient profile provides an assessment of the nutritional quality of foods based on a continuous scale, then the nutrient profile may be used as a continuous variable. Depending on the nutrient profile, a standardization of the scale may be discussed.

In both approaches, the nutrient profile of foods needs to be combined with the amount consumed in the survey, using a weighting procedure. This procedure may use the weight, the energy or the number of portions by which each of the foods consumed. The development of dietary indexes based on nutrient profiling have been described in detail⁶⁻⁸. The dietary index needs to take into account all the foods that are consumed, and not only pre-packaged foods in order to yield an accurate estimate of the nutritional quality of the diet (alcoholic beverages may be considered separately). Indeed, this dietary index aims at providing insights as to the validity of the nutrient profile underlying the FOPL, and not directly its application as a FOPL. As such, it requires to be applied on all the foods that are consumed, in a holistic approach to the diet.

For a dietary index to adequately characterize the nutritional quality of the diet, it needs to be associated with food groups' consumption and nutrient intake. Healthier diets according to the nutrient profiling system of the foods consumed need to correspond to healthier diets in terms of recommended food group consumption (e.g. higher consumption of fruit and vegetables, whole grains, fish, and lower amounts of sugary, fatty and salty foods) and nutrient intakes (e.g. higher intakes of fibers, vitamins, minerals and lower intakes of added sugars, added fat, saturated fat, sodium and alcohol). While for some nutrients the correlation is expected if it is taken into account within the nutrient profile itself, this step allows investigating the diet as a whole, and associations with other nutrients need to be considered also. As an example, a correlation between the dietary index and alcohol intake (which is not usually considered within a nutrient profiling system) in the expected direction (e.g. healthier diets with the nutrient profile are associated with lower intakes of alcohol) would be further validation of the dietary index, as it would validate the index as an overall index of nutritional quality of the diet.

Alternatively, the dietary index derived from the nutrient profile may be compared to other diet quality indicators at the individual level, such as the Mediterranean diet score or the Healthy eating index.

1.3. ASSOCIATION WITH THE NUTRITIONAL STATUS OF THE INDIVIDUAL

An additional step of validation is the investigation of the association between the dietary index derived from the nutrient profile and the nutritional status of individuals.

Nutritional status can be characterized using variables such as the body mass index, blood pressure or biological markers of the nutritional status (glycaemia, cholesterol (high density and low density), triglycerides, vitamin status). Such investigation requires detailed dietary surveys with clinical investigations to be performed, using a cross-sectional design.

The objective of this type of study is to investigate whether the dietary index is associated with the nutritional status of individuals. Healthier diets using the dietary index should therefore be associated with lower levels of glycaemia, low-density cholesterol, blood pressure and higher levels of high density cholesterol, vitamins and minerals.

Given the cross-sectional nature of the data that is used in this type of study, the direction of the associations may not be directly predicted for body mass index and to a lower extent for blood pressure, glycaemia and cholesterol. Indeed, cross-sectional data in this case may be subject to reverse causality, as subjects at risk of obesity, diabetes or dyslipidemia are more likely to be on a specific diet, with therefore a healthier overall diet. Specific analysis taking into account weight management diets or specific medications for dyslipidemia, diabetes, hypertension or cardiovascular disease may be required to overcome this limitation of cross-sectional studies.

1.4. PROSPECTIVE ASSOCIATION WITH HEALTH

The last important step in the validation of a nutrient profiling system is its association with health outcomes. Indeed, when a dietary index derived from a nutrient profile of foods is found to be associated with health outcomes (with healthier diets leading to a reduction in nutrition-related chronic diseases), it supports the contention that the modification of the nutritional quality of the foods consumed (through measures using the nutrient profiling system) may help preventing the onset of non-communicable diseases in the long term, and thus participate in the reduction of their burden over time.

This type of study requires the use of cohort data with a detailed dietary assessment and a long-term follow-up of individuals, which are not always available. More specifically, while the previous studies may rely on cross-sectional surveys of a representative sample of the population, cohort studies rely on active participation of subjects over a long period of time, entailing some form of selection bias. However, while this may limit the external validity of the study, the internal validity of such studies is strong, provided the methodology for the data collection of diet are robust.

In this type of study, the main exposure variable tested is again the dietary index derived from the nutrient profile of the foods consumed. Outcomes of interest correspond to all nutrition-related chronic diseases, and more particularly: cardiovascular disease, cancer, type 2 diabetes, hypertension, dyslipidemia, metabolic syndrome and overweight and obesity.

In the European region, the EPIC study (European Prospective Investigation into Cancer and Nutrition), run in 10 European countries and launched in 1992 could be used for this type of investigation⁹. Alternatively, cohort studies within one country and having a detailed dietary assessment may be considered.

For examples of such studies, several have been conducted in France in the SU.VI.MAX and NutriNet-Santé studies to validate the nutrient profiling system underlying the Nutri-Score, and showing that less healthy diets, using a dietary index derived from the nutrient profile are associated with the onset of cancer, cardiovascular disease, metabolic syndrome and obesity in men ⁹⁻¹⁵.

2. VALIDATION OF THE GRAPHICAL FORMAT

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. ¹⁶. The various steps in the validation correspond to the investigation of attitudes, understanding and use of FOPLs in purchasing situations. An expansion of this theoretical framework can be proposed, with the investigation of the potential modifications to dietary intakes, nutritional status and health of the population of the use of a FOPL, through simulation studies.

While the validation of a nutrient profile usually investigates only one nutrient profile (internal validity testing), the validation of the graphical format requires a comparison of multiple types of FOPL, in order to select the most appropriate scheme (external validity testing). Attention should be drawn to the fact that this testing may somewhat modify the objectives pursued if the format that is more appropriate for the population may not entirely align with the original objectives of the development of a FOPL, but this step will ensure that the model selected is the most useful for consumers. Again, the list of studies described below does not attempt or claim to be a fully comprehensive overview of all possible methods for validating the graphical format of a FOPL.

2.1. ATTITUDES

Attitude towards a label corresponds to the subjective assessment an individual makes of a given FOP label. A favourable attitude towards a label is considered a positive element for a labelling system. Again, and particularly for this type of study, it is of the utmost importance that such analysis of subjective opinion is performed comparatively across labelling systems throughout, with the same level of information provided to participants for each of the tested labels. Indeed, given the very high societal demand for a FOP label, whichever it should be, very positive ratings may be expected for any type of labelling scheme (usually up to 80-90% favourable ratings in the investigation of a single scheme). Therefore, while attitude surveys appear very easy to perform, the methods used for such studies needs to be carefully planned to avoid any bias towards any specific type of label.

- 1. **Qualitative assessment**: a qualitative assessment using focus group or interviews methods, the attitude towards each tested format may be assessed: usefulness, spontaneous interpretation etc. Such analysis can be conducted on small samples, provided they reflect sufficient variability in the respondents' profiles.
- 2. Quantifative assessment: using self-administered questionnaires, it is possible to assess the various dimensions of the attitude towards labels: attractiveness, awareness, trustworthiness, perceived cognitive workload etc. The questionnaire can be as short as 15 questions, using either closed choices (selecting among the various FOP options tested) or Likert scales (one scale for each label). The results can be used overall and compared across socio-demographic data. The responses can also be used in multiple correspondence analyses or clustering procedures to highlight specific groups of the population with preferences for a specific format of FOP label. For examples see 17-21

2.2. UNDERSTANDING

Studies on understanding are detailed in the main part of this report.

2.3. POTENTIAL USE IN PURCHASING SITUATIONS

Testing the potential use of a FOPL in purchasing situation provides information as to the actual modification of purchasing behavior from consumers that can be expected when exposed to a FOPL. This allows investigating the potential improvement in the nutritional quality of purchases, which is one of the main goals for FOP labelling. However, given the difficulty of setting trials on this issue, such studies are not considered core studies to perform to select the format of a label.

These types of studies require that participants complete a task of grocery shopping in the absence and presence of a FOPL, and compare the nutritional quality of the resulting shopping carts. However, the implementation of field trials in actual supermarkets to investigate the potential effects of FOPLs on the nutritional quality of purchases is challenging, for multiple reasons, both operational and theoretical. A recent Cochrane review showed that evidence on the effects of FOP labelling on actual purchases and consumption is weak, mostly due to methodological challenges in the implementation of very strict and rigorous methods in this area²². The main challenges are the following:

- 1. Nutrition is only one of the many determinants of dietary behavior, and one single measure such as the implementation of a FOPL is not expected to modify behaviors to a drastic measure, in particular with a short delay. Therefore, in order to identify significant differences, such trials require very high power and a high number of participating supermarkets and consumers.
- 2. The use of a FOPL requires awareness from consumers, along with a favorable perception and understanding of its meaning, and some studies have suggested that accompanying strategies improving the knowledge of the consumer of the FOPL and its use are necessary²³. However, such information may not be made easily accessible to participants in a trial, which by essence is conducted on a fraction of the population over a short period of time. Large mass-media communication campaigns in particular may not be used during a comparative trial.
- 3. Trials on FOPLs require labelling all foods or a very high number of foods to yield positive results. Indeed, in order to improve the awareness of the consumer of the existence of a label, the presence of it need to be clearly visible on the front of food packages. Consumers are more likely to overlook labels that are affixed only on a fraction of foods. Studies in which labelling was applied only on a fraction of foods have indeed shown inconsistent results^{24,25}.
- 4. Trials need to be conducted on a sufficiently long period of time to yield positive results. Indeed, most of the short-term trials (<12 weeks) conducted in real purchasing environments have failed to show any positive effect of a FOPL on the nutritional quality of consumer purchases^{24,26}. This relates to both the low magnitude of the expected effect and the limited awareness of consumers in the absence of large information campaigns on food labelling.

Given all these requirements, the setting of such field trials is challenging. Indeed, conducting a trial in real-life settings such as supermarkets require heavy and complex investments in both funding (for example, the large-scale trial conducted in France prior to the selection of the Nutri-Score costed overall 2M€) and operational aspects (selection of the supermarkets, labelling of foods for experimental purposes etc.)²⁷.

Some solutions to these challenges have been proposed, in the form of experimental supermarkets. These can either be computer-based interfaces (online experimental supermarkets or virtual supermarkets) or physical experimental supermarkets. Comparisons may be performed with a before/after approach with the same participant running the task twice, or with different samples, exposed either to a FOPL or a control situation. Again, given the fact that any FOP label is expected to improve behavior, comparative studies with various types of formats are required to be tested.

These experimental interfaces allow for the investigation of a larger number of subjects, and for computer-based interfaces, for the implementation of randomized trials. Indeed, while randomized trials are considered as the gold standard in terms of methodology, no randomization of the interventions at the individual level is possible when conducting a trial in physical supermarkets.

Limitations of these experimental studies rely on the fact that the task is simulated, as participants do not actually purchase the foods they select. However, the inclusion of incentives for participants may help limiting this bias and reveal real food choices and preferences. Moreover, for interfaces relying on computer-based tasks (or recruitment online), the study may lead to a selection bias of participants who possess computer skills or are familiar with purchasing online, excluding therefore more vulnerable populations. Such limitations need to be weighed against the market penetration of computers and the Internet, to assess their extent before selecting experimental methods.

Experimental studies investigating the effects of FOP labelling on purchases include:

- 1. Online experimental supermarket: Online experimental supermarkets rely on platforms mimicking existing online grocery shopping websites. The interface is entirely controlled by the research team, and allows for the manipulation of labelling (adding a FOP labelling), price, promotional banners, etc. Participants are required to complete a shopping cart while browsing the products proposed in the supermarket. Using randomized methods, comparisons are conducted between participants exposed to a FOP label and a control situation with no FOP label. For examples, see Ducrot et al. ²⁸
- 2. **Virtual supermarkets**: Virtual supermarkets are similar to online experimental stores. However, they rely on virtual environments where the participant "pushes" a shopping cart across supermarket aisles. For examples, see publications from Waterlander et al. ^{29–31}

- 3. Frame-field experiments: Frame-field experiments are methodologies used in experimental economics to test the response of consumers to interventions in controlled environments. Some have been conducted in the field of nutrition labelling, providing insights as to the modification of consumer behaviour when exposed to a labelling system. Such studies recruited subjects to participate in a laboratory study, in a physical location. Then, the study relies on an experimental supermarket on a computer platform or a paper catalog of products. To ensure that purchases reflect real purchasing behaviours, a sample of the food products are actually sold to each participant at the end of the experiment (therefore unsing incentives to highlight actual food choices). Each participant is invited to constitute a first shopping cart before the implementation of any FOPLs, which was considered as a reference cart. Then, subjects are randomly assigned to an intervention group (consisting of a FOPL implemented on all foods in the experimental supermarket) or in a control group without any FOPL on products, and were invited to create a new shopping cart. The study then compares the nutritional quality of the shopping cart between the reference and the interventional situation and between the intervention and the control arms of the trial. For examples, see Crosetto et al. 32.33
- 4. Physical experimental supermarkets: experimental supermarkets are tools used for marketing research purposes, usually by the food industry to investigate consumer response to innovations or packaging modifications. However, they can also be used to test nudging interventions, or FOP labelling. Participants are required to complete a shopping task within an environment similar to a small grocery shop, where actual food products are proposed. The environment may be modified to include FOP labelling of products, and a comparison between a sample exposed to a label and a control sample yield insights as to the effects of FOP labelling on purchases. For examples, see Julia et al. 34

All these methods may be regarded as useful alternatives to test the use of FOP labelling in purchasing situations, for lower costs and higher quality methodology.

3. ASSESSMENT OF THE IMPACT OF THE FOPL

3.1. A PRIORI ASSESSMENT OF THE IMPACT OF THE FOPL

The implementation of a FOPL aims at improving the nutritional quality of purchases by consumers, and therefore indirectly their dietary intakes and ultimately their health. Measuring the potential impact of FOP labelling systems on diet and health prior to the implementation of a selected label is not technically feasible, given the delay for nutrition-related non-communicable diseases to develop. Moreover, if the implementation of a FOP label is included within a more general health and nutrition promotion program, estimating the impact associated to a specific measure within a large framework is very complex even with monitoring procedures.

Some methods, however, allow investigating the potential impact of FOPLs, even prior to its selection, through simulation studies. These simulation studies rely on the observed relationships between dietary elements (nutrient intakes, food groups' consumption) and biological markers, morbidity or mortality to provide an estimate of the gain associated with a modification of the diet. Hypothesis of dietary modifications in the presence of a label are used to run the model, which in turn provides estimates in terms of gains in terms of nutrient intakes and adherence to nutritional recommendations³⁶, intermediate conditions³⁶ (dyslipidemia, glycaemia, etc.) or mortality.

Such studies provide insights into the potential long-term effects of FOPLs, provided that the original hypotheses they rely upon are realistic, and that the study provides sensitivity analyses to test the robustness of the results.

Therefore, the major element of this type of study is the design of the hypothesis in the modification of consumer behavior. This hypothesis may be designed as predefined aims of a FOPL (e.g. dietary habits with only 'healthy' foods) or from previous research investigating the effects of FOP labelling on purchases.

Modeling the impact of FOP labelling on dietary intakes requires access to a detailed dietary survey (similar to the data required to validate the nutrient profiling system) to estimate the modifications in diets associated with FOPL use. To estimates the impact on mortality, the Preventable Risk Integrated ModEl (PRIME)³⁷, developed by the Nuffield Department of population health may be used.

3.2. A POSTERIORI EVALUATION OF THE IMPACT ON DIETARY BEHAVIOR AND HEALTH

Following up the impact of a FOPL on dietary behavior and, ultimately, health would provide policymakers with detailed estimates of the contribution of the implementation of a FOPL to the health status of the population. This outcome appears as the ultimate goal for a FOPL. However, capturing the specific impact of FOPL in isolation of other measures is difficult for a number of reasons.

First, the overall impact on an individual's food choices of a FOPL is likely to be of relatively low magnitude in the short run when considered in isolation to the many other determinants of food behaviour. Second, multiple determinants may interact with the FOPL to modify dietary behavior beyond food choices at the point of purchase: diets not only include individual foods, but also their frequency and amount of consumption, which are also likely to be affected by the FOPL. Third, the implementation of a FOPL is generally associated with a range of complementary dietary interventions implemented simultaneously at the population level, all of which contribute to the modification of dietary behavior, and ultimately health. And finally, nutrition-related chronic diseases require long-term exposure to manifest. Estimating the long-term effects of FOPLs on health would therefore require decades of follow-up to be performed and care should be taken not to set unrealistic objectives for measurable improvements in health outcomes from implementation of FOP labelling.

While dietary surveys performed at the national level may provide monitoring of the nutritional status of the population, an improvement in the diet would be linked to the overall nutritional policy of the country. Quantifying the specific contribution of a given policy (e.g. FOPLs) may be impossible.

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WHO/EURO:2020-1570-41321-56235

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