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POSITION PAPER ON FRONT-OF-PACK LABELS: "directive" versus "informative" approaches

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Summary

Front-of-pack labels (FOPL) aim at communicating to consumers the health value of food items in support of public health policies. Two main types can be discerned: "directive and semi-directive" FOPL using colour schemes (e.g., Nutri-Score) and "informative" FOPL (e.g., Nutrinform Battery). "Directive" approaches tend to show a "wear out effect" and, in addition, they suffer from various underlying conceptual problems. Usually, their nutritional scores are calculated using changing, arbitrary algorithms and involve a reductionist set of parameters of debateable validity. Thus, they overstate the effects of selected nutritional factors, such as saturated fat and energy, while overlooking the food matrix and the more holistic aspects of nourishment. Moreover, they do not reflect the portion that is actually consumed, ignore the preparation steps at home, and fail to serve as a useful basis for composing a healthy diet. Also, so long as the nutritional formulations match the algorithmic standards, they tend to allow ultra-processed products. Altogether this might confuse and mislead consumers. Overconfidence in "green"-coloured labels could even result in unbalanced dietary choices, whereas avoidance of "red" products may eliminate certain foods from the diet that are rich in essential nutrients (e.g., cheese), leading to opposite results than aimed for. The latter is particular relevant to vulnerable populations, such as the young, pregnant women, and older adults, or for individuals with specific needs. Taken together, "directive" FOPL such as Nutri-Score contradict the declared intent of the European Commission to empower consumers to undertake healthy and balanced diets based on easy accessible and robust information. Although "informative" systems usually also keep the focus on a few selected nutritional parameters, they have the merit of being less paternalizing and obviate the need to classify foods as "healthy" or "unhealthy". They also focus their attention on the individual portions that are consumed (even if the definition of portion size remains contentious). Given the importance of dietary patterns, rather than individual foods or nutrients, "directive" FOPL of the Nutri-Score type represent a regretful case of "nutritionism". Finally, attempts to associate the adoption of a FOPL with an improvement in the health status are few and mainly applied in virtual settings; none of which are longitudinal nor have they been able to identify a causal link.

Key words front-of-pack labelling (FOPL), NutrInform Battery, Nutri-Score, eating pattern, nutrient composition, nutrition information, overall balanced diet

1. Introduction

The prevalence of obesity and non-communicable diseases (NCD), such as cardiovascular diseases, cancer, chronic respiratory diseases, and type-2 diabetes, is increasing with a significant impact on morbidity, mortality, and quality of life (Bracale R et al, 2013; Popkin BM et al, 2020). Eating habits, as an important aspect of overall lifestyle, play a major role in this development (Smethers AD et al, 2018). Providing information to consumers on what constitutes healthy eating has therefore the potential to impact positively on dietary habits (Fruhbeck G et al 2016; Carruba MO et al, 2021), an opinion which has been endorsed by both the European Commission (art.35 of Regulation No 1169/2011) and the United Nations (art. 34 of the Political Declaration of the Summit of the Heads of State and Government of 09/27/2016, adopted by the UN General Assembly on 10 October 2018).

Prior strategies, which were based on "back of pack labels" (BOPL), unfortunately did not succeed in that mission, with public health policies increasingly finding themselves in dire straits due to the worsening situation of community health, especially regarding the continuing increase in NCDs. Therefore, the European Commission decided in 2011 to adopt a simpler procedure, but this time based on front-of-back labels (FOPL). The purpose of the latter strategy was to inform consumers more clearly, while also having an "educational" function.

FOPLs can be distinguished according to the complexity of the information that is provided (e.g., displaying nutrient-specific information or declaring a global judgement on the whole product), as well as their "directionality" (e.g., the kind of steering or evaluative message with regard to healthiness) (Muzzioli L et al, 2022). On these bases, they can be categorized as follows (Table 1):

- Informative "non-directive" labels that provide information such as the name of nutrients included, their amount in grams, and their percentage in relation to total daily needs and allowances (e.g., Nutrinform Battery)
- "Semi-directive" labels that do not only provide nutritional information but are also completed by an evaluative element such as a color, a word, or a sign that gives additional information on the healthiness level of the single nutrients, thereby emphasizing them [e.g., the English traffic light or *Multiple Traffic Light* (MTL) and Warning Signs which may feature the octagon "stop" or the words "rich in" or the Israeli system of red pictures for excess salt, fat or sugar and positive green symbols for healthy products (Gillon-Keren M et al, 2020)].
- "Directive" labels that include little information, often aggregated in a single symbol (e.g., Swedish Keyhole, Nutri-Score) and combining several criteria. Some of the "directive" labels (e.g. Swedish Keyhole and Dutch Healthy Choices) are part of a communication strategy aimed at increasing nutrition literacy in the population and are applied on products in combination with nutritional FOPL or BOPL. Other variants (e.g. Nutri-Score) only give an indication about the healthiness of the product, expressing judgements, opinions and/or recommendations, without providing specific information on single nutrients.

The aim of this opinion paper is to verify the usefulness of "directive" FOPL, and in particular of Nutri-Score, and make a briefly comparison with "informative" tools (such as the Nutrinform Battery system; NIB) as a means to promote a better nutritional and health status within the general population.

2. "Directive" front-of-pack labels

"Directive" systems (e.g., Nutri-Score) normally impose a "traffic light" system or colour code on

consumers, offering suggestions on what to purchase but without providing information on the nutritional characteristics of a food, or on its recommended portion size and frequency of consumption. The most widespread FOPL in Europe is represented by Nutri-Score (NS), which has been adopted in France in 2017. It is based on a colour scale ranging from green to red, accompanied by letters from A to E.

Choice of parameters in the algorithm

A major concern is that "Directive" systems (and NS in particular) score the nutritional value of foods based on a narrow set of selected nutritional criteria (e.g., energy, saturated fat, salt content, fibre, proteins, fruit/vegetables), without taking into account the extremely important relevance of other important nutritional factors (e.g., the contents of important micronutrients that are already limiting in many populations, such as iron, zinc, and vitamin B12, or other nutrients of importance, such as choline and long-chain omega-3 fatty acids). This results in both a lack of robustness of the nutritional message and a substantial degree of arbitrariness of the algorithms underpinning it.

Moreover, the true *causal* effect of the selected criteria on the health value of a food is in many cases highly uncertain and contextual. Energy content (in kcal), for instance, is not a very helpful basis as it overlooks the true drivers of overeating, which are the satiety-inducing effects of certain foods (or their craving effects, for that matter) and endocrine responses to the type and status of specific food components. As an example, it is known that some ultra-processed foods give rise to overeating (Hall KD et al, 2019), but the level of processing has not been taken into account in systems like NS (in contrast to other systems such as NOVA) (Monteiro CM et al, 2018). Differences in food processing of bakery products, for instance, affect the nutritional attributes of baked goods, which remains unaddressed by NS (Dewettinck et al, 2008).

The role of the food and diet matrix

The role of the food matrix is essential when addressing the nutritional effects of a given food product, which tends to be more than the sum of its individual nutrients, among other reasons due to nutrient interactions and the presence of a wide (and usually poorly charted) spectrum of bioactive compounds. The dairy matrix constitutes an often-cited example (Weaver CM, 2021). Therefore, the isolation of a few nutrients will be poorly informative of the true nutritional impact, especially when their health effects are uncertain. The situation becomes even more intricate when considering the diet matrix and the health effects that relate to dietary patterns, consisting of various food combinations over a period of time.

For instance, the evidence in support of the use of the single and simplified category of "saturated fat" as a health discriminator for food-based recommendations is debatable to say the least, given that many systematic reviews and meta-analyses fail to substantiate harmful effects (see, e.g., Gershuni VM, 2018). Moreover, the category contains different types of fatty acids with varying biologic effects, which also depend on the food matrix. Therefore, some foods that are rich in saturated fat are *not* associated with increased disease (e.g., whole-fat dairy) (Astrup A et al, 2020). Similar concerns as for saturated fats relate to the setting of specific sodium targets to improve health in normotensive populations, realizing that the effects of sodium also depend on the dietary pattern, including modulation by potassium (Mente A et al, 2021).

As an example of a "positive" nutritional factor underpinning the algorithms, fibre content is indeed associated with improved health in various epidemiological studies, but this may be mainly because of its proxy role in the wholesomeness of foods (rather than fibre *per se*). The findings for fibre also

are contingent on the dietary and metabolic context (Sholl J et al, 2021). Therefore, the health bonus in NS may be overstated for *added* fibres (of which the effects are fibre- and context-dependent). The latter can be added to unhealthy products to create a health halo and for mere nutri-washing purposes (translated into a positive nutritional score), without necessarily making such foods intrinsically more healthful.

By ignoring all of the above-mentioned complexities, the simplified scores of "directive" FOPL like NS suffer from nutritional reductionism (*nutritionism*). They excessively focus on a narrow set of nutrients while ignoring both the wider scientific discussion and the holistic and versatile aspects of human diets (Leroy F et al, 2022). Reliance on the so-called transitive property of the individual nutritional factors mentioned above is problematic to begin with ["if a certain nutrient is statistically or epidemiologically linked to a certain disease, changing the concentration of that nutrient will have a positive effect on the prevention of the disease" (Donini LM et al, 2022)]. This principle has been disproved on many occasions (e.g., even if increased intake of folic acid, B6, and B12 vitamins reduces homocysteine levels, it fails to affect cardiovascular risk; Clarke R et al, 2010; Maruyama K et al, 2019). Upon scrutiny, many food items or groups (cheese, butter, total dairy, red meat) and single nutrients (saturated fat, sodium), in epidemiological studies, fail to lead to epidemiological meningful harmful associations with clinical health outcomes (Chen G-C et al 2017; Dehghan M et al 2018; Zhang H et al, 2021; Pimpin L et al, 2016; Pala V et al, 2019;110:1220–30; Fontecha J et al 2019; Hirahatake KM et al 2020; Astrup A et al, 2019; Schmidt KA et al 2021).

<u>Internationalization of an algorithm based on a national consumption pattern and food compositions</u>

To further illustrate the arbitrariness of the setup and the inherent difficulties in establishing unambiguous nutrient profiles at the EU level, it has to be underlined that 1) it is difficult to set the application of the nutrient intake recommendations for the general diet to individual foods, that 2) there is a lack of uniform data for the composition and consumption of foods across the EU, and that 3) there are differences in nutrient intake recommendations and dietary guidelines within EU countries themselves (EFSA scientific opinion, 2008). Because the NS system gives an overall evaluation of an individual food, it also does not outline the information on the individual factors included in the algorithms. The latter, however, could be the result of a large number of combinations of levels of different factors [high levels of one or more factors that are considered negative (energy, total sugar, saturated fatty acids and sodium content) and/or low levels of one or more factors that are considered positive (fruit, vegetables and nuts, fibre, protein and seed, walnut and olive oils content)]. As a consequence, whole-meal short-bread biscuits made with different recipes, almost invariably obtain the same scores regardless of the presence of characterizing ingredients (whole-meal flour varies from 20 to 70% of the total ingredients) and the lower or higher sugar content (from less than 2 to more than 20 g per 100 g) (Visioli F et al, 2021).

These uncertainties make the definition of FOPL (in particular that of the "directive" type) very complex, which may lead, not surprisingly, to the need for annual updates of the Nutri-Score algorithm as made in 2021 and 2022 by the Scientific Committee of NS (https://solidarites-sante.gouv.fr/IMG/pdf/annual report 2021.pdf; https://gouvernement.lu/dam-assets/documents/actualites/2022/07-juillet/29-mpc-nutriscore/rapport-du-comite-scientifique-du-nutri-score-juin-2022.pdf)

In that context, nutrient-centric FOPL are often endorsed by multinational corporations that produce ultra-processed foods. Even if this term is generating a great deal of confusion in certain

consumer groups and in the sector of food production, since its interpretation is controversial (Triptolemos foundation, 2020), given their expertise in extensive processing, this allows them to reformulate ("tweak") their products by somewhat reducing the levels of some of the negative nutrients with synthetic sweeteners (to decrease sugar), salt replacers, combinations of texturizers and flavouring agents to compensate for fat reduction, or by adding ingredients with a healthy aureole (e.g., fiber).

The following is an example of how this may translate into confusion and arbitrariness. The original algorithm of NS attributed one negative point both to 4.5 g of sugar and 1 g of saturated fatty acids. Subsequent adjustments led to the attribution of one point for 5 g of sugar and 1.5 g of saturated fatty acids, with highly questionable influences on health outcomes. A recent update report (https://gouvernement.lu/dam-assets/documents/actualites/2022/07-juillet/29-mpc-nutriscore/rapport-du-comite-scientifique-du-nutri-score-juin-2022.pdf) wishes to further modify the algorithms to accommodate criticism related to some highly questionable outcomes of the original NS setup (for instance, by ameliorating the outcome for fatty fish, which is currently receiving a discouraging NS).

The example of unprocessed red meat further confirms the arbitrariness of the scoring process. To accommodate the caution related to excessive consumption levels expressed by several health organizations (e.g., WHO/IARC), NS downgraded the score of unprocessed red meat using "a reduction in the number of maximal protein points [of red meat] to 2 points". Currently, red meat's positive score is "due to the favourable points allocated in the protein element of the algorithm, while lean plain meat will have relatively little unfavourable points on energy density, saturated fat or salt". To do so, the algorithmic modification is built on a hypothesis connecting red meat consumption to health risks, arguing that this would be caused by haem iron. As for saturated fat, it has to be underlined that such assumptions are based on a scientific debate still in progress (Leroy F et al, 2020; Stanton AV et al, 2022). A comprehensive analysis using the GRADE system has shown that the evidence for a causal role of red meat in the development of NCDs is of (very) low certainty and not fit for strong recommendations (Johnston BC et al, 2019). The haem iron rationale advanced by the NS committee contributes to this uncertainty, as potential harmful effects of haem iron are mitigated in a balanced dietary context, following risk assessment (Kruger C et al., 2018). This once more stresses the importance of the diet matrix (see above). Moreover, even if discouragement of red meat may be pertinent for some (e.g., those at risk of iron overload), blanket recommendations may exacerbate the health problems of others due to a reduced intake of valuable nutrients that are highly bioavailable in red meat, among which haem iron, especially in at risk populations. The latter include children, older adults at risk of sarcopenia, and pre-menopausal women (many of which already suffer from iron deficiency, even in the West, due to changing dietary patterns; Sun H eta la, 2021; Mei Z et al, 2021).

An additional problem related to the use of a single algorithmic setup for very different product groups is that it does not sufficiently separate foods that are high in some nutrients with a negative or positive score effect, i.e. saturated fat or fiber. For instance, the lack of discriminating criteria within a specific product group leads to an unbalanced distribution of cheeses within the NS spectrum, with >80% of the products receiving a D score (Van Tongeren et al., 2020). As argued above for meat, cheeses also serve as an important source of important and highly bioavailable nutrients (e.g., calcium and proteins). Also, white bread and whole-meal breads are scoring very similarly, while the latter would have to be promoted over the former, as to stimulate fibre and micro-nutrient intake. Finally, several studies show that the NS is not aligned with the national

dietary guidelines (see for example, for The Netherlands, Konings et al, 2022 and Van Tongeren et al 2020)

Consumption aspects related to portion size and preparation

In addition to the problems of robustness and arbitrariness mentioned above, the resulting information is disconnected from the reality of consumer behaviour and may therefore be misleading. "Directive" systems are often based on a standard quantity of food (per 100g or 100ml), which is not necessarily and, arguably, rarely corresponding to the portions actually consumed. Some foods that obtain a favourable score can be consumed in large quantities that may lead to concern (e.g., industrial vegetable pizza), while other foods may obtain unfavourable scores although they are generally consumed in small portions and have well-documented health benefits (e.g., olive oil) (Carruba MO et al, 2021). Also, some foods with green scores at retail level will still undergo cooking procedures at consumer level, potentially involving unhealthy preparation steps (e.g., frying).

Consumer education

For consumers, "directive" FOPL like NS are not a useful basis for choosing the overall composition of their diets, nor do they allow them to appropriately combine foods and adhere to a specific food pattern (Visioli F et al, 2021). Therefore, they lack the "educational" purpose originally envisaged by the European Commission. Worse still, "directive" FOPL like NS risk becoming misleading, for instance by distracting attention from the Nutrition Facts tables reported on the package (Oswald C et al, 2022). Typically, consumers associate a green colour with "healthiness" or "naturalness", regardless of the nutritional information provided on the BOPL. In fact, when the packaging for the same product was experimentally prepared with two different labels (green and red), consumers choose the product labelled in green and did not read the information featured on the nutritional label (Schuldt JP et al, 2013). Perceived and actual understanding of nutritional information can indeed differ considerably (Oswald C et al, 2022), so that it is not necessarily to be expected that "directive" FOPL may promote an improvement of nutritional literacy. Consumers will also be led to value a "green"-coloured food as healthier than a "red" one regardless of the food category they belong to, even if it is sometimes claimed that the system is not intended as a tool for comparing the nutritional value of products from different categories. A recent study has used NS for the standardized comparison of very different foods, leading to various debatable and questionable outcomes (Clark M et al, 2022). For instance, foods such as frozen chips, rolls, and wraps were presented as nutritionally superior to seafood, milk, cheese, and eggs. As an undesired outcome, an inexperienced consumer may mistakenly try to follow a diet composed only of products in groups A (dark green) and B (light green), which is not necessarily nutritionally adequate and could even lead to unbalanced diets. Therefore, the effectiveness of "directive" FOPL to lead to the adoption of healthy dietary patterns and a reduced risk of developing NCDs has yet to be demonstrated (Ikonen I et al, 2020; Peters S et al, 2022).

Effects on purchase behaviour

All the determinants that influence food choices are often assessed individually rather than in a holistic, synergistic and multidimensional context, while a representative purchasing scenario would need to be characterized by multiple stimuli to which the consumer is subjected ("bombarded") at the point of purchase. Information, condensed into a color or number, has sometimes been found to facilitate better food choices and improve the nutritional quality of the shopping basket (Egnell M et al, $2\bar{0}18$; Ducrot P et al, 2015), but may also have the opposite effect and misguide consumers which could result in higher consumption of unhealthy food (Orquin JL et al, 2015; Roberto CA et al,

2012). More recent studies seem to acknowledge the capacity of FOPL to improve the overall quality of the shopping basket, in particular when they are part of a communication strategy aimed at increasing nutrition literacy in the population (Swedish Keyhole and Dutch Healthy Choices) (Smed S et al, 2017 and 2019). However, the actual effect of FOPLs on consumers' behaviour and their direct positive correlation with the individual health status has yet to be proven (Donini et al, 2022).

Validity over time of FOPL messages

"Directive" warnings frequently show a wear out (fatigue) effect tendency, resulting in decreasing effectiveness of a warning message over time. The experience with cigarette warning labels has shown that, after a first success, they required the implementation of pictorial labels in addition to the text for more effective outcomes. Even so, after a prompt increase in effectiveness, the wearout effect was re-observed again, so that some governments decided in response to frequently change the displayed images frequently in order to maintain results over time (Hammond D et al, 2007; White V et al, 2015). More "informative" approaches, provided that they are able to achieve educational effectiveness, by contributing to a broader nutritional awareness, may reduce this effect by empowerment of consumers. Ideally, consumers should be enabled to situate more appropriately individual foods and nutrients within a context of overall nutritional needs and dietary patterns, rather than being misled by simplistic colour schemes or other examples of "health halos" based on simplified claims, such as being "low in calories" or "low in fat" (Oostenbach LH et al, 2019). The experience with "light" food products, whose association with alleged healthier qualities lead to a greater consumption but failed to materialise in reduced obesity, suggests caution in classifying single foods as "good" or "bad" based on simplistic assumptions (Wansink B et al, 2006; Geyskens K et al, 2007; Cleeren K et al, 2016). Moreover, the use of artificial sweeteners may come with negative health trade-offs that are not captured in the score, thereby undermining the validity of the current favourable NS of, for instance, light sodas (Suez et al. 2022).

3. "Informative" front-of pack labels

An example of an "informative" FOPL is provided by the Italian Nutrinform Battery (NIB), which adopts the cell phone battery symbol to summarize the daily consumption of five elements: calories, fat, saturated fat, sugar, and salt. These batteries show the amount of each element contained in a portion of the food considered, as well as its contribution to the daily requirement according to the Dietary Reference Values established by the European Food Safety Authority (EFSA). The filling of the batteries is compared to the recommended amount for each nutritional element. In this way, the system informs the consumer to situate the intake of these nutrients per food in their overall daily meal formulations, so that they can manage the daily constitution in balanced manners.

As for "directive" FOPL, restricting the information to five parameters only offers a narrow view on the true nutritional value of a food and the importance of the food matrix. Also, the same objections to the validity of these criteria, in view of the totality of the scientific evidence, can be raised as the ones mentioned above for NS. However, "informative" approaches are less paternalizing and judgemental towards consumers and do not have the intention to label individual foods as "healthy" and "unhealthy". They also focus their attention on the average portions size as defined by national organisations, helping to understand how these will fit into the daily dietary consumption pattern in combatting obesity (Berry EM, 2020). The inclusion of portions in the setup is key, especially in the current foodscape with its emphasize on the oversizing of ultra-processed foods, which is likely responsible for overeating. "Informative" FOPL may help consumers to be aware of proper food servings and encourage the food industry, not only to reformulate potentially health-critical

products, but also to reduce the portion sizes (Carruba MO et al, 2021). That being said, it is difficult to identify true portion sizes, especially in "family packs" and other formulations with suggested portion sizes, as these depend on individual preferences and eating cultures. The definition of food portions is not always specified in the different national nutritional guidelines and can sometimes vary from one manufacturer to another. It also opens pathways for producers of unhealthy foods to manipulate the declared portion size and, therefore, the FOPL message.

Starting from an "informative" principle, systems such as the NIB attempt to respond to the European Commission's and United Nations' request for better empowerment of consumers to induce them to undertake healthy and balanced diets. By referring to the overall characteristics of the diet, these systems overcome the limits represented by the difficulties in defining the nutritional profile of foods. There are several models available (e.g. Ofcom/FSA NP model, WHO-Euro model, Health Canada Surveillance Tool system), but still today there is no consensus on which of these has should be considered as a reference (Rayner M, 2017; Hagmann D et al, 2020). In contrast to "directive" FOPL, such as NS, "informative" FOPL, such as NIB, offer a better option to achieve proper combinations of various foods (e.g., the choice of food for which the system assigns a high content of fats and sugar can be "balanced" by eating other foods with lower content of these nutrients). Likewise, when relevant, they also facilitate the selection of foods according to specific individual needs (energy content, sodium, or saturated fat content) (Carruba MO et al, 2021). The presence of the battery symbol may enable respondents to see if their consumption aligns with the recommended daily intake, so that meals can be balanced accordingly [Mazzù MF et al, 2021 (a)]. Improved understanding and preference for "informative" (NIB) over "directive" (NS) FOPL was confirmed in different studies performed in various European countries [Sampalean NI et al, 2021; Baccelloni A et al, 2021; Mazzù MF et al, 2021 (b and c)].

Taken together, the above-mentioned arguments suggest that a strategy of "informative" FOPL is more suitable to optimize dietary patterns, instead of focusing on individual foods and nutrients, an approach which is well-supported by the scientific evidence (e.g., Hu FB, 2002; Serra-Majem L et al, 2020; Wahl D et al, 2016). Eating patterns are made up of the combination of a variety of different foods. For example, foods like olive oil, cheeses, preserved meats, baked goods, and even sweets, may seem harmful on an individual and simplistic assessment, but are nevertheless an integral part of Mediterranean diets, widely acknowledged as a healthy eating pattern. Based on NS, salad dressings may have a better score compared to olive oil due to differences in energy density and saturated fat, but this is fully overlooking the healthy benefits that olive oil offers within a Mediterranean diet culture (supported by the rationale that it also is rich in monounsaturated fatty acids and antioxidants). The often subtle interactions between different foods and between different nutrients, as well as the complexities of food matrices and how these are affected by food processing (for the better or worse), make a model more or less effective in preventing NCDs. An approach based on the dichotomic classification of foods into "healthy" and "unhealthy" products may present several pitfalls related to the oversimplifications of this approach (Visioli F et al, 2021). The validity of focusing on single nutrients (as it happens in particular in "directive" FOPL) has been challenged in a report from the European Food Safety Authority (EFSA, 2022): "even though the effects of some individual nutrients and non-nutrient components of food on chronic disease risk are well established, these are usually found in foods and diets as complex mixtures, where synergistic or antagonistic effects may come into play".

As a drawback, the provision of somewhat more detailed information, as with the NIB system, could be challenging for communication purposes due to the numerous numerical references present.

This problem conflicts with the need for simple and immediate information, by requiring a graphic and advertising design that may not always be effective. Also, the contextualization of the information offered requests basic nutritional knowledge. Be that is it may, it is in our opinion still preferable to the simplistic approach of a single colour or letter.

4. Front-of-pack labels and health status

"Directive" FOPL are mostly focused on the content of nutrients with "unfavourable" effects. In the NS setup, such nutrients confer up to 40 negative points compared to nutrients with "favourable" effects, which bear a maximum of 15 positive points (Visioli F et al, 2021). This is in contrast with the observations that dietary policies focusing on the promotion of the intake of under-consumed beneficial components likely will likely have a greater effect than policies targeting "negative" nutrients. Among a list of fifteen nutritional factors of which the influence on health is allegedly highest, eleven were shown to refer to foods and nutrients that are consumed in insufficient quantities (e.g., whole grains, nuts, seeds, and seafood). Regardless of the fact that their true causal role in the development of disease is still controversial, only four of them (i.e., sodium, red meat, processed meat, and sugar-sweetened beverages) were consumed in excessive amounts (GBD Diet Collaborators, 2019; Foreman KJ et al, 2018).

Currently, the number of studies that associate the adoption of a FOPL with an improvement in health status are very few and mainly concern NS. None of them are longitudinal or have been able to identify a causal link between the adoption of the FOPL and the change in health status (Peters S eta al, 2022). At best, the association is with the consumption of a certain food (an association with the variation of a risk biomarker was rarely found, and associations outlining impact on morbidity or mortality are missing). Many of the studies have only virtually applied the NS to pre-existing cases, thereby assuming that the adoption of the NS could - if applied to that specific case series influence the adoption of different dietary patterns (which in reality were spontaneously adopted by the enrolled subjects) and their eventual health effects. The use of data extracted from existing studies, to which the possible effect of NS was subsequently applied with mathematical models, is a very questionable experimental approach from a methodological point of view, which by definition cannot demonstrate the presence of causal relationships between the considered parameters. Moreover, a real-life setting may give significantly different results due to important interfering and confounding factors (Storcksdieck Genannt Bonsmann S et al, 2020; Clarke N et al, 2021). Prospective controlled studies are missing (Donini LM et al, 2022): consumers were not exposed to the labels and did not choose the products accordingly, nor were their choices of labelled products observed over the long term, assessing the potential effect of FOPL on health against no FOPL exposure. These studies examined FOPLs in isolated conditions, unaffected by external factors. Thus, they overlooked confounding factors such as compensatory consumption, increased physical activity, biases, overconsumption of foods perceived as more nutritious or healthy and, whether or not consumers use FOPLs as a mean of information before purchase (Smed S et al, 2007). The few studies that have been carried out in real-world supermarkets (most of them using NS) gave conflicting results [some studies found no significant effects on consumer behaviour, whereas others found positive results in terms of a significant reduction in the purchase of products considered unhealthy; Donini LM et al, 2022]. This indicated that FOPL or shelf labels may at best achieve a small degree of success (< 2.0%) at persuading shoppers to buy healthier foods (Temple NJ, 2020; Smed S et al, 2007). Smed et al (2017, 2019)(DOI: 10.1017/S1368980019001423) showed that the placement of the Dutch Choices logo on products fulfilling the criteria for the logo, lead in some product groups to the switch from non-logoproducts to logo products. In other product groups no change was observed. These studies were done by reporting alal the products purchased in ahouseholds as well by analysing data from retail selling of products. A meta-analysis,

including 114 articles on the impact of FOPL on outcomes (consumers' ability to identify healthier options, product perceptions, purchase behaviour, and consumption), has shown that, although FOPL help consumers to identify healthier products, their ability to nudge consumers toward healthier choices is more limited (Ikonen L et al, 2020).

A labelling system with a positive character that incorporates more informative nutrition signals, may contribute to educative empowerment, and avoids messaging connoting judgment about what consumers are eating (e.g., red lights) (Seward MW et al, 2018). Focusing on positive "to-do" rather than on "not-to-do" behaviors can arguably increase the percentage of people adopting healthier eating habits (Pem D et al, 2015). Positive, gain-framed messages give an actionable message that seems to be effective with the general audience who are likely to have limited knowledge of the message's topic, leaving a positive feeling and a motivated attitude (Buckton CH et al, 2015; Rolls BJ et al, 2004).

5. Conclusions

There is no robust evidence that the adoption of a "directive" FOPL system like NS will improve the nutritional skills and awareness of consumers, thereby improving their purchasing choices in a reallife context. Neither should we assume that this will consequently improve the effective quality of their diets and that this would favourably modify their health status and reduce the incidence of NCD or mortality from any cause. Moreover, the structure and logic of a "directive" FOPL like NS does not provide much valuable and meaningful educational information (Andrés X et al, 2020). An information campaign putting emphasis on single nutrients or individual foods (which is the logical basis of "directive" FOPL as NS) does not consider the synergistic interactions occurring between different food items and food components, ignores the relevance of important micronutrients (vitamins, minerals, and other bioactive compounds), and neglects the potential influences related to the frequency of consumption, the influence of (ultra)processing and the food matrix, and the further preparation and cooking by consumers. Many of the assumptions, such as those that relate to the health impact of saturated fat, are much less evidence-driven than often assumed. A "negative-based" communication approach, relying on bans or simplistic summaries and limiting information to single nutrients, does not capture the complexity of dietary patterns as part of a thorough lifestyle modification (Dean M et al, 2011; Donini LM et al, 2022; Martini D et al, 2022). In contrast, and despite also coming with limitations, "informative" FOPL at least have the advantage of situating the FOPL information in a broader dietary context of daily intake and recommendation, thereby opening a broader dietary perspective on overall equilibrium.

Given that food is more than the sum of nutrients or mere "fuel for the body" " (which, albeit, should be of the highest octane), and acknowledging that eating is deeply rooted in culture and has important social meaning and functions, it is our opinion that more constructive approaches are needed. Preferably, these should *positively* emphasize the importance of dietary patterns that have a proven record of healthiness and are typified by a long-standing contribution to the benefits of commensality, culinary legacy, and food traditions.

Conflicts of interests

On a non-remunerated basis, FL is a board member of various academic non-profit organizations including the Belgian Association for Meat Science and Technology (president), the Belgian Society for Food Microbiology (president), and the Belgian Nutrition Society, and has a seat in the scientific

committee of the Institute Danone Belgium, the World Farmers' Organization, the Advisory Commission for the "Protection of Geographical Denominations and Guaranteed Traditional Specialties for Agricultural Products and Foods" of the Ministry of the Brussels Capital Region, and a Scientific Advisory Committee of the Food and Agriculture Organization of the United Nations.

LMD is member of different boards of scientific societies dealing with eating behaviours and food science (Italian Soc for the Study of Eating Disorders (SISDCA), Italian Society of Obesity (SIO); Eur Soc of Clinical Nutrition and Metabolism (ESPEN)].

All other authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Table 1: Different examples of Front-of-Pack Labels

	Informative	Semi-directive	Directive
	Non-Directive	Jeilli-directive	Directive
Definition	Provides information such as the name of nutrients included, their amount in grams, and their percentage in relation to total daily requirements	Provides not only nutritional information, but also an evaluative element such as a color, a word, or a sign that gives additional information emphasizing the healthiness levels of single nutrients	Includes little information, often aggregated in a single symbol, and combining several criteria. Some of them (Swedish Keyhole and Dutch Healthy Choices) are applied on products in combination with nutritional information labels front-of-pack or back-of-pack. Other (e.g. Nutri-Score) only give an indication about the healthiness of the product, expressing judgements, opinions and/or recommendations, without providing specific information on single nutrients.
Examples	Cascuna porcione 125g (1 vascetto) conference: Cascular Cascu	1) English traffic light or Multiple Traffic Light - MTL Each 1/2 pack serving contains MED LOW MED HIGH MED Sat Fat Salt 10.8g 1.1g 18% 1% 29% 54% 18% 1.1g 18% 1% 29% 54% 18% of your guideline daily amount Source: Food Standards Agency 2) Warning Signs which may feature the octagon "stop" or the words "rich in" (Chile) 3) Israeli system of red pictures for excess salt, fat or sugar and positive green symbols for healthy products Warning FOPL High Sadum Level High Sugar Level Fositive FOPL	1) Swedish Keyhole (B) (B) (B) (C) (B) (C) (C) (B) (C) (C) (C) (C) (C) (C) (C) (C) (C) (C