



EUROPEAN COMMISSION

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

Message 201

Communication from the Commission - TRIS/(2024) 1097

Directive (EU) 2015/1535

Notification: 2023/0601/FR

Forwarding of the response of the Member State notifying a draft (France) to of Italy.

MSG: 20241097.EN

1. MSG 201 IND 2023 0601 FR EN 24-04-2024 25-04-2024 FR ANSWER 24-04-2024

2. France

3A. Ministères économiques et financiers

Direction générale des entreprises

SCIDE/SQUALPI - Pôle Normalisation et réglementation des produits

Bât. Sieyès -Teledoc 143

61, Bd Vincent Auriol

75703 PARIS Cedex 13

3B. Ministère de la santé et de la prévention

Direction générale de la santé.

Sous-direction de la prévention des risques liés à l'environnement et à l'alimentation (SD-EA)

Bureau alimentation et nutrition (EA3)

14 avenue Duquesne

75350 Paris 07 SP

4. 2023/0601/FR - C50A - Foodstuffs

5.

6. On 24 October 2023, the French authorities notified under Directive (EU) 2015/1535 a draft order laying down the complementary form of presentation of the nutritional declaration recommended by the State pursuant to Articles L. 3232-8 and R.3232-7 of the Public Health Code (notification No 2023/0601/FR).

As part of this notification, and pursuant to Article 6(2) of Directive (EU) 2015/1535, the Italian authorities issued a detailed opinion on 23 January 2024, extending the standstill period until 24 April 2024.

The purpose of the French authorities' comments below is to respond to each of the questions raised by the Italian authorities on the draft text notified.

1. On the characteristics of the system

As a reminder, Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers contains basic provisions for ensuring a high level of consumer protection in the field of food information, while respecting differences in consumers' perception and information needs, while ensuring the proper functioning of the internal market.

In accordance with Article 9(1)(l) of this Regulation, a nutrition declaration must appear on the packaging of pre-packaged food. This mandatory nutrition declaration shall provide information on the energy value of this food and the presence of certain nutrients. More specifically, Article 30(1) specifies that the mandatory nutrition declaration shall include elements on the energy value and amount of fat, saturated fatty acids, carbohydrates, sugars, protein and salt. In addition, Article 35(1) of Regulation (EU) No 1169/2011 provides that the energy value and the amounts of nutrients



EUROPEAN COMMISSION

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

referred to in Article 30 may be expressed in other forms and/or presented by means of graphs or symbols in addition to words or numbers, if certain requirements are met. In addition, paragraph 2 of this provision provides that Member States may recommend food business operators to use one or more additional forms of expression or presentation of the nutrition declaration which they consider best meet the requirements laid down in points (a) to (g) of paragraph 1. Lastly, in that regard, it should be noted that it is apparent from Recital 34 of the same Regulation that the mandatory nutrition information to be provided on packaging 'should encourage action on nutrition in the context of public health policies, which could give rise to scientific recommendations for nutritional education of the public, and enable them to make informed choices on food'.

With this in mind and in view of the impact of nutrition on the health of the population, based on sound scientific evidence and a stakeholder consultation process, France introduced in 2017 a graphical, simple, visible and readable system, based on voluntary food business operators, complementary to the mandatory nutrition declaration, in accordance with Article 35 of Regulation (EU) No 1169/2011, and which contributes to enabling consumers to make informed food choices. More specifically, Article L.3232-8 of the Public Health Code provides that 'in order to facilitate consumer choice with regard to the energy and nutrient intake to their diet, the mandatory nutrition declaration provided for in Regulation (EU) No 1169/2011 may be accompanied by an additional presentation or expression by means of graphs or symbols'.

Thus, the Nutri-Score has a threefold objective:

- inform consumers, at the time of their purchase, of the overall nutritional quality of foods, enabling them to compare products and guide their choices towards better nutritious foods and drinks for a daily diet that is more favourable to health;
- encourage manufacturers to improve the nutritional quality of the foods that they produce, as part of a reformulation or innovation for new products, by offering them the opportunity, through the system, of adding value to their effort in the context of market competition rules;
- facilitate the provision of nutritional advice to patients by the health professional, whether as part of primary prevention or treatment of a disease.

The supplementary form of presentation of the nutrition declaration consists of nutrition label in accordance with a set of specifications laid down by the Order of 31 October 2017, revised on 30 August 2019. This Order was notified under Directive No 2015/1535 (notification No 2017/159/F). In accordance with the provisions of this Order, the nutrition label, Nutri-Score, is calculated on the basis of a single overall score taking into account, for each foodstuff or drink, a negative component and a positive component. The negative component takes into account energy density, saturated fat, sugars and salt. The points of the positive component are awarded on the basis of the content of fibres, proteins, as well as fruits, vegetables and dried vegetables, for the vitamins and micronutrients they contain. The nutritional score underlying the Nutri-Score is based on an adaptation of the nutritional profile of the Food Standards Agency, which has been the subject of extensive scientific validation.

The draft text notified by the French authorities revises the Order of 31 October 2017, as amended in August 2019, and more specifically the Nutri-Score nutritional label calculation system, on the basis of the changes recommended by the Nutri-Score Scientific Committee on Transnational Governance and adopted by the national authorities who are members of its steering committee. The French authorities refer to the information provided when this draft text was notified as regards the new calculation methods and the objectives pursued by this amendment.

2. On the absence of incompatibility with the provisions of Article 35 of Regulation (EU) No 1169/2011 (INCO)

First, the Italian authorities consider that the Nutri-Score system does not fall within the scope of Article 35 of Regulation (EU) No 1169/2011 and is therefore incompatible with this provision.

As a reminder, in accordance with Article 35(1) of the Regulation, in addition to the forms of expression provided for in Article 32(2) and (4) and Article 33 and the presentation provided for in Article 34(2), the energy value and the amounts of nutrients referred to in Article 30(1) to (5) may be expressed in other forms and/or presented by means of graphs or symbols in addition to words or numbers, if certain requirements are met.

On this point, the French authorities consider that Nutri-Score is a complementary form of presentation or expression of the mandatory nutrition declaration, based on the voluntary participation of food business operators, which:

- (i) is based on robust consumer studies, which are scientifically valid and not misleading the consumer, in accordance with point (a)(1) of Article 35 of Regulation (EU) No 1169/2011. Indeed, the Nutri-Score is a form of expression of the nutrition declaration, taking into account a set of mandatory elements on nutrition labelling and in particular in the



EUROPEAN COMMISSION

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

mandatory nutrition declaration, for 100 g/100 ml of the product: energy, saturated fatty acids, sugars, salt, proteins, fibres and percentage of fruits, vegetables, legumes and nuts. It is based on the calculation of a nutritional score that characterises the nutritional quality of each food. The original nutritional score was developed by an Oxford team for the Food Standard Agency (Rayner et al. 2009). Its adaptation in the French context was carried out by the High Council for Public Health in 2015. The results of the Nutri-Score studies and its calculation algorithm showed that this system enabled to: (1) classify foods and beverages consistently with nutritional recommendations, (2) help individuals to better identify and compare products according to their nutritional composition, in particular the most disadvantaged (lowest levels of education, low levels of knowledge of nutrition) (CREDOC 2017; Ducrot et al. 2015a Ducrot et al. 2015b – see numerous references on the website of the French Ministry of Health <https://sante.gouv.fr/prevention-en-sante/preserver-sa-sante/nutrition/nutri-score/etudes-et-rapports-scientifiques/>)

- (ii) is the result of the consultation of a wide range of interest groups, in accordance with Article 35(1)(b). As a reminder, in the context of the notification to the Commission of the draft order on the Nutri-Score in April 2017, the French authorities had already demonstrated that this system was the result of discussions initiated with all stakeholders by the Minister for Health in March 2015, through 10 consultation meetings, supplemented by 12 meetings of the steering committee for the study under real purchasing conditions between January 2016 and April 2017. At the end of 2016, this work was complemented by consultation between public authorities, representatives of the food industry, consumer associations, patients and scientists concerned, and a study under real conditions carried out for 10 weeks in 60 supermarkets across France. The study was conducted in accordance with a protocol drawn up by an independent scientific committee which collected a large amount of purchasing data; it was implemented by the French Food and Health Fund, with financial resources coming half from the private food sector and half from the public authorities. Implementation of the study in the shops was very strictly controlled under the supervision of a steering committee comprising representatives of the public authorities, the agri-industrial sector, distributors and consumers. A representative of the European Commission was been invited as an observer. The data collected in the shops were then sent to a team of scientists, led by the Toulouse School of Economics, for their analysis. This analysis covered 2,914,722 data from the till receipts of 191,790 fidelity card customers from the 60 supermarkets covered. Full transparency of the process was ensured through continuous communication on the website of the Ministry of Health. Regarding work on the new Nutri-Score calculation algorithm, a call for inputs from stakeholders (consumer associations, scientists, manufacturers, etc.) was launched in September 2021. The points raised by stakeholders were forwarded to the European Scientific Committee to feed into their work on developments in the calculation methodology.

- (iii) aims to facilitate consumers' understanding of the contribution of the foodstuff to the energy and nutrient intake from a diet or of the importance, in this regard, of the food concerned, in accordance with Article 35(1)(c). In this sense, studies have shown that, among the various logos tested, Nutri-Score is the system that best helps consumers to identify and compare the nutritional quality of products (Ducrot et al. 2015, Egnell et al. 2018), to then make choices of better nutritional quality (Scientific Committee of the Experimentation Study 2017; Crosetto et al. 2017; Ducrot et al. 2016; Julia et al. 2016, Finkelstein et al. 2019, Egnell et al. 2019, Egnell et al. 2021a, Egnell et al. 2021b, Egnell et al. 2021c – see numerous references on the website of the French Ministry of Health <https://sante.gouv.fr/prevention-en-sante/preserver-sa-sante/nutrition/nutri-score/etudes-et-rapports-scientifiques/>). These studies have demonstrated the very good interpretation of the Nutri-Score, including by people with a low level of education. Thus, these examples show that the Nutri-Score enables consumers to make an informed choice to improve the overall nutritional quality of their diet.

- (iv) is supported by scientifically valid evidence that the average consumer understands how the information is expressed or presented in accordance with point (d)(1) of that Article. In line with the above, several scientific studies have been carried out demonstrating that Nutri-Score is the most effective system to help the consumer compare the nutritional quality of products. Studies have also shown that this type of 5-colour format is perceived as easy and quick to understand by consumers.

- (v) is based on the harmonised reference intakes set out in Annex XIII to Regulation (EU) No 1169/2011; The Nutri-Score is based on the reference intakes by using a fixed percentage of the reference intakes for the allocation of the number of



EUROPEAN COMMISSION

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

points for each nutrient considered for the calculation of the nutritional score.

- (vi) is objective and non-discriminatory, in accordance with Article 35(1)(f). The expression form chosen for the Nutri-Score system makes it possible to compare products in the same category according to the specific nutritional composition of that category, and the nutrient(s) having the highest variability. For example, in breakfast cereals, sugar is a nutrient that enables us to compare a variety of products objectively. Saturated fatty acids and salt need to be taken more into account within the delicatessen. The method of calculating the Nutri-Score applicable to a food is both transparent and implemented on the basis of information available to all. It represents the nutritional quality of the food objectively and enables to use the variability of the composition of products in a given family of foods (e.g. chocolate-flavoured breakfast cereals) to show this in a way that is easily interpreted by the consumer, which cannot be perceived as discriminatory.

- vii) does not preclude the free movement of goods. In fact, the Nutri-Score system is based on voluntary participation of food business operators, so that manufacturers are in no way obliged to affix the Nutri-Score logo in order to be able to market their products. In this sense, the Nutri-Score system does not contravene the competition rules and the principles of the internal market of the European Union, as laid down in Article 34 of the Treaty on the Functioning of the European Union, according to which 'quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States', in order to 'not affect intra-EU trade in food products', and as interpreted by the Court of Justice (see: ECJ, 2003, Schmidberger, C 112/00, pt 56).

In the light of all these factors, the French authorities are justified in asserting that the Nutri-Score system, insofar as it complies with all the requirements of Article 35(1) of Regulation No 1169/2011, represents a form of expression of the nutrition declaration. This finding also entails the validity of the Nutri-Score system in the light of paragraph 2 of this Article, which provides that Member States may recommend that food business operators use one or more additional forms of expression or presentation of the nutrition declaration which they consider best meet the requirements laid down in paragraph 1(a) to (g).

Secondly, the Italian authorities note that Article 35(1) refers in particular to Article 30(3), which provides that 'where the labelling of a pre-packed foodstuff 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, saturated fatty acids, sugars, and salt.' The Italian authorities therefore consider that 'when the mandatory nutrition declaration can be repeated on the labelling of the foodstuff, the elements which may be declared shall be exclusively those referred to in points (a) or (b)'. They note in this regard that the new calculation algorithm is based on the allocation of points based on the content of salt, sugar, protein, fibre, fruit, vegetables and dried vegetables, and is thus not limited to substances that may be repeated in accordance with Article 30(3) of Regulation (EU) No 1169/2011.

However, it is not apparent from the wording of Article 35(1) of Regulation (EU) No 1169/2011 that the additional forms of expression and presentation of the mandatory nutrition declaration concern only the elements mentioned in Article 30(3) of that Regulation. The repetition of the information permitted by Article 30(3) must therefore be distinguished from the complementary form of the nutrition declaration provided for in Article 35 of the Regulation, having regard not only to the wording of those provisions but also to their subject matter. Article 30(3) concerns the repetition of any of the information contained in the nutrition declaration, whereas Article 35 provides for the possibility for economic operators to express the information in the mandatory nutrition declaration in other forms of additional expression or presentation.

Thirdly, the Italian authorities claim that Nutri-Score does not comply with Article 33(2) of Regulation (EU) No 1169/2011, which constitutes 'proof of the incompatibility of Nutri-Score with the requirements of that Regulation'.

Article 33(1) of the Regulation provides that, in certain cases expressly provided for, the energy value and amounts of nutrients referred to in Article 30 may be expressed per portion and/or per consumption unit, easily recognisable by consumers. Paragraph 2 of that provision states that 'by way of derogation to Article 32(2), in the cases referred to in Article 30(3)(b) 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. When the amounts of nutrients are expressed on the basis of per portion or per consumption unit alone in accordance with the first subparagraph, the energy value shall be expressed per 100 g or per 100 ml and on the basis of per portion or per consumption unit.' On this point, the Italian authorities argue that Nutri-Score is incompatible with Article 33(2) of Regulation (EU) No 1169/2011 in so far as the nutritional score of foods is calculated on 100 g/100 mL of the product, and not on a portion or consumption unit.

On this point, the French authorities would like to point out at the outset that the above provisions are not drafted in



EUROPEAN COMMISSION

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

binding terms. Therefore, the competent authorities have the possibility to choose whether or not to express the energy value and nutrient amounts per portion and/or consumption unit. Moreover, considering that the Nutri-Score system falls within the scope of Article 35 of Regulation (EU) No 1169/2011, it does not fall within the optional forms of expression per portion or per consumption unit provided for in Article 33. These provisions are mutually exclusive, so that the same system cannot fall within the scope of both Article 35 and Article 33. This interpretation is confirmed by the wording of Article 35(1): 'in addition to the forms of expression provided for in Article 32(2) and (4) and Article 33 and the presentation provided for in Article 34(2), the energy value and the amounts of nutrients referred to in Article 30(1) to (5) may be expressed in other forms and/or presented by means of graphs or symbols in addition to words or numbers, provided that the following requirements are met'. Consequently, the position of the Italian authorities is not tenable in the present case and would render the aforementioned provisions meaningless.

Finally, the Italian authorities consider that the guiding principle of Article 35 of Regulation (EU) No 1169/2011 is the possibility for Member States to adopt additional forms of expression that facilitate the understanding of the nutritional characteristics of the foodstuff and not to give an overall judgment on the effect on health of the foodstuff. They also maintain that Nutri-Score does not fall within the scope of this provision insofar as the Nutri-Score system constitutes a judgment based on the alleged 'wholesomeness' of the foodstuff.

As a reminder, Article 35 concerns optional forms of expression and presentations additional to the information on the mandatory nutrition declaration. Nutri-Score is in line with this logic, as demonstrated above.

We would also point out that Article L.3232-8 of the Public Health Code states, in accordance with Regulation (EU) No 1169/2011, that an additional presentation or expression, by means of graphs or symbols, may accompany the mandatory nutrition declaration 'in order to facilitate consumers' choice as regards the energy and nutrient intake to their diet. The Commission itself considers that these complementary forms of the mandatory nutrition declaration should 'aim to facilitate consumer understanding of the contribution of the food to the energy and nutrient intake of a diet' (Report from the Commission on the use of the additional forms of expression and presentation of the nutrition declaration, COM (2020) 207 final).

In this sense, Nutri-Score provides information on the nutritional quality of products in a simplified form that complements the mandatory nutrition declaration. It is based on a calculation method designed to assign a score to products in order to allow consumers to easily identify the overall nutritional quality of the products on the basis of a balance between the various favourable and unfavourable elements in the food/drink, and thus compare the products with each other. It is not intended to give an absolute assessment of the quality of a foodstuff, in a binary manner by characterising the product as 'healthy' or 'unhealthy'. Nutri-Score makes it possible to compare products within a category or between comparable food categories to help consumers choose the most favourable alternatives. Products classified as D or E on the Nutri-Score scale can still be consumed, but in appropriate frequencies and quantities, in line with the nutritional recommendations of the health authorities. In this way, Nutri-Score provides an indication of the relative contribution of the foodstuff in relation to the energy and nutrient intake of the diet, and is in line with Regulation (EU) No 1169/2011. The French authorities will also deal with some of these elements in point 5.

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

On this point, the French authorities would firstly like to point out that the information provided by Nutri-Score meets the requirements laid down in Article 36(2) of Regulation (EU) No 1169/2011, in that it 'does not mislead consumers', 'is not ambiguous or confusing for consumers' and is based on 'relevant scientific data'.

Secondly, with regard to the Italian authorities' argument that when the Nutri-Score label attributes a 'generally positive message (e.g. Using the colour green)', it qualifies as a "nutrition claim", the French authorities would like to point out that the French authorities' reply was already given with regard to the possible qualification of a 'nutrition claim' in the detailed opinion issued by Italy in 2017. In addition, the French authorities consider that the Italian authorities are contradicting themselves since, in point 4 of its detailed opinion, they argue that Nutri-Score is not a nutrition claim but a health claim. The French authorities will reply to this in point 4.

The Italian authorities also argue that when Nutri-Score has an orange and red colour, it does not fall within the voluntary forms of expression referred to in Article 36 of the above-mentioned Regulation. The French authorities would once again like to remind the Italian authorities that Nutri-Score is a global calculation system that is unique. Therefore, it is impossible to separate, based on the colours shown, the applicable Articles. As a result, Articles 35 and 36 may apply in conjunction with the Nutri-Score system, without distinguishing their application according to the colours of Nutri-Score. Finally, the Italian authorities interpret Article 36 of Regulation (EU) No 1169/2011 excessively rigorously, taking the view



EUROPEAN COMMISSION

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

that 'any additional form of expression of the energy value and quantities of nutrients must necessarily fall within the scope of Article 35 and must therefore be excluded from the voluntary information provided for by Article 36 for operators', whereas, according to a teleological reading, the two Articles are not in conflict. In this sense, as set out above, the French authorities consider that these two Articles are complementary and could therefore apply together. Thus, although the Nutri-Score was adopted in accordance with the conditions laid down in Article 35, it does not contravene the provisions of Article 36, particularly since food business operators must undertake voluntarily to adopt the Nutri-Score, which falls within the scope of Article 36 of the above-mentioned Regulation.

4. On the non-applicability of the provisions of Regulation (EC) No 1924/2006 (claims)

The Italian authorities argue that the French notification refers to Regulation (EC) No 1924/2006 and that the Commission itself indicates that Nutri-Score could be considered as a health claim. However, the Italian authorities believe that Nutri-Score cannot be considered as a nutrition claim as it does not fall under any of the headings or categories covered by the Annex to Regulation (EC) No 1924/2006 on nutrition and health claims made on foods.

However, on the basis of Article 10(3) of the said Regulation, the Italian authorities state that Nutri-Score must be considered as a health claim, 'providing an overall assessment of the intrinsic quality of the individual foodstuff, thus giving an indication which suggests and implies the existence of a relationship between the food and human health'. On this point, the Italian authorities state that, in principle, health claims are prohibited, subject to exceptions, in particular by obtaining authorisation under the supervision of the European Food Safety Authority (hereinafter 'EFSA'). The Italian authorities thus stress that they are not aware of any such authorisation having been issued to the French authorities. Finally, the Italian authorities state that with the adoption of a colour system such as Nutri-Score, consumers could be misled and prefer to consume a food labelled with a 'green claim', regardless of their own dietary needs. Indeed, the colour green would encourage the consumer to consume more of a food presented as not 'clearly harmful to health'. Firstly, according to Article 2(2)(5) of Regulation 1924/2006, a 'health claim' is defined as 'any claim which states, suggests or implies the existence of a relationship between, on the one hand, a food category, a foodstuff or one of its constituents and, on the other hand, health'.

In this instance, the French authorities consider that Nutri-Score does not fall within the concept of health claim within the meaning of Regulation (EC) No 1924/2006. The Nutri-Score logo displayed on food packaging does not have the purpose or effect of affirming, suggesting or implying the existence of a relationship between the foodstuff in question or one of its components and health. The Nutri-Score is not intended to describe a commodity as 'healthy' with ad libitum or 'unhealthy' consumption and to prohibit its consumption. In the studies carried out to assess consumer choices, it was never observed that the purchase of Nutri-Score D or E branded products had been stopped and that there was an exclusive shift to products A and B. The fears expressed by some about a system that would lead to systematic distrust in lower-rated products has never been observed or proven. Nutri-Score encourages people to balance their shopping baskets by favouring, depending on product categories, those with a more favourable score, while continuing to purchase D/E products but in smaller quantities. The proper use of Nutri-Score was pointed out in the French Public Health communication tools, particularly in the context of a brochure available on mangerbouger.fr: 'Nutri-Score for better eating a glance', which explains in a pedagogical way that 'a Nutri-Score C is therefore not necessarily good or bad: everything depends on the product' and that 'foods classified as D and E can very well form part of a balanced diet, provided that they are consumed in small quantities and not too often'. A general public communication campaign will also be disseminated in the coming months by Public Health, France, in order to recall the fundamentals for the proper use of Nutri-Score. As the graphic format of the logo has been retained, these elements remain valid for the new Nutri-Score algorithm and make it possible to state with certainty that the Nutri-Score logo does not imply the existence of a relationship between the foodstuff concerned, or one of its components, and health.

Thus, Nutri-Score is a front-of-pack logo informing consumers about the nutritional quality of products in a simplified, comprehensible form that complements the mandatory nutrition declaration, in accordance with Recital 34 and Article 30 of Regulation (EU) No 1169/2011. The French authorities would like to point out that the 5-colour system of the Nutri-Score logo is there purely for information purposes, and does not prohibit the consumption of certain foods which would be marked differently from green. Therefore, and as has been explained, this cannot be considered as a health claim. Secondly, Article 10(1) to (3) of Regulation (EC) No 1924/2006 states:



EUROPEAN COMMISSION

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

'1. Health claims shall be prohibited unless they comply with the general requirements of Chapter II and the specific requirements of this Chapter, and unless they are authorised in accordance with this Regulation and included in the lists of permitted claims referred to in Articles 13 and 14. / 2. Health claims shall only be permitted if the following information is included in the labelling, or if no such labelling exists, in the product presentation and advertising: /(a) an indication of the importance of a varied and balanced diet and a healthy lifestyle; /(b) the quantity of the foodstuff concerned and the consumption method required to achieve the claimed beneficial effect; /(c) where appropriate, an indication to persons who should avoid consuming the foodstuff in question; and /d) an appropriate warning with regard to products likely to present a risk to health in the event of excessive consumption'.

In this case, with regard to the question of EFSA authorisation for health claims, the French authorities point out that Nutri-Score is not intended to be accompanied by the information referred to in the above-mentioned paragraphs of Article 10. Nutri-Score is a form of expression that is self-sufficient. The above-mentioned provisions and the opinion of the Italian authorities on this point are therefore not applicable to the specific case. Nutri-Score is not and never claimed to be a health claim. This therefore explains why EFSA was never consulted in the context of the above-mentioned provisions.

Finally, the system inherent in health claims appears, on the one hand, in the light of the argument put forward by the Italian authorities mentioned above and, on the other hand, to the assessment of the Court of Justice of the European Union (CJEU), to concern only claims that are 'beneficial' for health by virtue of the colour green. Indeed, the Court of Justice in its judgment of 30 January 2020, C-524/18, explains that 'Recital 14 of this Regulation sets out the necessity to ensure that the substances for which a claim is made have been shown to have a beneficial nutritional or physiological effect' (point 55). However, Nutri-Score must be considered as a whole, since it is based on a 5-colour/5-letter system (from green/A to dark orange/E). It is therefore impossible to separate the colours and to consider that only the colour green would fall within the category of health claim. This would be tantamount to separating the system itself and notifying certain aspects of the system under Regulation (EU) No 1169/2011 and others under Regulation (EC) No 1924/2006. Such an approach would, on the one hand, make the exercise extremely complicated and, on the other hand, it would distort the Nutri-Score system, which legally and scientifically forms an indivisible whole.

5. On the relevance of the new 'Nutri-Score' algorithm

In its detailed opinion, the Italian authorities question whether EFSA's report on nutritional profiling published in 2022 has been taken into account in the development of the new Nutri-Score calculation algorithm.

In the present case, in the various reports of the Nutri-Score Scientific Committee, the EFSA reports, and in particular the report on the elements to be considered in a nutritional profile, are referred to in detail and the decisions were taken in accordance with the conclusions of these reports. Among the nutritional profiles currently used in front-of-pack labelling, Nutri-Score is the one that takes into account the largest number of elements highlighted by the EFSA. Finally, the EFSA itself recalls in its conclusion that the inclusion of the different components in the context of a nutritional profile of foodstuffs depends on the feasibility of the model in practice.

Furthermore, the EFSA report, which is not intended to be binding, is intended to contribute to the European Commission's discussions on the harmonisation of front-of-pack nutrition labelling. It should also be noted that, to date the main existing nutrition labelling schemes (e.g. Multiple Traffic Lights, Keyhole, Warning logos, NutrInform system) do not incorporate all the nutrients or elements suggested by EFSA.

In addition, the Italian authorities are particularly concerned about the following points.

- Taking into account the protein content

In the context of the EFSA report, proteins are not considered a nutrient 'of concern' since the average intakes in the European adult population comply with the reference intakes.

Historically, the nutrient profile developed by the Food Standards Agency (FSA) for the UK Communications Office (Ofcom) did not include proteins as part of the profiling model. The different options tested included nutrients 'of concern' in view of their low intakes among the population, such as iron and calcium. Proteins had in the end been incorporated in the stakeholder consultation process, replacing calcium and iron in the model (for which it is not mandatory to display them on the nutrition declaration). The use of proteins as a proxy for the content of these micronutrients of interest has been shown to be relevant for classifying foodstuffs consistently compared with the initial models. Thus, in the FSA nutritional profiling model on which Nutri-Score is based, proteins are not included as a nutrient of concern as such, but as a proxy for other nutrients of interest (especially calcium and iron).

As regards iron and calcium, the EFSA report acknowledges that certain population groups are at risk of deficiency. The



EUROPEAN COMMISSION

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

EFSA also recognises the possibility of including nutrients in nutrient profiling models as a proxy for other elements of public health interest. Thus, all these elements confirm the interest in considering the component 'proteins' in the algorithm as a proxy for iron and calcium levels, and not for the protein content directly.

The 'protein' component of the original Nutri-Score algorithm did not sufficiently distinguish between foods according to their iron and calcium content. In particular, certain groups of foods with limited iron and calcium content had a substantial number of points (e.g. prepared meals, snacks, etc.). The Scientific Committee on Nutri-Score Transnational Governance has therefore improved the 'protein' component of the algorithm so that it can serve more of this proxy role. In the revised algorithm, the point allocation thresholds for protein content are increased and the maximum number of points is extended from 5 to 7 points. Thus, in the updated nutritional profile, only the source foods of these essential nutrients can benefit from all the points on the protein component (fish, legumes, cheeses).

Under the new Nutri-Score calculation algorithm, cheeses with a lower content of saturated fatty acids and salt, and richer in calcium, get a better score, for example.

- Taking into account potassium and other trace elements

For operational reasons and to ensure transparency for consumers and supervisory authorities, Nutri-Score is based on the elements of the mandatory nutrition labelling (nutrition declaration and mandatory list of ingredients) provided for in Regulation (EU) No 1169/2011, with the exception of fibres, which are not mandatory but authorised (Article 30), without restriction. However, where the products contain a substantial amount of fibre, its quantity is generally included in the nutrition declaration on the back of the packaging.

However, integrating vitamins, minerals and trace elements into Nutri-Score's nutritional profile even though levels are rarely displayed on food nutrition labelling would lead to many difficulties:

- In terms of operational feasibility: this would involve dosing their quantities in the food, with significant costs for operators;

- In terms of control and transparency, few products display the vitamin and mineral content in the nutrition declaration; Finally, during the development of the nutritional profile of the FSA, underlying the Nutri-Score algorithm, the fruit and vegetable content (included in the mandatory ingredients list) was integrated as part of the model as a proxy for micronutrient levels. Indeed, the presence of fruits and vegetables is associated with a naturally higher content of vitamins and minerals, which are therefore taken into account indirectly in the final score. Again, EFSA recognises the possibility of integrating nutrients in nutrient profiling models as a proxy for other elements of public health interest. This component has been retained in the revised algorithm and incorporates the content of fruit, vegetables and pulses.

- Taking into account cereal products as favourable elements

The nutritional recommendations of European countries recommend increasing the consumption of wholegrain products. Nevertheless, this recommendation is mainly related to their naturally high fibre content, having beneficial effects on health and the prevention of chronic diseases.

Moreover, there is no consensus on the definition of a wholegrain cereal product between European countries.

Wholegrain foods (including wholemeal flour) are defined differently from one country to another, including within the European Union (Leitsätze für Brot und Kleingebäck. BMEL.

https://www.bmel.de/SharedDocs/Downloads/DE/_Ernaehrung/Lebensmittel-Kennzeichnung/LeitsaetzeBrot.pdf?__blob=publicationFile&v=4; Ministerio de la Presidencia, Relaciones con las Cortes e Igualdad. Real Decreto 308/2019, de 26 de abril, por el que se aprueba la norma de calidad para el pan. 2019. <https://www.boe.es/eli/es/rd/2019/04/26/308>

; Koninkrijksrelaties M van BZ en. Warenwetbesluit Meel en brood. <https://wetten.overheid.nl/BWBR0009669/2017-10-01>; Royal Order of 2 September 1985 on bread and other bakery products (MB 1985 11 07) as amended by

AR 20020204 - MB 20020319 as amended by AR 20090619 - MB 20090706. Brussels: 1985.

https://ng3.economie.fgov.be/NL/metrology/showole_FR.asp?cParam=3559

; van der Kamp JW, Poutanen K, Seal CJ, et al. The HEALTHGRAIN definition of 'whole grain'. Food Nutr Res 2014;58. doi:10.3402/fnr.v58.22100

; Ross AB, van der Kamp J-W, King R, et al. Perspective: A Definition for Whole-Grain Food Products-Recommendations from the Healthgrain Forum. Adv Nutr Bethesda Md 2017;8:525-31. doi:10.3945/an.116.014001; EFSA Panel on Dietetic Products N and A (NDA). Scientific Opinion on the substantiation of health claims related to whole grain (ID 831, 832, 833, 1126, 1268, 1269, 1270, 1271, 1431) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA J 2010;8:1766.

Thus, due to the lack of uniformity and specific Regulations within the European Union on how to declare 'wholegrain



EUROPEAN COMMISSION

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

cereals', their addition to the 'fruit, vegetables and pulses' component of the Nutri-Score algorithm was not retained by the Scientific Committee on Transnational Governance. Apart from the operational and lack of transparency in the system that this could have caused, this food group is recognised primarily as a source of fibre, which is directly integrated into the Nutri-Score algorithm. The EFSA considers fibre, not wholegrain cereal products, as important to include in the context of a nutritional profile for foodstuffs.

Nevertheless, the Scientific Committee has modified the 'fibre' component of the algorithm in order to increase the threshold for awarding points, thus allowing products that are sources of fibre and fibre-rich products to be better rated compared to their refined alternatives. Indeed, only products which are at least sources of fibre can be given points in the fibre component (at least 3 g/100 g of fibre are to be awarded a point, consistent with the European regulation on the 'source of fibre' claim), and only a very high fibre content can be given the maximum points (> 7.4 g fibre/100 g). On the other hand, products that are not sources of fibre are not included in the algorithm. This makes it possible to better highlight products that are true sources of fibre, differentiating better between wholegrain and refined products, in line with the nutritional recommendations of European countries.

- Taking into account the variability of eating habits and traditions in the different countries of the European Union and the different methods of consumption (frequency and quantity)

Nutri-Score is a public health tool that has been the subject of extensive scientific work in France, in other countries in Europe and internationally, which has proven to be effective in helping consumers compare the nutritional quality of food and to make more informed choices that are of better nutritional quality in different countries (Egnell M, Talati Z, Galan P, Andreeva VA, Vandevijvere S, Gombaud M, Dréano-Trecant L, Hercberg S, Pettigrew S, Julia C. Objective understanding of the Nutri-Score front-of-pack label by European consumers and its effect on food choices: an online experimental study. *Int J Behav Nutr Phys Act.* 2020 Nov 19;17(1):146. doi: 10.1186/s12966-020-01053-z. Erratum in: *Int J Behav Nutr Phys Act.* 2020 Dec 16;17(1):164. PMID: 33213459; PMCID: PMC7678195; Egnell M, Talati Z, Hercberg S, Pettigrew S, Julia C. Objective Understanding of Front-of-Package Nutrition Labels: An International Comparative Experimental Study across 12 Countries. *Nutrients.* 2018 Oct 18;10(10):1542. doi: 10.3390/nu10101542. PMID: 30340388; PMCID: PMC6213801.)

However, its calculation algorithm has been assessed and developed in order to improve the match between the classification of food and beverages on the Nutri-Score scale and the main nutritional recommendations in the various European countries: the full products promoted for consumption in Europe – especially in the Nordic countries – are classified as Nutri-Score A, and oils with a lower level of saturated fatty acids such as olive oil – whose consumption should be preferred among oils, due to lower levels of saturated fatty acids – have their score improved with a Nutri-Score B (better score for an oil).

It should be recalled that in most EU countries, the associated nutritional and food pyramid recommendations are consistent with each other, and in particular with the Mediterranean diet, which is characterised by high consumption of fruit, vegetables, pulses, cereals (especially wholegrain), moderate consumption of fish and dairy products, and low consumption of meat, delicatessen and sweet, fatty and salted products. These food pyramids are consistent with the Nutri-Score algorithm, the frequency of consumption and recommended amounts gradually decreasing in the continuum proposed by the rating. The Mediterranean diet also favours olive oil among the added fats without recommending an ad libitum consumption. In addition, the consistency between Nutri-Score and Mediterranean diet was demonstrated in a study published in December 2022 (Vlassopoulos, A.; Katidi, A.; Savvidou, T.; Kapsokefalou, M. Alignment of Nutri-Score with Mediterranean Diet Pyramid: A Food Level Analysis. *Nutrients* 2022, 14, 5097. <https://doi.org/10.3390/nu14235097>). In this respect, the match between the Mediterranean diet promoted in particular in Italy and the Nutri-Score classification of food and beverages is clearly visible with the new algorithm, which classifies less fatty, sweet or salty foods or dishes that are rich in fibre, fruit and vegetables, dried vegetables and nuts more favourably.

However, it is important to remember that Nutri-Score is a tool used in global nutrition policies, which mobilise different levers of complementary and synergistic actions (nutritional recommendations, food education, improvement of food supply, etc.). Thus, Nutri-Score does not aim to replace all levers, in particular nutritional recommendations, but acts in addition to them. Nutritional recommendations provide a general framework on healthy eating habits to help consumers identify groups of foods whose consumption should be encouraged or limited, while taking into account possible cultural specificities. Nevertheless, there is considerable variability in nutritional composition within food groups or for similar products of different brands. The Nutri-Score is therefore a useful tool to help consumers compare the nutritional value of pre-packed food products and encourage them to consume products of better nutritional quality, as part of a



EUROPEAN COMMISSION

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

comprehensive nutrition prevention policy, complementing nutrition recommendations and not as a substitute. In particular, this comparison of products may be important for food categories that are not necessarily covered by nutritional recommendations (for example pre-cooked meals).

- It does not provide that an individual food cannot correspond to the nutritional profile of a nutritionally adequate diet; By definition, a nutritional profile intends to demonstrate the contribution of a foodstuff to a balanced diet. It does not reduce the diet as a whole to a single foodstuff. It complements the nutritional recommendations, which provide information on the overall structure of the diet over time. The food categories to be favoured as part of the diet (in terms of quantity or frequency) are classified in the best Nutri-Score classifications, and products whose frequency of consumption or the amount consumed as part of a balanced diet should be limited are classified in the worst classifications.

Nutri-Score makes it possible to assess the overall nutritional quality of foods in order to compare products with each other. It is not intended to give an absolute assessment of the quality of a foodstuff, in a binary way by characterising the product as 'healthy/corresponding to the nutritional profile' or 'unhealthy/not corresponding to the nutritional profile'. Nutri-Score makes it possible to compare the nutritional quality of products with each other, where relevant in terms of product category or consumption occasion. Products classified as D or E on the Nutri-Score scale can still be consumed, but in appropriate frequencies and quantities.

- Taking into account added or free sugars

For matters of operational feasibility and transparency for consumers and supervisory authorities, the definition of 'sugars' used for Nutri-Score is that of the mandatory nutrition labelling as defined in Regulation (EU) No 1169/2011, namely that of simple sugars present in food: 'all monosaccharides and disaccharides present in food, but excludes polyols'.

Indeed, as mentioned above, Nutri-Score is based on the nutritional information on the back of the package, which indicates only the total sugar content. In its current version, Nutri-Score does not distinguish between free, added or natural sugars in its algorithm. Any inclusion of specific forms of sugar would require either elements outside the mandatory or voluntary nutrition declaration (e.g. added/free sugars or any specific type of mono- or disaccharides) that form the basis of Nutri-Score, or calculation elements. In view of the practical difficulties associated with the estimation and inclusion of free and added sugars and the implications in terms of transparency and control, the Scientific Committee decided to maintain the basic principle of using only the information available in the nutrition declaration on the back of the packaging, and thus to keep the simple sugars.

The EFSA report on nutrient profiles further states that total sugars can be taken into account as a proxy for added or free sugars in the context of categorical nutrient profiles as free and/or added sugars are the most variable share of total sugars within a product category. In the case of Nutri-Score, the concomitant consideration of fruits and vegetables, on the one hand, and proteins, on the other hand, ensures that non-free sugars are not penalised (fruits and vegetables, dairy products) in the system and that it is therefore the free/added sugars that are the main factor of variation in the classification of products within Nutri-Score.

- More emphasis on non-favourable than favourable elements

In the overall weighting of the algorithm, the components for the unfavourable elements (i.e. calories, saturated fatty acids, sugars, salt) have more weight than the components for the favourable elements (i.e. proteins, fibres, fruits, vegetables and dried vegetables). It is important to remember that this nutritional profile is based on that of the FSA – also giving more weight to unfavourable elements – and which has been the subject of much scientific validation work.

Chronic diseases and obesity in Europe are mainly linked to excessive consumption of energy-rich products with too much fat and sugar, leading to excess calories, weight gain, obesity and diabetes, as well as insufficient consumption of certain raw products (e.g. fruits and vegetables). High fasting blood sugar is the third risk factor for mortality in the European Union, and a high body mass index is the fourth (based on data from the Global Burden of Disease). In this case, Nutri-Score applies to pre-packed products, mostly industrial and thus processed, or even ultra-processed. These products have, for the most part, particularly high levels of salt, sugars or saturated fats, so it is essential to focus on these nutrients, the consumption of which must be limited for health reasons.

However, the balance between positive and negative elements in the calculation algorithm, even if it gives more weight to the negative elements, is consistent with the final classification of products: raw products rich in favourable nutrients, whose insufficient consumption is a risk to health, are classified mainly as Nutri-Score A (i.e. fruits, vegetables, dried vegetables, seeds, nuts, etc.).



EUROPEAN COMMISSION

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

- New classification for milk

In the current Nutri-Score algorithm for foods, foodstuffs with more than 80% milk are considered to be foods and not beverages. This classification based on a threshold has been challenged many times by stakeholders and can cause confusion for consumers, as products close in terms of composition and mode of consumption are required to be classified by the general food algorithm for some and by the beverage algorithm for others (depending on whether they are below or above this 80 % threshold). It was therefore decided by the Scientific Committee to treat milk and dairy drinks uniformly.

Physiologically, milk and milk-based drinks have characteristics similar to other drinks (especially in terms of viscosity). Thus, the food algorithm was considered unsuitable by the experts given the liquid nature of these products and their diluted nutritional content. The classification of milk-based drinks in the food algorithm does not allow for differentiation between alternatives according to sugar content. The classification of milk as a solid food does enable to differentiate between the different types of milk (skimmed, semi-skimmed, whole) according to their fat content, even though many countries explicitly recommend the consumption of lower-fat milk. Finally, milk and dairy drinks tend to be consumed in quantities comparable to other beverages.

In addition, it is important to mention that in the current Nutri-Score algorithm there is a threshold effect on the protein content, allowing the Nutri-Score of milk to be tipped without any real change in its nutritional composition. In fact, when Nutri-Score was adopted in October 2017, all semi-skimmed milks were classified as Nutri-Score B and then only some were switched to Class A. This is due to an insubstantial change in the protein content of these products: from 3.2 g/100 g of protein corresponding to a Nutri-Score B to 3.3 g/100 g, tipping milk into A. These elements relativise the potential 'downgrading' of (semi-)skimmed milk to B in the new algorithm for beverages given that these products were already classified as B initially.

Apart from water, which remains the only beverage recommended for unlimited consumption, the classification of skimmed and semi-skimmed milk as Nutri-Score B is the best classification for beverages, and corresponds to a good nutritional quality product, which is favourably perceived by consumers. Milk consumption remains encouraged in the nutritional recommendations of European countries. In France, it is recommended to eat two dairy products per day for adults and three for children, alternating between different types of dairy products (milk, yoghurt, cheese, etc.). Specific communication on Nutri-Score, and in particular on the case of dairy products, will be carried out in France in order to educate people about Nutri-Score and its new algorithm.

European Commission

Contact point Directive (EU) 2015/1535

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