



EUROPEAN COMMISSION

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

Message 077

Communication from the Commission - TRIS/(2024) 1818

Directive (EU) 2015/1535

Notification: 2023/0601/FR

Message further to the dialogue between the Commission and the Member States following recourse to the official reactions expressly laid down by Directive (EU) 2015/1535.

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2. Italy

3A. MINISTERO DELLE IMPRESE E DEL MADE IN ITALY

Dipartimento Mercato e Tutela

Direzione Generale Consumatori e Mercato

Divisione II - Normativa tecnica - Sicurezza e conformità dei prodotti, qualità prodotti e servizi

Via Molise, 2 - 00187 Roma

3B. MINISTERO DELLE IMPRESE E DEL MADE IN ITALY

Direzione generale per la politica industriale, la riconversione, la crisi industriale, l'innovazione, le PMI e il made in Italy

Divisione V - Industrie Made in Italy e industrie creative

Via Molise 2-00187 Roma

4. 2023/0601/FR - C50A - Foodstuffs

5.

6. Italy would like to thank France for its reply. Italy has carefully read what has been reported.

It should be noted that both the technical legal and scientific questions raised by Italy once again have not always received clear and comprehensive answers.

Technical legal issues:

Italy asked very clearly whether Nutriscore refers to:

Article 35 of Regulation 1169/2011/EU?

Article 36 of Regulation 1169/2011/EU?

Regulation 1924/2006/EU?

Article 35 of Regulation 1169/2011/EU

France states that it can 'legitimately be said that the Nutri-Score system, in so far as it meets all the requirements of Article 35(1) of Regulation No 1169/2011, constitutes a form of expression of the nutrition declaration. This finding also implies the validity of the NutriScore system in the light of paragraph 2 of that article.'

It is somewhat surprising to read what the French authorities have said.

It should be recalled once again that it was the Commission (confirming, inter alia, what Italy has always argued since the first French notification of the system in 2017) by notification No 303 - Communication from the Commission - TRIS



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(2017) 01957, to declare that ‘The labelling system annexed to the notified project does not require an indication of the energy value or the energy value and quantities of nutrients as such, but refers to the overall nutritional quality of the food in question’. Therefore, the Nutri-Score rating system does not fall within the scope of Article 35(1) of Regulation (EU) No 1169/2011’.

Considering that the French authorities themselves refer to the Commission’s report regarding the use of additional forms of expression and presentation of the nutrition declaration, (COM(2020) 207 final), France is invited to consider the provisions of Article 3.

In paragraph 1.1 of that article, the Commission analyses the ‘Additional forms of expression and presentation under the FIC Regulation’, while paragraph 1.2 refers to ‘Other front-of-pack nutrition labelling schemes’. Paragraph 1.2 reads as follows: ‘Some FOP schemes developed by Member States or food business operators do not fall under Article 35 of the FIC Regulation since they do not repeat information provided in the nutrition declaration as such but provide information on the overall nutritional quality of the food (e.g. through a symbol or letter).’ It is indisputable that, for the Commission, these systems do not fall within the scope of the FIC Regulation, also because it would be unclear why the Commission wanted to distinguish with two different paragraphs the FOP systems under consideration.

Whereas, on the other hand, the French authorities take absolutely no account of the Commission’s assertions in both 2017 and 2020 and confirm, without any doubt, that the system proposed by them is compatible with Article 35 of the FIC Regulation, a clear position by the Commission’s legal services on the compatibility of the systems which ‘do not repeat information provided in the nutrition declaration as such but provide information on the overall nutritional quality of the food (e.g. through a symbol or letter)’ with the FIC Regulation and in particular Article 35 thereof can no longer be postponed.

At this point, without a clear and definitive stance from the Commission, it seems unnecessary to reiterate that the reference in Italy’s detailed opinion to Articles 30 to 34 of the FIC Regulation was precisely intended to confirm the correctness of the Commission’s assertions.

In the light of the above, we would reiterate that the reference to Articles 30 to 34 of the FIC Regulation in Italy’s detailed opinion is intended to confirm the correctness of the Commission’s assertions, which seems necessary, as already hoped, for a clear and definitive position.

Article 36 of Regulation 1169/2011/EU

“The French authorities once again remind the Italian authorities that Nutri-Score is a single global calculation system. Therefore, it is not possible to distinguish, on the basis of the colours represented, the applicable articles. Consequently, Articles 35 and 36 may apply in conjunction with the Nutri-Score system, without distinguishing their application on the basis of the colours of Nutri-Score.”

As Luxembourg has already replied to the same statement, Italy agrees that the system is unique, and it is indeed the only case in which it is not clear what Union law the system is based on.

The reason why, according to Italy, it is important to know the legal source is that Member States are free to adopt national rules, provided that such rules comply with Union law.’ In order to determine whether a rule of a Member State complies with ‘Union law’, it would first be necessary to identify the standard to which reference is made. It is unfortunate to have to reiterate once again that Italy believes that it is instead very important to identify said reference standard, otherwise what source of law should be relied upon to judge the correctness of a Member State’s action? Failing this, it could occur, for example, that if compliance with Article 35 is contested, the reply will be that the system falls under Article 36, and vice versa; this would undermine legal certainty.

As Luxembourg had already pointed out (“the Luxembourg authorities agree with the French authorities in assessing that Italy gives an excessively strict reading of Article 36 of Regulation (EU) No 1169/2011”), France also considers that “the Italian authorities interpret Article 36 of Regulation (EU) No 1169/2011 in an excessively strict manner”. As already stated in the detailed opinion, Italy considers that the two articles refer to different cases. This does not seem to constitute an



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'excessively strict reading' as it is clear that the two articles are placed in different Chapters of the Regulation; If the provisions of Article 35 were an appendix to Article 36, we do not understand the need to place its contents in a separate article, namely Article 36.

As already explained in the detailed opinion, Article 35 is, for Italy, the only way, under existing legislation, to submit voluntary forms additional to the nutrition declaration that Member States can recommend, if the requirements set by the rule itself are met. For Italy, Article 35 regulates voluntary forms of expression when they refer to the nutrition table (which is only one of the mandatory claims in Article 9).

On the contrary, Article 36 refers to any voluntary information that operators may affix to packaging without, of course, misleading consumers. If a voluntary system under Article 36 is recommended by Member States, it clearly loses its "voluntary" character, as operators will feel "obliged" to comply, given that it is the State authorities that recommend it. Italy does not believe this is the intention expressed by the legislator with Article 36.

As stated in the detailed opinion and reiterated at all times, if that were not the case, food business operators would always be able to voluntarily supplement all the harmonised mandatory claims (Article 9) provided for in the Regulation by simply referring to Article 36. Does France consider that all the indications harmonised by Regulation 1169/2011/EU can, at their own discretion, be supplemented by operators by referring to Article 36? If the legal basis is Article 36, does it mean that voluntary forms additional to the nutrition declaration may also not meet the requirements under Article 35? Please note in this respect that the requirements of Article 35 and 36 are not identical. Why did the Community legislator consider it necessary, only for voluntary forms additional to the nutrition declaration, to provide for an ad hoc article (Article 35)?

On the contrary, Italy takes the view that Article 36 is only addressed to economic operators who, at their own discretion, may provide consumers with voluntary information on the elements referred to in Articles 9 and 10 of the Regulation, without observing any recommendations from the States assessing their scientific basis.

Regulation (EC) No 1924/2006

As already mentioned in the detailed opinion, the Commission, in its report COM (2020) 207 final of 20 May 2020, states that:

'when such a system assigns a positive overall message (e.g. green), it also complies with the legal definition of "nutrition claim" as it provides information on the beneficial nutritional quality of a food within the meaning of Regulation (EC) No 1924/2006 on nutrition and health claims made on products' but also that 'FOP systems falling within the scope of the Claims Regulation may only be used on the territory of a Member State if that same Member State has adopted them in accordance with Article 23 of the Claims Regulation (Regulation (EC) No 1924/2006), which outlines the notification procedure to the Commission.'

Italy would like to thank the French authorities for finally confirming, after seven years, that "EFSA has never been consulted under the above mentioned provisions" as "such an approach would make the exercise extremely complicated and, on the other hand, distort the Nutri-Score system, which legally and scientifically constitutes an indivisible whole"

Once again, the French authorities stress the uniqueness of the system even by stating that 'Nutri-Score is a self-sufficient form of expression' and that the notification provided for by the Community rules would therefore be too complicated.

It is stated that the system is "legally [...] an indivisible whole", if this were not the case, it would be necessary to "separate the system itself and notify some aspects of the system under Regulation (EU) No. 1169/2011 and others under Regulation (EC) No. 1924/2006".

The French authorities' approach is interesting, namely not to do something (expected) because it is extremely complicated.



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France disputes Italy's assertion that Nutriscore is a health claim. Italy considers that the French authorities are in contradiction as it is France itself which refers to studies according to which Nutriscore guarantees the best results in terms of consumer choice of healthier food. If it were true that Nutriscore allows for the choice of a healthier food, doesn't this mean that this logo 'affirms, suggests or implies the existence of a relationship between a food category, a food or one of its constituents and health'?

Thus, if Nutriscore is neither a nutrition claim nor a health claim, it constitutes a unique system apparently lacking a legal basis and therefore the same purpose is not understood.

Criticism of the new 'Nutri-Score' algorithm.

The French authorities state that 'in the various reports of the Nutri-Score Scientific Committee, detailed reference is made to EFSA reports, and in particular to the report on the elements to be considered in a nutrient profile, and decisions were made in accordance with the conclusions of these reports'.

This assumption is surreptitious since the new Nutriscore algorithm significantly disregards the latest report adopted by EFSA on 24 March 2022 for the development of a harmonised, mandatory FOPNL system 'Scientific advice related to nutrient profiling for the development of harmonised mandatory front-of-pack'. The counter-arguments put forward by France to the observations submitted by Italy are also unable to overcome/respond to the main problems/discrepancies identified.

a) The protein content (further valorised/enhanced by the new algorithm) is not considered relevant according to EFSA indications as the European population takes in more proteins than necessary; (EFSA: 'average protein intake in Europe is above the Population Reference Intake in most population groups and countries and no beneficial effect on muscle mass or function can be expected by further increasing protein intake').

The reasoning put forward by the French counter-arguments that proteins are an indirect indicator (proxy) of other elements of public health interest (iron/calcium) is by no means convincing and is merely a trick to justify its increase in importance in the updated algorithm (so far as red meat and cheese that are the main sources are in many cases penalised by the new algorithm). A number of passages from the EFSA document are set out below: Foods that contain relatively high concentrations of iron include meat, fish, cereals, beans, nuts, egg yolks, dark green vegetables, potatoes and fortified food products. The iron content of dairy products and many fruits and vegetables is much lower.

Bioavailability of iron from plant foods (non haem iron) is generally much lower than that from animal (haem-iron) foods (due to a different absorption mechanism for non-haem iron versus haem-iron); 'The main contributors to calcium intake, as reviewed by EFSA NDA Panel (2015a), are milk and dairy products that are responsible for between 38% and 85% of the intake, followed by grains and grain-based products (2-35%), water and water-based beverages (1-18%) and vegetables and vegetable products (1-11%).

b) It does not include whole grain products as a favourable component; The justifications for not including whole cereals/whole cereal products as positive elements like vegetables/fruit are outdated, misleading and inappropriate. The importance of inserting/enhancing whole cereals is not due to fibre input alone (as would be suggested by the French remembrance writers in the passage 'EFSA believes that fibres, and not whole cereal products, are important to be included in the context of a nutritional profile'), since the resulting benefits are much more complex than plants and legumes, which have been included among the positive elements characterising the current algorithm.

Contrary to what the drafters of the French counter-arguments argue, it is clear from the EFSA report that whole cereals are an independent case to be covered by legumes and vegetables: Starchy foods provide complex carbohydrates. When consumed in the form of whole grain products, they are also a good source of dietary fibre, B-vitamins, tocopherols and folate. This food group in FBDGs of European countries comprises mainly cereals (including breakfast cereals) and cereal-derived products, such as bread, pasta, rice, couscous or bulgur. Generally, FBDGs recommend eating starchy foods several times per day (generally between 3 and 11 servings per day, portion sizes vary between FBDGs) with an emphasis on whole grain products). Diets high in whole grains have been associated with lower mortality from all causes, CVD and cancer in prospective cohort studies. In a dose response meta-analysis, these associations were monotonic, showing a decrease in risk for total, CVD and cancer mortality of about 7, 9 and 5 %, respectively, for each serving (16 g)



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increase in whole grain intake per day (Zong et al., 2016)".

The claim that there is no consensus definition of whole cereal or whole grain cereal product is also specious and surreptitious, since the Whole Grain Initiative (<https://www.wholegraininitiative.org/>) has recently developed some consensus definitions for whole/whole grain cereals summarised in the Communication 'van der Kamp, J.-W.; Jones, J.M.; Miller, K.B.; Ross, A.B.; Seal, C.J.; Tan, B.; Beck, E.J. Consensus, Global Definitions of Whole Grain as a Food Ingredient and of Whole-Grain Foods Presented on Behalf of the Whole Grain Initiative' published in *Nutrients* 2022, 14, 138. <https://doi.org/10.3390/nu14010138>.

The main definitions are as follows:

Definition of Whole Grain: Whole grains shall consist of the intact, ground, cracked, flaked or otherwise processed kernel after the removal of inedible parts such as the hull and husk. All anatomical components, including the endosperm, germ, and bran must be present in the same relative proportions as in the intact kernel.

Definition of a whole-grain food: A whole-grain food shall contain at least 50% whole-grain ingredients based on dry weight

Requirements for designating the presence of 'whole grain' front-of-pack Foods containing a minimum of 25% whole-grain ingredients based on dry weight, may make a front-of-pack claim on the presence of whole grain but cannot be designated 'whole grain' in the product name.

The importance of including whole cereals/whole cereal products as positive foods is further explained in point (e).

c) For the oils and fats category, the advancement of the position from C to B of olive oil was intentionally proposed for the sole purpose of silencing the scientific community's grievances due to the established scientific evidence linked to the benefits of extra virgin olive oil (within the Mediterranean diet) compared to all other seed oils (as also stated by EFSA in the Nutrition Profiles document: Plant-based Mediterranean-type diets rich in olive oil have been traditionally associated with low CVD risk in observational and intervention studies (Rosato et al., 2019). The relationship between higher olive oil consumption and lower risk of CHD has also been observed in two large prospective cohort studies (Guasch-Ferre et al., 2020).

Indeed, the methodology used by Nutriscore to differentiate oils/fats on the colour/alphabetical scale is based solely on the (positive) content of unsaturated fatty acids and the (negative) content of saturated fatty acids. It continues to be omitted and not clarified that alongside olive oil in Class B other seed oils (rapeseed/canola and walnut) have been promoted that have nothing to do with the Mediterranean diet and the superior quality of extra virgin olive oil (characterized, like most other seed oils, by a significantly higher unsaturated and polyunsaturated fatty acid composition than olive oil). It should be noted that the only oil to be rewarded should be extra virgin olive oil (EVOO), which, in addition to its balanced fatty acid composition, has a number of bioactive substances such as polyphenols, vitamins, vegetable sterols, etc., since it is exclusively extracted using physical methods. All other seed oils (including rapeseed/canola) are mostly extracted with solvents and/or subjected to drastic refining treatments to make them edible, thus losing almost all the bioactive substances that may be present (as well as containing unfavorable newly formed compounds).

d) It does not consider that an individual food cannot correspond to the nutritional profile of a nutritionally adequate diet and does not consider the variability of eating habits and traditions in the different EU countries and the different ways of consumption (frequency and quantity), as stated on several occasions in the EFSA's Nutrition Profile Document.

The replies provided by the notifying Member State do not in any way clarify the issues raised, offering vague, misleading and inappropriate reasons.

For example, one of the reasons/justifications given 'is not intended to provide an absolute assessment of the quality of a food product, in a binary manner, by categorising the product as being - healthy or unhealthy' completely distorts the reality and truth of the facts: Nutriscore is indisputably a binary system because it differentiates products in red (bad) and green (good) - green/red nuances do not exceed the binary approach but serve only to mask this distortion. The binary approach is also supported by the fact that no useful elements are provided to the consumer to understand the reasons for assigning the product to the different Nutriscore classes. In fact, the algorithm behind the Nutriscore is incomprehensible and inexplicable to any kind of even advanced consumer, even more so to the "average normally informed and reasonably observant and circumspect" consumer as defined by nutrition labeling regulations, or even to



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those characterized by a low level of education. Therefore, in the case of Nutri-Score, the consumer's choice is made exclusively, passively and with a binary approach with the red colour code = bad and green = good (including the various nuances), without any possibility of knowing the real reasons for this codification: the consumer is not considered a person worthy of being informed/educated in order to make an informed choice (stick or carrot, electric shock or reward, red or green). The fact that the meaning of Nutri-Score is not understandable or is likely to distort the market by confusing/misleading the consumer is also indirectly confirmed by the French reply document in which it is envisaged to use an information campaign to restore the appropriate use of Nutri-Score '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 Nutri-Score', which is tantamount to saying that Nutri-Score lends itself to misuse, as shown on several occasions by the counter-arguments put forward by Italy.

In addition, the French pleadings rightly confirm Italy's assertion that: '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.' Nutriscore, with its algorithm based on a (questionable) balance of positive and negative factors that each food must individually achieve (not in a diet), pursues the opposite result with the approval of reformulated products in order to achieve the best colour/alphabetic (green/A) performance. This is severely penalised in terms of cultural identity, biodiversity, taste, well-being, health and livelihoods.

e) It attaches greater importance to non-favourable vs. favourable components

Contrary to what is stated in the document in defence of the adoption of the new Nutriscore algorithm, we reiterate that the prevalence of favourable/positive components of the diet on health is now consolidated practice, as is also fully explained in the article entitled 'Health effects of dietary risks in 195 countries, 1990-2017: a systematic analysis for the Global Burden of Diseases Study 2017', published in 2019 in the prestigious journal Lancet and also promoted by the WHO. The study highlights that the number of deaths from diet-related, non-communicable diseases largely depends on diets lacking in favourable components (in decreasing order, whole grain cereals, fruit, vegetables, omega-3 fatty acids from fish, dietary fibre, polyunsaturated fatty acids, legumes, calcium, milk) rather than on diets characterised by non-favourable components (salt, trans fatty acids, sugars, processed red meat). The above-mentioned article clearly highlights that, with the exception of high sodium intake, the main dietary risks associated with deaths are linked to the low consumption of certain food groups, such as whole cereals, fruit, vegetables, seeds, nuts and legumes.

f) Arbitrariness of the Nutriscore algorithm

Nothing was answered about the boundless arbitrariness of the Nutriscore algorithm. A paradigmatic example of its arbitrariness is the recent overhaul of the NUTRI-SCORE algorithm. After France, NUTRISCORE was also adopted on a voluntary basis by Germany, Belgium, the Netherlands, Luxembourg and Switzerland, so that a joint committee composed mainly of experts from those countries considered it necessary to intervene in the FOP label generation algorithm in order to harmonise it to the individual countries' nutritional recommendations. The changes were significant with a real overturning of the original algorithm. Clearly, the proposed changes may, in some cases, be acceptable because they are in line with the nutritional recommendations of the Dietary Guidelines but they raise important policy issues.

On the one hand, such a radical intervention highlights the limitations of the previous algorithm which, however, has always been presented as scientifically robust and to be adopted as an absolute reference for the whole of the EU. It is clear that any scientific 'product' needs to be updated to adapt to new evidence, but the fact that in just a few years there has been a complete overturning of the algorithm leads to doubts as to the rigour of its structure.

The critical point of the arbitrariness of this system therefore emerges loudly. Today, a sufficiently qualified expert committee (but not validated at Community/EFSA level and not representative of all the necessary expertise) has made these changes. A system based on such a great degree of arbitrariness may quickly go out of control, with the risk that each expert committee, each country, each sector, each individual industry could structure an algorithm at its own wishes, justifying it, on a case-by-case basis, with valid reasons regarding the adherence to nutrition and health recommendations. This would generate enormous variability/confusion on the scores achieved by individual foods, making their understanding extremely difficult for the consumer.



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European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu