



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Message 115

Communication from the Commission - TRIS/(2023) 3668

Directive (EU) 2015/1535

Notification: 2023/0548/LU

Forwarding of a detailed opinion received by a Member State (Italy) (article 6, paragraph 2, second indent of Directive (EU) 2015/1535). This detailed opinion extends the standstill period until 22-03-2024.

Detailed opinion - Avis circonstancié - Ausführliche Stellungnahme - Подробно становище - Podrobné stanovisko - Udførlig udtalelse - Επιπεριστατωμένη γνώμη - Dictamen circunstanciado - Üksikasjalik arvamus - Yksityiskohtainen lausunto - Detaljno mišljenje - Részletes vélemény - Parere circostanziato - Išsamiai išdėstyta nuomonė - Sīki izstrādāts atzinums - Opinioni dettaljata - Uitvoerig gemotiveerde mening - Opinia szczegółowa - Parecer circunstanciado - Aviz detaliat - Podrobné stanovisko - Podrobno mnenje - Detaljerat yttrande

Extends the time limit of the status quo until 22-03-2024. - Prolonge le délai de statu quo jusqu'au 22-03-2024.- Die Laufzeit des Status quo wird verlängert bis 22-03-2024.- Удължаване на крайния срок на статуквото до 22-03-2024. - Prodłużuje lhůtu současného stavu do 22-03-2024. - Fristen for status quo forlænges til 22-03-2024. - Παρατείνει την προθεσμία του status quo 22-03-2024. - Amplía el plazo de statu quo hasta 22-03-2024. - Praeguse olukorra tähtaega pikendatakse kuni 22-03-2024. - Jatkaa status quon määraaika 22-03-2024 asti. - Produžuje se vremensko ograničenje statusa quo do 22-03-2024. - Meghosszabbítja a korábbi állapot határidejét 22-03-2024-ig. - Proroga il termine dello status quo fino al 22-03-2024. - Status quo terminas pratęsiamas iki 22-03-2024. - Pagarina "status quo" laika periodu līdz 22-03-2024. - Jestendi t-terminu tal-istatus quo sa 22-03-2024. - De status-quoperiode wordt verlengd tot 22-03-2024. - Przedłużenie status quo do 22-03-2024. - Prolonga o prazo do statu quo até 22-03-2024. - Prelungește termenul status quo-ului până la 22-03-2024. - Predlžuje sa lehota súčasného stavu do 22-03-2024. - Podaljša rok nespremenjenega stanja do 22-03-2024. - Förlänger tiden för status quo fram till 22-03-2024.

The Commission received this detailed opinion on the 21-12-2023. - La Commission a reçu cet avis circonstancié le 21-12-2023. - Die Kommission hat diese ausführliche Stellungnahme am 21-12-2023 empfangen. - Комисията получи настоящото подробно становище относно 21-12-2023. - Komise obdržela toto podrobné stanovisko dne 21-12-2023. - Kommissionen modtog denne udførlige udtalelse den 21-12-2023. - Η Επιτροπή έλαβε αυτή την επιπεριστατωμένη γνώμη στις 21-12-2023. - La Comisión recibió el dictamen circunstanciado el 21-12-2023. - Komisjon sai üksikasjaliku arvamuse 21-12-2023. - Komissio sai tämän yksityiskohtaisen lausunnon 21-12-2023. - Komisija je zaprimila ovo detaljno mišljenje dana 21-12-2023. - A Bizottság 21-12-2023-án/én kapta meg ezt a részletes véleményt. - La Commissione ha ricevuto il parere circostanziato il 21-12-2023. - Komisija gavo šią išsamiai išdėstyta nuomonę 21-12-2023. - Komisija saņēma šo sīki izstrādāto atzinumu 21-12-2023. - Il-Kummissjoni rċeviet din l-opinioni dettaljata dwar il-21-12-2023. - De Commissie heeft deze uitvoerig gemotiveerde mening op 21-12-2023 ontvangen. - Komisja otrzymała tę opinię szczegółową w dniu 21-12-2023. - A Comissão recebeu o presente parecer circunstanciado em 21-12-2023. - Comisia a primit avizul detaliat privind 21-12-2023. - Komisia dostala toto podrobné stanovisko dňa 21-12-2023. - Komisija je to podrobno mnenje prejela dne 21-12-2023. - Kommissionen mottog detta detaljerade yttrande om 21-12-2023. - Fuair an Coimisiún an tuairim mhionsonraithe sin maidir le 21-12-2023.

MSG: 20233668.EN

1. MSG 115 IND 2023 0548 LU EN 22-03-2024 21-12-2023 IT DO 6.2(2) 22-03-2024

2. Italy

3A. MINISTERO DELLE IMPRESE E DEL MADE IN ITALY

Direzione generale per il mercato, la concorrenza, la tutela del consumatore e la normativa tecnica



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Divisione VI - Normativa tecnica - Sicurezza e conformità dei prodotti
00187 Roma - Via Molise, 2

3B. Ministero delle imprese e del Made in Italy

Ministero dell'agricoltura, della sovranità alimentare e delle foreste

Ministero della salute

4. 2023/0548/LU - C60A - Labelling

5. article 6, paragraph 2, second indent of Directive (EU) 2015/1535

6. Following the examination of the 'Preliminary draft Grand-Ducal Regulation amending the Grand-Ducal Regulation of 7 May 2021 on the use of the Nutri-Score logo', corresponding to notification 2023/0548/LU-C60A, by the competent Italian Ministries (Ministry of Health, Ministry of Business and Made in Italy and Ministry of Agriculture, Food Sovereignty and Forestry), Italy issues the following detailed opinion.

Italy had previously issued a detailed opinion on the previous notification of Luxembourg 2020/0391/L, which set out the conditions for the use of the 'Nutri-Score' logo.

It is currently considered necessary to re-propose a series of technical legal findings related to the use of the Nutri-Score logo that have already been represented in the past, but which, in Italy's view, have not received exhaustive answers either from the countries that previously notified the use of the logo, nor from the Commission's legal services. Italy would be grateful to Luxembourg if it would clarify the following critical issues in a timely manner.

1. System characteristics

Draft Luxembourg standard 2023/0548/LU - C60A provides for the incorporation of the new version of the Regulation on the use of the Nutri-Score logo developed by the French Public Health Authority, as well as clarifications on the competence of the Minister of Agriculture to test the affixing of the Nutri-Score logo on non pre-packaged foods as a pilot project.

Italy considers it appropriate to issue a detailed opinion to understand how this system can be compatible with the European legislation currently in force, both on food labelling and on nutritional claims.

At the outset, it is argued that Luxembourg did not consider it necessary in its notification to indicate the rule under which the notification is to be made, even though it should be regarded as essential information for the assessment of the draft Regulation, both by the Commission and by the Member States.

However, it should be noted that it is apparent from the reading of the Grand-Ducal Regulation that the Recitals, the articles and the Preamble to Annex I indicate, respectively:

- Article 36 of Regulation 1169/2011/EU and Regulation 1924/2006/EC
- articles 30 to 34 of Regulation 1169/2011/EU
- articles 35 to 37 of Regulation 1169/2011/EU

It is also appropriate to consider that, similar to France's previous notification of 2017 (notification 2017/159/F) concerning the adoption of the Nutri-Score system, in the accompanying message to the current proposal for amendment (2023/0601/FR), it is reiterated again in point 8 that:

'The draft Decree was drawn up taking into account Article 35(2) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of information on food to consumers. In application of this provision, France recommends that food industry operators use a complementary form of expression in their nutrition declaration. Operators are free to choose whether or not to apply this recommended form. This complementary form consists of a logo called 'Nutri-Score'.

Already in 2017, Italy intervened with a detailed opinion indicating, among other things, that the system could not be regarded as falling under Article 35.



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

That approach, as of 2017, was also supported by the Commission itself, which observed, in Message No 303 – ‘Commission Communication – TRIS (2017) 01957’, that ‘The labelling system annexed to the notified project does not require an indication of the energy value or the energy value and the quantities of nutrients as such, but refers to the overall nutritional quality of the foods in question. Therefore the Nutri-Score system does not fall within the scope of Article 35(1) of Regulation (EU) No 1169/2011’.

The Commission’s 2017 comments also stated that ‘In the absence of Union harmonisation legislation, Member States are free to adopt national rules aimed at protecting legitimate public objectives, provided that those standards comply with Union law’.

On 20 May 2020, the Commission confirmed (Report COM(2020) 207 final), now without a doubt, that systems such as Nutriscore are not among those eligible under Article 35.

2. Compatibility with the provisions of Article 35 of Regulation (EU) No 1169/2011

As regards the compatibility of the system with Article 35, Italy will not repeat in full what was already written at the time of the French, Belgian and German notification, given that it has been confirmed by the Commission itself that the system does not fall within the scope of that article.

In any event, since both the French authorities, in an explicit manner, and the Luxembourg authorities, in the above-mentioned references to the legislative text, still make Article 35 of Regulation No 1169/2011 the basis of the Nutriscore system, it is considered useful to propose below a series of observations aimed at demonstrating that certain conditions of applicability laid down by that provision have not been complied with.

Article 35(1) provides that ‘In addition to the forms of expression referred to in Article 32(2) and (4) and Article 33 and to the presentation referred to in Article 34(2), the energy value and the amount of nutrients referred to in Article 30(1) to (5) may be given by other forms of expression and/or presented using graphical forms or symbols in addition to words or numbers (...)’. In particular, attention should be paid to the reference to paragraph 3 of Article 30, which provides: ‘Where the labelling of a pre-packed food provides the mandatory nutrition declaration referred to in paragraph 1, the following information may be repeated thereon:

- a) the energy value; or
- b) the energy value together with the amounts of fat, saturates, sugars, and salt.’

This means that, where the mandatory nutrition declaration can be repeated on the labelling of the food, the items that can be reported are exclusively those referred to in points (a) or (b). In that regard, it should be noted that, as stated in notification 023/0601/FR, the Nutri-Score calculation algorithm for foods incorporates changes in the allocation of points based on the content of salt, sugar, protein, fibre, fruit, vegetables and dried vegetables, thus not limited to substances that may be repeated under the provisions of Article 30(3) cited above.

If it were to be argued that Nutriscore does not give rise to repetition of the information because its graphic form does not make the algorithm and the elements that constitute it visible to the consumer, one could easily reach the conclusion initially outlined, namely that said system cannot be framed in the forms of expression and presentation referred to in Article 35. If one were to attempt to assimilate the system to a health or nutritional claim to the extent that it states, suggests or implies the existence of a relationship between a category of food, a food or one of its components and health, or that a food has particular characteristics, one would highlight the need for notification in accordance with Regulation (EC) No 1924/2006, a notification of which Italy, to date, is unaware. In relation to this interpretation, a number of comments are also made in point 4 of this opinion.

A further differentiation of Nutriscore from the requirements of Regulation 1169/2011 lies in the provisions of Article 33(2): ‘By way of derogation from Article 32(2), in the cases referred to in point (b) of Article 30(3) the amount of nutrients and/or the percentage of the reference intakes set out in Part B of Annex XIII may be expressed on the basis of per portion or per consumption unit alone.’ It follows that the calculation of the Nutriscore algorithm, based on 100 g of product, is not in line with the provision referred to, which provides exclusively for the expression per portion or unit of consumption.

That being said, it is clear that the system is not covered by Article 35 and that, even if it were to be maintained that the classification was correct, it would have to be concluded that it did not comply substantially with the rules laid down in Regulation No 1169/2011.

There is therefore no doubt that the notified project does not comply with existing legislation with Union law.



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

3. Compatibility with the provisions of Article 36 of Regulation (EU) No 1169/2011

In its report COM(2020) 207 final of 20 May 2020, the Commission stated, in so far as it concerns the systems which do not fall within the scope of Article 35, such as Nutriscore, that 'Such schemes are considered as 'voluntary information' under Article 36 of the FIC Regulation which shall not mislead the consumer, not be ambiguous or confusing for the consumer and shall, where appropriate, be based on the relevant scientific data. At the same time, when such a scheme attributes an overall positive message (for example through a green colour), it also fulfils the legal definition of a "nutrition claim" as it provides information on the beneficial nutritional quality of a food as defined in Regulation (EC) No 1924/2006 on nutrition and health claims made on foods' but also that 'FOP schemes falling in the scope of the Claims Regulation can only be used in the territory of a Member State if they have been adopted by the Member State in question in accordance with Article 23 of the Claims Regulation outlining the notification procedure to the Commission.' In that regard, Italy does not agree that the Nutriscore system, when it is coloured orange and red, falls within the forms of voluntary expression referred to in Article 36 of Regulation No 1169/2011, since it is considered clear that the first paragraph of Article 35 constitutes the only way to submit voluntary forms additional to the nutrition declaration which the Member States may recommend, if they consider that the requirements laid down by that provision are met. On the contrary, Article 36 is addressed to economic operators who, at their own discretion, may provide the consumer with voluntary information on the elements referred to in Articles 9 and 10 of the Regulation, notwithstanding any recommendations of the Member States assessing their scientific basis.

The provisions of Article 35(1) assume in fact the characteristics of a real exception to the general principle that envisages, as the mode of presentation of the nutritional declaration, the use of the tabular form indicated in the regulation and annexes of reference.

As any exception, even this cannot be applied by analogy to cases other than those specifically indicated in the text of the law, nor even interpreted extensively beyond the formal and literal meaning, and expressed in the article of reference.

The application of Article 36 in fact draws on the already-harmonised provisions where it states that 'Where food information referred to in Articles 9 and 10 is provided on a voluntary basis, such information shall comply with the requirements laid down in Sections 2 and 3 of Chapter IV.'

In the opinion of Italy, Article 36(1) must be interpreted as meaning that, with reference to the information referred to in the exhaustive list from Articles 9 and 10 of the regulation, voluntary information may be provided only if the food in question is exempted from the obligation to provide such information and with the recommendation that it complies with the requirements set out in Sections 2 and 3 of Chapter IV.

The list of mandatory claims in Article 9(1)(l) contains the nutrition declaration.

However, with reference precisely to this information, the European legislator has decided, under the provisions of Article 35, to allow for voluntary forms of expression relating to the energy value and quantity of nutrients.

This clearly points to the intention to regulate and harmonise the criteria and methods for adopting voluntary information relating to the claim of the nutritional table provided for in Article 9.

In conclusion, it is believed that any additional forms of expression of the energy value and quantities of nutrients must necessarily fall within the scope of Article 35, and are therefore excluded from the voluntary claims provided for operators by Article 36.

Italy has always believed that if this were not the case, food business operators would always have the possibility to voluntarily integrate all the harmonised indications provided for by the regulation by simply referring to Article 36.

4. Compatibility with the provisions of Regulation (EC) No 1924/2006

The Luxembourg notification refers to Regulation 1924/2006, and the Commission itself states in its report that the Nutriscore system 'may be covered' as a beneficial indication under this Regulation, only for products with a green score. In the opinion of Italy, under the current legislation, this is a generic indication that could only be acceptable if accompanied by a specific health indication that has already been approved.

Article 10 of Regulation (EC) No 1924/2006 states in paragraph 3 that: 'Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14.'

Based on Article 10 of Regulation (EC) No 1924/2006, in general, health claims are prohibited. Only those that are in



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

compliance with the general and special regulations are permitted, as well as those that have also obtained authorisation in accordance with community provisions and, finally, are included on the list of authorised claims.

In this regard, it is important to emphasize that authorisation for health claims pertains to the European Commission, which decides based on the opinions expressed by the European Food Safety Authority (EFSA), which examines and verifies the validity of the scientific evidence supporting the claims that commercial operators want to use. It is clear that claims which do not meet the criteria set out above are imperatively prohibited.

Nevertheless, it has been noted that for nutritional and health claims there are legal provisions governing the presence of labels or, in the absence of labelling, the presentation and advertising of an expression relating to both the importance of a complete diet and a balanced and healthy lifestyle, both for the quantity of food and the methods of consumption necessary to obtain the desired beneficial effect.

If it is understood correctly, it will therefore be necessary to make consumers understand that if the same symbol appears in a green colour (light green and dark green) it must be considered a beneficial nutrition claim, without the need to specify whether it refers to the energy value or to any given nutrient: low calorie, reduced calorie, low fat, low sugar, low sodium, etc.

As such, it could happen that those looking for low-sodium products may end up buying a food whose claim (the green colour) refers instead to a low-sugar intake.

In reality, such a system should not be able to fall within the definition of 'nutrition claim' under Article 2(4) of Regulation (EC) No 1924/2006.

In fact, the algorithm used and the resulting value do not make it possible to highlight to the consumer if that individual food is characterised by:

- a reduced or increased intake or,
- a non-intake of energy (caloric value) and/or
- containing in reduced or increased proportions, or
- containing no other nutrients.

The consumer will therefore be led to believe that, regardless of their dietary needs, the product is certainly preferable to others in the same category, encouraging its consumption (without limits) since it is understood that the green colour has identified a food that is certainly not harmful to health.

Any colour other than green summarises the nutritional value of the food as a whole and is seen as a sign of danger (as the colour red is universally seen) to the consumer, without clearly identifying the reason (energy value? salt? sugar? fat?).

5. Criticism of the new Nutriscore algorithm

The new algorithm, which would be part of the so-called 'nutritional profiles' that as is known, are not yet identified and harmonised at the European level, disregards the guidance on nutrient profiling issued by EFSA in 2022, and has, in this respect, the following critical points:

- The protein content is further emphasised, while it is not considered relevant by EFSA profiling (since the whole European population consumes more protein than necessary);
- it does not take into account the importance of the content of potassium and other micronutrients;
- it does not include whole grain products as a favourable component;
- it does not consider the variability of eating habits and traditions in the different countries of the European Union as well as the different methods of consumption (frequency and quantity);
- it does not provide that an individual food cannot correspond to the nutritional profile of a nutritionally adequate diet;
- it does not provide for the presence of added/free sugars;
- it attaches greater importance to non-favourable components than favourable ones;
- it penalises drinking milk (having included it among the drinks) which is downgraded from a score of A to B when EFSA lists it among products that promote calcium intake.

This lack of attention to the EFSA nutrient profiling document is serious, since the adoption of the new notified algorithm is motivated by the need to meet the results of the most advanced research and the indications of the institutions responsible for promoting healthy nutrition.

Against this background, Italy requests the following information:



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

1. what is the legal basis on which the notification in question is based;
2. when and if the procedure provided for in Article 23 of Regulation 1924/2006 was completed;
3. which European standard is applied for all products that have a 'score' other than green on which the Nutriscore is based;
4. whether from a legal point of view, in application of EU Regulation 1169/2011, it is possible for MS to legislate voluntarily in accordance with Article 36;
5. whether voluntary operator information can be assessed and justified under Article 36 of the TFEU as with national measures;
6. the reasons for disregarding the nutrition profiling claims issued by EFSA in 2022.

For a detailed analysis of the problems inherent in the Nutriscore system from a strictly nutritional point of view, please refer to the annex to this detailed opinion:

Annex 1

The limits of front-pack labels of a directional type. University of La Sapienza-Rome

ANNEX 1

The limits of front-pack labels of a directional type

University of La Sapienza-Rome

1. Algorithm arbitrariness: 'Directional' systems (and in particular Nutriscore – NS) often evaluate the nutritional value of foods through arbitrary or undefined algorithms.

The NS algorithm has already been modified twice on the basis of the opinion of a panel of experts, which, although qualified, represents a low level on the scale of scientific validity of publications.

In addition, there are some inherent difficulties in establishing standardised nutritional profiles at a European level, such as the applicability to individual foods of nutrient intake recommendations set for the general diet, the lack of uniform data for food composition and consumption across the Union, and differences in nutrient intake recommendations and guidelines for proper nutrition adopted by individual countries (EFSA Scientific Opinion, 2008). A study conducted in the Netherlands (where NS was adopted) showed that for cheeses, ready meals, soups and sauces (2299 products verified):

- o there was an uneven distribution of the products between the different categories of the NS;
- o the NS scores of a large amount of products were not in line with the Dutch dietary criteria and guidelines; and
- o there was no high correlation between NS and nutrients that affect health in most product groups (Van Tongeren C et al, 2020).

The latest revision of the Nutriscore algorithm has further changed the table leading to the worsening of some scores (prosciutto crudo from D to E; olives C to E) and to the improvement of others (olive oil from C to B, corn oil from D to C). These changes have presumably occurred in connection with new calculations made by changing the value attributed to protein content, salt or considering other aspects that are not always clear. These new considerations are based solely on the opinion of the experts involved in the drafting of the Nutriscore and are not supported by literature on the impact on health status and/or nutrition literacy that should justify the adoption of the label.

For the sake of completeness, please note that the most recent changes concerned:

- o SUGAR, a change in the scoring scale; moves from a scale from 1 to 10 to a new scale from 1 to 15 points, thus attributing an even more negative role;
- o SALT, a change in the scoring scale; moves from a scale from 1 to 10 to a new scale from 1 to 20 points, thus attributing an even more negative role;
- o FIBRE, the scoring scale in the old version started at 0.9 g while in the new version it starts at 3 g. This means that to obtain 1 'positive' point in the old version you needed 0.91 g and in the new version you now need more than 3 g;
- o PROTEIN, the point allocation scale in the old version started at 1.6 g and in the new version it starts at 2.4 g, but at the same time the scale increases from 5 points to 7 points in the new version, and there is a new limit for red meat of 2 points;
- o There is a new calculation method for the new category Oils, Fats and Nuts;
- o CHEESES, although some of these are penalised because of salt, most score better because they have more protein points in the new version and the algorithm calculation predicts that protein points will always be subtracted for them.



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

- Note that the change of label may pose problems for the consumer who may find products (perhaps from different companies) with different labels on sale for the next two years.

2. Non-real reference standard: 'directional' systems (e.g. NS) are based on a standard amount of food (100 g or 100 ml) that almost never corresponds to the portions usually consumed.

The resulting information is therefore separated from the reality of the consumer's behaviour and provides unnecessary or even misleading information. Some foods may obtain favourable scores per 100 g, although they are generally consumed in much larger quantities (e.g. plant-based pizza, diet soft drinks), while other foods may obtain (again per 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).

3. Restriction of the algorithm: the final result (colour or letter) is the (unknown) combination of different information

Front-pack labels such as Nutriscore provide an overall assessment of the individual food, which may be the result of a large number of combinations of levels of different factors considered, e.g. 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 seeds, nuts and olive oils). Although the system is not recommended as a tool to compare the nutritional values of products of different categories (although the algorithm was developed in this way), consumers will inevitably be led to consider a 'green' food healthier than a 'red', regardless of the food group they belong to.

4. Loss of information especially for the most fragile categories

A system that does not provide information on why a certain colour has been attributed to a particular food is absolutely useless and perhaps dangerous for the most fragile categories (such as children, the elderly, individuals with specific health needs), who have specific nutritional needs, and that could be misled by the colour/letter of the FOPL. For example, consumers who have problems with being overweight/obese and who want to control their caloric intake may choose a product that has a green label, but with a higher energy density, compared to a product of the same category that has a label.

5. Limitation of parameters considered with prevalence of those considered negative

'Directional' FOPLs focus on nutrient content with 'unfavourable' effects (in the NS these nutrients give up to 40 negative points compared to nutrients with 'favourable' effects, which bring a maximum of 15 positive points) (Visioli F et al, 2021). This approach is at odds with more recent scientific evidence that states that dietary policies focused on promoting the intake of dietary components for which current intake is below the optimal level may have a greater effect than policies that are only 'negative'. Among the 15 nutritional factors that most affect health, 11 refer to foods and nutrients that are consumed in insufficient amounts, such as whole grains, nuts, seeds and seafood. Only four of these factors that affect health (sodium, red meat, processed meat and sugary drinks) are consumed in excessive amounts. Excluding sodium, these play a negligible role as determinants of health status (GBD Diet Collaborators, 2019; Foreman KJ et al, 2018). The evidence we have from the literature shows that it is the food patterns as a whole that have a positive (see Mediterranean diet) or negative (see the Western diet) impact on health status. Individual foods or nutrients have minimal effect. They often represent a biomarker of unhealthy behaviour: both saturated fatty acids and butter (among the most frequently 'incriminated' nutrients/foods) taken individually have not demonstrated any harmful effects, but they represent the indicator of a set of other elements (being overweight/obese, sedentary, etc.) that overall represent a risk to health.

6. Low educational potential: indications lead to not consuming a certain food rather than acquiring 'correct' eating behaviour

'Directional' FOPLs are not an effective tool for the consumer to properly combine different foods or to adopt a specific



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

eating pattern (Visioli F et al, 2021). Therefore, they are not an 'educational' tool and do not achieve the objectives proposed by the European Commission, which demands that food information to consumers should enable them to undertake healthy and balanced diets. On the contrary, 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 directional FOPLs distract attention from the nutrition labels on the package (Oswald C et al, 2022).

7. Decreased effectiveness of 'negative' messages over time

'Directional' warnings often show a tendency to a 'wear' effect (decrease in the effectiveness of a warning message over time). Experience with labels on cigarette packets has shown that, after a first success, it was necessary to implement the label with an image for a more effective result. Even so, after a rapid increase in effectiveness, the wear effect has been observed again and, for this reason, some governments have decided to change the images displayed frequently to maintain the effectiveness of the messages over time (Hammond D et al, 2007; White V et al, 2015). An educational approach (as in 'informational' FOPLs) can reduce this effect by empowering consumers.

8. 'Halo' effect with overestimation of the positive effect of foods labelled 'green'

The messages proposed by the 'directional' FOPL can induce consumers to perceive products bearing a 'green' label as healthier and to underestimate the energy content of foods classified as 'healthy'. This can affect food purchase intentions, leading consumers to over-consumption of these foods precisely because they are perceived as 'healthy'. An inexperienced consumer may erroneously attempt to follow a diet consisting only of products from groups A (dark green) and B (light green) which is not necessarily nutritionally adequate.

9. Simplistic approach that bases reasoning on foods (to be consumed or avoided) and is unable to promote food models for which we have evidence of effectiveness in the prevention of chronic and degenerative diseases

The simplistic approach of the 'directional' FOPL does not necessarily lead to the adoption of healthy food patterns, but more simply to increase the consumption of certain foods (e.g. those rich in protein) and to penalise the consumption of others (olive oil or eggs, respectively rich in fatty acids or cholesterol). The end result is often an unbalanced diet (high protein content, for example) the effect of which on the risk of developing non-communicable diseases has yet to be demonstrated (Ikonen I et al, 2020). The American Dietetic Association (ADA) has published a summary paper that warns nutrition professionals against classifying foods as good or bad because they might favour unhealthy eating behaviours. When recommendations focus their indication on foods to be avoided, the summary states, this 'good/bad' dietary dichotomy is automatically created (Mobley AR, 2009). In a 2013 document, the ADA also states that:

- o the food model as a whole must be the most important objective to achieve the goal of healthy eating;
- o all foods may fall under this scheme if consumed in moderation, with adequate portions and combined with physical activity;
- o the classification of individual foods as good or bad is excessively simplistic and can promote unhealthy eating behaviours;
- o focusing on variety, moderation, and proportionality in the context of a healthy lifestyle, rather than focusing on nutrients or individual foods, can help reduce consumer confusion and prevent unnecessary dependence on supplements.

Freeland-Graves JH, Nitzke S; Academy of Nutrition and Dietetics. Position of the academy of nutrition and dietetics: total diet approach to healthy eating. *J Acad Nutr Diet.* 2013 Feb;113(2):307-17. doi: 10.1016/j.jand.2012.12.013

10. Lack of scientific evidence on real effectiveness: current evidence shows an effect on the 'consumption' of certain foods, but not on the impact they have on consumers' 'health'

At the moment the studies that associate the adoption of a FOPL with an improvement in health are very few and mainly concern the NS. None of these are longitudinal and can identify a causal link between the adoption of FOPL and the change in health status. At best, the association is with the consumption of a particular food (often in virtual contexts); an association with the variation of a risk biomarker has rarely been found; never with the impact on morbidity or mortality.



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Single Market Enforcement
Notification of Regulatory Barriers

Many of the studies, in fact, have virtually applied the NS to pre-existing cases hypothesising that the adoption of NS can, if applied to that specific case, influence the adoption of different dietary patterns (which in reality were spontaneously adopted by the enrolled subjects) and the appearance, over time, of positive effects on the state of health. The use of data extracted from existing studies, to which the possible effect of NS was subsequently applied with mathematical models, is a methodologically questionable experimental model, which by definition cannot demonstrate the presence of causal relationships between the parameters considered. In addition, a real-life environment may provide significantly different results due to major interfering and confounding factors (Storcksdieck Genannt Bonsmann S et al, 2020; Clarke N et al, 2021).

The literature review being completed by Italian scientific institutions on the impact of NS on health status and nutrition knowledge has resulted in the selection of 46 articles

- o 30 are related to food choices, but most of them (25) focus only on buying intentions and not on actual sales;
- o 15 try to show the effect on health, but 14 are retrospective (these studies have not explored the realistic impact of NS on health status in a longitudinal perspective, but have assessed disease risk through macrosimulation) and only one is prospective but, again, it is a simulation of what could happen if...;
- o there is no study on the ability of NS to improve nutritional knowledge;

finally only a verification of the ability of the NS to increase adherence to a healthy diet (Dubois P et al. J Acad Market Science 2023) and concludes that 'Compared to what could have been expected based on the results of recent laboratory studies, the effects of even the best nutrition label, Nutri-Score, were disappointingly small [slightly increased purchases of the best tercile of products in terms of nutritional quality (those considered healthier), slightly decreased purchases of products in the second tercile and had no effect on products in the lowest tercile (those considered less healthy); insignificant effects on the purchases of unlabelled products (among which the typical foods of the Mediterranean diet are often included: fruits, vegetables, legumes, bread)]. Enthusiastic estimates of the impact that adoption of the FOPNL would have on mortality from non-communicable diseases must be significantly downgraded'.

European Commission

Contact point Directive (EU) 2015/1535

email: grow-dir2015-1535-central@ec.europa.eu