

RESEARCH TO SUPPORT THE DEVELOPMENT OF FRONT-OF-PACKAGE LABELING REGULATIONS FOR FOOD PRODUCTS IN THE AMERICAS

Methods, Tools, and Procedures



PAHO



Pan American
Health
Organization



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REGIONAL OFFICE FOR THE
Americas

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Washington, D.C., 2021

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Preface

Front-of-package nutrition labeling is one of the policies recommended by the Pan American Health Organization (PAHO) to promote healthy choices and ultimately contribute to reducing the prevalence of obesity and noncommunicable diseases in the Region of the Americas. A wide range of front-of-package (FOP) nutrition labeling schemes have been developed worldwide, often seeking different objectives.

When developing an FOP nutrition labeling regulation, solid scientific evidence is required to support the selection of a specific scheme for achieving the policy objectives. Although decisions can be based on a review of the evidence published in peer-reviewed literature and governmental reports evaluating the impact of different FOP nutrition labeling schemes, policymakers frequently rely on domestic production of scientific evidence to support their decisions. The generation of domestic evidence strengthens the scientific basis underlying FOP nutrition labeling regulations.

In this context, the objective of the present publication is to provide essential information that needs to be taken into account for conducting research to support the development of FOP nutrient labeling regulations in the Region. A wide range of methods, tools, and procedures are presented to assess the ability of FOP nutrition labeling to improve understanding of nutrition information, to modify perceptions of product healthfulness, and to influence food choices. Advantages and disadvantages are discussed, and suggestions for implementation are provided. The publication is expected to contribute to strengthening the scientific basis underlying FOP nutrition labeling regulations in the Region.

The publication includes a brief introduction to FOP nutrition labeling, followed by general considerations for conducting research to support the development of regulations, and detailed information about a wide range of quantitative and qualitative research methods. Finally, general considerations for policymakers and researchers are provided.

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Abbreviations and acronyms

ANOVA	analysis of variance
AOI	areas of interest
FOP	front-of-package
FOPL	front-of-package labeling
GDA	guideline daily amounts
GMO	genetically engineered (genetically modified organism)
ICF	informed consent form
NCD	noncommunicable disease
PAHO	Pan American Health Organization



1. Background and Context

The prevalence of overweight, obesity, and noncommunicable diseases (NCDs)—cardiovascular diseases, cancer, diabetes, and chronic pulmonary diseases—continues to increase in the Americas for all age groups. The Americas is the region with the highest prevalence of overweight and obesity in the world. The global prevalence of overweight and obesity in adults is 39 percent, whereas in the Americas it is 63.7 percent among males and 61.0 percent among females (Pan American Health Organization, 2018a). NCDs are the major cause of disability and premature death. In 2016, NCDs were responsible for 78 percent of all deaths in the Region (Pan American Health Organization, 2018a). Thirty-four percent of these NCD-related deaths occurred prematurely in people between the ages of 30 and 69 years, the most economically productive time of people's lives (Pan American Health Organization, 2018b). This implies that NCDs have a huge economic impact on societies, due to their associated health care costs and the fact that they undermine the capital and labor pillars of societal income (Theodore, 2011; Bloom, Chen, McGovern, 2018).

Unhealthy eating is the main modifiable factor that is driving this situation (GBD

2017 Risk Factors Collaborators, 2019). The expansion of unhealthy diets has been characterized by the rapid replacement of unprocessed or minimally processed foods and freshly prepared dishes by ultra-processed products (Monteiro et al., 2019; Swinburn et al., 2019). In particular, consumption of ultra-processed products and of processed products that are nutrient poor and energy-dense and contain excessive levels of nutrients associated with NCDs (i.e., sugars, fats, saturated fats, trans fats and sodium) has been identified as one of the main contributors to the epidemic of overweight and obesity, and also leads to diets that lack sufficient levels of essential nutrients (Pan American Health Organization, 2015; Monteiro et al., 2019).

The current food environment is characterized by the wide availability of ultra-processed food products, which are usually inexpensive and intensively promoted (Monteiro et al., 2019; Pan American Health Organization, 2015; Swinburn et al., 2019; Stanton, 2015; Story, Kaphingst, Robinson-O'Brien, & Glanz, 2008). These products tend to become the default option for consumers, who need to invest relatively more time, effort, and money to eat healthily (Hawkes et al., 2015;

Thaler & Sunstein, 2008). For this reason, the influence of environmental factors on eating behavior should be tackled to achieve a reduction in the prevalence of obesity and NCDs at the population level (Swinburn, Egger, & Raza, 1999; Swinburn et al., 2019). The development of policies that create supportive food environments that encourage people to eat healthily has been recognized as a key priority (Swinburn et al., 2019). These policies are more cost-effective and are expected to have a more lasting effect than individual approaches to obesity (Cecchini et al., 2010; Capacci et al., 2012; Swinburn et al., 1999; 2019). Among these policies, nutrition labeling, subsidies, taxes, restrictions on food advertising, and changes in the availability of healthy and/or unhealthy foods have received special attention (Cecchini et al., 2010; Hawkes et al., 2015; PAHO, 2015; 2019; Swinburn et al., 2019).

Information provisioning is usually regarded as a core policy for encouraging healthier food choices (Mazzocchi et al., 2015). In particular, the inclusion of nutrition information on food packages enables consumers to make informed choices regarding the nutritional composition of the foods they consume (Cowburn & Stockley, 2005).

Nutrient declarations are compulsorily included on the back of food packages in many countries around the world (World Health Organization, 2019). However, several studies have reported that people find it difficult to find and understand conventional nutrition information and that they seldom use it for making their food purchases (Cheftel, 2005; Cowburn

& Stockley, 2005; Feunekes, Gortemaker, Willems, Lion, & van den Kommer, 2008; Grunert & Wills, 2007; Sharf et al., 2012).

Considering that people spend little time and cognitive effort when making their food purchases, the inclusion of simplified nutrition information schemes can improve their ability to find and understand nutrition information, encouraging informed food choices (Hawley et al., 2012; van Kleef & Dagevos, 2015). For this reason, the inclusion of front-of-package (FOP) nutrition labeling has been identified as a priority for policy making worldwide (World Health Organization, 2017). The inclusion of FOP nutrition labeling on food packages can also be regarded as a “nudge” in the choice situation by making health-related aspects more salient and encouraging consumers to avoid unhealthy products (Reisch & Sunstein, 2016). In summary, FOP nutrition labeling mainly aims to: i) provide simple nutrition information that is easy to find and easy to understand; ii) allow consumers to make informed decisions regarding the foods they consume; and iii) discourage consumption of products with excessive amounts of sugars, fats, saturated fats, trans fats and/or sodium.

The Plan of Action for the Prevention of Obesity in Children and Adolescents, unanimously approved by Member States of the Pan American Health Organization (PAHO) in the 53rd session of the Directing Council, proposed development and implementation of regulations on FOP labeling that promote healthy choices (Pan American Health Organization, 2014). This requires establishment of FOP labeling schemes that can ultimately

reduce purchase and consumption of products that are not recommended as part of a healthy diet, inform consumers about the contents of these products and their potential health effects, prohibit misleading or otherwise manipulative practices, and facilitate healthier decisions about what to buy and eat.

Several FOP nutrition labeling schemes have been developed worldwide, though they differ in purpose and in the extent to which they assist consumers to improve decisions (Hodgkins et al., 2012). Non-directive or non-interpretive schemes only provide numerical information about nutrient content (e.g., guidelines daily amount). Semi-directive schemes include numerical information and classify nutrient content as low/medium/high (e.g., traffic-light system). Directive or interpretive schemes, in turn, provide cues about product healthfulness, which can either be based on specific nutrients (e.g., nutritional warnings) or on the overall

product (e.g., the Australian Health Star Rating).

Research on the efficacy and effectiveness of FOP nutritional labeling schemes in encouraging more healthful food choices is growing, as is research on public acceptance and perception of this public policy. Many studies have shown that directive or interpretive schemes are more effective in assisting consumers to accurately and quickly evaluate product healthfulness/harmfulness and to encourage healthy food choices than other schemes, such as the guideline daily amounts (GDA) or the traffic-light system (Ares et al., 2018; Arrúa, Curutchet et al., 2017; Arrúa, Machín et al., 2017; Ducrot et al., 2016; Julia et al., 2016; Mhurchu et al., 2017). Among these different families of FOPL systems, warning labels have performed best in meeting the purpose to allow populations to quickly and easily identify products that contain excessive amounts of sugars, fats, saturated fats, trans fats and/or sodium (PAHO, 2020).

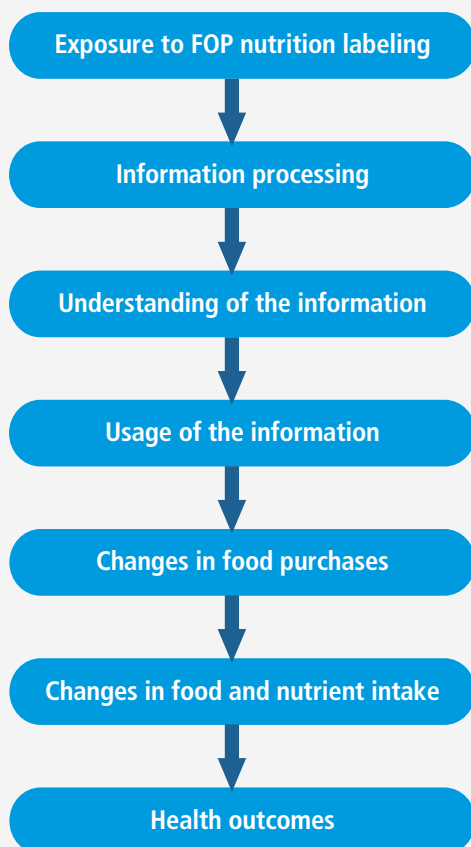
2.

Efficacy of FOP Nutrition Labeling from the Consumers' Perspective

From a public health perspective, the efficacy and effectiveness of FOP nutrition labeling mainly depends on its ability to encourage consumers to make healthier food choices and to reduce purchase and consumption of products that impair diets and health. In order to achieve this objective, several steps should be fulfilled (Grunert & Wills, 2007), as shown in Figure 1.

First, consumers need to be exposed to the FOP labeling scheme, i.e., the scheme included on the front of the package needs to catch consumers' attention. Visual attention is the degree to which an individual looks at a stimulus (Solomon, Bamossy, & Askegaard, 2002), which is a pre-requisite for information acquisition and processing (Holmqvist, Nyström, Andersson, & van de Weijer, 2011). When looking at a stimulus the brain uses attentional mechanisms to select part of the available information for further processing, whereas processing of non-selected information is suppressed (Wedel & Pieters, 2007). There are two types of attentional capture: bottom-up and top-down (Pieters & Wedel, 2004). Bottom-up attention is a rapid and

Figure 1. Conceptual model showing the steps that must be fulfilled for assessing the efficacy and effectiveness of front-of-package nutrition labeling



automatic type of attentional capture that depends on the physical characteristics of the stimulus (e.g., its color, size, and shape) (Koch, 2004). It occurs even when the individual is not specifically searching for a target stimulus (Wolfe, 1998). Top-down attentional capture is related to motivation and occurs when the individual is explicitly looking for the target stimulus. Consumers' in-store food purchase decisions are habitual behaviors that occur in very short time frames (van't Riet, Sijtsema, Dagevos, & De Bruijn, 2011). Therefore, FOP nutrition labeling needs to rapidly catch consumers' attention, even if they are not consciously looking for it, so that they can take the nutrition labeling information into account in their decision-making process (Bialkova & van Trijp, 2010; 2011). In this sense, FOP labeling schemes that automatically capture consumers' attention can act as a nudge in the decision-making process, encouraging consumers to take into account the nutritional composition of foods when making their choices (Thaler & Sunstein, 2008).

Once consumers are aware of the existence of FOP labeling, the information included in that labeling is then processed (Grunert & Wills, 2007). Considering that consumers do not usually invest large cognitive effort when making their food purchases (Frewer & van Trijp, 2007), FOP labeling should be read and understood very quickly, without requiring a large cognitive effort (Pettigrew, Talati, Miller, Dixon, & Ball, 2017). The information conveyed by FOP labeling should facilitate consumers'

understanding of the nutritional value of foods and enable them to make inferences about the products, i.e., to evaluate how harmful products are and to compare among products in the same category to identify the most (or least) harmful product.

Once the information is understood, consumers need to take into account the information included on the FOP labeling scheme in their decision-making process. FOP labeling is expected to modify consumers' food choices and to discourage selection of products with excessive content of nutrients associated with noncommunicable diseases, which are the major cause of morbidity and mortality worldwide and in the Americas. This change in food choice would lead to changes in dietary quality. However, this can only be expected if FOP labels are able to modify consumers' perception about products' healthfulness/harmfulness (Entman, 1993; Dar-Nimrod & Heine, 2011). In the long term, changes in the purchase and consumption of products could lead to improvement in diets and health outcomes, which will only be able to be achieved after the FOP labeling scheme is in place with a sustained and prolonged enforcement of the policy (Cecchini et al., 2010; Egnell et al., 2019); and preferably, this should be done in conjunction with other regulatory policies that help in reducing the demand for non-recommended products, including the regulation of marketing and of the school environment, as well as the application of fiscal policies to reduce the affordability of such products.



3.

Selection of an FOP Nutritional Labeling Scheme

Selection of an FOP nutrition labeling scheme should be based on solid scientific evidence that supports the decision to introduce a specific scheme for achieving the policy objectives. In other words, evidence that is actionable and context-sensitive and demonstrates that the scheme will improve responsiveness of health actions. For this purpose, policy makers can base their decisions on review of the evidence published in peer-reviewed literature and governmental reports evaluating the impact of different FOP nutrition labeling schemes. This means that the domestic production of scientific evidence is not strictly required when foreign evidence from rigorous high-quality studies is available.

The generation of domestic evidence to support decision-making could strengthen the scientific basis underlying development of FOP nutrition labeling regulations. Conducting studies at the domestic level could advance this purpose. Such studies should mainly aim at obtaining evidence to select the FOP nutrition labeling scheme that best aligns with policy objectives. Considering that a key objective of FOP

nutrition labeling is improving consumer's ability to understand nutrition information, **the priority for domestic research should be studies aimed at evaluating the influence of FOP nutrition labeling on objective understanding of nutrition information and its impact on healthfulness perception.** Studies to assess the impact of FOP nutrition labeling schemes on consumer's food choices, and particularly their intention to purchase food products with high content of nutrients associated with noncommunicable diseases, can also be conducted for supporting FOP nutrition labeling regulations, but with a lower priority level. Domestic research exploring differences between FOP nutrition labeling schemes in other elements of the conceptual model presented in Figure 1 can provide additional insights but are not essential to support decision-making. These additional studies can be conducted if time and resource constraints allow.

In the following sections, the main objectives of research supporting the development of FOP nutrition labeling regulations are discussed and methodological details are provided.

4.

Objectives of the Research for Supporting FOP Nutrition Labeling Regulations

Research in support of FOP nutrition labeling regulations is usually conducted to achieve three main objectives: i) comparing the efficacy of FOP nutrition labeling schemes, ii) evaluating the potential impact of FOPL schemes, and iii) evaluating how consumers understand and interpret FOP nutrition labeling schemes.

Comparison of FOP nutrition labeling schemes aims at evaluating the efficacy of different schemes and identifying the scheme that best aligns with the policy objectives. Following the conceptual model outlined in Figure 1, schemes can be compared in terms of three main aspects: attentional capture, information processing and understanding, and ability to modify food purchases. This type of research is relevant during the first steps of the design of the policy to inform decision-making and support governmental decisions.

Once a scheme is selected, the potential impact of FOP nutrition labeling schemes

could be evaluated based on the evaluation of changes in purchase intention, mainly for products with excessive content of nutrients associated with NCDs (i.e., free sugars, total, saturated and trans fats, and/or sodium). Results from such studies can provide information to estimate the potential impact of the policy on product purchases. In addition, changes in purchase intention can be used to predict the potential impact of the policy on nutritional and health outcomes.

Finally, the evaluation of consumers' interpretation of FOP nutrition labeling schemes can provide evidence of public support of the policy, as well as useful insights for the design of communication campaigns. This type of research is conducted using qualitative methods and is not recommended to support decisions regarding the selection of an FOP nutrition labeling scheme that can achieve the policy objectives.



5.

General Considerations for Conducting Research to Support FOP Nutrition Labeling Regulations

5.1. Schemes to Consider in the Research

When research for supporting FOP nutrition labeling regulations is required, it should mainly focus on demonstrating the efficacy of the scheme that best fits the policy objectives. For this reason, when conducting primary research, a control condition that represents the current situation of the packages available in the market (which is usually no FOPL scheme) should be included. The control condition could be operationalized in different ways. One of the simplest options is to only consider the front of the packages and to operationalize the control condition as no nutritional information. Another option is to consider the GDA system as a “control” condition as it includes the same numerical information as conventional back-of-pack nutritional information. Finally, when 3-dimensional packages are used in the research, the control condition should include the

compulsory nutritional information required by national regulations.

Countries that have implemented FOPL have faced proposals from actors that oppose effective measures to reduce the demand for products that unbalance diets and increase the risk for weight gain, overweight/obesity and NCDs. These actors usually argue for alternative schemes when the one proposed by the government is known to be effective. For this reason, it is desirable to consider the scheme proposed by major opponents and incorporate it into the research design to obtain information about its comparative performance. However, it should be acknowledged that the opposing actors usually change the scheme they are defending depending on the characteristics of the scheme selected by the government.

5.2. Design of Labels and Packages

FOP nutrition labeling research requires the design of labels or packages featuring different schemes following an experimental design. Research can be conducted with different types of stimuli: labels, 2-dimensional pictures of packages, 3-dimensional representations of packages, and real packages. The selection of the type of stimuli mainly depends on the data collection procedures selected for the research.

Labels and packages included in the research should correspond to product categories that frequently contain excessive amounts of nutrients associated with NCDs and that are widely consumed in the country. It is recommended to include different product categories, as the influence of FOP nutrition labeling on consumer perception is expected to be category-dependent. In this sense, research has shown that the largest impact of FOPL schemes on consumer perception is expected on product categories with excessive content of nutrients associated with NCDs that consumers inaccurately perceive as healthful (e.g., Arrúa, Machín, et al., 2017; Ares et al., 2018; Maubach & Hoek, 2008). Examples include cereal bars, breakfast cereals, yogurts, fruit juices, crackers, and instant soups.

Two strategies can be used to create the labels and packages: creation of mock packages, and modification of products available in the market. Both strategies have advantages and disadvantages,

and researchers are advised to select the one that better suits their study objectives and possibilities.

The use of mock-up labels and packages has the main objective of avoiding the influence of participants' previous knowledge and experience with existing commercial products. Given the habitual nature of food choice, participants may not notice FOPL schemes when looking at familiar products. Therefore, mock labels and packages may encourage participants to more carefully inspect all the available information. The graphic design of the mock labels and packages should be similar to products available in the market and include all the information required by national regulations.

The usage of packages of real products commercially available in the country has the main advantage of mimicking what would happen in real life when FOP nutrition labeling schemes are implemented. Consumers would have to notice a difference in the packages due to the inclusion of FOPL. So, the main disadvantage of real products is that consumers' evaluations may be based on their previous knowledge of the products without taking into account the FOP nutrition labeling schemes included on the packages. In addition, some institutions may face restrictions on the possibility of modifying commercial packages for research-related purposes.

Figure 2. Examples of mock-up packages of breakfast cereals featuring the Facts Up Front system (left) and the traffic-light system (right)



Regardless of the type of products included in the research, packages and labels featuring different FOP nutrition labeling schemes should be created by digital manipulation of the images. All the schemes should be included in the same area of the

label and in a similar size, as illustrated by the example in Figure 2. Researchers are advised to use existing regulations to obtain input on the graphic design of the FOP nutrition labeling schemes.

5.3. Research Population, Sampling, and Recruitment

Research should be conducted with participants who represent the target population of the policy. Considering that the target population of FOP nutrition labeling is usually the whole population of the country, studies are conducted with adults as they are mainly responsible for

food purchase. Studies with children and adolescents can also be conducted, as they are the target population of several ultra-processed products with excessive content of nutrients associated with NCDs promoted by means of various forms of marketing (Chapman, Nicholas, Banovic, &

Supramaniam, 2006; Elliot, 2007; Ferreira, Silva, Moraes, & Tancredi, 2015; Jenkin, Madhvani, & Bowers, 2014).

5.3.1 Sampling Design

Research that can be used to support FOP nutrition labeling regulations is conducted with a subset of members of the target population using a sampling procedure. Two approaches can be used for obtaining a sample of participants: population-based probabilistic and non-probabilistic sampling.

In probabilistic sampling, each member of the target population (e.g., all the adults living in the country) have a non-null probability of being included in the sample (Lavrakas, 2008). This approach allows for the sample to be representative of the target population. In order to obtain a probabilistic sample, a list of all the members of the target population, or of clusters where the target population can be found (e.g., households, schools, worksites, neighborhoods, and sampling enumeration areas), should be organized in a sampling frame (Biener & Lyberg, 2003). Following a random process, different probabilistic designs can be used for selecting subjects from the sampling frame to participate in the research. For example, the sampling frame can be an enumerated list of city blocks from which a household and an individual within the household are selected. Although probabilistic sampling provides the most accurate results, due to the costs and time associated with it, non-probabilistic quota sampling designs can also be used for obtaining accurate and reliable results (Lavrakas, 2008; Biener & Lyberg, 2003). Quota sampling has been the most

frequent approach used in studies conducted to support FOP nutrition labeling regulations.

Non-probabilistic sampling does not attempt to select a random sample of the population of interest. Instead, participants are selected based on a specific criterion. Different non-probabilistic sampling procedures are available. In particular, quota sampling is based on the nonrandom selection of a target number of participants with specific characteristics that resemble the target population (Lavrakas, 2008). The target population is divided into mutually exclusive groups based on different characteristics (e.g., age, gender, and socioeconomic status). Quotas are set for each group according to their distribution in the target population. Then, participants are recruited based on specific criteria until the quota of all groups is reached. For example, people can be selected by intercepting people in public places in different regions of the country until a specific number of participants in age and gender groups is obtained.

In the case of exploratory research or studies dealing with low-level cognition processes that do not largely differ among individuals, (e.g., studies involving the attentional capture of FOP nutrition labeling schemes), convenience sampling can be used. In convenience sampling, participants are selected based on ease of obtaining the sample. In this approach, a sample that represents the target population is not obtained. Examples of convenience sampling procedures include those intercepting consumers in a shopping mall or recruiting university students, in both cases participants are selected in a single location without specific quotas. Although recruitment is easily completed

without a substantial burden on the available resources, ability to generalize the findings is limited. Researchers are advised not to use convenience sampling for evaluating more complex aspects of consumer perception, such as interpretation of FOP nutrition labeling, harmfulness/healthfulness perception or purchase intention.

5.3.2 Number of Participants

The number of participants to include in the research depends on the objective of the research, the methods selected to address the objective and the experimental design. The number of participants should be sufficient to achieve valid and reliable results but should not involve unnecessary recruitment of participants (Council for International Organizations of Medical Sciences, 2016).

The minimum number of participants to be included in quantitative research is usually based on sample size calculations (Devane, Begley, & Clarke, 2004). Considering that FOP nutrition labeling research usually aims at comparing experimental conditions (e.g., FOP nutrition labeling versus a control condition), the sample size for a specific experiment is calculated based on the significance level and power considered in the statistical test used for analyzing the data, as well as the effect size (i.e., the minimum magnitude of the difference between two experimental conditions that want to be estimated) (Lenth, 2001; McCrum-Gardner, 2010). When several measures are collected in the study, sample size calculations can be performed based on the primary outcome or the outcome

that requires the largest sample size. There are many software packages and websites for performing sample size calculations, including GPower (www.gpower.hhu.de), Epi-info (<https://www.cdc.gov/epiinfo/index.html>), and the website of the Obstetrics and Gynaecology of the Chinese University of Hong Kong (<http://tinyurl.com/yep8bfz>).

In the case of qualitative research such as focus groups, the final number of participants is usually defined *a posteriori* based on the analysis of the results. Further details are provided in Section 6.2.1.

5.3.3 Recruitment

Research to support FOP nutrition labeling regulations generally requires the evaluation of visual stimuli in the form of packages or labels. For this reason, telephone-based interviews are not feasible. Research could be based on face-to-face interviews, self-administered questionnaires, or online studies. Recruitment of participants for face-to-face interviews or self-administered questionnaires can be based on street intercepts, consumer databases, or social media.

The accelerated growth of internet access makes it possible to conduct online research with large samples of participants in short time frames at reduced costs (Slater & Yani-de-Soriano, 2010). Participants can be recruited using online panels of marketing agencies, consumer databases, or directly through social media. Researchers should be aware of the drawbacks of online research. First of all, differences in internet access by country and sociodemographic group may exist (Siah, 2005). In addition, the number

of participants who start the study and quit before reaching the end is usually larger than face-to-face interviews as participants are free from any possible social pressure while quitting (Reips, 2002). In this sense, it is important to keep the length of the study as short as possible to minimize boredom and reduce the percentage of participants that do not complete the study. In addition, researchers are advised to provide detailed instructions to assure participants' understanding of the task,

as participants do not have the possibility of asking questions to a researcher while completing the research (Montgomery & Ritchie, 2002). Finally, the visualization of products and FOPL schemes in a computer or smartphone screen may not resemble what occurs in a face-to-face interview. When size, resolution and proportionality of products, images and FOP labels depicted are not made comparable between the physical and the virtual environments, the validity of the study may be compromised.

5.4. Ethical considerations

As in any research involving humans, FOPL research should comply with a series of rules and principles to protect the rights and welfare of research participants (World Health Organization, 2011). Researchers have the duty to comply ethical guidelines recommendations and to have their research protocol approved by an Ethics Committee (World Medical Association, 2018).

Research participants should be provided with all the relevant information about the research and the opportunity to give their free and informed consent to participate in the research or to decline to do so (World Health Organization, 2011). When the research is targeted at children or adolescents, permission should be obtained from a legally authorized representative and children and adolescents should provide their assent to participate.

Information should be communicated in a language participants can easily

understand. Researchers are advised not to include specific details about nutritional information or FOPL schemes in the description of objectives included in the information form, as it may bias the responses. Instead, researchers are advised to inform participants that the research is related to the evaluation of food packages or labels.

Researchers are advised to follow the recommendations provided in the International Ethical Guidelines for Health-related Research Involving Humans (Council for International Organizations of Medical Sciences, 2016) for preparing the research protocol to be submitted to the Ethics Committee and the informed consent for research participants. Templates for these documents are usually provided by Ethics Committees. An example of an informed consent form, based on the templates provided by World Health Organization (2018), is provided in Annex 3.



6.

Study Designs and Methods for FOP Nutrition Labeling Research

Addressing the objectives outlined in Section 4 requires a mixed-methods approach, i.e., a combination of qualitative and quantitative research. This approach strengthens the rigor of the research and enriches the analysis. Qualitative and quantitative research address different objectives to support the development of FOP nutrition labeling regulations. Qualitative research provides deep insights on how consumers interpret and understand FOPL, whereas quantitative research enables the comparison of FOP nutrition labeling schemes and the evaluation of their potential impact on consumer perception and behavior.

Qualitative research can be conducted before or after quantitative research. Qualitative methods are used before quantitative research when the objective is to obtain insights on consumer perception of FOP nutrition labeling that will be further tested using quantitative methods.

Conversely, when qualitative research is conducted after quantitative research it can provide insights to deepen the understanding of consumer perception and explain the findings of quantitative research. Given the large amount of work that has already been conducted on consumer perception of FOPL schemes, this last approach is recommended, i.e. quantitative first, followed by qualitative. It is not recommended to use qualitative research to support the selection of a specific FOPL scheme for a policy.

In the international literature, a wide range of qualitative and quantitative methodologies have been used to study consumer perception of FOP nutrition labeling schemes and the impact of related public policy on behavioral outcomes. In the following sections, the most relevant methodologies are presented and recommendations on how to implement them for FOPL research are provided.

6.1. Quantitative Research Methods to Evaluate the Influence of FOPL on Consumer Perception and Behavior and to Compare the Performance of FOPL schemes

Quantitative research can be used to evaluate the impact of FOPL schemes on consumer perception and behavior. Quantitative methods aim to measure specific variables to test specific hypotheses (Creswell, 2013). Unbiased numerical data are obtained and analyzed using statistical procedures to test specific hypothesis, which enables research to generalize and replicate the findings (Creswell & Plano Clark, 2011). Different aspects of consumer perception and behavior can be assessed using quantitative methods, with understanding of the information and purchase intention being the most important aspects to evaluate in the context of developing FOPL regulations.

6.1.1 Experimental designs used in quantitative research to evaluate the efficacy of FOPL schemes

An experimental design is essential to test the efficacy of FOP nutrition labeling schemes. The experimental design depends on the specific objectives of the study and the methods selected to address them. In general, research aimed at evaluating the effectiveness of FOPL schemes needs to compare participants' perception or behavior in two experimental conditions: FOPL versus a control condition without FOPL. When different FOPL schemes are compared, each experimental condition

corresponds to a different scheme. Two types of experimental designs can be used for this purpose: between-subjects and within-subjects.

Between-subjects designs imply that each participant completes the study in a single experimental condition (Neuman, 2014). For example, a participant can evaluate a set of labels either with FOPL or without (control condition) but cannot evaluate both sets of labels. Randomization is the preferred method for assigning participants to experimental conditions. This method has several advantages: it increases the likelihood that the groups of participants are comparable in terms of individual characteristics on the study outcomes, it removes potential researcher bias in the assignments of participants to the experimental conditions, and it increases the validity of the results by ensuring that the results are due to differences between experimental conditions and not to extraneous factors (Charness, Gneezy, & Kuhn, 2012). Between-subjects studies involving a control condition and random allocation to experimental conditions are frequently referred to as randomized controlled trials. Before the analysis of the data, the groups of participants should be compared to ensure that they do not differ in their personal characteristics, such as gender, age, socioeconomic status, and educational level.

In within-subjects designs, the same group of participants completes the study in all the experimental conditions, which are presented in randomized order to minimize carry-over effects (Neuman, 2014). For example, using this type of design a participant would evaluate the same set of labels with and without FOPL. The main advantage of this type of experimental design is that it reduces error associated with individual differences, as the same participants complete the study in all the experimental conditions. This increases the power of the test and reduces the total number of participants needed to detect differences between experimental conditions (Charness et al., 2012). However, its main disadvantage is that carry-over effects may exist, which creates an extraneous confounding variable to the study. In other words, the evaluation of labels in one experimental condition (e.g., with an FOPL scheme) can influence the evaluation of labels in a different experimental condition (e.g., control). For example, if participants see a label with a warning sign, they may decrease healthfulness perception of the same label without the warning in a subsequent evaluation. Due to the relevance of this type of carry-over effect, within-subjects designs are usually limited to studies involving low-level processes, such as visual search. The other common application of this approach is the comparison of a single FOP nutrition labeling scheme with a control condition. In this case, participants evaluate the control condition first and then the labels with FOPL.

6.1.2 Methods to evaluate the objective understanding of nutrition information

FOPL schemes are expected to induce changes in consumers' ability to understand nutritional information, as well as in the way they judge product healthfulness based on nutritional information. Objective and subjective aspects of healthfulness perception can be evaluated. Objective evaluation involves participants' ability to use the information included on FOP nutrition labeling to complete specific tasks that have a correct answer, such as the identification of the least harmful product among a series of alternatives and classification of nutrient content. Subjective harmfulness perception involves participants' evaluation of how harmful they think specific products are.

6.1.2.a Identification of the least harmful product

FOP nutrition labeling is expected to facilitate the identification of the most/least harmful products within a product category. The effectiveness of FOPL schemes in this respect can be evaluated by presenting participants with a series of packages/labels and asking them to identify the most or the least harmful. This methodological approach only focuses on participants' ability to make comparisons across products.

Experimental procedure

Sets of two to five products (more than one is needed, but not too many) of different

food categories are usually used. Within each set, products should have different nutrient content and one of the products should be clearly less harmful than the rest. A recommended procedure for designing the sets is to consider the nutritional composition of commercial products available in the market as a starting point and to create different alternatives by modifying the content of key nutrients in different amounts. For each set, one key nutrient should be regarded as target and its content modified by 50 to 200 percent between the most/least harmful alternative and the rest of the products. It is advisable that the least harmful product can be clearly distinguished from the rest in its FOP nutrition labeling scheme (e.g., by including a different number of nutritional warnings compared with the rest of the products). For the rest of the products, nutrient content should be modified by trivial amounts that should not modify their categorization in the FOP nutrition labeling scheme (e.g., all the products should feature the same nutritional warnings or

be categorized in the same category in the traffic-light system). An example of how a set of products can be created is shown in Annex 1. It is advisable not to use more than 10 to 12 of products, as the task may become too tedious for participants.

The series of packages or labels are presented to participants monadically (i.e., one by one), following a randomized balanced order that minimizes order and carry-over effects. Labels are usually identified using three-digit numbers to minimize any type of bias in the response. In addition, the position of the labels in the set should be balanced to avoid order effects.

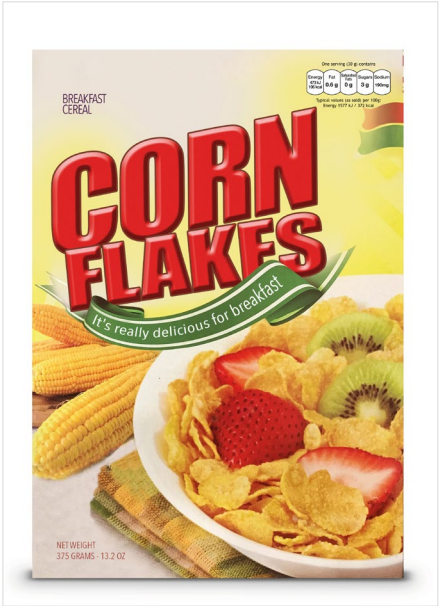
Participants are asked to look at each of the series and to select the least harmful alternative. Examples of the tasks are shown in Figure 3. If data collection is performed using a software program, the time elapsed from the display of the set and participants' response can be measured as an indicator of the task difficulty.

Figure 3. Examples of choice tasks aimed at identifying participants' ability to identify the least harmful product in a set: (a) set of two labels of breakfast cereals featuring the GDA system, (b) set of three labels of cream crackers featuring nutritional warnings

a) 213



678



Which is the least harmful product?

213

678

b) 806



912



116



Which is the least harmful product?

806

912

116

Data analysis

The percentage of participants selecting the correct alternative is calculated. Generalized linear models with different link functions, including logistic regression, can be used to evaluate the influence of FOP nutrition labeling scheme, the set of products and the interaction between these two variables on the probability of consumers correctly identifying the least harmful product in each set. In addition, analysis of variance can be used to compare the average number of correct responses across FOP nutrition labeling schemes.

Example of application

Borgmeier & Westenhoefer (2009) compared participants' ability to identify the most healthful product in five experimental conditions: no label, healthy choice logo, traffic-light system, a monochromatic GDA system, and a colored-coded GDA system. A total of 28 pairs of foods of different product categories (drinks, fat/oils/sauces, meat/fish/sausages, fruits/vegetables, dairy products, bread/cereals/grain products, candies/snacks). A total of 420 participants were randomly allocated to one of the five experimental conditions and were asked to identify the most healthful food in each pair.

Significant differences in the average number of correct responses were found between the experimental conditions, which indicates that the FOP nutrition labeling schemes differed in their ability to facilitate the identification of the healthful products. As expected, the control condition without nutritional information showed the lowest average number of correct

responses (20.2 out of 28). Conversely, the traffic-light system yielded a higher average number of correct responses (24.8) than the rest of the schemes.

6.1.2.b Classification of nutrient content

FOP nutrition labeling is expected to facilitate the interpretation of information about nutrient content, and particularly the consumer's ability to determine if the content of nutrients associated with NCDs is higher than recommended for a healthy diet. The effectiveness of FOP nutrition labeling schemes to facilitate categorization of products according to their nutrient content can be evaluated using multiple choice questions, as described in the following sections.

Experimental procedure

Packages of products of different food categories are used, as well as products of the same category with different nutrient content (i.e., products with and without excessive amounts of nutrients associated with NCDs). Products with different nutritional composition should be considered, including products without excessive amounts of nutrients associated with NCDs. It is advisable not to use more than 10 to 12 products, as the task may become tedious for participants.

Packages or labels are presented to participants one by one, following a randomized balanced order that minimizes order and carry-over effects. Participants are asked to look at each of the packages/

labels and to categorize the content of one or more target nutrients. Two types of questions can be used for this purpose:

- **Multiple choice questions:** Participants have to indicate if the content of specific nutrients is higher than recommended for a healthy diet (e.g., Is the sugar content of this product higher than recommended for a healthy diet?) using different response options (e.g., Yes, No, I don't know) or classify the content of nutrient content (e.g., How would you classify the sugar content of this product?) into specific categories

(e.g., low/medium/high). An example is provided in Figure 4a.

- **Choose-all-that-apply questions:** Participants are asked to indicate if the content of any nutrient is higher than recommended for a healthy diet (e.g., Is the content of any of the following nutrients higher than recommended for a healthy diet?) using a list of options (e.g., sugar, sodium, total fat, saturated fat, none of the nutrients). Participants can select all the options they consider applicable. An example is provided in Figure 4b.

Figure 4. Examples of nutrient classification tasks of a breakfast cereal label using different types of questions: (a) multiple choice question, (b) choose-all-that-apply question

a) 678



Is the sugar content of this product higher than recommended for a healthy diet?

- ☐ Yes
- ☐ No
- ☐ I don't know

b) 678



**Is the content of any of the following nutrients higher than recommended for a healthy diet?
Choose all the options that apply**

- ☐ Sugar
- ☐ Sodium
- ☐ Total fat
- ☐ Saturated fat
- ☐ None of the nutrients

Data analysis

The percentage of participants selecting each response option is calculated. For multiple choice questions, data can be analyzed using a chi-square test to compare the performance of different FOP nutrition labeling schemes. Alternatively, a logistic regression can be used to evaluate the influence of the scheme, the product, and the interaction between scheme and product on the probability of consumers correctly classifying nutrient content. For choose-all-that-apply questions, data can be analyzed using Cochran's Q test to evaluate significant differences between FOPL schemes. When differences are significant and more than three experimental conditions are compared, the sign test should be used to evaluate significant differences between each pair of experimental conditions. The total number of correct responses can also be calculated and compared across experimental conditions.

Example of application

A randomized controlled online trial with 1,607 Brazilian adults (mean age 39.2 years old, 53.4 percent female) was conducted by Khandpur et al. (2018) to compare participants' ability to correctly classify the nutrient content of food labels with different FOP nutrition labeling schemes. First, participants evaluated the labels of three products (savory snack, biscuits with chocolate filling, and flavored lemonade) without FOP nutrition labeling and were asked to indicate if the product contained nutrients in levels higher than recommended for a healthy diet using the following response options: sugar, sodium, saturated fat and "none of these nutrients are in excess". Then, they were randomly allocated

to one of two experimental conditions: traffic-light system and nutritional warnings.

FOP nutrition labeling significantly increased participants' ability to identify excess nutrient content. The average percentage of participants who correctly identified excessive nutrient content increased from 49.4 percent to 57.8 percent between the control condition and the traffic-light system. The improvement in the understanding of excessive nutrient content was higher for nutritional warnings. The average percentage of participants who correctly identified excessive nutrient content in the evaluated products was 79.9 percent for nutritional warnings, compared with 52.8 percent in the control condition (no FOP nutrition labeling).

6.1.2.c Healthfulness/harmfulness scales

Scales are frequently used in social research to measure how people think or feel about something (Brace, 2008). They assign numbers to a construct according to a rule. In the context of FOPL research, scales can be used to evaluate consumers' perceived healthfulness or harmfulness of specific products.

Perceived healthfulness/harmfulness can be measured using structured rating scales representing the healthfulness/harmfulness continuum. For this purpose, structured scales (i.e., with a limited number of response options) with their extremes anchored with expressions (i.e., "not healthy" or "not harmful" on the left extreme of the scale and "very healthy" or "very harmful" on the

right extreme of the scale) are used. There is little agreement on the optimum number of points on scale but in general between 5 and 10 points are used (Fowler, 2014). In general, 7 or 9 points scales are better than five-point scales because they tend to increase ability to discriminate among stimuli (Brace, 2008).

Although scales can be used with people of different age and educational levels, it should be taken into account that they may be difficult to understand for some groups of the population, particularly people with low educational level, children, or the elderly. In addition, another drawback of the method is that it is based on the evaluation of individual products and it does not provide a comparative evaluation of products.

Experimental procedure

Packages representing products of different

food categories, as well as products of the same category with different nutrient content (i.e., products with and without high content of nutrients associated with NCDs) are used. It is advisable not to use more than five to six products, as the task may become tedious for participants.

Packages or labels are presented to participants monadically (i.e., one by one), following a randomized balanced order that minimizes order and carry-over effects. Participants are asked to look at each of the packages/labels and to rate their perceived healthfulness/harmfulness by selecting a response option of the scale, as illustrated by the example in Figure 5. Products with high scores on the scale correspond to healthful/harmful products, whereas products with low scores correspond to unhealthful/least harmful products.

Figure 5. Example of an experimental task aimed at evaluating the healthfulness of a chocolate flavored milk label featuring the traffic-light system, using a 7-point scale



How healthful is this product?

1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not healthful						Very healthful

Data analysis

The average and median value of the responses are calculated, as well as the standard deviation. Data are usually analyzed using parametric statistical methods for normally-distributed data, such as a t-test or analysis of variance. The specific test to be used depends on the experimental design of the study. Researchers are advised to check the assumptions of the selected parametric tests prior to the analysis.

Example of application

Arrúa, Machín et al. (2017) used scales to evaluate consumers' healthfulness perception of labels of five products: breakfast cereals, crackers, frozen lasagna, instant soup, and toast bread. A total of 387 participants were randomly divided into three experimental conditions, each of which evaluated the labels with different FOP nutrition labeling schemes (GDA, traffic-light system, and nutritional warnings). For each of the labels, participants were asked to rate their perceived healthfulness using a 7-point scale (1=not healthful, 7=very healthful).

Significant differences in the average perceived healthfulness of the products were found between the three experimental conditions. On average, participants who evaluated labels featuring nutritional warnings gave lower scores (3.6) than participants who evaluated labels featuring the GDA or traffic-light system (4.0). For example, in the case of breakfast cereals, the average perceived healthfulness for the GDA system was 4.7,

compared to 4.4 for the traffic-light system and 4.0 for nutritional warnings.

6.1.3 Purchase intention

From a public health perspective, the main objective of FOP nutrition labeling is to discourage consumption of products with excessive content of nutrients associated with NCDs. For this reason, evidence supporting changes in consumers' food choices is valuable for supporting the development of FOP nutrition labeling regulations. Some of the methods available to evaluate purchase intention are presented below.

6.1.3.a Purchase intention scales

Scaling is the simplest method to evaluate purchase intention. This methodological approach relies on participants' evaluation of their willingness to purchase a product based on the information available on the package/label.

Structured scales composed of 5, 7, or 9 points are the most common for evaluating purchase intention. In general, odd number of points are used to allow neutral responses and 7 or 9 points scales are the most frequent (Brace, 2008). The extreme ends of the scale are anchored in "I would definitely not purchase it" (left) and "I would definitely purchase it" (right), whereas the mid-point is anchored with "Maybe yes, maybe not". Figure 6 provides an example of an experimental task aimed at evaluating purchase intention.

The evaluation of purchase intention using scales has several drawbacks, including its difficulty of use for some consumer segments and its lack of ecological validity, as participants do not measure their purchase intention using scales when making their food purchases in their everyday life. In addition, the hypothetical nature of the task could lead to response bias as participants do not have to perform a real purchase of products they will consume.

Experimental procedure

Packages/labels of products of different food categories are presented to

participants. Most of the products should have excessive content of at least one nutrient associated with NCDs. Different products of the same category could be used. It is advisable not to use more than five or six products, as the task may become tedious for participants.

Participants are asked to imagine that they are in the supermarket purchasing food. It is explained that they are going to see a series of products and that they have to indicate if they would purchase them. After looking at each product participants have to rate their purchase intention using the scale, as shown in Figure 6.

Figure 6. Example of an experimental task aimed at evaluating purchase intention of a chocolate flavored milk featuring the traffic-light system, using a 7-point scale



Would you purchase this product?

1

2

3

4

5

6

7

Definitely NOT

Definitely YES

Data analysis

The average and median value of purchase intention scores are calculated, as well as the standard deviation. Data are analyzed using parametric statistical methods for normally-distributed data, such as a t-test or analysis of variance, to compare the purchase intention of the products featuring different FOPL schemes. Researchers are advised to check the assumptions of the selected parametric tests prior to the analysis.

Example of application

An online study was conducted by Gorski Findling et al. (2018) to compare consumers' purchase intention of a fruit juice package in six experimental conditions: control (no FOP nutrition labeling), single traffic-light system, multiple traffic-light system, Facts Up Front, NuVal (label showing a 1 to 100 score according to product healthfulness), and a 0–3 star ranking. Participants were randomly allocated to one of the six experimental conditions. They were asked to look at the package using a five-point intention to purchase scale. Results showed no significant differences ($p=0.23$) between the experimental conditions: average intention to purchase scores ranged between 3.8 and 4.1. This result suggests that none of the evaluated FOP nutrition labeling schemes were efficient at discouraging consumers' intention to purchase the product.

6.1.3.b Choice experiments

Choice experiments can be used to evaluate whether FOPL schemes encourage


participants to select the product they would buy among a series of options. The main advantage of this approach is its ecological validity, as participants have to select a product as they would do in their everyday life. However, responses can be biased as participants do not have to do an actual purchase or consume the products. In addition, the number of options included in this type of task is usually smaller than the number of options available in the market.

Experimental procedure

A total of 10 to 12 products of different food categories are used. Within each set, products should have different nutrient content and one of the products should be clearly less harmful than the others. The procedure described in Section 6.1.2.a and Annex 1 can be used to design the choice sets.

Participants are asked to imagine that they are in the supermarket purchasing for food. It is explained that they will be presented with a series of sets of products and that they will have to indicate which product they would purchase. Participants have to indicate which product they would purchase. The option "I would not purchase any of these products" could also be included. The sets of products are presented one by one, following a randomized balanced order. An example of the task is shown in Figure 7. The order in which each set of products is presented should be randomly different for each participant within every group.

Figure 7. Examples of choice tasks aimed at evaluating participants' choice of cream crackers featuring nutritional warnings

806	912	116
		
Which product would you buy?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
806	912	116
<input type="checkbox"/> I would not purchase any of these products		

Data analysis

The percentage of participants selecting the least harmful alternative is calculated. A logistic regression analysis can be used to evaluate the influence of FOPL scheme, the product category, and the interaction between these variables on the probability of consumers selecting the least harmful product in each set. In addition, analysis of variance can be used to compare the average number of sets for which participants select the least harmful alternative across FOP nutrition labeling schemes.

Participants were randomly allocated to two experimental conditions: control condition (no FOP nutrition labeling) and health star rating. The authors reported no significant differences between the control condition and the health star rating in the percentage of consumers who selected the most healthful product alternative. This suggests that in this specific situation the health star rating was not efficient in encouraging more healthful food choices.

6.1.3.c Simulated online shopping experiments

Example of application

Hamlin & McNeill (2016) presented two pairs of breakfast cereals to 1,200 consumers from Dunedin (New Zealand). For each pair, participants were asked to indicate the product they would purchase.

Simulated shopping experiments based on websites that emulate online grocery stores can be used to increase the ecological validity of purchase intention evaluations. The idea is that participants can select

products as if they were purchasing food in their real life. However, it should be taken into account that participants only complete a simulated purchase with no real expenditure or consumption implication and therefore participants may not make the same choices as in a real purchase situation. In addition, the experimental task can be difficult for participants who are not familiar with online shopping websites. Finally, differences in the visualization of FOPL schemes between real packages and online grocery stores should be considered. This could reduce the ecological and external validity of the study, introducing bias and compromising the validity of the conclusions regarding the effect of FOPL on purchase decisions. For this reason, the use of online shopping experiments is only recommended as complementary to other measures of purchase intention.

Experimental procedure

A shopping simulation should be created using a website that emulates an online grocery store. A set of product categories is selected based on the usual distribution of products in supermarkets (e.g., fruit and vegetables; bread and bakery; meat and seafood; milk and dairy products; beverages; coffee, tea and cocoa; sweets and chocolates; condiments, spices, sauces, and dressings; rice, pasta, and pulses; tinned and jarred food; frozen food; jams, honey and spreads; crisps and snacks; biscuits and crackers). For each product category, a set of commercial products with different characteristics in terms of brand, price, and nutritional composition, should be included to obtain a wide overview of the main products available in the market. It is advisable to include a total of at least

200 to 300 products. Each product is represented with its name, description, price, and a picture. When FOPL schemes are included, they should be displayed next to the product to increase its saliency, and they should be matched in terms of the surface area they occupy on the screen. Nutritional information should be obtained from the labels of the commercial products included in simulated grocery store.

A between-subjects design is used to allocate participants to different experimental conditions featuring products with different FOP nutrition labeling schemes. Participants are asked to imagine that they have to purchase food for a specific occasion (e.g., to make a weekly food purchase for their household, to purchase food for a family dinner, or to purchase food for a healthy family dinner) using the website of an online grocery store. Detailed instructions about how the website works should be provided. Participants are asked to select all the products they would purchase by clicking an “Add” button next to each product. After selecting each product, participants indicate the number of units they want to purchase. Once they finish selecting the products, they click on the shopping cart to review their purchase and submit their response.

Data analysis

The following measures are calculated: average nutritional composition of the products purchased in the simulation, total amount of nutrients associated with NCDs purchased by participants, average number of products with excessive content of nutrients associated with NCDs, and total expenditure in each category.

Differences in the variables among experimental groups are evaluated using analysis of variance or a t-test, depending on the number of experimental conditions included in the study.

Example of application

Machín et al. (2018) used a simulated shopping experiment to evaluate the influence of two FOP nutrition labeling schemes on consumers’ food purchases when facing the goal of preparing a healthful dinner for their family. A total of 1,182 people (91 percent females) in Uruguay were recruited using a Facebook advertisement. Participants were randomly allocated to one of the three experimental conditions: control (without nutritional information), traffic-light system, and nutritional warnings.

The online grocery store included a total of 232 products, divided into 16 categories: beverages; breads and bakery; cold cuts, sausages, and cheeses; condiments and spices; crackers and cookies; frozen foods; fruit; infusions and cocoa; meat; milk and

dairy products; oils, dried and canned foods; pastas and pre-made pie crusts; sauces and dressings; snacks; sweets and desserts; vegetables. Products were presented using the description, a picture, the price and the corresponding FOP nutritional information (control, traffic-light system, or nutritional warnings). Participants were asked to imagine that they were purchasing for food to prepare a healthy dinner for themselves and their family. The average nutritional composition of the products purchased in the simulation was calculated and ANOVA (analysis of variance) was used to compare the experimental conditions.

Table 1 shows the average nutritional composition of the products included in the simulated shopping cart for participants in the three experimental conditions. Both FOP nutrition labeling schemes caused a significant reduction in the average content of calories, sugars, and saturated fat compared with the control. Meanwhile, only nutritional warnings significantly decreased the average sodium content of the products with respect to the control condition without nutritional information.

Table 1. Average nutritional composition of the products purchased in a simulated shopping experiment comparing three FOP nutrition labeling schemes

	Control	Traffic-light system	Nutritional warnings
Calorie content (kcal/100g)	181 ^a	171 ^b	170 ^b
Sugars (g/100g)	7.1 ^a	6.4 ^b	6.2 ^b
Saturated fat (g/100g)	2.0 ^a	1.8 ^b	1.7 ^b
Sodium (mg/100g)	399 ^a	363 ^{a,b}	323 ^b

Note: Average values within a row with different letters are significantly different ($p<0.05$). Source: Machín et al., 2018.

6.1.4 Attentional capture and visual processing of FOPL schemes

Visual attention toward FOPL schemes is a key determinant of their effectiveness (Bialkova & van Trijp, 2010). Although this type of research is not strictly necessary for the design of FOP nutrition labeling regulations, it can provide useful information on the comparative performance of FOPL schemes to support decision-making.

Attention to food labels and packages has traditionally focused on self-reported retrospective (Verbeke & Ward, 2006; Mackison et al. 2010). However, considering that attention is not necessarily active and conscious, measures based on memory have been demonstrated not to be good indicators of what people actually attend to (Kellogg, 1980; Baddeley, 1990; Rosbergen, Pieters, & Wedel, 1997). In addition, when people are asked to think about their behavior, they may modify their responses to give socially desirable answers that please the researcher (Podsakoff, MacKenzie, Lee, & Podsakoff, 2003). For this reason, implicit methods that do not require consumers to provide answers to questions have been recommended for assessing visual attention. In the following sections, two of the most useful methods are presented: visual search and eye tracking.

6.1.4.a Visual search

Visual search is a widely-used method in the field of experimental psychology to evaluate how people search and find objects with their vision. It was developed by Treisman and Gelade (1980) to study visual attention. Visual search is a computer-based task in which

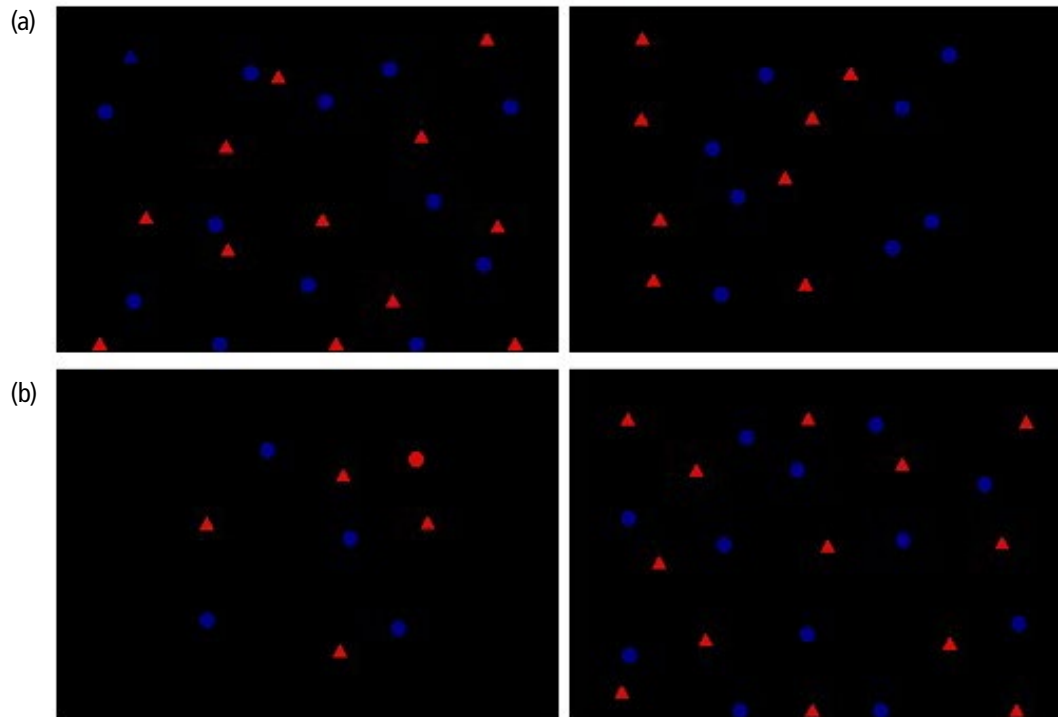
participants are presented with series of images composed of target elements among different distractors. Participants are required to indicate whether the target element is present on the screen or not. The time needed by participants to respond can be regarded as a measure of the attentional capture of target stimulus (Rensink, O'Regan, & Clark, 1997).

Experimental procedure

Visual search tasks can be conducted using different software, but researchers are advised to use the free software Psychopy (Peirce, 2007). Details on how to use the software can be found on the website (<https://psychopy.org/documentation.html>).

Participants usually perform short training tasks before the test to get familiar with the experimental procedure and reduce individual variability (Treisman & Gelade, 1980). The training tasks are not related to labels. Instead, they can include geometrical figures. The task consists of identifying a target figure (e.g., red circles) among a series of similar distractors (e.g., red triangles and blue circles). Participants are asked to indicate, as fast as possible, whether or not the target object (red circle) appears on the screen by pressing "Y" (for yes) or "N" (for no). The response time of participants in identifying the target object among distractors is recorded. Usually, the training tasks consist of two series of about 50 to 90 trials, each involving a different target object. Each series should include trials with different number of objects in the search space and the position of the target object should be randomized among trials. At least two training sessions are recommended. Figure 8 provides an example of the training trials.

Figure 8. Example of training tasks in which the target object to be found is a blue triangle (a) or a red circle (b)



Once the training tasks are completed, participants are asked to complete the visual search tasks with food labels. Different tasks can be used to evaluate different aspects of consumers' information processing:

- **Detection of the presence of FOPL schemes:** Labels of different products in two different variants should be designed: with and without FOPL.

Labels are presented one by one and participants are asked to indicate whether each of the labels features an FOPL scheme or not. This task provides information on the attentional capture of the FOPL scheme, i.e., the time needed by participants to find the scheme on the label. Figure 9 provides an example of screen captures of the task.

Figure 9. Example of a task in which participants have to indicate whether the label features an FOP nutrition labeling scheme: (a) label featuring octagonal warning and (b) label without FOP nutrition labeling

(a)



(b)



- **Classification of nutrient content:** Labels of different products in two different variants should be designed: with and without excessive amounts of one target nutrient. Participants are presented with the labels one by one and are asked to indicate whether the product represented by the label contains excessive amounts of the

target nutrient. The task provides information about the time needed by participants to process the information included on the FOPL scheme to classify nutrient content as excessive. Figure 10 provides an example of screen captures of the task.

Figure 10. Example of a task in which participants have to indicate whether a label featuring FOP nutrition labeling scheme has excessive content of a target nutrient: (a) label with nutritional warning for excessive sugar content, and (b) label without nutritional warning for excessive sugar content

(a)



(b)



- **Identification of labels with high or excessive content of key nutrients:** Sets of two to five labels of different product categories should be designed in two different variants: one of the products should have excessive content of a target nutrient and none of the other products within the category should have excessive content of the target nutrient. Participants are presented with the sets

one by one and are asked to indicate whether there is a label indicating the product has an excessive content of the target nutrient. The task provides information about the time needed by participants to process the information included on the FOPL scheme and identify the most harmful alternative. Figure 11 provides an example of a screen capture of the task.

Figure 11. Example of a task in which participants have to detect the presence of a label that identifies whether the product contains an excessive amount of sugars



The experimental procedure is similar regardless of the type of task implemented in the study. The study usually consists of 50 to 100 trials per experimental condition: approximately 60 to 70 percent of the trials should include the target element (e.g., a label featuring the FOPL scheme or a label with excessive content of the target nutrient), whereas the remaining 30 to 40 percent should not. Labels or sets of labels are usually presented in duplicate or triplicate. If different FOPL schemes are evaluated, blocks of trials for each FOPL scheme should be implemented. Researchers are recommended to allow participants to rest for 5 to 10 minutes between blocks.

Participants are presented with the labels/sets one by one and are asked to answer the question by pressing a key (e.g., "Y" for yes and "N" for no). It is explained that they should respond as fast as possible. Before the test, explain to participants

how to interpret the FOPL and have them complete a series of dummy trials to get familiar with the experimental procedure, which corresponds to 10 percent of the total number of trials of the experimental condition. The response key as well as the time elapsed from the display of the stimulus to the response are recorded.

Data analysis

The percentage of participants giving correct responses for each experimental condition is calculated. A logistic regression can be used to compare FOPL schemes in terms of the likelihood of correct responses.

Response times corresponding to incorrect responses are discarded from the analysis, as well as response times longer than three standard deviations from the mean for each experimental condition (Kruijne & Meeter, 2016; Wolfe, Palmer, & Horowitz,

2010). Response times usually do not follow a normal distribution. Researchers can use a logarithmic transformation of the data and use ANOVA (analysis of variance) to compare FOPL schemes. Alternatively, non-parametric methods can be used. In addition, given that ANOVA has been regarded as robust and non-sensitive to deviations of normality, rough data have also been analyzed using ANOVA.

Example of application

Bialkova & van Trijp (2010) used visual search to evaluate the influence of scheme (e.g., “Choices” logo, monochromatic GDA, and color-coded GDA), display size (e.g., standard size versus double size) and location on pack (e.g., top-left, top-right, or down-right) on participants’ ability to identify the presence of FOP nutrition labeling on the label. A total of 24 participants (ages ranging between 19 and 33 years, recruited among staff of Wageningen University) performed a visual search task using labels of yogurt as stimuli. Response times were recorded and analyzed using analysis of variance.

The analysis of response times of the trials where an FOP nutrition labeling scheme was included on the label showed a significant effect of size and location. The shortest response times were found when the schemes were double-sized and located on the top-right corner of the label. No significant effect of the type of scheme was found. These results suggest that participants found the FOP nutrition labeling scheme faster when their size was doubled and when they were located in the top-right corner of the label.

6.1.4.b Eye-tracking

Eye movements are good indicators of information acquisition (Holmqvist et al., 2011). In order to acquire information from a specific part of an object an individual needs to move their eyes until the light from that part of the object falls into the fovea, the most sensitive area of the retina (Wedel & Pieters, 2007). The human gaze is characterized by fast movements between points, called saccades, followed by stops at specific points, called fixations (Duerschmid & Danner, 2018). When the gaze is fixated on a specific point for a certain time period, the individual is acquiring visual information, which may be subsequently processed (Holmqvist et al., 2011). Eye-tracking techniques can be used to study how consumers acquire information from labels and specifically how they visually process FOPL schemes.

Eye-trackers allow measurement and analysis of eye movements based on pupil and corneal reflection method (Holmqvist et al., 2011). Eye-trackers can be grouped in two main categories: screen-based eye-trackers, which use visual stimuli on a monitor and an integrated eye-tracking module, and wearable eye-trackers, which are usually built on glasses and enable measurement of eye movements while participants freely move around and interact with objects (Duerschmid & Danner, 2018). Screen-based eye-trackers are more common in FOPL research and will be the focus of the following sections.

Experimental conditions

The experimental tasks described in the previous sections can be implemented

in screen-based eye-trackers to obtain information about how consumers visually process FOPL schemes. The test is conducted in a separate room to avoid distractions. Participants are asked to sit at a distance of approximately 65cm from the monitor and to move as little as possible during the task. Before starting the tests, participants should complete the calibration procedure of the eye-tracker software. Then, the experimental task is implemented while participants' eye movements are recorded at specific sampling intervals, depending on the sampling frequency of the eye-tracker (e.g., 30, 60, 120, 300 Hz). Before each image is shown on the screen, a fixation cross should appear for 0.2 seconds to make participants fixate at a fixed pre-defined point before looking at each image, which enables the comparison of eye movements across participants and stimuli (Holmqvist et al., 2011).

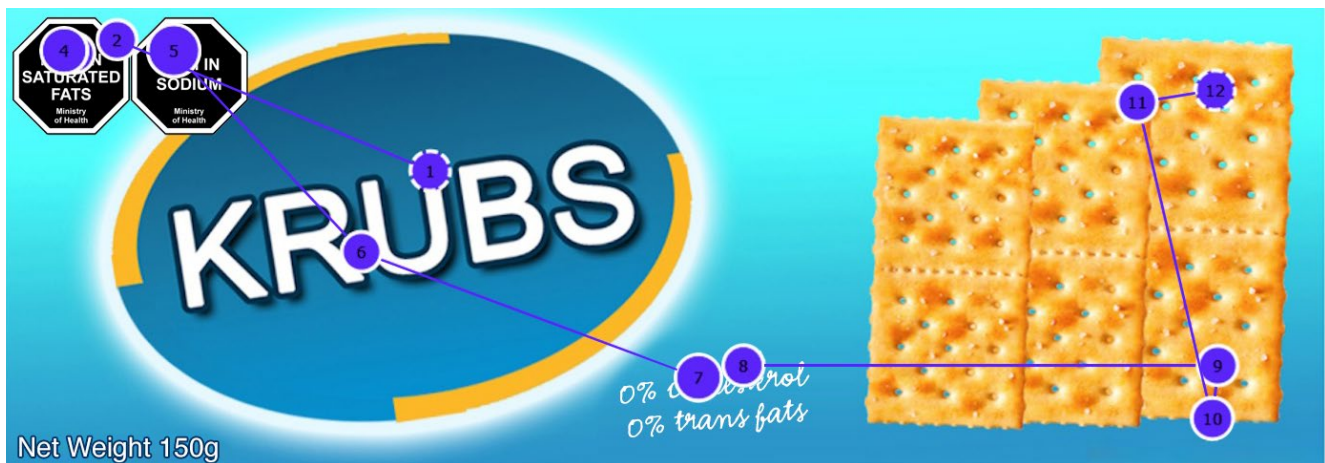
Data analysis

Eye movements are classified into fixations and saccades using one of the filters included in the eye-tracker software. Areas of interest (AOI) should be defined on each of the stimulus to evaluate eye-tracking measures. The FOPL scheme should be one of the AOIs. The most important eye-tracking measures are the following: percentage of consumers who fixated their gaze on the AOI, time to first fixation, total fixation duration, and fixation count (Holmqvist et al., 2011). The percentage of consumers who fixated their gaze on an AOI is a measure of the attentional capture of an AOI (Wolfe, 1998). It is related to the proportion of participants who extracted information from an AOI to complete the task (Pieters & Wedel, 2004). Time to first fixation is a measure of the

time from the start of the stimulus display until the participant fixates his/her gaze on the AOI for the first time, being indicative of the attentional capture of the AOI and the order in which participants process them for completing the task (Holmqvist et al., 2011). Fixation count is the total number of times that a consumer fixates his/her gaze on an AOI. This attention measure has been related to information processing (Jacob & Karn, 2003). An AOI with larger information density and/or more difficulty for extracting information is expected to have a higher fixation count as well as an AOI more relevant for consumers (Holmqvist et al., 2011). Total fixation duration is the total duration of all the fixations within an AOI and is related to the difficulty a participant has in extracting information from an AOI and its relevance for consumers (Holmqvist et al., 2011).

Graphical representations of the data can also be obtained. Individual gaze plots represent the eye movements of individual participants, as shown in the example in Figure 12. In this plot, fixations are represented using circles, which are identified with a number corresponding to the order of the fixation (from the display of the stimuli). The size of the circles is proportional to the duration of the fixation (i.e., the bigger the size, the longer the fixation). The lines between fixations correspond to saccades (i.e., rapid eye movements between two fixations). In order to rate intention to purchase a cracker label, the participant first fixated his/her gaze on the brand and then on the nutritional warnings highlighting high total fat and sodium content. Next, he/she fixated on the nutrient claim of 0 percent cholesterol, 0 percent trans fats. Finally, he/she fixated on the image of the product.

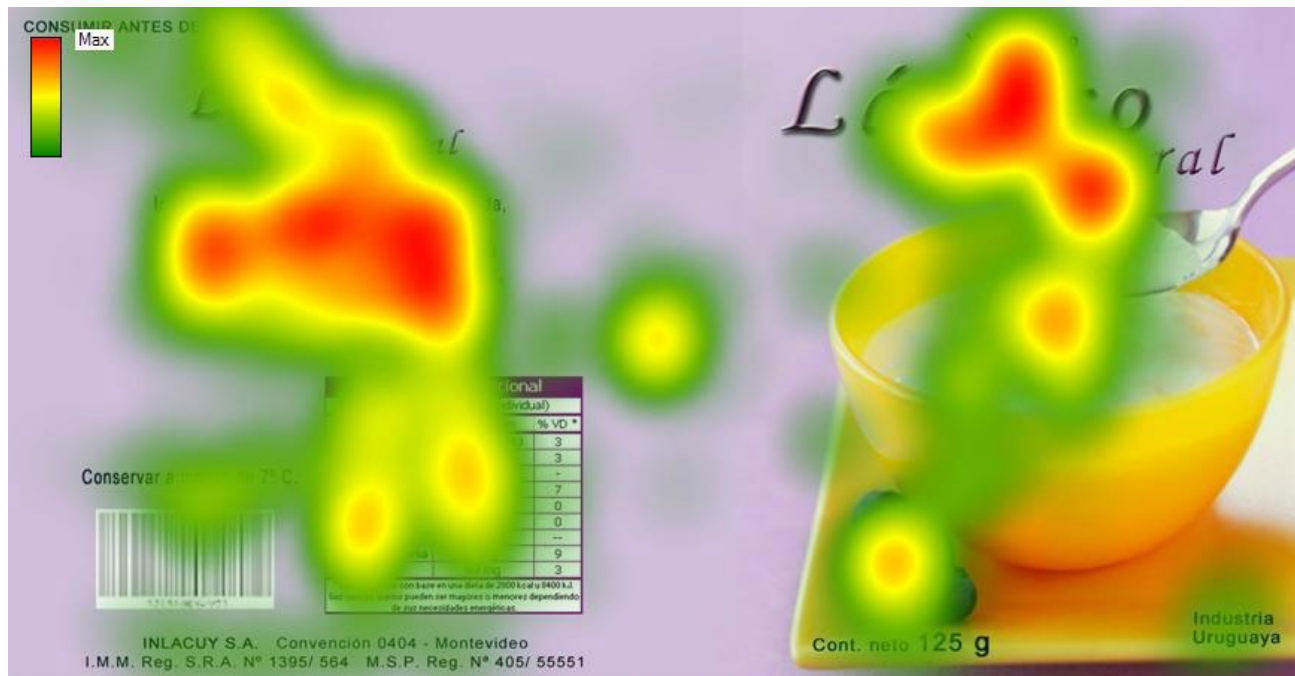
Figure 12. Example of a gaze plot generated in an eye-tracking task in which participants were asked to look at the label and indicate their purchase intention



Heatmaps provide an aggregate visualization of the average fixation count or fixation duration in the different areas of the label. The number of fixations (or duration of fixations) on each point of the label is represented using a color scale from green to red, which represents areas with fewer fixations (or shorter fixation duration) and a large number of fixations (or longer fixation duration), respectively. Figure 13 shows an example of a heatmap based on fixation count, obtained in an eye-tracking task in which participants were asked to look at a yogurt label to rate how

healthful the product was. The red areas on the left side of the label correspond to the list of ingredients and the nutritional table, which received the largest number of fixations. These indicate that these two areas received the largest attention for the evaluation of product healthfulness. It is interesting to note that the values of the daily guideline amounts were represented with a light green color, suggesting that consumers did not perform an in-depth inspection to make their healthfulness perception judgments.

Figure 13. Example of a heatmap generated in an eye-tracking task in which participants were asked to look at the label and indicate their perceived healthfulness



Example of application

Tórtora, Machín & Ares (2018) used eye-tracking to evaluate visual processing of labels during a choice task. A total of 124 participants were shown 16 pairs of labels differing in category of product (cookie or crackers), type of product (product with a health association or a product with a hedonic association), nutrient claim (claim versus no claim), and FOP nutrition labeling scheme (Facts Up Front system versus nutritional warnings). They were asked to select the one they would prefer to buy by

making a mouse click on it. An example of a set of labels is shown in Figure 14. The eye movements of the participants were recorded using a remote eye-tracker (Tobii Technology, Stockholm, Sweden). Areas of interest (AOI) were defined on the labels to calculate eye-tracking measures: brand, image, nutrient claim, Facts Up Front system and nutritional warnings. Fixation count and the percentage of participants that fixated their gaze were calculated for each AOI.

Figure 14. Example of a set of labels used in a choice task



Table 2 shows the average results for the eye-tracking measures for cookie labels. Nutritional warnings were among the areas of the labels with the highest percentage of participants who fixated their gaze. An average of 75 percent of the participants fixated their gaze on nutritional warnings to select the label they would buy, suggesting that they were relevant for decision-making. The attentional capture of nutritional warnings was higher than that

of the Facts Up Front system, as evidenced by higher percentage of participants who fixated their gaze on the former scheme. In addition, the average fixation count on nutritional warnings was significantly lower than average fixation count on the Facts Up Front system. This suggests that participants needed to invest more visual attention to extract information from the Facts Up Front system compared to nutritional warnings.

Table 2. Percentage of participants who fixated their gaze on different areas of interest and fixation count during a choice task with cookie labels

Area of interest	Percentage of participants who fixated their gaze (%)	Fixation count
Brand	85 ^a	2.4 ^c
Image	60 ^c	2.0 ^d
Nutrient claim	56 ^c	2.9 ^b
Nutritional warnings	75 ^b	2.5 ^c
Facts Up Front system	57 ^c	4.5 ^a

Note: Average values with different letters are significantly different for a significance level of 5 percent. Source: Tórtora et al., 2018.

6.2. Qualitative research methods to explore consumers’ interpretation of FOPL

Qualitative methods can be used to explore how people perceive and interpret FOP nutrition labeling schemes from their own perspective, rather than measuring the impact of such schemes on specific behavioral outcomes (Green & Thorogood, 2004). These methods focus on individual perception and give special attention to acknowledging the complexity of the topic of interest (Creswell, 2013). Qualitative methods aim at answering “what”, “how” and “why” and usually involve flexible research strategies (Green & Thorogood, 2004). However, it should be highlighted that these methods are only explorative and do not enable to infer about the comparative performance of different FOPL schemes to the population of interest.

In the context of front-of-package nutrition labeling, two methods deserve special attention: focus groups and open-ended questions included in online surveys.

6.2.1 Focus groups

Focus groups are one of the most popular qualitative methodologies for studying consumers’ perception and have been extensively used in sociology, marketing research, health sciences, communication research, and education (Guerrero & Xicola, 2018). A focus group can be defined as “a technique involving the use of in-depth group interviews in which participants are selected because they are a purposive, although not necessarily representative, sampling of a specific population, this group being ‘focused’ on a given topic” (Lederman, 1990). In a focus group, participants can freely express their opinions and jointly discuss their views about a specific topic, even if it cannot yet be observed in real (Flick, 2009). The discussion should be guided by an experienced moderator, who should be willing to listen to the discussion and encourage participants to share their

opinions (Prince & Davies, 2001). The social interactions during the focus groups enables researchers to obtain deeper and richer information compared to that usually obtained from one-to-one interviews (Guerrero & Xicola, 2018).

The aim of a focus group is not to make inferences about a larger population but to get an in-depth understanding of how people think and talk about a specific topic (Krueger & Casey, 2008). In the specific case of nutrition labeling, focus groups can be used to study how consumers use and understand nutrition information, as well as how they perceive and understand different FOP nutrition labeling schemes. Examples of the application of focus group in this context can be found in the papers published by De la Cruz-Góngora et al. (2017) and Talati et al. (2016).

Focus groups are conducted with small groups of participants, from 7 to 12, in order to obtain a good diversity of views and to give all of them the opportunity to express their opinions (Krueger, 1998). The participants in a focus group should be fairly homogeneous in terms of the main sociodemographic characteristics that underlie the object of study (e.g., age and socioeconomic status) to facilitate the interaction, but should not know each other (Guerrero & Xicola, 2018). Therefore, participants are selected based on the criteria that they have something to say on the topic, are within the age-range, have similar sociodemographic characteristics and would be comfortable talking to the moderator and each other (Richardson & Rabiee, 2001).

The number of focus groups to conduct is defined by the number of subgroups or

subpopulations required for the research, which are usually determined by theoretical sampling (Freitas et al., 1998). For example, researchers may want to conduct focus groups with consumers of different socioeconomic status to better capture the diversity among participants and identify the influence of this variable on consumers' perception. Within each consumer sub-group, different focus groups should be conducted until redundant information is generated (Krueger & Casey, 2008). Therefore, a minimum of two groups per consumer sub-group is recommended.

Focus groups should be carried out in a neutral place without special associations about the topic of the study (Escobar & Bonilla-Jiménez, 2009). The site should be ventilated, illuminated, comfortable, free of noise, and have good acoustics (Guerrero & Xicola, 2018). Participants' ability to easily access the site should be considered. The room should be equipped with chairs to enable participants to be seated in circle.

The discussion of a focus group is led by the moderator, who should be skillful in group discussions and have previous experience with focus groups. The moderator is responsible for keeping the discussion on the topic, creating a friendly and trusting atmosphere, eliminating communication barriers, and engaging participants to express their opinions (Escobar & Bonilla-Jiménez, 2009). An assistant moderator is usually present during the focus group but does not participate in the discussion. The main role of the assistant is to help the moderator by performing the following tasks: welcome participants as they arrive, take notes throughout the discussion, debrief with the moderator, and provide feedback on the analysis and reports.

The discussion is recorded in audio or sometimes video recorded to facilitate the allocation of expressions to individual participants and to analyze facial expressions and gestures.

Although focus groups allow researchers to obtain rich information about participants' perception about a specific topic, one of their main disadvantages is that the group dynamics can make participants change their postures and attitudes according to the group (Guerrero & Xicola, 2018). Participants may feel pressured by the other members of the group to assume a position that is not theirs. In addition, competition for dominance among group members can be established, which can reduce the richness and validity of the data (Merton, Fiske, & Kendall, 1990). Finally, it is important to stress that the information obtained in focus groups is exploratory and usually requires validation in quantitative studies using a larger representative sample of participants. This is particularly relevant when comparing FOP nutrition labeling schemes, as focus groups do not allow researchers to make inferences about the schemes that apply to the target population of the policy, which in the case of FOP would be the general population.

Procedure

Focus groups usually last between 60 and 120 minutes (Guerrero & Xicola, 2018). The discussion is held around a semi-structured discussion guide that highlights the main topics that need to be covered. It is composed of three main sections: introduction, discussion, and closing.

- **Introduction:** Before starting the focus groups the moderator should provide a formal welcome to the participants, thank them for their participation, make a general presentation of the study, explain the rules of the discussion, and ask for their informed consent. The presentation of the study should be as general as possible to avoid any response bias or priming toward a specific direction. The moderator should also encourage each of the participants to provide a brief self-introduction to generate a sense of group identity (Merton et al., 1990).
- **Discussion:** Discussion is focused on the main topic and involves different types of questions (opening, introductory, and key questions), that are asked in a sequence that goes from general to specific. The questions should be general and open-ended to get participants involved in the discussion, avoiding dichotomous questions that can be answered with "yes" or "no". In the specific case of FOP nutrition labeling schemes, the discussion can start with general questions about motives underlying their food purchases (e.g., When you go to the supermarket to buy food, what do you take into account for selecting products?), the information of food packages they usually look at (e.g., What information do you usually look for on food labels?), and how participants evaluate product healthfulness (e.g., How do you know how healthful food products are?). Then, food packages, including packages with different FOP nutrition labeling schemes, can be used to prompt the discussion and participants can be asked to provide

their spontaneous reactions (e.g., What do you think about this product?). Once participants provide their first general impressions, specific questions about the FOP nutrition labeling schemes are used (e.g., What do you think about this symbol? What does it mean? What would you do if your usual product contains this symbol?). In addition to the main questions, follow-up questions are asked to explore the topics in-depth and to encourage participants to reflect and raise their own issues.

- **Closing:** The closing should lead participants to reflect on the entire discussion and to provide their general position about the central topics. After that, the moderator can provide a summary of the whole discussion and ask participants if they agree with the summary. Anonymous sociodemographic characteristics of the participants are collected using simple questionnaires that are administered at the end of the discussion. Finally, the moderator should thank the participants for their collaboration.

An example of a focus group discussion guide targeted at exploring participants' perception of different FOP nutrition labeling schemes is provided in Annex 2.

Data analysis

The audio or video recording of the focus groups are transcribed for analysis. Bold font type characters are usually used to identify the moderator's questions and statements. If possible, each speaker should be identified before his/her comments using some type of coding highlighting his/her

main characteristics (e.g., age and gender). The transcripts should not allow participants to be linked with specific statements in order to ensure confidentiality.

Print the transcripts and order them according to the identified subgroups of participants considered in the theoretical sampling and the order in which they were held. Ideally, all transcripts are read at one sitting. Transcripts of the focus group discussions are analyzed using content analysis based on inductive coding (Krippendorff, 2004). First, fragments related to each of the main topics of the discussion guide are identified. Within each of those topics, fragments are arranged into themes and categories, which are created as they emerged when examining and reexamining the transcripts. This procedure is done by one researcher and usually verified by two additional researchers (Hennink, Hutter, & Bailey, 2011). Disagreements among the researchers are resolved through open discussion until agreement about the best code is reached.

After the analysis is completed, a report summarizing the results in a concise form is prepared. The report should be brief but comprehensive, including both general trends and isolated minority opinions (Guerrero & Xicola, 2018).

Example of application

Talati et al. (2016) conducted focus groups with 50 adults (27 males and 23 females) in Western Australia to explore their reaction to different FOP nutrition labeling schemes (GDA, traffic-light system, and health star rating). Participants were shown examples of the different schemes, as well as mock

packages featuring FOP nutrition labeling. The moderator asked participants to imagine that they were looking at the products in a supermarket. Spontaneous thoughts about the schemes and the packages were asked using general open-ended questions (e.g., What do you think about this?).

According to participants' accounts, the decision to use FOP nutrition labels for making food purchases was mainly determined by their trust and ease of use. In the case of the GDA system, participants stated that the industry often uses unrealistic small serving sizes to report favorable percentages. In addition, this scheme was perceived as more difficult to understand due to the large amount of information and less likely to be considered for decision-making at the point of purchase. On the contrary, semi-directive and directive schemes were regarded as easy to find and understand and were deemed useful for making comparisons across products.

6.2.2 Open-ended questions

Open-ended questions are basically questions that require an elaborated response from participants. These questions do not place limits on the responses and enable participants to freely express their ideas in their own vocabulary. Their main advantage is that participants answer these questions individually and therefore their responses are not influenced by the presence of other participants or researchers.

The main drawback of open-ended questions is that the questionnaires are structured and do not allow the introduction of follow-up questions to deepen the understanding of consumer responses. However, this drawback is usually overcome by the large consumer sample. Open-ended questions can be included in online surveys or face-to-face interviews with large consumer samples. However, the qualitative nature of the responses makes results from open-ended questions explorative, and not necessarily appropriate for drawing conclusions on the comparative performance of different FOPL schemes. In addition, if online surveys are conducted online, the limitations associated with internet-based research should be considered, as described in Section 5.3.

Procedure

Open-ended questions should be conducted with a large consumer sample that is representative of the population of interest or that at least includes heterogeneity in sociodemographic characteristics. Although the questionnaire can include different sections and address different objectives, the potential effect of the different sections on participants' responses to open-ended questions should be considered.

Open-ended questions should aim to explore participants' general understanding of FOPL schemes. Participants can be presented with the graphic design of an FOPL scheme and can be asked to explain their general impression (e.g., What do you think this symbol would mean on the front of the package of a food product?) or

what they would do if they find a product they usually buy featuring the symbol (e.g., What would you do if a food product you usually buy contained this symbol on the package?). Follow-up questions prompting participants to explain their responses can be asked (e.g., Why would you do that?). All the questions should encourage participants to elaborate their responses and questions that encourage “yes” or “no” responses should be avoided. It is important to highlight that if several FOPL schemes are included in the same survey, their presentation order should be random and balanced between participants within a study group (control or comparisons) to avoid order and carry-over effects. A sociodemographic questionnaire should be included at the end to characterize participants and to enable the evaluation of differences in the responses of different sociodemographic groups.

Data analysis

Responses to open-ended questions are analyzed using content analysis based on inductive coding (Krippendorff, 2004), as previously described for focus groups. Responses are classified into themes and categories, created as they emerged from the responses. The procedure is done by triangulation to minimize the subjectivity of the coding process. Once the final categories are defined, frequency of mention is determined by counting the number of participants who mentioned responses related to each theme and category, and expressed as a percentage of the participants. Differences in the frequency of mention of participants with

different sociodemographic characteristics can be evaluated using a chi-square test.

After the analysis is completed, a report summarizing the results in a concise form is prepared, including the themes and categories and their corresponding frequency of mention. In general, categories mentioned by a very small percentage of participants are not reported. However, researchers can select the minimum frequency of mention selected as cut-off point such as 5 percent or 1 percent, which are frequent options.

Example of application

Ares, Aschemann-Witzel et al. (2018) used open-ended questions to explore people's perspectives on nutritional warnings as an FOP nutrition labeling scheme. A total of 1,416 people were recruited from Facebook and participants were presented with the following text: “The Ministry of Health is evaluating the inclusion of complementary information about the nutritional composition of packaged foods. Products with excessive content of sugar, fat and salt should include warnings (as those shown in the figure) in the front of their package.” This was followed by the graphic design of the warnings. Participants were asked to answer the following question in a blank space: What do you think about this proposal? No word limit was imposed on the responses. Responses were coded into themes and sub-themes using content analysis following an inductive coding approach. The percentage of participants who mentioned each theme and sub-theme was calculated.

Table 3. Frequency of mention of themes and sub-themes identified in the content analysis of responses to an open-ended question aimed at exploring citizens' perceptions of nutritional warnings

Theme and sub-theme	Frequency of mention (percent)
General attitude toward the scheme	95.3
Positive attitude	93.1
Negative attitude	2.2
Indifference	0.1
Advantages of the scheme	32.9
Easy to understand	8.8
Enables informed choices	8.3
Makes decision-making easier	7.8
Easy to find on the packages	7.0
Counters marketing strategies	1.0
Expected positive consequences	15.9
Raises consciousness	6.4
Encourages more healthful choices	3.3
Improves the health status of the population	3.4
Others	2.8
Factors conditioning the success of the policy	14.2
Communication campaigns	3.6
Large size of the scheme on the packages	3.5
Different graphic design	2.0
Others	5.1
Reasons for implementation	13.1
Nutrition information is difficult to find and understand	6.9
Health problems of the Uruguayan population	3.0
The food industry uses deceitful marketing strategies	2.3
Information is a consumer right	0.9
Disadvantages of the scheme	8.7
It does not include quantitative information about nutrient content	2.7
Criteria for defining excessive content of nutrients is not clear	2.4
Others	3.6
Additional policies needed to encourage healthier food choices	14.7
Other labeling policies (GMO labeling, allergens)	13.1
Others	1.6

Source: Ares et al., 2018.

Seven themes were identified in the responses: general attitudes toward the scheme, advantages of the scheme, expected positive consequences, factors conditioning the success of the policy, reasons for implementation, disadvantages of the scheme, and additional policies needed to ensure the success of the policy. Table 3 shows the frequency of mention of the identified themes and sub-themes. Results show that the great majority of participants (93.1 percent) have a positive attitude toward nutritional warnings, emphasizing that it is a good policy that

would contribute to raising consciousness and encourage people to make more healthful food choices. Participants also noted a series of advantages of the proposed scheme, including the fact that it would be easy to find on the packages and easy to understand. Disadvantages of the scheme were only mentioned by 8.7 percent of the participants and were mainly related to the lack of quantitative information about nutrient content (that would be included in the nutritional table) and lack of details about the criteria to classify nutrient content as excessive.

7.

General recommendations

Research can provide valid and reliable information to support the development of FOP nutrition labeling regulations. A wide range of methodological approaches are available to evaluate the influence of FOP nutrition labeling schemes on consumers' perception and behavior. An overview of the most popular methodological approaches is provided in Table 4.

Table 4. Overview of the most popular methodological approaches used in FOP nutrition labeling research

Methodological approach	Type of approach	Objective	Description	Special requirements	Advantages	Disadvantages
Identification of the least harmful product	Quantitative	To evaluate the influence of FOP nutrition labeling on consumers' ability to identify the least harmful/most healthful product alternative	Participants are presented with sets of labels or packages and are asked to identify the least harmful/most healthful product	Sets of images of labels or packages	Provides information about a key objective of FOP nutrition labeling The task is similar to what participants do in their real life when comparing products The task is easy to understand	It only focuses on participants' ability to make comparisons across products
Classification of nutrient content	Quantitative	To evaluate the influence of FOP nutrition labeling on consumers' ability to identify products with excessive content of nutrients associated with NCDs	Participants are presented with labels or packages and are asked to indicate if the content of a target nutrient exceeds the recommendations for a healthy diet	Images of labels or packages	Provides information about a key objective of FOP nutrition labeling	It is not a natural task for consumers
Harmfulness/Healthfulness scales	Quantitative	To evaluate the influence of FOP nutrition labeling on perceived harmfulness/healthfulness	Subjective healthfulness perception is evaluated by asking participants to rate their perceived harmfulness/healthfulness of labels or packages	Images of labels or packages	It measures subjective harmfulness/healthfulness perception	It is not a natural task for consumers It is based on the evaluation of individual products. Scales can be difficult to understand to some consumer segments
Purchase intention scales	Quantitative	To evaluate the influence of FOP nutrition labeling on participants' purchase intention	Participants are presented with labels or packages and are asked to indicate their purchase intention using scales	Images of labels or packages	It is based on the evaluation of individual products	Participants do not purchase the products The task is not similar to what participants do in their real life Scales can be difficult to understand for some consumer segments
Choice tasks	Quantitative	To evaluate the influence of FOP nutrition labeling on participants' choice of products	Participants are presented with sets of labels or packages and are asked to select the one they would purchase	Sets of images of labels or packages	The task is similar to what participants do in their real life when purchasing for food The task is easy to understand	The choice has no real implication for participants Limited number of options

Methodological approach	Type of approach	Objective	Description	Special requirements	Advantages	Disadvantages
Simulated online shopping experiments	Quantitative	To evaluate the influence of FOP nutrition labeling food purchases	Participants have to perform a simulated purchase of food products using an online grocery store	Online grocery store Pictures and information of a large number of products	The task is similar to a real online purchase situation	Participants do not purchase the products The task can be complicated for some participants The task may not resemble the actual sizes, resolution and proportionality of products and FOP labels depicted in real life, compromising validity Computer and smartphone screen sizes and resolutions vary and may introduce bias to the response
Visual search	Quantitative	To evaluate attentional capture of FOP nutrition labeling schemes	The time needed to find a target visual stimuli is measured	Software for data collection Images of labels or packages	Results are not influenced by response bias	They only measure low-level processes
Eye-tracking	Quantitative	To evaluate visual processing of FOP nutrition labeling schemes	Eye movements are recorded while participants evaluate labels or packages	Eye-tracker Images of labels or packages	Results are not influenced by response bias Provide information about the cognitive effort needed to process the information	Requires specialized equipment
Focus groups	Qualitative	To obtain in-depth information about consumers' perception and understanding of FOP nutrition labeling schemes	Group discussions with 5-12 participants each, who should be relatively homogeneous and represent the target population. The discussion is guided by a trained moderator	Trained moderator. Quiet and comfortable room equipped with chairs in an area easily accessible to the participants. Audio recorder	Provide in-depth information They allow follow-up questions	Exploratory Not appropriate for evaluating the effectiveness of FOP nutrition labeling schemes. Responses may be influenced by the group Differences between schemes cannot be accurately measured
Open-ended questions	Qualitative	To obtain in-depth information about consumers' perception and understanding of FOP nutrition labeling schemes	Inclusion of open-ended questions in online surveys	Online system for conducting the study Consumer database for recruiting consumers	Cost-effective Appropriate for large consumer samples	Exploratory Not appropriate for evaluating the effectiveness of FOP nutrition labeling schemes They do not allow follow-up questions Differences between schemes cannot be accurately measured

Methods for FOP nutrition labeling research should be carefully selected based on the policy objectives and the research questions, as well as time and resource constraints. FOP nutrition labeling policy is generally framed as a tool to help consumers make informed decisions by easily identifying products with high or excessive content of nutrients associated with NCDs. Therefore, the essential research results needed to support regulations should demonstrate that the selected FOP nutrition labeling scheme facilitates understanding of nutritional information and improves consumer ability to identify products with excessive content of critical nutrients. Meanwhile, research aimed at evaluating the effect of FOP nutrition labeling on purchase intention can also contribute to the estimation of the potential impact of the policy from a public health perspective.

Questionnaires should be kept as simple as possible to avoid boredom and fatigue. When the method requires the evaluation of labels and packages, researchers are advised not to ask a large number of questions for each stimulus, as participants may become biased. Prior questions can have a priming effect that modifies participants' responses. For this reason, when different aspects of consumers' perception are investigated, it is generally advisable to present the stimuli more than once and ask only one question in each presentation round. In this case, the order of the questions should not make information salient before specific questions are asked. The questionnaire should start with behavioral questions about purchase intention, followed

by questions related to healthfulness perception, and finally nutrient-related questions. If the opposite order is used, there is a danger that respondents will take into account specific information that they would never consider for evaluating product healthfulness or to decide their purchase intention. An example of how different questions can be structured in a single questionnaire is shown in Annex 4. Once the questionnaires are designed, it is advisable to pilot the questionnaire with a small group of participants before launching the study, to test that the questions are correctly understood and to check the time required by participants to complete it.

Reports of the results of FOP nutrition labeling research should be presented to stakeholders and made public to support the design of regulations. Researchers are advised to publish the results in peer-reviewed journals to put them under the scrutiny of experts in the field and check their validity. The peer-review process provides an external seal of approval to the research and contributes to proving its methodological quality.

The selection of an FOP nutrition labeling scheme should be based on solid evidence that supports the decision of introducing a specific scheme for achieving the policy objectives, which means actionable and context-sensitive evidence to improve responsiveness of health actions. For this purpose, policy makers should base their decisions on the best available independent evidence, and the domestic production of scientific evidence is not strictly required when foreign evidence

from rigorous high-quality studies is available. The generation of domestic evidence to support decision-making could strengthen the scientific basis underlying development of FOP nutrition labeling regulations that best align with public health policy objectives. The priority for domestic research to support policy making should be studies aimed at evaluating the influence of FOP nutrition labeling on objective understanding of nutrition information and its impact on product healthfulness perception. Researchers are advised to prioritize quantitative over qualitative methods and face-to-face over online data collection approaches, and between-subjects over within-subjects designs.

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ANNEXES

Annex 1.

Example of How Sets of Products with Different Nutritional Composition Can Be Created for a Choice Task

The table shows the nutritional composition of a commercial brand of whole-wheat crackers and the corresponding nutritional warnings that should be included on the FOP according to the PAHO Nutrient Profile Model.¹ Considering that the product should only include one nutritional warning for excessive content of sodium, this nutrient should be selected as target nutrient to create the alternative products of the set.

Table Annex 1. Nutritional composition of three products for a choice task and inclusion of warnings for each nutrient

Nutrient	A - Commercial product	B - Least harmful alternative	C- Alternative product
Calories (kcal/100g)	425	434	400
Proteins (g/100g)	11	12	10
Carbohydrates (g/100g)	66	65	63
Sugars (g/100g)	4	5	7.7
% calories from sugars	4	5	8
Warning for sugars	No	No	No
Total fat (g/100g)	13	14	12
% calories from total fat	28	29	27
Warnings for total fat	No	No	No
Saturated fat (g/100g)	1	2	1.3
% calories from saturated fat	2	4	3
Warnings for saturated fat	No	No	No
Sodium (mg/100g)	825	429	728
mg sodium/calorie	1.9	0.9	1.8
Warning for sodium	Yes	No	Yes

In order to be differentiated according to the PAHO Nutrient Profile Model,¹ the sodium content of the least harmful alternative should be lower than 1 mg of sodium/kcal. As shown in the table in Annex 1, the sodium content of this product (B) can be reduced to reach a mg of sodium/kcal ratio below 1, whereas the rest of the nutrients can be modified in trivial amounts with respect to the commercial product. The third alternative of the set (C) can be created by modifying all nutrients in trivial amounts, leading to a product with the same nutritional warnings as product A. For each product, the package/label featuring its corresponding warnings should be designed.

1 Pan American Health Organization. (2016). *Pan American Health Organization Nutrient Profile Model*. Washington, DC: Pan American Health Organization.

Annex 2.

Example of a Discussion Guide for a Focus Group

A. Welcome, introduction and instructions

Good afternoon and welcome to our session. Thank you for taking the time to join us to talk about food. We appreciate your time and effort. My name is *(name)* and assisting me is *(name)* and we work for *(institution)*. This session is designed to assess how you select the foods you normally eat and what you take into account when making your food purchases. We are having discussions like this with several groups of people around the country. The session will take no more than two hours.

We would like to record the session because we don't want to miss any of your comments. People always say very important things during the discussion and we are not able to write fast enough to get all of them. We will not use your names in the reports, so we can assure confidentiality. May I turn the recorder on? *[If yes, the recorder is switched on]*

We will have an open discussion, so everyone is expected to express their thoughts and opinions. You will not have a specific order to talk. We want to know the views and perceptions of each of you. There will be no right or wrong answers but rather different points of view. Please feel free to share your thoughts even if they are different from what others have said. When you have something to say, please wait until the other person has finished. The important thing is that only one person speaks at a time. Does anyone have any questions? *[Answers]*

Before we begin, we will handle these informed consent sheets that provide some general information about the study. We will ask you to carefully read the sheet and to sign them if you agree to express your consent to participate in this discussion.

First, we would like everyone to introduce themselves. Can you please tell us your name?

B. Guiding questions for the main discussion

- Well, let's begin. I want you to think about the last time you went to the supermarket to purchase food. *What did you take into account for selecting food products you bought?*
- *What information did you read on the labels?*
- *How do you know how healthful food products are?*

[In order to prompt the discussion about nutrition labeling, food packages with different FOP nutrition labeling schemes (e.g., no FOP label, warning system, traffic-light system) are shown]

to participants one by one (please refer to Section 6.2). Participants are asked to provide their spontaneous reactions toward each of the products.]

What do you think about this product? Is there anything special that catches your attention?

[Then, participants' attention is directed toward each of the FOP nutrition labeling schemes and the following questions are posed:]

- *What do you think about this symbol?*
- *What does it mean to you?*
- *What would you do if your usual product contains this symbol?*

[A comparative evaluation of the schemes can also be made based on the following questions:]

Which of the symbols do you prefer?

- *Which of the symbols is easier to understand?*
- *Which would be the most helpful to you?*

C. Closing

Of all the things we have discussed today, what would you say are the most important issues?

[A brief oral summary is provided by the moderator and the following questions are asked:]

Is this an adequate summary?

- *Have we missed anything?*

Thank you for participating. This has been a successful and useful discussion. Your opinions will be a valuable asset to the study. We hope that you have found the discussion interesting and exciting. Before you leave, I would like you to complete this form that includes some simple questions about you [Hand out the sociodemographic questionnaire.].

Annex 3.

Generic Protocol for Research on Front-of-Package Nutrition Labeling Using Between-Subject Experiment Design to Assess and Compare the Performance of FOPL Systems

Start date: (Date Month Year)
Duration: (X months)
Collaborating partners: University of (name of the university or research center)
Ministry of (name of the ministry and country)
Pan American Health Organization

Principal investigators

Name and title	Contact information

Co-investigators

Name and title	Contact information

Other collaborators

Name & title	Contact information

Abstract

Like many other countries in the Region of the Americas, (*name of the country*) has shown an increasing prevalence of obesity as well as noncommunicable diseases (NCDs) over the past few decades. NCDs cause X% of deaths annually in the country. Unhealthy eating is one of the main modifiable risk factors for NCDs. Healthier choices by consumers would result in a decrease in nutrition-related diseases, and would lead to a reduction in health care costs. Front-of-package labeling (FOPL) on foods has been shown to help consumers evaluate product harmfulness and make healthier choices. FOPL will soon be implemented as a standard in most countries.

The goal of this research project is to evaluate the efficacy of different FOPL schemes in (*name of the country*). A cross-sectional survey will be conducted among (*n = size of the sample of*) individuals recruited (*at supermarket stores or online*). The objectives are to compare different FOPL schemes in terms of ability to facilitate consumers' identification of harmful products and those with excessive content of certain nutrients, identify factors that influence choice of products, and determine how consumers in (*name of the country*) perceive different FOPL schemes.

The results of this research will guide the identification and development of an FOPL scheme that is appropriate for implementation/use by consumers in (*name of country*). The major significance of the outcome of this research is to reduce obesity and NCDs as consumers using FOPL information make healthier choices/ultimately leading to reductions in health care costs and benefits to the economy. The research will be carried out by the University of (*name of the university or organization*), Ministry of Health of (*name of the country*), and the Pan American Health Organization.

1. Background and context

The prevalence of overweight, obesity and noncommunicable diseases (NCDs)—cardiovascular diseases, cancer, diabetes and chronic pulmonary diseases—continues to increase in the Americas for all age groups. The Region of the Americas has the highest prevalence of overweight and obesity in the world: The global prevalence of overweight and obesity in adults is 39 percent, whereas in the Americas it is 63.7 percent among male and 61.0 percent among female.² NCDs are the major cause of disability and premature death in the Americas: in 2016, NCDs were responsible for 78 percent of all deaths in the Region.¹ Thirty-four percent of these NCD-related deaths occurred prematurely in people between the ages of 30 and 69 years, when people are in the most economically productive time of their life.³ This implies that NCDs have a huge economic impact on societies, due to their associated health care costs and the fact that they undermine the capital and labor pillars of societal income.^{4,5}

2 Pan American Health Organization. (2018a). *CORE INDICATORS: Health situation in the Americas 2018*. Washington, DC: Pan American Health Organization.

3 Pan American Health Organization. (2018b). *PAHO Mortality Data*. Available at: <https://www3.paho.org/data/index.php/en/indicators-mortality/mortality-by-cause-of-death-level-by-country.html>

4 Theodore, K. (2011). Chronic noncommunicable diseases and the economy. *West Indian Medical Journal*, 60 (4), 392-396.

5 Bloom, D.E., Chen, S., McGovern, M.E. (2018). The economic burden of noncommunicable diseases and mental health conditions: results for Costa Rica, Jamaica, and Peru. *Revista Panamericana de Salud Pública*, 42, e18.

Sedentary lifestyle and unhealthy eating are the main modifiable factors that drive this situation.⁶ The expansion of unhealthy diets has been characterized by the rapid replacement of unprocessed or minimally processed foods and freshly prepared dishes by ultra-processed products.^{7,8,9,10} In particular, consumption of processed and ultra-processed products that are nutrient poor, energy-dense and contain high levels of nutrients associated with NCDs (i.e., sugar, fats, or sodium) has been identified as one of the main contributors to the epidemic of overweight and obesity, leading to diets that lack sufficient levels of essential nutrients.^{7,8}

The current food environment is characterized by an increasingly wide availability of ultra-processed foods, most of which are inexpensive and intensively promoted.^{6,7,8,9,11,12} These products tend to become the default option for consumers, as eating healthily requires and investment of relatively more time, effort and money.^{13,14} For this reason, the influence of environmental factors on eating behavior should be tackled to achieve a reduction in the prevalence of obesity and NCDs at the population level.^{6,15} The development of policies that create supportive food environments that encourage people to eat healthily has been recognized as a key priority.⁶ Such policies are more cost-effective and are expected to have a more lasting effect than individual approaches to obesity.^{13,16,17} Among these policies, nutrition labeling, subsidies and taxes, restrictions on food advertising and changes in the availability of healthy/unhealthy foods have received special attention.^{6,8,9,12,16}

Provision of information is usually regarded as a core policy for encouraging healthier food choices.¹⁸ In particular, the inclusion of nutrition information on food packages can help consumers to make informed

- 6 GBD 2017 Diet Collaborators. (2019). Health effects of dietary risks in 195 countries, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. *The Lancet*, 393, 1958-1972.
- 7 Swinburn, B.A., Kraak, V.I., Allender, S., Atkins, V.J., Baker, P.I., Bogard, J.R., et al. (2019). The Global Syndemic of Obesity, Undernutrition, and Climate Change: The Lancet Commission report. *The Lancet*, 393, 791-846.
- 8 Monteiro C.A., Cannon G., Lawrence M., Costa Louzada M.L., Pereira Machado P. *Ultra-processed foods, diet quality, and health using the NOVA classification system*. Rome: FAO; 2019.
- 9 Pan American Health Organization. (2015). *Ultra-processed food and drink products in Latin America: Trends, impact on obesity, policy implications*. Washington, DC: Pan American Health Organization.
- 10 Pan American Health Organization. (2019). *Ultra-processed food and drink products in Latin America: Sales, sources, nutrient profiles, and policy implications*. Washington, DC: Pan American Health Organization.
- 11 Stanton, R. A. (2015). Food retailers and obesity. *Current Obesity Reports*, 4, 54–59.
- 12 Story, M., Kaphingst, K. M., Robinson-O'Brien, R., & Glanz, K. (2008). Creating health food and eating environments: Policy and environmental approaches. *Annual Review of Public Health*, 29, 253–272.
- 13 Hawkes, C., Smith, T. G., Jewell, J., Wardle, J., Hammond, R. A., Friel, S., et al. (2015). Smart policies for obesity prevention. *The Lancet*, 385, 2410–2421.
- 14 Thaler, R. H., & Sunstein, C. R. (2008). *Nudge. Improving decisions about health, wealth, and happiness*. New York: Yale University Press.
- 15 Swinburn, B., Egger, G., & Raza, F. (1999). Dissecting obesogenic environments: The development and application of a framework for identifying and prioritizing environmental interventions for obesity. *Preventive Medicine*, 29, 563–570.
- 16 Capacci, S., Mazzocchi, M., Shankar, B., Macias, J. B., Verbeke, W., Perez-Cueto, F. J. A., et al. (2012). Policies to promote healthy eating in Europe: A structured review of policies and their effectiveness. *Nutrition Reviews*, 70(3), 188–200.
- 17 Cecchini M., Sassi F., Lauer J.A., et al. (2010). Tackling of unhealthy diets, physical inactivity, and obesity: health effects and cost-effectiveness. *The Lancet* 376:1775-1784.
- 18 Mazzocchi, M., Cagnone, S., Bech-Larsen, T., Niedzwiedzka, B., Saba, A., Shankar, B., et al. (2015). What is the public appetite for healthy eating policies? Evidence from a cross-European survey. *Health Economics, Policy, and Law*, 10(3), 267–292.

decisions.¹⁹ Several studies have reported, however, that people find it difficult to find and understand conventional nutrition information and that they seldom use it in making their food purchases.^{18,20,21,22,23}

Considering that people spend little time and cognitive effort when making their food purchases, the inclusion of simplified nutrition information schemes can improve their ability to find and understand nutrition information, encouraging informed food choices.^{24,25} For this reason, the inclusion of front-of-pack (FOP) nutrition labeling has been identified as a priority for policy-making worldwide.²⁶ In summary, FOP nutrition labeling aims: i) to provide simple nutrition information that is easy to find and easy to understand; ii) to allow consumers to make informed decisions regarding the foods they consume; and iii) to discourage consumption of products with excessive amounts of sugar, fats, and sodium.

To this end, the Plan of Action for the Prevention of Obesity in Children and Adolescents proposed the development and implementation of regulations on FOP labeling that promote healthy choices. It was unanimously approved by Member States of the Pan American Health Organization (PAHO) in the 53rd Session of the Directing Council.²⁷ This requires establishment of FOP systems that can ultimately reduce purchase and consumption of products that are not recommended by the health authority as part of a healthy diet, alert consumers about the contents of these products and their potential health effects, prohibit misleading or otherwise manipulative practices, and facilitate healthier purchase decisions.

Several FOP nutrition labeling schemes have been developed worldwide to achieve different purposes.²⁸ Non-directive or non-interpretive schemes provide numerical information about nutrient content (e.g., guidelines on daily amount). Semi-directive schemes include numerical information and classify nutrient content as low/medium/high (e.g., traffic-light system). Directive or interpretive schemes provide cues about product harmfulness and may either be based on specific nutrients (e.g., nutritional warnings) or on the overall product (e.g., the Australian Health Star Rating).

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- 19 Cowburn, G., & Stockley, L. (2005). Consumer understanding and use of nutrition labeling: a systematic review. *Public Health Nutrition*, 8, 21-28.
 - 20 Cheftel, J. C. (2005). Food and nutrition labeling in the European Union. *Food Chemistry*, 93, 531-550.
 - 21 Feunekes, G. I. J., Gortemaker, I. A., Willems, A. A., Lion, R., & van den Kommer, M. (2008). Front-of-pack nutrition labeling: Testing effectiveness of different nutrition labeling formats front-of-pack in four European countries. *Appetite*, 50, 57-70.
 - 22 Grunert, K.G., & Wills, J.M. (2007). A review of European Research on consumer response to nutrition information on food labels. *Journal of Public Health*, 15, 385-399.
 - 23 Sharf, M., Sela, R., Zentner, G., Shoob, H., Shai, I., & Stein-Zamir, C. (2012). Figuring out food labels. Young adults' understanding of nutritional information presented on food labels is inadequate. *Appetite*, 58, 531-534.
 - 24 Hawley, K.L., Roberto, C.A., Bragg, M.A., Liu, P.J., Schwartz, M.B., Brownell, K.D. (2012). The science on front-of-package food label. *Public Health Nutrition*, 16, 430-439.
 - 25 van Kleef E., Dagevos H. (2015). The growing role of front-of-pack nutrition profile labeling: A consumer perspective on key issues and controversies. *Critical Reviews in Food Science and Nutrition*, 55, 291-303.
 - 26 World Health Organization. (2017). *Tackling NCDs: 'best buys' and other recommended interventions for the prevention and control of noncommunicable diseases*. Geneva: World Health Organization.
 - 27 Pan American Health Organization. (2014). *Plan of Action for the Prevention of Obesity in Children and Adolescents. 53rd Directing Council, 66th Session of the Regional Committee of WHO for the Americas*. Washington, DC: Pan American Health Organization.
 - 28 Hodgkins, C., Barnett, J., Wasowicz-Kirylo, G., Stysko-Kunkowskac, M., Gulcand, Y., Kustepeli, Y., et al. (2012). Understanding how consumers categorise nutritional labels: A consumer derived typology for front-of-pack nutrition labeling. *Appetite*, 59, 806–817.

2. Efficacy of FOP nutrition labeling from the consumers' perspective

From a public health perspective, the efficacy of FOP nutrition labeling mainly depends on its ability to encourage consumers to make healthier food choices and to reduce consumption of nutrients associated with NCDs. In order to achieve this objective, several steps should be fulfilled.

First, consumers need to be exposed to the FOP nutrition labeling scheme (i.e., the scheme included on the front of the package needs to catch consumers' attention). Visual attention is the degree to which an individual look at a stimulus²⁹ and this is a pre-requisite for information acquisition and processing.³⁰ When looking at a stimulus the brain uses attentional mechanisms to select part of the available information for further processing, whereas processing of non-selected information is suppressed.³¹ There are two types of attentional capture: bottom-up and top-down.³² Bottom-up attention is a rapid and automatic type of attentional capture that depends on the physical characteristics of the stimulus (e.g., its color, size, and shape).³³ It occurs even when the individual is not specifically searching for a target stimulus.³⁴ Top-down attentional capture is related to motivation and occurs when the individual is explicitly looking for the target stimulus. Consumers' in-store food purchase decisions are habitual behaviors that occur in very short time frames.³⁵ Therefore, FOP nutrition labeling needs to rapidly catch consumers' attention, even if they are not consciously looking for it, so that they can take this information into account in their decision-making process.^{36,37} In this sense, FOP nutrition labeling schemes that automatically capture consumers' attention can act as a nudge in the decision-making process, encouraging consumers to take into account the nutritional composition of foods when making their choices.¹³

Once consumers are aware of the existence of FOP nutrition labeling, they will move on to processing the information included in that labeling.²¹ Considering that consumers do not usually invest large cognitive effort when making their food purchases,³⁸ FOP nutrition labeling should be read and understood very quickly.³⁹ The information conveyed by FOP nutrition labeling should facilitate consumers' understanding of the nutritional value of foods and enable them to make inferences about the products, that is, to evaluate

29 Solomon, M., Bamossy, G., & Askegaard, S. (2002). *Consumer behaviour: A European perspective*. Harlow: Prentice-Hall.

30 Holmqvist, K., Nyström, M., Andersson, R., & van de Weijer, J. (2011). *Eyetracking. A comprehensive guide to methods and measures*. Oxford: Oxford University Press.

31 Wedel, M., & Pieters, R. (2007). A review of eye-tracking research in marketing. *Review of Marketing Research*, 4, 123–147.

32 Pieters, R., & Wedel, M. (2004). Attention capture and transfer in advertising. Brand, pictorial, and text-size effects. *Journal of Marketing*, 68, 36–50.

33 Koch, C. (2004). *The quest for consciousness: A neurobiological approach*. Englewood, CO: Roberts and Company Publishers.

34 Wolfe, J. M. (1998). Visual search. In H. Pashler (Ed.), *Attention* (pp. 13–74). East Sussex: Psychology Press.

35 van't Riet, J., Sijtsma, S. J., Dagevos, H., & De Bruijn, G. J. (2011). The importance of habits in eating behaviour. An overview and recommendations for future research. *Appetite*, 57, 585–596.

36 Bialkova, S., & van Trijp, H. (2010). What determines consumer attention to nutrition labels? *Food Quality and Preference*, 21, 1042–1051.

37 Bialkova, S., & van Trijp, H. C. M. (2011). An efficient methodology for assessing attention to and effect of nutrition information displayed front-of-pack. *Food Quality and Preference*, 22, 592–601.

38 Frewer, L., & van Trijp, H. C. (2007). *Understanding consumers of food products*. Cambridge, UK: Woodhead Publishing.

39 Pettigrew, S., Talati, Z., Miller, C., Dixon, Kelly, B., & Ball, K. (2017). The types and aspects of front-of-pack food labeling schemes preferred by adults and children. *Appetite*, 109, 115–123.

the harmfulness of products and to compare among products in the same category to identify the most/least harmful.

Once the information is understood, consumers need to take into account the information included on the FOP nutrition labeling scheme in their decision-making process. FOP nutrition labeling is expected to modify consumers' food choices and to discourage the selection of products with a higher content of nutrients associated with noncommunicable diseases, which are the major cause of morbidity and mortality worldwide and in the Americas. This change in food choice would lead to changes in nutrient intake. However, this can only be expected if FOP labels are able to modify consumers' perception of healthfulness.^{40,41} In the long term, changes in nutrient intake would lead to improvements in health outcomes. Such changes may be estimated after the regulation is in place with a sustained prolonged enforcement of the policy.

3. Food labeling in *(name of the country)*

High intake of energy-dense nutrient-poor food is a major contributor to obesity and noncommunicable diseases (NCDs) in *(name of the country)*, as in many other countries. Successive surveys have shown an increasing prevalence of obesity and NCDs in the past few decades. The preliminary results of the *(name and year of the latest survey conducted in the country)* revealed that since *(year)*, there has been a XX.X% increase in obesity. The survey found that XX.X% of adults were overweight, including XX.X% who had obesity. Over the same period, hypertension and diabetes mellitus have increased by XX.X% and XX.X% respectively, to XX.X% with hypertension and XX.X% with diabetes.

These rates are alarming. NCDs are a major driver of morbidity and mortality and cause XX% of deaths in *(name of the country)*. In addition to the strain on resources in the health sector, NCDs place a high economic burden on the country, attributed to reasons such as absenteeism and presenteeism (i.e., when employees go to work, but are not fully functioning, due to an illness or medical condition).

On the other hand, healthier consumer choices and the resulting decrease in risk of nutrition-related illnesses can lead to reductions in health care costs and benefits to the economy. Demand by consumers for nutrition label information is increasing as they become more informed. Nevertheless, findings of the *(name and year of the latest survey on reading and/or use of food labeling information)* are that only XX.X% of the population in *(name of the country)* are reading food labels.

[The inclusion of a paragraph on the current status of the country in terms of existing labeling policies and regulations is desirable here.]

[The inclusion of a paragraph on the current mandates of the country to adopt labeling policies and regulations including the application of FOPL is desirable here.]

40 Entman, R. M. (1993). Framing: Towards clarification of a fractured paradigm. *Journal of Communication*, 43, 51–58.

41 Dar-Nimrod, I., & Heine, S. J. (2011). Genetic essentialism: On the deceptive determinism of DNA. *Psychological Bulletin*, 137, 800–818.

There has been very active discussion at the local level in *(name of the country)* about the efficacy of FOPL schemes in providing information that consumers can use for making informed choices about what they eat—and in discouraging consumption of food products that are high in sugar, fats, and sodium. The goal of this research project is to evaluate the efficacy of different FOPL schemes in *(name of the country)*. The proposed research is not intended to be a sole source of information for the policy decision, but is expected to add to the existing body of evidence to support the advance of food labeling regulations.

4. Justification

The incidence of NCDs is increasing at an alarming rate in *(name of the country)*. FOPL information can result in modification of consumers' food choices to discourage selection of products high in nutrients (sugar, fats, and sodium) that are associated with the development of NCDs. Changes in intake of these nutrients would lead to improved health outcomes. It is therefore necessary to contribute to the evidence on the efficacy of different FOPL schemes in their ability to modify consumer harmfulness perception, provide accurate information and change purchase decisions.

5. Goal

The goal of the research is to [assess or compare] the efficacy of [a] front-of-package nutrition labeling scheme(s) in *(name of country)*.

6. Specific objectives

The specific objectives are to:

1. Compare different FOPL schemes in terms of their efficacy in facilitating the identification of the product least harmful to health.
2. Compare different FOPL schemes in terms of their efficacy in facilitating the identification of products with excessive content of nutrients associated with noncommunicable diseases.
3. Compare different FOPL schemes in terms of their efficacy in changing the intention to purchase products with excessive content of nutrients associated with noncommunicable diseases.
4. Determine how consumers in *(name of the country)* perceive different FOPL schemes.

7. Methods

The study will consist of a cross-sectional survey in supermarkets (or online) using a between–subjects design. *(Number of schemes to be compared)* FOPL schemes will be compared:

(Below there are examples of FOPL schemes that could be tested. It is desirable to focus on the systems that are known to be more effective in other countries and meet the regulatory purpose, in order to optimize the use of resources and time.)

1. Control (no FOPL applied) (alternatively the guidelines daily amounts system can be used as a control, as it does not contain interpretive elements)
2. Guideline daily amounts (GDA) system;
3. Traffic-light system (GDA with textual descriptors and traffic-light colors indicating low/medium/high);
4. Nutri-Score system (overall summary score about the healthfulness of the product indicated by color coded letters that range from A to E);
5. Health-Star Rating system (overall summary score about the healthfulness of the product indicated by a number of stars that range from 0.5 to 5 stars);
6. High-in single icon system (textual nutritional warnings for specific critical nutrients placed in one single icon);
7. Multiple-icons warnings (textual nutritional warnings that apply one icon for each specific critical nutrient).

The schemes will be compared in terms of the following outcomes:

- Percentage of participants who correctly identify the product least harmful to health;
- Percentage of participants who correctly identify products with high content of nutrients associated with NCDs;
- Percentage of participants that would purchase the product least harmful to health.

8. Survey

Study design

This will be a cross-sectional survey conducted among adult shoppers at *popular* supermarkets across (*name of the country*), of varying socioeconomic status. Permission to conduct the survey will be sought from each supermarket and participant. Each participant will be asked to respond to a questionnaire administered by an interviewer that has been designed to fulfil the study objectives.

The (*number of schemes to be studied*) FOPL schemes will be presented in differing order to successive respondents. Selected participants each will be asked to evaluate packages featuring one of the (*number of schemes to be studied*) schemes. The presentation order of the FOPL schemes, as well as the order of the products within each scheme, will be random and balanced in their distribution among all the participants.

Sample selection

A total of 300 (or more) adult participants per each control/comparison group, 18 years and over will be recruited. The selected sample size will allow for detection of differences between FOPL schemes of approximately 13 percent in the percentage of participants who correctly identify products with nutrient content above nutritional recommendations with a confidence level of 95 percent and a power level of 80 percent.

Participants will be randomly divided into (*number of schemes to be studied including the control*) groups, each of which will evaluate packages featuring one of the FOPL schemes listed above. The quotas for gender, age, and educational level will be complied with for each of the groups.

Inclusion criteria:

- Residents of (*name of the country*), 18 years and older

Exclusion criteria:

1. Persons who are visually impaired
2. Persons unable to give informed consent

Instruments

FOPL Stimuli

Images of packages featuring different FOPL schemes will be developed (see *Annex 3 for examples and samples*). The packages will not correspond to commercial products available in the (*name of the country*) market but will have similar characteristics in terms of graphic design and nutritional composition.

The packages will correspond to different categories of ultra-processed food and drink products commonly consumed in (*name of the country*). A total of XX (*equals to 3 multiplied by Y product categories*) packages will be used, corresponding to three alternatives of Y product categories. (e.g., if 4 categories are used – 12 different packages will be designed, three for each category)

The categories are:

(examples of categories of products that could be used)

1. Breakfast cereals
2. Milk-based flavored drinks
3. Cookies/crackers
4. Yogurts

Questionnaire

The questionnaire will be divided into five sections:

- **Section 1:** Effect of FOPL schemes on consumers' intention to purchase products.
- **Section 2:** Effect of FOPL schemes on consumers' ability to identify the product least harmful to health.
- **Section 3:** Effect of FOPL schemes on consumers' ability to identify products with nutrient content above nutritional recommendations.
- **Section 4:** Consumers' perception of FOPL schemes.
- **Section 5:** Socio-demographic information.

The questionnaire will be pretested among a group of mixed socioeconomic status.

Procedures

Permission to conduct the study in each supermarket will be sought prior to the day(s) of the data collection. On the agreed date(s), members of the study team will visit each supermarket and will identify themselves to the management. The study team will locate themselves in an agreed area where they will not interrupt the normal business of the supermarket. An area that is high traffic and near to the entrance or exit of the supermarket is recommended.

The content of the questionnaire and the confidentiality of the interview will be explained to the selected participants and they will be asked to give written informed consent. The questionnaire will be administered to each participant. Each participant will be presented with the situations included in the questionnaire. The participants will be asked for their responses for each section.

Sometimes they will see the image of packages, not real packages.

After completing the questionnaire, each participant will be thanked for participating.

Training

Training of field staff will be conducted by the project team and an acceptable level of reliability will be established between observers.

Data management

Data from the interviewer-administered questionnaires will be captured electronically on a tablet computer. The data will be reviewed at the end of each day by the field supervisor, for completion and accuracy. The validity and reliability of collected data will be assessed.

Analysis

After participants have been presented with pictures of different sets of packages, and then asked to select, for instance, the least harmful, the next step is to calculate the percentage of participants who selected package A, package B, or package C. The percentage of participants selecting each alternative package will be calculated. A logistic regression analysis will be used to evaluate the influence of the FOPL scheme, product category and their interaction on the probability of the consumers' selection for each section of the questionnaire. In addition, analysis of variance will be used to compare the average number of sets for which participants select the least harmful alternative across FOP nutrition labeling schemes. Results will be presented by location (urban/rural), gender, age, and educational level.

9. Limitations

Presentation of images of the labels and not actual packages may constrain participants' ability to consider all aspects of nutrition information on the food label.

10. Ethical consideration

Approval will be sought from the Ethics Committee of (*name of Ethics Committee Review Board in the country*) and the PAHO Ethics Review Committee (PAHO ERC).

11. Benefits and risks

The information collected will be used to guide the development of public health policy. This is a minimal risk study and there are no anticipated risks to the participants.

12. Right to withdraw or refusal to participate

Each respondent's participation is voluntary and they may refuse to participate or withdraw from the study at any time.

13. Confidentiality

No personal identifiers will be taken from respondents. All data will be kept confidential and available only to the research team.

14. Informed consent

Respondents will be provided with the relevant information about the research and provided with an opportunity to give their free and written informed consent to participate, or to decline to do so. The questionnaire will be administered in (*language in which the questionnaire will be administered*).

15 Compensation

Respondents will not receive compensation for participating in this study.

Annex 3A.

Questionnaire

Instructions to prepare the questionnaires

Each questionnaire is unique within each study group (i.e., control, or exposed to GDA, traffic-light, or warning front-of-package scheme) since the order of the images to be shown to each interviewee is balanced and randomized within each study group. The questionnaire featured here refers to the one assigned for interviewee 0001 of a study group. The codes of the images in their precise order are shown under the questions in accordance with the randomization sheets (ANNEX 3C). To produce the other questionnaires, simply change the code of the interviewee and find the codes of the images to be added to the questionnaire in the randomization sheets (ANNEX 3C). Repeat the same procedure within each study group (control and comparisons). All interviewees under code 0001 pertaining to the different study groups (control and comparisons) will see images of mock-up products in the same randomized order, with the sole difference of the FOPL scheme they will see presented on the packages.

Sample questionnaire 0010001 linked to booklet A, which refers to the warning label (WL).

Questionnaire

Interviewer | 0 | 1 |

Interviewee | 0 | 0 | 0 | 1 |

Booklet | A |

Introduction

The Ministry of (*name of the ministry and country*), University of (*name of the university or research center*), and the Pan American Health Organization are conducting a study to understand how people perceive food packages and you are invited to participate.

The objective of this study is to find out how people in (*name of the country*) perceive food packages. For this purpose, you will be presented with a series of food packages and you will be asked to answer a series of simple questions that will take you about 15 minutes. You are being invited to this study because your opinion can contribute to our understanding and knowledge of the topic. Your participation in this research is entirely voluntary.

The questionnaire will focus on your perception of food packages. There will be no direct benefit to you, but your participation is likely to help us find understand how people use food packages to make their decisions.

[Collect informed consent]

[Now, have the corresponding booklet at hand as indicated above (i.e. booklet A for interviewee 0001, B for the interviewee 0002, and so on)]

Section 1

Please imagine that you are in the supermarket purchasing food. You want to purchase several products. You will see sets of packages and you will be asked to indicate the one you would purchase. You can also indicate that you would not select any of the available products. Please look at the following packages and indicate the one you would buy if you were at the supermarket purchasing food.

Which product would you buy? *(Show the respondent the four set of three products following the order in the booklet. The same question must be repeated, when showing each set of products in the order indicated in the booklet. **For every set, interviewers can only mark one option corresponding to the product chosen by the interviewee.**)*

1.1 (Present the **first** set of images following the order in the booklet, and mark the corresponding code of the one chosen by the respondent below)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
868	351	964	I would not purchase any of these products

1.2 (Present the **second** set of images following the order in the booklet, repeat the question above i.e. 1., and mark the option corresponding to the code of the one chosen by the respondent below)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
626	114	942	I would not purchase any of these products

1.3 (Present the **third** set of images following the order in the booklet, repeat the question above i.e. 1., and mark the option corresponding to the code of the one chosen by the respondent below)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
215	566	301	I would not purchase any of these products

1.4 (Present the **fourth** set of images following the order in the booklet, repeat the question above i.e. 1., and mark the option corresponding to the code of the one chosen by the respondent below)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
516	497	695	I would not purchase any of these products

Section 2

Please imagine that you are still in the supermarket purchasing food. This time you want to select the **least harmful product** in different categories. You will see sets of packages and you will be asked to indicate the product least harmful to your health.

Please look at the following packages and indicate the least harmful for your health.

Which is the product least harmful to health? *(Show the respondent the four set of three products following the order in the booklet. The same question must be repeated, when showing each set of products in the order indicated in the booklet. **For every set, interviewers can only mark one option corresponding to the product chosen by the interviewee.**)*

2.1 (Present the **first** set of images following the order in the booklet, and mark the option corresponding to the code of the one chosen by the respondent below)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
964	868	351

2.2 (Present the **second** set of images following the order in the booklet, repeat the question above i.e. 1., and mark the option corresponding to the code of the one chosen by the respondent below)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
114	942	626

2.3 (Present the **third** set of images following the order in the booklet, repeat the question above i.e. 1., and mark the option corresponding to the code of the one chosen by the respondent below)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
566	301	215

2.4 (Present the **fourth** set of images following the order in the booklet, repeat the question above i.e. 1., and mark the option corresponding to the code of the one chosen by the respondent below)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
695	516	497

Section 3

Please imagine that you are still in the supermarket purchasing food. You have selected a product and you want to decide whether the content of any nutrient is higher than recommended for a healthy diet. You will see a series of packages and you will be asked to indicate whether the content of any of the listed nutrients is higher than recommended for a healthy diet.

Please look at the following packages and indicate if the content of any nutrient is higher than recommended for a healthy diet. You can select all the options that apply.

Is the content of any of the following nutrients in this product higher than recommended for a healthy diet? I will read the options to you. (**Show the product and read the options to the interviewee.**)

3.1 (*Show the products following the order in the corresponding booklet.*)

3.2 (*Read the options and mark the option(s) according to the answer of the interviewee.*)

- ☐ **Sugar** is higher than recommended for a healthy diet
- ☐ **Sodium** is higher than recommended for a healthy diet
- ☐ **Total fat/Fat** is higher than recommended for a healthy diet
- ☐ **Saturated fat** is higher than recommended for a healthy diet
- ☐ **Trans fat** is higher than recommended for a healthy diet
- ☐ **None of the nutrients** is higher than recommended for a healthy diet

3.3 (*Show the **products** following the order in the corresponding booklet.*)

3.4 (*Read the options and mark the option(s) according to the answer of the interviewee.*)

- ☐ **Sugar** is higher than recommended for a healthy diet
- ☐ **Sodium** is higher than recommended for a healthy diet
- ☐ **Total fat/Fat** is higher than recommended for a healthy diet
- ☐ **Saturated fat** is higher than recommended for a healthy diet
- ☐ **Trans fat** is higher than recommended for a healthy diet
- ☐ **None of the nutrients** is higher than recommended for a healthy diet

3.5 (Show the **products** following the order in the corresponding booklet.)

3.5.1 (**Read the options** and **mark** the option(s) according to the answer of the interviewee.)

- ☐ **Sugar** is higher than recommended for a healthy diet
- ☐ **Sodium** is higher than recommended for a healthy diet
- ☐ **Total fat/Fat** is higher than recommended for a healthy diet
- ☐ **Saturated fat** is higher than recommended for a healthy diet
- ☐ **Trans fat** is higher than recommended for a healthy diet
- ☐ **None of the nutrients** is higher than recommended for a healthy diet

3.6 (Show the **products** following the order in the corresponding booklet.)

3.7 (**Read the options** and **mark** the option(s) according to the answer of the interviewee.)

- ☐ **Sugar** is higher than recommended for a healthy diet
- ☐ **Sodium** is higher than recommended for a healthy diet
- ☐ **Total fat/Fat** is higher than recommended for a healthy diet
- ☐ **Saturated fat** is higher than recommended for a healthy diet
- ☐ **Trans fat** is higher than recommended for a healthy diet
- ☐ **None of the nutrients** is higher than recommended for a healthy diet

Section 4

The packages you have just evaluated included information about the content of specific nutrients (sugar, fats, and sodium) using the following signs.



4.1 Did you see the signs in the packages you evaluated?

- ☐ Yes
- ☐ No
- ☐ Not sure

4.2 Did you take the signs into account for answering the questions?

- ☐ Yes
- ☐ No

4.3 What do you think of including these signs on the package of food products?

Section 5

The following socio-demographic information will be collected:

5.1 Gender

☐

Male

☐

Female

☐

Other

5.2 Date of birth: |__|_| / |__|_| / |__|_|_|_| 5.2.1 Age: |__|_|

5.3 Age range:

☐

18–29

☐

30–49

☐

50–69

☐

70+

5.4 Highest educational level completed:

☐

Primary

☐

Secondary/Vocational to Grade 9

☐

Secondary/Vocational to Grade 11-13

☐

Tertiary/Graduate/Post-Graduate

5.5 Are you the person who normally purchases food for the household? ☐ Yes ☐ No

5.6 Have you or anyone in your household ever been told by a doctor or other health worker that you have:

5.6.1 Diabetes or raised blood sugar?

☐

Yes

☐

No

5.6.2 Hypertension or high blood pressure?

☐

Yes

☐

No

5.6.3 Heart disease?

☐

Yes

☐

No

5.6.4 High cholesterol?

☐

Yes

☐

No

5.6.5 Overweight or obesity?

☐

Yes

☐

No

Annex 3B.

Information Sheet, Consent Forms, and Letter to Supermarket

Informed consent form for adults

The informed consent form has two parts:

Part I: Information sheet (to share information about the study with participants)

Part II: Certificate of consent (for signatures)

Part I: Information sheet

(This form will need adaptation for use in an online survey.)

The Ministry of (*name of the ministry and country*), University of (*name of the university or research center*), and the Pan American Health Organization are conducting a study to understand how people perceive food labels and you are invited to participate. Before you can decide, we will provide you detailed information about the study. You may find some words that you do not understand. Please direct all questions to the researcher who is accompanying you. If you have more questions, you can ask them of the researcher or contact other researchers using the telephone or email address indicated at the end of this information sheet.

The objective of the study is to generate local knowledge about how people perceive food labels. For this purpose, you will be presented with a series of food packages and you will be asked to answer a series of simple questions that will take you about 15 minutes. You are being invited to this study because your opinion can contribute to our understanding and knowledge of the topic. Your participation in this research is entirely voluntary. It is your choice whether to participate or not. You may change your mind later and stop participating at any point of the study.

A researcher will provide you with the questionnaire. You may answer the questionnaire yourself, or it can be read to you and you can say out loud the answer you want the researcher to write down. If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question. The information recorded is confidential and your name is not being included on the forms. We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key.

The questionnaire will focus on your perception of food packages and in general no personal information or sensitive information is sought. There will be no direct benefit to you, but your participation is likely to

help us find understand how people use food packages to make their decisions. You will not be provided any incentive to take part in the research.

None of the responses you provide will be shared with anybody outside the research team, and nothing will be attributed to you by name. The knowledge that we get from this research will be published so that other interested people may learn from the results. Each participant will receive a summary of the results.

If you have any questions, you may ask them now or later. If you wish to ask questions later, you may contact any of the following:

Dr. (Xxxxx Yyyyy)

(Position), (Name of the department)

Ministry of (name of the ministry and country)

(Address details)

E-mail: (xxx@xxx.gov.xx)

Tel: (x-xxx-xxx-xxxx)

This proposal has been reviewed and approved by the (name of local ethics committee), which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about this committee, contact the (name of the organization), contact (name, address, telephone number, email).

Certificate of consent

Statement by the participant

I have been invited to participate in research about food packages. I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have been asked has been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Print name of participant

Signature of participant

Date

Statement by the researcher/person taking consent

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this informed consent form (ICF) has been provided to the participant.

Print name of researcher/person taking the consent

Signature of researcher/person taking the consent

Date

Letter to supermarket

The Ministry of *(name of the ministry and country)*, University of *(name of the university or research center)*, and the Pan American Health Organization are conducting a study to generate local knowledge about how people perceive food labels. The target population for the survey are *(name of the country)* residents who purchase foods and beverages for themselves or their households.

This survey will be carried out in several supermarkets across *(name of the country)*. We are requesting your permission to carry out this survey among your customers in your supermarket.

The research team will locate themselves in agreed areas, where they will not interrupt the normal flow of customers within the supermarket. We will invite customers to review a set of food labels. These are specially designed labels and are not for products that are sold in *(name of country)* supermarkets. We will ask them about their understanding of the information on the labels.

We estimate that the research team will be in the supermarket for a few days until we achieve the required sample.

We hope that you will be able to accommodate this request. For further information and clarification, please contact:

Dr. *(Xxxxx Yyyyy)*

(Position), (Name of the department)

Ministry of *(name of the ministry and country)*

(Address details)

E-mail: *(xxx@xxx.gov.xx)*

Tel: *(x-xxx-xxx-xxxx)*

Annex 3C.

Example of Randomized Sheet for the Presentation of Packages/Images

		Booklet	A	D	E	F	G	H	I	K	M	N	O	P
		FOPL Scheme	WRN	GDA	WRN	GDA	GDA	WRN	TFL	TFL	GDA	WRN	TFL	TFL
Question 1	Position 1.1.1		cereal 868	yogurt 626	yogurt 942	cracker 497	cereal 964	cracker 516	yogurt 114	cereal 351	flavored milk 215	flavored milk 566	cracker 516	flavored milk 301
	Position 1.1.2		cereal 351	yogurt 114	yogurt 626	cracker 695	cereal 868	cracker 497	yogurt 942	cereal 964	flavored milk 566	flavored milk 301	cracker 497	flavored milk 215
	Position 1.1.3		cereal 964	yogurt 942	yogurt 114	cracker 516	cereal 351	cracker 695	yogurt 626	cereal 868	flavored milk 301	flavored milk 215	cracker 695	flavored milk 566
	Position 1.2.1		yogurt 626	cracker 516	cracker 497	flavored milk 301	yogurt 114	flavored milk 215	cracker 695	yogurt 626	cereal 351	cereal 964	flavored milk 215	cereal 351
	Position 1.2.2		yogurt 114	cracker 497	cracker 695	flavored milk 215	yogurt 942	flavored milk 566	cracker 516	yogurt 114	cereal 964	cereal 868	flavored milk 566	cereal 964
	Position 1.2.3		yogurt 942	cracker 695	cracker 516	flavored milk 566	yogurt 626	flavored milk 301	cracker 497	yogurt 942	cereal 868	cereal 351	flavored milk 301	cereal 868
	Position 1.3.1		flavored milk 215	cereal 868	cereal 351	yogurt 942	flavored milk 566	yogurt 626	cereal 964	flavored milk 215	cracker 516	cracker 695	yogurt 626	cracker 497
	Position 1.3.2		flavored milk 566	cereal 351	cereal 964	yogurt 626	flavored milk 301	yogurt 114	cereal 868	flavored milk 566	cracker 497	cracker 516	yogurt 114	cracker 695
	Position 1.3.3		flavored milk 301	cereal 964	cereal 868	yogurt 114	flavored milk 215	yogurt 942	cereal 351	flavored milk 301	cracker 695	cracker 497	yogurt 942	cracker 516
	Position 1.4.1		cracker 516	flavored milk 215	flavored milk 301	cereal 351	cracker 695	cereal 351	flavored milk 566	cracker 516	yogurt 626	yogurt 114	cereal 868	yogurt 942
	Position 1.4.2		cracker 497	flavored milk 566	flavored milk 215	cereal 964	cracker 516	cereal 964	flavored milk 301	cracker 497	yogurt 114	yogurt 942	cereal 351	yogurt 626
	Position 1.4.3		cracker 695	flavored milk 301	flavored milk 566	cereal 868	cracker 497	cereal 868	flavored milk 215	cracker 695	yogurt 942	yogurt 626	cereal 964	yogurt 114
Question 2	Position 2.1.1		cereal 964	cracker 497	cereal 351	flavored milk 215	cracker 516	cereal 351	flavored milk 566	flavored milk 215	yogurt 626	cracker 695	yogurt 626	cracker 516
	Position 2.1.2		cereal 868	cracker 695	cereal 964	flavored milk 566	cracker 497	cereal 964	flavored milk 301	flavored milk 566	yogurt 114	cracker 516	yogurt 114	cracker 497
	Position 2.1.3		cereal 351	cracker 516	cereal 868	flavored milk 301	cracker 695	cereal 868	flavored milk 215	flavored milk 301	yogurt 942	cracker 497	yogurt 942	cracker 695
	Position 2.2.1		yogurt 114	flavored milk 301	yogurt 942	cereal 351	flavored milk 215	yogurt 626	cereal 964	cereal 868	cracker 516	flavored milk 566	cracker 516	flavored milk 215
	Position 2.2.2		yogurt 942	flavored milk 215	yogurt 626	cereal 964	flavored milk 566	yogurt 114	cereal 868	cereal 351	cracker 497	flavored milk 301	cracker 497	flavored milk 566
	Position 2.2.3		yogurt 626	flavored milk 566	yogurt 114	cereal 868	flavored milk 301	yogurt 942	cereal 351	cereal 964	cracker 695	flavored milk 215	cracker 695	flavored milk 301
	Position 2.3.1		flavored milk 566	yogurt 942	flavored milk 301	cracker 516	yogurt 626	flavored milk 215	cracker 695	cracker 516	cereal 351	yogurt 114	cereal 868	yogurt 626
	Position 2.3.2		flavored milk 301	yogurt 626	flavored milk 215	cracker 497	yogurt 114	flavored milk 566	cracker 516	cracker 497	cereal 964	yogurt 942	cereal 351	yogurt 114
	Position 2.3.3		flavored milk 215	yogurt 114	flavored milk 566	cracker 695	yogurt 942	flavored milk 301	cracker 497	cracker 695	cereal 868	yogurt 626	cereal 964	yogurt 942
	Position 2.4.1		cracker 695	cereal 351	cracker 497	yogurt 626	cereal 868	cracker 516	yogurt 114	yogurt 626	flavored milk 215	cereal 964	flavored milk 215	cereal 351
	Position 2.4.2		cracker 516	cereal 964	cracker 695	yogurt 114	cereal 351	cracker 497	yogurt 942	yogurt 114	flavored milk 566	cereal 868	flavored milk 566	cereal 964
	Position 2.4.3		cracker 497	cereal 868	cracker 516	yogurt 942	cereal 964	cracker 695	yogurt 626	yogurt 942	flavored milk 301	cereal 351	flavored milk 301	cereal 868
Question 3	Position 3.1		flavored milk 215	cracker 516	yogurt 626	cracker 695	flavored milk 301	cereal 351	cereal 964	cracker 695	flavored milk 301	yogurt 114	cracker 516	cereal 351
	Position 3.2		cereal 964	flavored milk 215	cracker 516	flavored milk 215	cereal 964	yogurt 626	yogurt 114	flavored milk 215	cereal 351	cracker 695	flavored milk 301	yogurt 626
	Position 3.3		cracker 695	yogurt 114	cereal 964	yogurt 114	cracker 695	flavored milk 301	flavored milk 215	yogurt 114	cracker 516	cereal 351	yogurt 626	flavored milk 301
	Position 3.4		yogurt 114	cereal 964	flavored milk 301	cereal 351	yogurt 626	cracker 516	cracker 516	cereal 351	yogurt 626	flavored milk 215	cereal 964	cracker 695

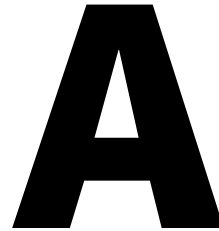
WRN = warning labeling system

GDA = guideline daily amount system

TFL = traffic-light labeling system

Annex 3D.

Example of Booklet to Accompany the Questionnaire



Section 1

868



351



964



626



114



942



215



566



301



516



497



695



Section 2

964



868



351



114



942



626



566



301



215



695



516



497



Section 3

215



964



695

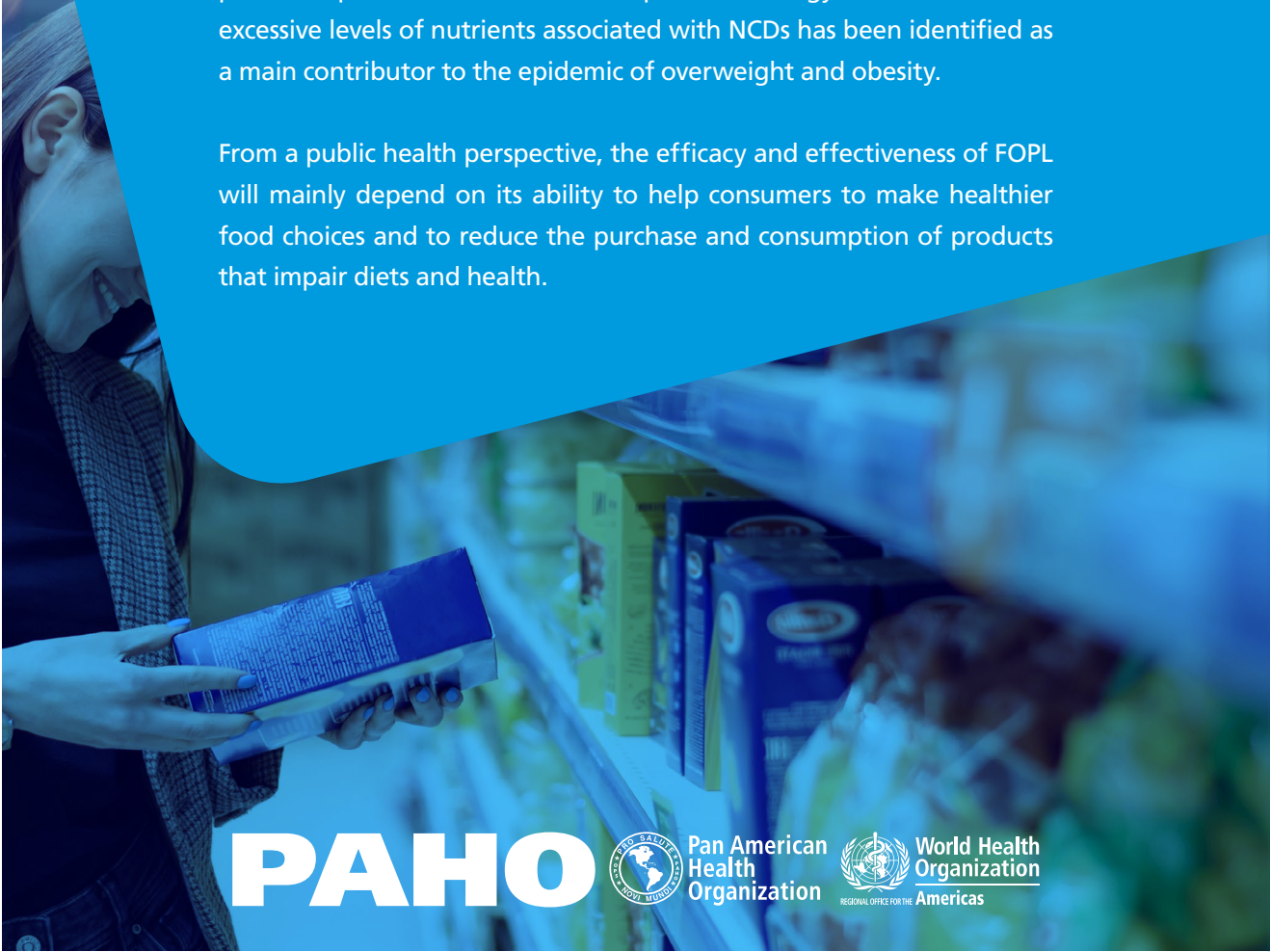


114



Section 4



A woman with blonde hair, wearing a patterned jacket, is looking at a blue box of a product in a grocery store aisle. The background shows shelves stocked with various products, including boxes of cereal or snacks. The image is overlaid with a large blue shape containing text.

This publication explores the subject of front-of-package labeling (FOPL) for food products as a means to help combat the trend toward unhealthy eating. It presents methods, tools, and procedures for research on FOPL with a view to enhancing its role in regulations governing food products in the Region of the Americas. The publication indicates how research on FOPL should be conducted, how results should be communicated, how FOPL schemes should be selected, and what the research priorities should be. It also contains useful annexes that include, for example, a focus group discussion guide, a questionnaire, and a protocol for FOPL research.

The Americas is the region of the world with the highest prevalence of overweight and obesity. In 2016, noncommunicable diseases (NCDs) were responsible for 78% of all deaths in the Region. Thirty-four percent of these NCD-related deaths occurred prematurely in people between the ages of 30 and 69 years. This implies that NCDs have a huge economic impact on societies.

Unhealthy eating is the main modifiable factor that is driving this situation. In particular, consumption of ultra-processed products and of processed products that are nutrient-poor and energy-dense and contain excessive levels of nutrients associated with NCDs has been identified as a main contributor to the epidemic of overweight and obesity.

From a public health perspective, the efficacy and effectiveness of FOPL will mainly depend on its ability to help consumers to make healthier food choices and to reduce the purchase and consumption of products that impair diets and health.

PAHO



Pan American
Health
Organization



World Health
Organization
REGIONAL OFFICE FOR THE
Americas