WORLD TRADE ORGANIZATION

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** BRAZIL	
	If applicable, name of local government involved (Article 3.2 and 7.2):	
2.	**Agency responsible:** Brazilian Health Regulatory Agency (Anvisa)	
	Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:	
	National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2563.2765 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas	
	The comments to this Draft Regulation shall be sent to https://pesquisa.anvisa.gov.br/index.php/981335?lang=pt-BR	
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:**	
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Public Taking of subsidies	
5.	**Title, number of pages and language(s) of the notified document:** Public Taking of subsidies n° 1 of 21 May 2018 - Portuguese	
6.	**Description of content:** Brazil was one of the first countries to adopt mandatory nutrition labelling as part of the public health strategy to promote adequate and healthy food habits and to combat overweight.	
	This measure provided consumers with a suitable profile of nutrients contained in the food and considered to be of nutritional importance so that a wise choice of food can be made. Additionally, it encouraged the voluntary reformulation of foods in a way that benefited public health.	
	The process conducted by Anvisa helped to ensure consumers' right to information about the basic compositional characteristics of foods and contributed to Mercosur being the first economic bloc to have harmonized compulsory nutrition labelling, which has facilitated trade between countries.	
	After the implementation of this regulatory measure, some inconsistencies and practical limitations of the regulation were identified and addressed through amendments in the legislation. However, the need for a more comprehensive review was identified.	
	Thus, Anvisa provided the technical subsidies to support the request for revision of this issue in Mercosur and established a Physical Working Group on Nutrition Labelling, with the participation of several stakeholders, with the aim of assisting in the identification of problems in the transmission of nutritional information and alternatives that could help	

improving the effectiveness of this information to consumers.

The results of these studies contributed to the inclusion of this topic in the Regulatory Agenda 2017/2020 and to the approval of the regulatory initiative for the revision of nutrition labelling regulations at the end of 2017.

The subsidies obtained in this process identified that the main regulatory problem is the difficulty of Brazilian consumers in using the nutrition labelling. Several reviews of international scientific literature and researches in Brazil revealed that a significant portion of consumers have difficulty understanding and using nutrition labelling.

This problem accentuates the information asymmetry, undermines consumers' ability to make wise food choices, reduces the effectiveness of nutrition labeling, and damages consumers' basic right to information on food composition.

Different factors that contribute to this problem were identified: (a) the low level of education and nutritional knowledge of the Brazilian population; (b) confusions about the nutritional quality of foods that are generated by the nutrition labelling model; (c) difficulty in visualizing, reading, processing and understanding the nutritional table; (d) inconsistencies in the veracity of the declared nutrition information; and (e) lack of nutritional information in many foods.

In this sense, several regulatory causes that explain this scenario and that are within the legal competencies of Anvisa were diagnosed. Other causes of a non-regulatory nature have also been identified which require the involvement of other stakeholders and are essential for effective resolution of the regulatory problem.

In this sense, the objective of regulatory intervention is to facilitate the use of nutritional labeling to make wise food choices by Brazilian consumers. To achieve this objective, six specific objectives were defined: (a) improving the visibility and readability of nutritional information; (b) facilitate understanding of the main nutritional attributes of food; (c) reduce situations that create confusion about the nutritional composition of foods; (d) facilitate nutritional comparison between foods; (e) improve the accuracy of declared nutritional values; and (f) broaden the scope of nutrition information.

To identify the most appropriate alternatives, Anvisa conducted an evaluation of the proposals for improvement of nutrition labelling presented by several stakeholders and reviews of international regulatory experiences and of studies comparing the effects of various front-of-pack nutrition labelling (FOPL) models on the attention, understanding and use of this information by consumers.

This work showed that there is no regulatory and scientific consensus on the FOPL models that would be most effective for each group of consumers. Beside that it was identified that the proposals presented to Anvisa had several limitations.

In relation to the international regulatory scenario, it was noted that, in recent years, many countries have adopted actions to facilitate the use of nutritional information by consumers, and that the adoption of FOPL models was the main alternative found.

This approach communicates the main nutritional attributes of foods to consumers, in a simple, visible and easily understandable way. The increase in this type of initiative constitutes a new stage in the regulation of nutrition labeling, fruit of the knowledge accumulated during more than two decades of researches and regulatory initiatives.

The survey revealed that more than 40 countries already have some type of FOPL models implemented and that there is no standardization of designs, nutrient profiles and approaches for their implementation (voluntary and mandatory).

In part, this situation is explained by the fact that such models must meet the needs of the population of each country, considering their literacy levels, communication barriers and local culture, and that the information needs to be understood by all segments of the population.

However, there has been a recent trend in the adoption of semi-interpretive FOPL models, such as traffic lights and alerts, which focus on the qualification of nutrient content of greater relevance for health.

These approaches guarantee the transmission of information, in a more qualified and interpretive way, than the non-interpretive models and, more proportionally, than the interpretive models, since it keeps the autonomy of consumers to judge the nutritional quality of the food.

Regarding the form of implementation, although most of the FOPL models have been adopted voluntarily, it was noticed a recent trend for the mandatory declaration of this information. Although the voluntary approach generates less commercial questions and opposition from food industry, this approach reduces the effectiveness of the FOPL models due to the low adhesion of food industries. In addition, this situation allows for similar products are labeled differently, which induces consumers to deception.

The review showed that the nutrients most commonly used in FOPL models are sugars, sodium and saturated fats. The declaration of nutritional information per 100 grams or milliliters is the most frequent in these models.

In most cases, no systematized information on the monitoring and impact of FOPL models has been identified. In part, this can be explained by the recent nature of these initiatives.

However, some ex-ante and ex-post impact analyzes identified indicate that semi-interpretative FOPL in the form of alerts have a favorable cost-benefit ratio. Other data suggest that such models help consumers understanding the nutritional content of foods and encourage manufacturers to reformulate their products.

In relation to the review of scientific studies, it was observed that knowledge about the effects of different FOPL models on consumers' ability to understand and use nutritional information still in development.

The current panorama of publications reveals a growth of research in Latin America, following the regulatory changes taking place in the region. A similar situation was observed in France and in Australia and New Zealand, where the adoption of the Nutri-Score and HSR models, respectively, was preceded by surveys with the local population that compared the effects of different alternatives.

This scenario shows the importance of basing regulatory initiatives on nutrition labeling in current scientific evidence, to ensure that the selected alternative is effective and proportional to address the regulatory problem. This fact becomes more relevant because of the high commercial sensitivity of this topic.

The reviewed studies tested several FOPL models, through different methodologies that investigated the effects of these models in different stages of the processing and use of information.

It should be noted that there are several limitations in these studies that make it difficult to extrapolate their results to Brazilian consumers. However, these findings allow an objective assessment of the potential differences among FOPL models.

Among the FOPL models tested, those who did not use interpretive resources, such as GDA, were considered the most difficult to understand, being often used as a control in the studies. Most of the experiments sought to compare the performance of semi-interpretive and interpretive models, being more common the studies with qualitative traffic lights, octagonal alerts, HSR and Nutri-Score.

Among the few studies conducted in Brazil, three used representative samples of the population. However, two presented considerable methodological limitations. One of them evaluated only the opinion and the preference of the population, not providing data on parameters of understanding and use of the information. The other, although experimental, presented the models tested in locations and with different presentation features in the packaging. Thus, there is no way to measure and isolate the effect of these differences on the results.

The evidence reviewed shows that the semi-interpretative FOPL in the form of alerts have better performance in relation to the traffic lights in relation to: (a) capture of attention; (b) understanding the information on high content of negative nutrients; (c) reduction of the perception of healthfulness of products with high content of negative nutrients; (d) reduction in perceived frequency of consumption of foods with a high content of negative nutrients; (e) reduction in purchase intent of foods with a high content of negative

nutrients (results found only with the use of scales).

In contrast to the interpretive models, the alerts perform better than HSR and similar, but with small advantages to the Nutri-Score, mainly regarding the perception of healthfulness of foods viewed as healthy, but that have versions with high content of negative nutrients.

The most tested FOPL models were black octagons alerts. Only two studies tested the triangle model in the same color, with few differences in the effectiveness of this format when compared to the octagon.

The alert in the form of red circle proposed for implementation in Brazil, which has also been studied and has a similar approach being implemented in Israel, has not been tested in the Brazilian population.

In addition, few studies have focused on the factors related to the location and visibility of the models, key characteristics that influence the ability of the consumer to perceive the information conveyed.

The revisions and the complementary information submitted to Anvisa by stakeholders made it possible to analyze different non-normative and normative options to deal with the regulatory problem.

In this sense, two non-normative alternatives were identified to solve some factors that explain this problem: (a) co-regulation to deal with the lack of information about the nutritional composition of foods in food services and e-commerce services; and (b) education and information actions to address the disarticulation of nutrition education measures about the use of labeling and the difficulties of manufacturers and the SNVS in determining and monitoring the nutritional value of foods. Such actions are under partial governance of Anvisa, and require the involvement of other institutions.

The main alternatives proposed were normative, considering that most causes have a regulatory nature due to gaps, inconsistencies and outdated normative framework on nutritional food labeling.

It was suggested to make the following changes in the nutrition table: (a) to change the nutritional value declaration base to 100 grams or milliliters; (b) to modify the list of mandatory nutrients to exclude trans fats acids and to include total and added sugars; (c) to restrict the declaration of nutrients to the mandatory list of nutrients and to the nutrients that are object of fortification or of nutrition and health claims; (d) to maintain the %DV (Daily Value) statement, updating the NRV (nutrient reference values) and changing the footnote to indicate which %DV values are considered high and low.

One of the main changes proposed was the adoption of a FOPL model that: (a) is applied in a mandatory way and complementary to the nutrition table; (b) informs the high content of added sugars, saturated fats and sodium, in a simple, ostensible, understandable way; (c) uses colors, symbols and qualitative descriptors instead of the %DV; (d) is based on the amount per 100 g or ml of the food , to ensure consistency with the nutrition table; (e) uses the most restrictive nutrient profile model developed by the Anvisa for the classification of high in added sugars ($\geq$ 10 g for solids and $\geq$ 5 g for liquids), saturated fats ($\geq$ 4 g for solids and $\geq$ 2 g for liquids) and sodium ($\geq$ 400 mg for solids and $\geq$ 200 mg for liquids).

With reference to nutrition claims, it was proposed to: (a) change the basis for the determination of criteria to 100 grams or milliliters; (b) modify the composition criteria to ensure consistency with Anvisa's nutritional profile model and to avoid its use in foods with low nutritional quality; (c) define criteria for the provision of such information, to avoid nutrition claims being made more emphasized than FOPL; (d) prohibit nutrition claims on trans fat acids.

Specific recommendations concerning the scope of nutrition labeling were also presented, especially and rules for precision of nutritional values.

However, there are still gaps that need to be addressed in relation to the definition of: (a) threshold values for the declared nutritional value; (b) criteria for the presentation of nutrition labeling, including the legibility rules and the design of FOPL; (c) criteria for the presentation of nutrition claims consistent with FOPL; and (d) deadlines for implementing the proposed changes.

It was also identified the need to investigate, in a more systematized way, how the different FOPL models in the form of alert are evaluated and understood by the Brazilian population, which is intended to be done through the researches selected in the Notice CNPq/Anvisa n° 17/2017.

The possible impacts of the recommended alternatives are also discussed. It should be noted that the costs of regulating nutrition labeling have not been identified as a relevant issue by countries implementing mandatory nutrition labeling and FOPL.

Some possible benefits and additional costs for consumers, government and food industry of the proposed non-normative and normative measures were raised. The document also addresses the perspectives and challenges for the implementation, monitoring and enforcement of the proposed actions.

Documents related:

Preliminary Regulatory Impact Analysis Report on Nutrition Labeling – link:

http://portal.anvisa.gov.br/documents/33880/2977862/Análise+de+Impacto+Regulatório+sobre+Rotulagem+Nutricional_versão+final+3.pdf/2c094688-aeee-441d-a7f1-218336995337

Annex I Preliminary Report of Regulatory Impact Analysis – link:

http://portal.anvisa.gov.br/documents/33880/2977862/Relatorio_AIR_AnexoI/d14779f4-d2ae-427d-9cc5-b23ee16bae82

Regulatory Acts related to Nutrition Labeling – link:

http://portal.anvisa.gov.br/documents/33880/2977862/Atos+normativos+relacionados+à+Rotulagem+Nutricional.pdf/c0103d35-d1c6-43b6-88ac-ee690513d273

Frontal Nutrition Labeling Models – link:

http://portal.anvisa.gov.br/documents/33880/2977862/Atos+normativos+relacionados+%C3%A0+Rotulagem+Nutricional.pdf/c0103d35-d1c6-43b6-88ac-ee690513d273

Public Call Notice No. 3, dated 22 May 2018 – link:

http://portal.anvisa.gov.br/documents/33880/2977862/Edital_TPS_Rotulagem_Nutricional.pdf/ecb7052f-d529-47d5-9490-be0e6c0d8ed1

The Public Subsidies Taking is a consultation mechanism, open to the public, to collect data, information or evidence on the Preliminary Regulatory Impact Analysis Report, in order to assist regulatory decision-making by Anvisa. More information available in http://portal.anvisa.gov.br/tomada-publica-de-subsidios in Portuguese only.

7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human Health
8.	**Relevant documents:** Relevant documents are referenced in item 6
9.	**Proposed date of adoption:** To be determined after the end of the consultation period. **Proposed date of entry into force:** To be determined after the end of the consultation period.
10.	**Final date for comments:** 9 September 2018

11. **Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:**

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