



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/(2024) 0196

Directive (EU) 2015/1535

Notification: 2023/0601/FR

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 24-04-2024.

Detailed opinion - Avis circonstancié - Ausführliche Stellungnahme - Подробно становище - Podrobné stanovisko - Udførlig udtalelse - Εμπεριστατωμένη 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 - Avis detaliat - Podrobné stanovisko - Podrobno mnenje - Detaljerat yttrande

Extends the time limit of the status quo until 24-04-2024. - Prolonge le délai de statu quo jusqu'au 24-04-2024. - Die Laufzeit des Status quo wird verlängert bis 24-04-2024. - Удължаване на крайния срок на статуквото до 24-04-2024. - Prodłużuje lhůtu současného stavu do 24-04-2024. - Fristen for status quo forlænges til 24-04-2024. - Παρατείνει την προθεσμία του status quo 24-04-2024. - Amplía el plazo de statu quo hasta 24-04-2024. - Praeguse olukorra tähtaega pikendatakse kuni 24-04-2024. - Jatkaa status quon määräaika 24-04-2024 asti. - Produžuje se vremensko ograničenje statusa quo do 24-04-2024. - Meghosszabbítja a korábbi állapot határidejét 24-04-2024-ig. - Proroga il termine dello status quo fino al 24-04-2024. - Status quo terminas pratęsiamas iki 24-04-2024. - Pagarina "status quo" laika periodu līdz 24-04-2024. - Jestendi t-terminu tal-istatus quo sa 24-04-2024. - De status-quoperiode wordt verlengd tot 24-04-2024. - Przedłużenie status quo do 24-04-2024. - Prolonga o prazo do statu quo até 24-04-2024. - Prelungește termenul status quo-ului până la 24-04-2024. - Predlžuje sa lehota súčasného stavu do 24-04-2024. - Podaljša rok nespremenjenega stanja do 24-04-2024. - Förlänger tiden för status quo fram till 24-04-2024.

The Commission received this detailed opinion on the 23-01-2024. - La Commission a reçu cet avis circonstancié le 23-01-2024. - Die Kommission hat diese ausführliche Stellungnahme am 23-01-2024 empfangen. - Комисията получи настоящото подробно становище относно 23-01-2024. - Komise obdržela toto podrobné stanovisko dne 23-01-2024. - Kommissionen modtog denne udførlige udtalelse den 23-01-2024. - Η Επιτροπή έλαβε αυτή την εμπεριστατωμένη γνώμη στις 23-01-2024. - La Comisión recibió el dictamen circunstanciado el 23-01-2024. - Komisjon sai üksikasjaliku arvamuse 23-01-2024. - Komissio sai tämän yksityiskohtaisen lausunnon 23-01-2024. - Komisija je zaprimila ovo detaljno mišljenje dana 23-01-2024. - A Bizottság 23-01-2024-án/én kapta meg ezt a részletes véleményt. - La Commissione ha ricevuto il parere circostanziato il 23-01-2024. - Komisija gavo šią išsamiai išdėstytą nuomonę 23-01-2024. - Komisija saņēma šo sīki izstrādāto atzinumu 23-01-2024. - Il-Kummissjoni rċeviet din l-opinioni dettaljata dwar il-23-01-2024. - De Commissie heeft deze uitvoerig gemotiveerde mening op 23-01-2024 ontvangen. - Komisja otrzymała tę opinię szczegółową w dniu 23-01-2024. - A Comissão recebeu o presente parecer circunstanciado em 23-01-2024. - Comisia a primit avizul detaliat privind 23-01-2024. - Komisia dostala toto podrobné stanovisko dňa 23-01-2024. - Komisija je to podrobno mnenje prejela dne 23-01-2024. - Kommissionen mottog detta detaljerade yttrande om 23-01-2024. - Fuair an Coimisiún an tuairim mhionsonraithe sin maidir le 23-01-2024.

MSG: 20240196.EN

1. MSG 115 IND 2023 0601 FR EN 24-04-2024 23-01-2024 IT DO 6.2(2) 24-04-2024

2. Italy

3A. MINISTERO DELLE IMPRESE E DEL MADE IN ITALY
Dipartimento Mercato e Tutela



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Direzione Generale Consumatore e Mercato
EX Divisione VI – Normativa tecnica – Sicurezza e conformità dei prodotti
Via Molise, 2 - 00187 Roma

3B. Ministero delle imprese e del Made in Italy
Ministero dell'agricoltura, della sovranità alimentare e delle foreste
Ministero della salute

4. 2023/0601/FR - C50A - Foodstuffs

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

6. Following the examination of the “Decree laying down a complementary form of presentation of the nutritional declaration recommended by the State”, corresponding to notification 2023/0601/FR, by the competent Italian Ministries (Ministry of Health, Ministry of Business and Made in Italy and Ministry of Agriculture, Food Sovereignty and Forests), Italy issues the following detailed opinion.

Italy had previously issued a detailed opinion in relation to France’s previous notification 2017/159/F, which set out the conditions of use of the ‘Nutri-Score’ logo.

It is currently considered necessary to re-propose a number of technical-legal issues related to the use of the Nutri-Score logo that have already been represented, but which – in Italy’s opinion – at the moment have not received comprehensive answers either from the countries that previously notified the use of the logo, nor from the legal services of the European Commission.

Italy would be grateful to France if it would clarify the following critical issues in a timely manner.

1. System characteristics

The draft French standard revises the specifications for the calculation of the Nutri-Score logo for food products, currently defined by the Decree of 31 October 2017 laying down the form of supplementary submission of the nutrition declaration. The draft decree therefore aims to formally adopt the new Nutri-Score algorithm by modifying the current calculation method.

Italy considers it appropriate to issue a detailed opinion in order to understand how this system can be compatible with the Union legislation currently in force, both on the labelling of foodstuffs and on claims covered by Regulation (EC) 1924/2006.

First of all, it is argued that, in the notification notice, France considered that it indicated Article 35 of Regulation 1169/2011/EU as the legal reference under which the notification was made.

In fact, similar to the previous notification submitted by France in 2017 (notification 2017/159/F) concerning the adoption of Nutri-Score, 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’.

Back in 2017, Italy intervened with a detailed opinion indicating, among other things, that the system could not be regarded as falling under the case referred to in Article 35 of Regulation 1169.

That approach, as from 2017, was also supported by the Commission itself, which observed, by Message No 303 – ‘Commission communication – TRIS/(2017) 01957, that: ‘The labelling system attached to the notified draft does not require indication of the energy value and the amount of nutrients as such, but rather it refers to the overall nutritional quality of the foodstuff in question. The Nutri-Score scoring system therefore falls outside 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



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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. Incompatibility with the provisions of Article 35 of Regulation 1169/2011.

With regard to the compatibility of Nutri-Score with Article 35 of Regulation 1169, also in view of the position taken by the Commission on this point, Italy reiterates the same considerations as those set out in the French, Belgian, German and Luxembourg notification, which are to be considered fully recalled.

Nevertheless, since the French authorities explicitly reiterate the argument that the regulatory anchoring of the Nutri-Score is to be found in Article 35 of Regulation 1169, it is considered appropriate to summarise certain observations below in order to demonstrate the failure to comply with certain conditions of applicability laid down by the aforementioned legal provision.

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 2023/0601/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 Article 30(3) cited above. It must therefore be concluded that the Nutri-Score scheme is incompatible with those provisions.

The argument that Nutri-Score does not actually give rise to a repetition of the information contained in the mandatory nutrition declaration is also questionable, since its graphic form does not make the algorithm and therefore the elements that constitute it visible to the consumer. This argument is to be disputed precisely because that said system cannot be framed in the forms of expression and presentation referred to in Article 35.

Another element to be considered as proof of the incompatibility of Nutri-Score with the requirements of Regulation 1169 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 Nutri-Score 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 quite clear that the Nutri-Score does not comply with the requirements of Article 35 and that, even in the unlikely event that it were to be upheld, it would have to be concluded that it is fundamentally incompatible with the rules of Regulation 1169. In light of all the above, it is quite clear that the Nutri-Score does not comply with Article 35 of Regulation 1169, since the guiding principle of the article is the possibility for Member States to adopt additional forms of expression that facilitate the understanding of the nutritional characteristics of the food and not, on the contrary, to offer an overall judgement on the health effect of the food itself. The Nutri-Score does not fall within the scope of this provision, as the scheme translates into a merit judgement on the alleged ‘wholesomeness’ of the foodstuff.

3. Incompatibility with the provisions of Article 36 of Regulation 1169/2011/EU

In its report COM(2020) 207 final of 20 May 2020, the Commission stated, in the part dealing with systems that do not fall under Article 35 of Regulation 1169/2011 (such as the Nutri-Score) 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



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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.' Italy, in this regard, rejects the argument that the Nutri-Score, when it is coloured orange and red, falls under the voluntary forms of expression referred to in Article 36 of Regulation 1169, since it is considered that the provisions of the first paragraph of Article 35 are the only way to submit voluntary forms in addition to the nutrition declaration that the Member States can recommend. On the contrary, Article 36 is addressed to economic operators who, at their own discretion, can provide voluntary information to the consumer regarding the elements referred to in Article 9 and 10 of Regulation 1169/2011, regardless of any recommendations by the 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) of Regulation 1169/2011 must be interpreted as meaning that, with reference to the information referred to in the exhaustive list from Articles 9 and 10, 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. It follows that, in doing so, it was intended to regulate and harmonise the criteria and arrangements for adopting voluntary information relating to the indication of the nutrition 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 considered that if this were not the case, food business operators would still have the possibility to voluntarily supplement all the harmonised indications provided for in Regulation 1169/2011, simply by referring to Article 36.

In addition, Article 36 of the Regulation provides that, with regard to mandatory food information, mandatory particulars and supplementary mandatory particulars for specific types or categories of foods, if provided on a voluntary basis, certain requirements must be confirmed.

These requirements dictate the following: (i) not to mislead the consumer; (ii) not to be ambiguous or confusing to the consumer; and (iii) where appropriate, to be based on relevant scientific data.

Italy considers that Nutri-Score misleads the consumer by providing a summary assessment of the individual food product, apart from any consideration on the nutritional profiles of the various foods that contribute to defining a balanced diet. Coloured indications on products are, in fact, biased by nature, i.e. they tend to suggest to consumers that they may freely consume (green colour) or may not consume at all (red colour) a certain food.

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

The French notification refers to Regulation 1924/2006, and the Commission itself states in its report that the Nutri-Score 'could fall' as an indication (rectius, 'claim') within the scope of that regulation, only for products with a green score.

First of all, Italy does not consider that the Nutri-Score can qualify as a nutrition claim. Regulation 1924 provides that nutrition claims are permitted only if they comply with the general conditions set out in Regulation 1924 and if listed in the relevant annex.

The Nutri-Score cannot be classified as a nutrition claim as it does not fall within any of the entries or categories covered by the Annex.

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 1924/2006/EC provides in paragraph 3 that: 'Reference to general, non-specific benefits of the



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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.’

Italy considers, therefore, that the Nutri-Score should qualify as a health claim, offering an overall assessment of the intrinsic quality of the individual food, thus setting out an indication that suggests and implies the existence of a relationship between the food and human health.

In general, according to Article 10 of Regulation 1924/2006, health claims are prohibited. Only those that are in compliance with the general and special regulations are permitted, as well as those that have also obtained authorisation in accordance with Union provisions and, finally, are included on the list of authorised claims.

In the case of use of a health claim, the application for authorisation shall be submitted by the competent national authority of a Member State, which shall, inter alia, inform the European Food Safety Authority (‘EFSA’), making the application and the relevant documentation available. On its behalf, EFSA, in addition to informing the Member States and the Commission, is required to issue an opinion in which: (i) it ensures that the proposed wording for the health claim is based on scientific evidence; (ii) it assesses whether the wording meets the criteria laid down in Regulation 1924; (iii) it comments on the proposed wording for the health claim, assessing whether it is understandable and meaningful for the average consumer.

Indications that do not meet the above criteria are prohibited.

Italy is not aware that the required involvement of EFSA has occurred.

Moreover, it is necessary to repeat how, with the adoption of a traffic light system such as the Nutri-Score, the consumer will be led to believe, regardless of their own dietary needs, that a product is definitely preferable if it is labelled with a green claim over others in the same category, encouraging its (unlimited) consumption, since it is understood that the colour green identifies a food that definitely does not harm health.

Any colour other than green summarises the nutritional value of the food as a whole and is seen as a sign of danger (universally, the colour red) 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:

1. when and if the procedure provided for in Article 23 of Regulation 1924/2006 was completed;
2. which European standard is applied for all products that have a ‘score’ other than green on which the Nutriscore is based;
3. 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;
4. whether voluntary operator information can be assessed and justified under Article 36 of the TFEU as with national measures;
5. the reasons for disregarding the nutrition profiling claims issued by EFSA in 2022.



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For a detailed analysis of the critical issues inherent to the Nutriscore system from a strictly nutritional point of view, including with specific regard to the problems related to the new algorithm, please refer to the annexes to this detailed opinion:

Annex 1

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

Annex 2

Comments on France's notification 2017/159/F.
CREA Food and Nutrition Research Centre

Unlike Annex 1, which is included below, the content of Annex 2, due to the technical limitations of the TRIS platform, will be conveyed to the Member States by e-mail to the address of the national contact points, as indicated by the Commission's DG for Internal Market, Industry, Entrepreneurship and SMEs.

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



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points in the new version and the algorithm calculation predicts that protein points will always be subtracted for them.

- 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 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



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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:

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. 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*



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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'.

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