



Italian Committee for Biosafety, Biotechnology and Life Sciences (CNBBSV)

POSITION PAPER ON FRONT-OF-PACK LABELS

“Directive” versus “informative” front-of-pack labels.

Edited by

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Summary

In 2011 the European Commission decided to adopt a simpler procedure represented by a **front-of-back label (FOPL)** able to inform consumers and to perform an "educational" function to hinder the increasing prevalence of obesity and **non-communicable diseases (NCD)**.

The aim of the present opinion paper is to verify the usefulness of "directive" FOPL, and in particular of Nutri-Score, compared to "informative" tools (in particular Nutrinform Battery) in promoting a better nutritional and health status.

The "**directive**" systems (e.g. Nutri-Score) impose on consumers a "traffic light" system that suggests what to buy without providing any information either on the nutritional characteristic of the food; they often score the nutritional value of foods through **arbitrary or not well defined algorithms**; they are based on a **standard quantity of food** (100g or 100ml) almost never corresponding to the portions actually consumed; they are not a useful basis for choosing the **overall composition of the diet** and therefore they do **not represent an "educational" tool** and do not allow to achieve the objectives proposed by the European Commission, which asks that food information to consumers should empower consumers to undertake healthy and balanced diets.

It is important to consider that "directive" warnings frequently show a **wear out effect** tendency (decreasing effectiveness of a warning message over time) and they may lead consumers perceive products carrying a "green" label definitely as healthier, possibly leading to an **unbalanced diet** (high-protein, for example). Finally they may perhaps be dangerous for the most **fragile categories** (such as children, older people, individuals with specific health needs), who have specific needs from a nutritional point of view, they could be misled by the colour/letter of the FOPL.

The "**informative**" systems (e.g. Nutrinform battery), although they also keep the attention on five parameters characterizing the food (calories, fat, saturated fat, sugar and salt), try to go further, without labelling the food as "healthy" and "unhealthy", and focus their attention on the individual portions actually consumed, helping to understand how these will fit into the daily dietary intake. With increasing strength, food science focuses its attention on **eating patterns** (e.g. Mediterranean diet - MD) rather than on individual foods or nutrients which is in contrast with the most recent scientific data stating that dietary policies focusing on promoting the intake of components of diet, for which current intake is less than the optimal level, may have a greater effect than policies only targeting "negative" nutrients.

At the moment, the studies that associate the adoption of a FOPL with an improvement in the **health status** are very few, mainly applied in virtual settings or to pre-existing cases: none of these are longitudinal and are able to identify a causal link between the adoption of the FOPL and the change in health status.

A **labelling system with a positive character** (as "FOPL "informative" systems) that incorporates more nutrition information and education, and avoids messaging connoting judgment about what consumers are eating (e.g. red lights) may be more appropriate for promoting a healthy and sustainable diet.

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The prevalence of obesity and **non-communicable diseases** (NCD) is increasing with a significant impact on morbidity, mortality and quality of life (Bracale R et al, 2013; Popkin BM et al, 2020). Lifestyle and in particular eating habits influence the nutritional status and, therefore, the prevalence of obesity and NCD such as cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes (Smethers AD et al, 2018).

The **information to consumers** positively impacts on eating habits and on the prevention of NCD (Fruhbeck G et al 2016; Carruba MO et al, 2021), and 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) believe that nutritional food information to consumers should empower them to undertake healthy and balanced diets.

Back of pack labels (BOPL) didn't succeed in providing an effective information to consumers and, therefore, in 2011 the European Commission decided to adopt a simpler procedure represented by a **front-of-back label (FOPL)** able to inform consumers and to perform an "educational" function. By 2022, the European Commission must take the decision on the single labelling system that all EU member countries have to adopt.

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

- 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 (e.g., Nutrinform Battery)
- Semi-directive labels, that provide not only nutritional information, but are 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, emphasizing them (e.g., the English traffic light or *Multiple Traffic Light* - MTL, Warning Signs which may feature the octagon "stop" or the words "rich in").
- Directive labels, that include little information, often aggregated in a single symbol (e.g., Swedish Keyhole, Nutri-Score) and combining several criteria. They 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 the present opinion paper is to verify the usefulness of “directive” FOPL, and in particular of Nutri-Score, compared to “informative” tools (in particular Nutrinform Battery) in promoting a better nutritional and health status.

1. “Directive” front-of-pack labels

The “directive” systems (e.g. Nutri-Score) impose on consumers a “traffic light” system that suggests what to buy without providing any information either on the nutritional characteristic of the food, or on recommended portions and frequencies.

The most known and widespread FOPL in Europe is represented by a “directive” tool named **Nutri-Score** (NS) that was adopted in France since 2017, and then in Belgium, Spain, Germany, the Netherlands, Luxembourg, and Switzerland between 2018 and 2020 and which is based on a colour scale from dark green to red, accompanied by letters from A to E. NS does not provide information on the various factors included in the algorithm (energy and nutrients), but an overall evaluation of the individual food, which could be the result of a large number of combinations of levels of different factors.

The “directive” systems (and in particular the NS) often score the nutritional value of foods through **arbitrary or not well defined algorithms**. In fact there are some inherent difficulties in establishing nutrient profiles at EU level, such as the application of the nutrient intake recommendations set for the general diet to individual foods, the lack of uniform data for the composition and consumption of foods across the EU, and differences in nutrient intake recommendations and dietary guidelines within EU countries (EFSA scientific opinion, 2008). These uncertainties make the definition of FOPL (in particular that of the “directive” type) very complex, which may lead, not surprisingly, to the “manipulation” of the final score of different foods based on specific interests (https://solidarites-sante.gouv.fr/IMG/pdf/annual_report_2021.pdf; ter Borg et al, 2021). For instance, the original algorithm of NS attributed one 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, demonstrating scientifically questionable subjectivity and arbitrariness.

As mentioned above, **NS does not provide information on the various factors included in the algorithm** (energy and nutrients), but an overall evaluation of the individual food, which could be the result of a large number of combinations of levels of different factors [high levels of one or more factors considered negative (energy, total sugar, saturated fatty acids and sodium content) and / or low levels of one or more factors considered positive (fruit, vegetables and nuts, fibre, protein and seed, walnut and olive oils content)]. As a consequence, for example, whole-meal short-bread biscuits made with different recipes, almost invariably obtain the same score 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). Still speaking about bakery products, food processing may have a very different contribution to the nutritional attributes of baked goods.

Representative is the comparison between sourdough made products and those obtained by chemical leavening. The same consideration should be extended to many if not all foods and beverages, which may be subjected or not to technological and, mainly, fermentation processes. A study conducted in The Netherlands (where NS was adopted) showed that, for Cheese, Ready meals, Soups and Meal sauces (2299 products verified), 1) there was an uneven distribution of the products among the different NS; 2) Nutri-Scores of a great amount of products were not in line with Dutch Choices criteria and dietary guidelines; and 3) there were no high correlation between NS and health influencing nutrients in most product groups (Van Tongeren C et al, 2020).

The "directive" systems (e.g. Nutri-Score) are based on a **standard quantity of food** (100g or 100ml) almost never corresponding to the portions actually consumed. The resulting information is therefore disjointed from the reality of the consumer behaviour and provides information that is useless or even misleading. Some foods may obtain a favourable score for 100 g, although they are generally consumed in much higher quantities (e.g vegetable pizza, diet soda), while other foods may obtain (always on 100 g) less favourable scores using the NS system, although they are generally consumed in much smaller portions (e.g: chocolate, olive oil) (Carruba MO et al, 2021). Although, the system is not intended as a tool for comparing the nutritional value of products from different categories, consumers will inevitably be led to consider a "green" food to be healthier than a "red" one, regardless of the group they belong to.

For the consumer, "directive" FOPL (e.g. Nutri-Score) is not a useful basis for choosing the **overall composition of the diet**, nor do they allow consumers to appropriately combine foods and adhere to a specific food pattern (Visioli F et al, 2021).

Therefore they do **not represent an "educational" tool** and do not allow to achieve the objectives proposed by the European Commission, which asks that food information to consumers should empower consumers to undertake healthy and balanced diets.

Moreover, the definition of a food through the attribution of a colour, without providing any supplementary information, risks becoming **educationally harmful** and misleading. In fact, the "directive" FOPL distracts attention from the Nutrition Facts labels reported on the package (Oswald C et al, 2022)

Different studies on the effect of food labels show that the consumer associates the green light to the meaning of "healthy" or "natural", regardless of the nutritional information indicated 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).

In a study conducted by Oswald C et al (2022), FOPL groups score were lower on a **nutrition literacy quiz**, indicating that their perceived and actual understanding of nutritional information differed and "directive" FOPL, for their intrinsic characteristics, cannot promote an improvement of nutritional literacy and the empowerment of customers.

It is important to consider that “directive” warnings frequently show a **wear out effect** tendency (decreasing effectiveness of a warning message over time). The experience with cigarette warning labels has shown that, after a first success, they requested the implementation of pictorial label in addition to the text for a more effective outcome. Even so, after a prompt increase in effectiveness, the wear-out effect was observed again, and because of that, some governments decided to change the displayed images frequently to maintain low- and middle results over time (Hammond D et al, 2007; White V et al, 2015). An educational approach (as in “informative” FOPL) may reduce this effect thanks to the empowerment of consumers.

The promotional messages proposed by the "directive" FOPL may lead consumers perceive products carrying a "green" label as healthier, and underestimate the energy content of food products classified as "healthy". This may influence food purchase intentions, leading consumers to increase food consumption and overall energy intake. The "informative" approach of the FOPL, which enables the users to enter individual foods and individual nutrients in relation to the overall nutritional needs, can, on the contrary, diminish this negative "**health halo**" reducing the tendency to overestimate the healthfulness of an item based on a single claim, such as being low in calories or low in fat (Oostenbach LH et al, 2019).

The attribution of an indisputably positive value through a green label can favour behaviours that are not necessarily positive for the consumers and could theoretically expose them paradoxically to a higher risk. The experience with "**light**" food products, whose association with alleged healthier qualities lead to a greater consumption of them contributing to the development of obesity rather than to the prevention of it, should suggest caution in classifying foods as good or bad (Wansink B et al, 2006; Geyskens K et al, 2007; Cleeren K et al, 2016).

Finally 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. The simplistic approach of “directive” FOPL does not lead necessarily to the adoption of healthy dietary patterns, but, more simply, to increase the consumption of some foods (for example those rich in proteins) and to penalize the consumption of others (olive oil or eggs, respectively rich in fatty acids or cholesterol). The final result is often an **unbalanced diet** (high-protein, for example) whose effect on the risk of developing NCDs has yet to be demonstrated (Ikonen I et al, 2020).

A fortiori, a system that does not provide information on why a certain colour has been attributed to a specific food is absolutely useless and perhaps dangerous for the most **fragile categories** (such as children, older people, individuals with specific health needs), who have specific needs from a nutritional point of view, they could be misled by the colour/letter of the FOPL. For example, the consumer who has overweight/obesity problems and who intends to keep the intake of calories under control, could choose a product with a green label, but with a higher energy density than a product of the same category that has a yellow label.

2. “Informative” front-of pack labels

The “**informative**” systems, although they also keep the attention on five parameters characterizing the food (calories, fat, saturated fat, sugar and salt), try to go further, without labelling the food as “healthy” and “unhealthy”, and focus their attention on the individual portions actually consumed, helping to understand how these will fit into the daily dietary intake. Differently from “directive” systems, they try to respond to the indications of the European Commission and United Nations, which believe that food information to consumers must empower consumers to induce them to undertake healthy and balanced diets.

In particular, since they refer to the overall characteristics of the diet, they overcome the limits represented by the difficulties in defining **nutritional profile** of foods. There are several models (i.e. Ofcom/FSA NP model, WHO-Euro model, Health Canada Surveillance Tool system), but still today there is no consensus on which of these has to be considered the reference for objectively defining the nutritional quality of food (Rayner M, 2017; Hagmann D et al, 2020).

Recently **Nutrinform Battery** (NIB) was proposed in Italy. It adopts the cell phone battery symbol to check 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 helps the consumer to manage the intake of nutrients in subsequent meals and to maintain a balanced diet without excluding any food a priori.

At the basis of the “informative” FOPLs are the concepts of “**portion**” and the Guideline Daily Amounts to be adopted. Focusing on portions is of the outmost importance since scientific literature clearly shows that the generalized increase in portion sizes is responsible for excessive food consumption. “Informative” FOPL may help consumers to be aware of the food servings and encourage the food industry, not only to reformulate potentially health-critical products, but also to reduce the portion sizes, eventually orienting consumers to prefer foods with lower impact on their daily calorie intake (Carruba MO et al, 2021).

The attention placed on single foods and individual nutrients is unlikely to be effective in terms of health promotion and disease prevention. Many studies and metanalysis did not find any negative association among clinical health outcomes and the consumption of **food items or food groups** (cheese, butter, total dairy, red meat), and **single nutrients** (saturated fatty acids, sodium) commonly considered to be detrimental or even harmful to health (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; Schmidt KA et al 2021).

A corollary is represented by the ascertained limits of the so-called transitive property [“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)]: increasing the intake of folic acid, B6 and B12 vitamins, leads to the reduction of homocysteine levels, but doesn’t affect the cardiovascular risk; eliminating eggs, which are rich in cholesterol, has a minimal response on plasma cholesterol concentrations and does not affect the low-density/high-density lipoprotein ratio (Clarke R et al, 2010; Maruyama K et al, 2019).

On the basis of the above-mentioned observations, it is reasonable to question the current attention on single foods and/or single nutrients as a strategy to improve the individual health status.

With increasing strength, food science focuses its attention on **eating patterns** (e.g. Mediterranean diet - MD) rather than on individual foods or nutrients (Hu FB, 2002; Serra-Majem L et al, 2020; Wahl D et al, 2016). Eating patterns are made up of the combination of different and many foods. For example, foods like olive oil, cheeses, preserved meats, baked goods and even sweets on an individual and simplistic assessment, may seem harmful but are nevertheless an integral part of MD. The interaction between different foods, between different nutrients and between different food matrices makes a model more or less effective in preventing NCDs. On the contrary, 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 put into question 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”.

"Informative" FOPL as NIB (differently from "directive" FOPL) allow and promote the proper **combination 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) and to select foods, when relevant, according to specific individual needs (energy content, sodium, or saturated fat content) (Carruba MO et al, 2021).

Facing “directive” FOPL, European **consumers** often find themselves in trouble trying to come across a coincidence between the indications that the NS gives and what has always been recognized as healthy. Based on NS, salad dressings may have a better score compared to olive oil: the higher level of energy density and of saturated fats makes this last “unhealthy” compared to a salad dressing. In fact, reducing the analysis of a food to some few parameters makes us lose sight of the global value of the food, which, specifically, thanks to its content in monounsaturated fatty acids and antioxidant substances, is not surprisingly the basis of MD.

In a study considering consumers' **subjective understanding and liking** of two different FOPL nutritional labels, it was found that NIB (compared to NS), giving consumers more specific details, enhances their subjective understanding of products' nutritional values with a clearer overview of the healthiness of the food. Moreover, the presence of the battery symbol may enable respondents to see if their consumption aligns with the recommended daily intake and then balance their meals accordingly (Mazzù MF et al, 2021 (a)). The better consumers' subjective understanding and liking of "informative" (NIB) compared to "directive" (NS) FOPL was confirmed in different studies performed in ten European countries: Italy; France; Germany; Greece; Poland; Portugal; Romania; Slovenia; The Netherlands and Spain [Sampalean NI et al, 2021; Baccelloni A et al, 2021; Mazzù MF et al, 2021 (b and c)].

The need for simple and immediate information requires **graphic and advertising research** that is not always effective. NIB system could be challenging to read due to the numerous numerical references present and it may request basic nutritional knowledge. On the other hand, reducing all the information that characterizes a food to a simple colour or letter inevitably leads to the adoption of a simplistic approach.

One limit of NIB may be represented by its link to portion of food. If it is true that the optimal reference must be to the **portion of a food** and not to a standard quantity (100g or 100ml) devoid of any relationship with the reality of consumption, it is also true that the definition of food portions is not always specified in the different national nutritional guidelines and can sometimes vary from one manufacturer to another. A further research in this field and the definition of clear indication on portion sizes is therefore required.

Finally, the fact that the "informative" FOPL are promoted in particular by the **Italian scientific and production world**, if at first sight it may seem a limitation of the proposal and an a priori defence of Made in Italy, in reality it represents a strong point since Italy represents an absolute "authority", recognized worldwide, in the field of the agri-food system and gastronomic sciences.

3. Front-of-pack labels and health status

Directive FOPL are focused on the content of nutrients with "unfavourable" effects (**in the NS these nutrients confer up to 40 negative points compared nutrients with "favourable" effects, which bear a maximum of 15 positive points**) (Visioli F et al, 2021). This approach in fact is in contrast with the most recent scientific data stating that dietary policies focusing on promoting the intake of components of diet, for which current intake is less than the optimal level, may have a greater effect than policies only targeting "negative" nutrients: among 15 nutritional factors that most influence health, 11 refer to foods and nutrients that are consumed in insufficient quantities, such as whole grains, nuts, seed, and seafood. Only four (sodium, red meat, processed meat, and sugar-sweetened beverages) are consumed to excessive amounts. Apart from sodium, these play a negligible role as real health determinants (GBD Diet Collaborators, 2019; Foreman KJ et al, 2018).

Based on these considerations the American Dietetic Association (ADA) published a position paper that warned nutrition professionals against classifying foods as good or bad because it could foster unhealthy eating behaviour. When recommendations focus their indication on the foods to avoid, the position paper stated, the good/bad dietary dichotomy is automatically created (Mobley AR, 2009).

At the moment, the studies that associate the adoption of a FOPL with an improvement in the **health status** are very few and mainly concern NS. None of these are longitudinal and are able to identify a causal link between the adoption of the FOPL and the change in health status. At best, the association is with the consumption of a certain food (often in virtual contexts); an association with the variation of a risk biomarker was rarely found; never with the impact on morbidity or mortality. Many of the studies, in fact, **virtually apply the NS to pre-existing cases** 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 the appearance, over time, of 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 questionable experimental model 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).

Searching in PubMed database and screening relevant articles combining the search terms front of pack label and health (no publication period, article type, or language restrictions were applied), 13 articles were identified (Donini LM et al, 2022). None of these is a prospective controlled study conducted in the field: 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 FOPNLs on health against no FOPNL exposure. These studies examined FOPNLs in isolated conditions, unaffected by external factors, overlooking confounding factors such as compensatory consumption, increased physical activity, biases, overconsumption of foods perceived as more nutritious or healthy and if consumers use FOPNLs as a mean of information before purchase

Finally the very 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)] indicating anyway that FOPL labels or shelf labels may achieve a small degree of success (< 2.0%) at persuading shoppers to buy healthier foods (Temple NJ, 2020). A meta-analysis, including 114 articles on the impact of FOP labels on outcomes (consumers' ability to identify healthier options, product perceptions, purchase behavior, and consumption), has shown that, although FOP labels 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 nutrition information and education, and avoids messaging connoting judgment about what consumers are eating (e.g. red lights) may be more appropriate for promoting a healthy and sustainable diet (Seward MW et al, 2018). Focusing on positive “to-do” rather than on “not-to-do” behaviors should 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).

Conclusion

There is no evidence that the adoption of the NS may improve the consumer's nutritional skills, that it would improve his purchasing choices in a **real life context**, that it consequently should improve the effective quality of his diet, and that the variations of his diet can favourably modify the health status of the consumer, reducing the incidence of NCD (e.g. cardiovascular diseases, cancer) or mortality from any cause.

On the other hand, the structure and logic of a "directive" FOPL make it implausible to obtain results in this direction since it doesn't provide any information aimed at the **education of consumers**. On the contrary, the “informative” FOPL, just because they aim to promote healthy eating behaviour giving information on the overall equilibrium of the diet, are presumed to be able to obtain significant results in terms of prevention of NCDs.

An information campaign putting emphasis on **single nutrients or on individual foods** (which is the logical basis of “directive” FOPNL as NS) does not consider the synergistic interactions occurring between different food items and food components, nor take into account the potential influence related to the frequency of consumption. Although it is not easy to communicate these directions to the consumers, a “negative based” communication approach, relying on bans or simplistic summaries and limiting information to single nutrients, does not capture the complexity of the dietary pattern changes as part of a thorough lifestyle modification (Dean M et al, 2011; Donini LM et al, 2022).

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