



Voluntary Report - Voluntary - Public Distribution

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Report Name: Dominican Republic Proposes Regulation for Front of Pack Nutritional Warning Labeling for Prepackaged Foods

Country: Dominican Republic

Post: Santo Domingo

Report Category: Agricultural Situation, FAIRS Subject Report, Trade Policy Monitoring

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Report Highlights:

On December 3, 2024, the Ministry of Public Health and Social Assistance (MISPAS) of the Dominican Republic published a draft regulation for a Front of Pack Nutritional Warning Labeling (EFAN) for prepackaged foods. Modeled after similar systems in Latin America, the EFAN will require labels with warning messages such as "EXCESS" for nutrients like sodium, sugars, and fats, and "CONTAINS" for sweeteners. The regulation outlines specific criteria for determining "excessive" levels of these ingredients and prescribes label sizes based on packaging dimensions. The regulation provides an 18-month implementation period, with an additional 6 months for the use of complementary labels.

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

The Proposed Regulation

On December 3, 2024, the Ministry of Public Health and Social Assistance of the Dominican Republic (MISPAS) published a draft regulation for a Front of Pack Nutritional Warning Labeling (EFAN) and opened the proposal for public comment <u>here</u>. A courtesy translation of the proposal is provided by Post in <u>Annex 1</u> of this report. As of December 13, 2024, this measure has yet to be notified to the WTO.

Legal Basis for the Regulation

MISPAS justifies the proposed regulation based on its authority under the General Health Law of the Dominican Republic (No.42-01) which empowers the Ministry to implement policies and measures to protect public health. The regulation is also grounded in the Law of Consumer Rights Protection (No.358-05), the Law of Protection and Basic Rights of Children and Adolescents (No.163-03) and the Law that creates the National System of Food and Nutritional Sovereignty and Security (No.589-16).

The proposed EFAN is modeled after the one promoted by the Pan-American Health Organization (PAHO) and that has been implemented in several Latin-American countries such as Chile, Argentina and others.

Key Provisions of EFAN

The draft regulation includes the following key elements:

- 1. <u>*Label Placement:*</u> The EFAN label must be placed on the main display panel of all prepackaged foods, except for those listed in Article 4 of the proposal.
- 2. <u>Nutrient Information</u>: The EFAN label will display information about the content of energy, sodium, sugars, total fat, saturated fat, trans fats, and sweeteners.
- 3. <u>*Warning Label Design:*</u> The EFAN will be presented as a black octagon with border, containing white capital letters. The warning messages will include:
 - a. "EXCESS" for nutrients such as total fat, saturated fat, trans fats, sodium, and/or sugars.
 - b. "CONTAINS" for sweeteners (see Graphic 1 below).

Graphic 1 EFAN Example **EXCESO** EXCESO SODIO GRASAS SATURADAS Manisterio de Baled EXCESO AZÚCARES EXCESO GRASAS TRANS Ministerio de Salud de Salud EXCESO GRASAS CONTIENE Ministeric de Salad

4. <u>Criteria for "Excess" or "Contains" labels:</u> The EFAN label will be triggered based on the following criteria:

 Table 1

 Evaluation Criteria to Determine Excessive Amounts of Nutrients or Ingredients

$\geq 1 \text{ mg of}$	$\geq 10\%$ of total	\geq 30% of total	$\geq 10\%$ of total	$\geq 1\%$ of total	Any amount of
sodium per 1	0,	••	••		sweeteners
kcal	sourced from	from total fats	from saturated	from trans fats	
	sugars		fats		

5. *Dimensions of the EFAM label:* The size of the EFAN label will be determined by the area of the main display panel on the packaging:

Table 2
Dimensions of the EFAN Symbol According to the Container Main Display

Between 10 and less than 30 cm ²	1.2 x 1.2 cm
Between 30 and less than 60 cm^2	2.0 x 2.0 cm
Between 60 and less than 100 cm^2	2.5 x 2.5 cm
Between 100 and less than 200 cm ²	3.0 x 3.0 cm
Between 200 and less than 300 cm ²	4.5 x 4.5 cm
Between 300 and less than 400 cm ²	5.0 x 5.0 cm
Between 400 and less than 500 cm^2	5.5 x 5.5 cm
Between 500 and less than 600 cm^2	6.0 x 6.0 cm
Between 600 and less than 900 cm^2	7.0 x 7.0 cm
Between 900 and less than 1200 cm^2	8.5 x 8.5 cm
Greater than or equal to 3001200 cm ²	5% of the main exhibition panel area size

6. *Implementation Period:* MISPAS will provide an 18-month period for companies to comply with the EFAN regulation after the resolution is approved. During this period, companies will be allowed to use a complementary label or sticker, with 6 months allocated for its implementation.

During the last few years, two different bills proposing an EFAN had been discussed but never approved in the Dominican Republic's congress. As this latest proposal is a Ministerial Resolution, it is expected to be implemented more quickly than a legislative bill.

Potential Impact over U.S. Food Exports to the DR

The Dominican Republic is an important market for U.S. consumer-oriented products. In 2023, the United States exported a record \$1.1 billion in consumer-oriented products to the Dominican Republic, ranking the country 12th globally, 3rd in the Western Hemisphere, and 1st in the Caribbean and Central America under the CAFTA-DR agreement. This figure is expected to increase by the end of 2024.

Within the category of consumer-oriented products, several products will likely be subject to the EFAN, including:

U.S. Exports of Selected Consumer-Oriented Products to the DR in 2023			
Product	Value (\$ Million)		
Dairy products	133		
Bakery goods, cereals and pasta	46		
Food preparations	39		
Condiments and sauces	35		
Fruit and vegetable juices	29		
Chocolate and cocoa products	19		
Processed fruit	11		
Confectionary	6		

 Table 3

 U.S. Exports of Selected Consumer-Oriented Products to the DR in 2023

Source: Built by Post with data from GATS/USDA.

An informal market assessment conducted by Post at a local supermarket chain on December 6, 2024, found that most U.S. prepackaged foods already have some form of front-of-pack labeling, such as Nutri-Score, reference intake labels, or health endorsement logos (e.g., heart health logos). However, none of the U.S. products observed meet the specific requirements set out in the proposed EFAN regulation (See <u>Annex 2</u> for examples).

In contrast, locally produced prepackaged foods often lack any type of front-of-pack labels, except for those intended for both local and export markets.

Annex 1

--Courtesy Translation--

Resolution No. XXXX-2024

WHICH ESTABLISHES THE PLACEMENT OF THE FRONT LABELING OF NUTRITIONAL WARNING (EFAN) OF THE DOMINICAN REPUBLIC.

The Ministry of Public Health and Social Assistance (MISPAS). State Institution organized in accordance with the Organic Law of Public Administration No. 247-12, G.O.Num.10691, of August fourteen (14) of the year two thousand twelve (2012) and the law General of Health No. 42-01, dated March eight (8) of the year two thousand one (2001), duly provided with your National Taxpayer Registry (RNC) No. 401007398, with address and main corporate seat on Héctor Homero Avenue Hernández Vargas, corner of Tiradentes Avenue, Ensanche La Fe, duly represented by Minister Dr. Víctor Elías Atallah Lajam, Dominican, older than age, married, holder of identity card and voter no. , doctor by profession, with domicile and residence in this city of Santo Domingo, National District.

CONSIDERING: That the ministers may dictate provisions and regulations on the services under their charge, as long as they do not conflict with the Constitution, laws, regulations or instructions of the Executive Branch.

CONSIDERING: What, from the exercise of the governing function, the Ministry of Public Health and Social Assistance, must establish the guidelines that guide the development of interventions that guarantee quality health in the System National Health Service of the Dominican Republic through continuous improvement and satisfaction of the needs and requirements of the population, impacting positively in the health-disease profile.

CONSIDERING: That one of the functions of the Ministry of Public Health and Social Assistance, as the governing body of the health sector, established by the General Law of Health No. 42-01, is to formulate all policies, measures, standards and procedures that, in accordance with the laws, regulations and other provisions pertain to the exercise of their functions and tend to protect the health of the population.

CONSIDERING: That it is the function of the State to ensure Public Health through the adoption of sanitary measures regulating activities aimed at preparing, register, import, export and market food products.

CONSIDERING: That in the General Health Law, chapter 111: Food and Nutrition, in article 39 establishes that the Ministry of Public Health and Social Assistance (MISPAS) in coordination with the actors related to the field of food and nutrition, will participate in the design, implementation and evaluation of the corresponding policies, plans and programs and in the food and nutritional surveillance.

CONSIDERING: That the production, processing, storage, manufacturing, import, trade in all its forms, transportation, manipulation, supply in any capacity and sale of food products are subject to the provisions of this law, its regulations and the administrative resolutions emanating from SESPAS (today

MISPAS), as well as the Dominican Technical Standards (NORDOM) and, failing that, the standards of the Food Code (CODEX). These provisions must establish the criteria and official definitions to ensure that these foods are healthy, suitable for human consumption, with nutritional quality and come from establishments authorized by SESPAS (today MISPAS), in accordance with article 127 of Law No. 42-01 General Health.

CONSIDERING: That in the General Health Law in chapter 111: Of the non-communicable diseases. stipulates in its article 79 that SESPAS (today MISPAS) and its territorial expressions, in coordination with the institution's competent authorities, will promote disease prevention and control activities not transmissible. Prevention will be understood in a broad and comprehensive sense, which It will be determined based on the health programs that are developed.

CONSIDERING: That in the General Health Law in chapter 11: Of the Information, Education and Communication for Health, in article 38 establishes that effective health information, education and communication are essential for human development and facilitate the formation of attitudes and behaviors that threaten health.

CONSIDERING: In that same sense, in accordance with the provisions of article 84 of Law No. 358-05 General Law for the Protection of Consumer Rights, in Regarding the right to information: Every supplier of goods and/or services is obliged to provide the consumer or user on the label or similar support, a information, at least, in Spanish, clear, truthful, timely and sufficient on the goods and services that it offers and markets, in order to protect the health and security of the latter, as well as its economic interests, in such a way that can make an appropriate and reasoned choice.

CONSIDERING: That Law No. 358-05, General Law for the Protection of Consumer Rights, in article 85, provides for a minimum content of the information indicating that, on the label, labeling or similar support, the Information provided to the consumer must be indicated in characters clear, well visible and easy to read by the consumer, as well as in the Spanish language, regarding the characteristics of goods and services. This information must summarize, at a minimum, as appropriate, environmental, health and safety warnings or health.

CONSIDERING: That in the General Health Law, chapter VIII: Food and Related Activities, stipulates in its article 125 that every person has right to demand that the food they acquire or receive, in any capacity, are healthy and correspond, in their quality, nature and safety, to the statements contained in its labeling or promotion or to which the supplier issue upon sale or delivery.

CONSIDERING: That article 170 of Law No. 136-03 Code for the System of Protection and Fundamental Rights of Children. Girls and Adolescents establishes food as an obligation of public order, this being one of the basic needs of the child or adolescent.

CONSIDERING: That the Ministry of Public Health and Social Assistance (MISPAS) through its competent bodies, it must ensure the application of measures consistent with the country's health policy and plans in the relative aspects to the surveillance and control of food quality.

CONSIDERING: That Law No. 589-16 that creates the National System for the Sovereignty and Food and Nutritional Security in the Dominican Republic recognizes in its article 6, paragraph 1, letter "e",

people the right to an adequate nutrition without discrimination and to live in conditions that allow have nutritional information and access appropriate foods from the point of view from a nutritional and cultural point of view.

CONSIDERING: That MISPAS, through the General Directorate of Medicines, Food and Health Products (DIGEMAPS), has the responsibility to guarantee the population access to healthy, safe and free of contamination, as well as establishing national policies aimed at ensure effective compliance with their regulations.

SEEN: The Constitution of the Dominican Republic, proclaimed on June 13, year 2015.

SEEN: Law No. 42-01 General Health, of March 8, 2001.

SEEN: Law No. 136-03 Code for the Protection System and Rights Fundamentals of Boys, Girls and Adolescents, August 7, 2003.

SEEN: General Law No.358-05 for the Defense of Consumer Rights and User, dated September 9, 2005.

SEEN: Law No. 589-16 that creates the National System for Sovereignty and Security Food and Nutrition in the Dominican Republic, July 5, 2016.

SEEN: Law No. 8-95 that declares the Promotion and Promotion of Breastfeeding, September 19, 1995.

SEEN: Decree No. 82-15 that creates the General Directorate of Medicines, Food and Health Products, April 6, 2015.

SEEN: Decree No.528-01, of May 14, 2001, which approves the Regulation General for Risk Control in Food and Beverages in the Republic Dominican Republic, May 14, 2001.

SEEN: The Dominican Standard 53 (NORDOM- 53): General Labeling of Previously Packaged Foods (Prepackaged) (4th Rev. 2014).

SEEN: The Dominican Standard 675 (NORDOM- 675): Food labeling prepackaged. Nutritional Labeling. Regulations for Nutritional Labeling, on May 19, 2011.

By virtue of the powers conferred on me by the General Health Law No. 42-01, I dictate this **RESOLUTION**:

ARTICLE FIRST: The placement of the Front Labeling of Nutritional Warning (EFAN), for prepackaged foods for human consumption in the Dominican Republic, in accordance with the requirements set forth in this resolution.

ARTICLE SECOND: The EFAN must be placed on the main display panel of all prepackaged foods for which they apply, based on what is described in ARTICLE FIVE of this resolution.

ARTICLE THREE: For the application of the EFAN, the content must be declared of energy, sodium, sugars, total fats, saturated fats, trans fats and sweeteners in the nutritional labeling of prepackaged foods for human consumption.

ARTICLE FOUR: The following will be excepted from the presentation of the EFAN food, beverages, or foodstuffs:

Foods sold in bulk, presented in portions, fractions and other presentations at the request of the public, although these are packaging at the time of sale;

Foods for therapeutic use (for example: high protein pasta made from peanuts for child malnutrition);

Food supplements;

Fruits, vegetables, grains, eggs, fish products, meats and products edible meat to which no oils, fats, sugars, sodium or sweeteners have been added;

Single ingredient products that do not contain additional additives;

Lodized and fluoridated salt, and salt substitutes;

Vinegar;

Vegetable oils (for example: soy, corn, sunflower, coconut, etc.);

Honey;

Coffee beans, roasted and ground coffee;

Herbal and fruit infusions, tea, decaffeinated tea, instant or soluble tea, or tea extract, or decaffeinated tea extract, and decaffeinated coffee, coffee instant or soluble, or coffee extract; or decaffeinated coffee extract that do not contain added ingredients; Breast milk substitutes.

Paragraph 1: In addition the following foods in which they have not been added oils, fats, sugars, sweeteners or salt:

Instant soluble coffee; Tea leaves and aromatic herbs, instant teas and tisanes; Seasoning-type dehydrated vegetables and herbs and spices without additives food; Cereal, legume or tuber flours; Legumes (beans, lentils, chickpeas, etc.); Dried fruits, fresh or pasteurized fruit juices; Nuts, peanuts and other oilseeds; Pasteurized or ultra-pasteurized (long-life) liquid and powder milk; Purified water intended for human consumption.

ARTICLE FIFTH: The EFAN is applicable for the following nutrients and critical ingredients: total fat, saturated fat, trans fat, sugars, sodium and added sweeteners.

Paragraph I: The EFAN declaration consists of the inclusion of a symbol in the form black octagon with border and white letters in capital letters, with the warning message "EXCESS", followed by the critical nutrient found in excess, whether total fat, saturated fat, trans fats, sodium, and/or sugars and with the warning message "CONTAINS" followed by the word addition of sweeteners when the product has been added with sweetener. Additionally, "Ministry of Health" will be included at the bottom of the

octagon. He symbol must be presented on a white background to avoid being confused with other elements of the product packaging, as shown observe in the following figure (Figure 1).

Figure 1. Symbol defined for the Front Nutritional Warning Labeling that declares excess nutrients and critical ingredients in foods prepackaged for human consumption in the Dominican Republic.



Paragraph II: The content of critical nutrients and ingredients in the food prepackaged will be evaluated using the energy and nutritional content of the product expressed in weight or volume, as appropriate.

ARTICLE SIX: The food is considered to have an excessive amount of the following nutrients or contains sweeteners:

Paragraph I: Sodium: if the ratio between the amount of sodium (mg) in any quantity given of the product and the energy (kcal) is equal to or greater than 1: 1.

Paragraph II: Free sugars: if in any given amount of the product, the amount of energy (kcal) from sugars (grams of sugars multiplied by 4 kcal) is equal to or greater than 10% of the total energy (kcal).

Paragraph III: Total fat: if in any given amount of the product the amount of energy (kcal) from total fat (grams of total fat multiplied by 9 kcal) is equal to or greater than 30% of the total energy (kcal).

Paragraph IV: Saturated fats: if in any given amount of the product the amount of energy (kcal) from saturated fat (grams of fat saturated multiplied by 9 kcal) is equal to or greater than 10% of the total energy (kcal).

Paragraph V: Trans fats: if in any given amount of the product the amount of energy (kcal) from trans fats (grams of trans fat multiplied per 9 kcal) is equal to or greater than 1% of the total energy (kcal).

Paragraph VI: Sweeteners: If the list of ingredients includes sweeteners artificial or natural, non-caloric or caloric sweeteners.

Table 1. Criteria for evaluating prepackaged foods and determining whether contains an excessive amount of critical nutrients or ingredients.

$\geq 1 \text{ mg of}$	$\geq 10\%$ of total	$\geq 30\%$ of total	$\geq 10\%$ of total	$\geq 1\%$ of total	Any amount of
sodium per 1	from energy	energy sourced	energy sourced	energy sourced	sweeteners
kcal	sourced from	from total fats	from saturated	from trans fats	
	sugars		fats		

ARTICLE SEVEN: The symbol(s) referred to in paragraph I of the ARTICLE FIFTH they will be located in the central portion of the upper margin of the main panel of exhibition. The main display panel is understood to be the part of the container with greater possibility of being exhibited, shown or examined and that contains the main description of the food or product.

Paragraph I: The dimensions of the referred symbols are determined in accordance according to the main display panel area of the container, according to the picture following:

Table 2. Dimensions of the symbols depending on the main panel of container display.

Between 10 and less than 30 cm^2	1.2 x 1.2 cm
Between 30 and less than 60 cm^2	2.0 x 2.0 cm
Between 60 and less than 100 cm^2	2.5 x 2.5 cm
Between 100 and less than 200 cm^2	3.0 x 3.0 cm
Between 200 and less than 300 cm^2	4.5 x 4.5 cm
Between 300 and less than 400 cm^2	5.0 x 5.0 cm
Between 400 and less than 500 cm^2	5.5 x 5.5 cm
Between 500 and less than 600 cm^2	6.0 x 6.0 cm
Between 600 and less than 900 cm^2	7.0 x 7.0 cm
Between 900 and less than 1200 cm^2	8.5 x 8.5 cm
Greater than or equal to 3001200 cm^2	5% of the main exhibition panel area size

Paragraph II: The EFAN must be placed in the primary and secondary packaging of the same (See the example in Annex A). In cases where the main panel display of the primary packaging has a surface area of less than 10 cm2, it must be place the EFAN in the secondary packaging, following the proportions in the table 2.

Paragraph III: EFAN symbols must be incorporated into the original design of the main display panel, visible, indelible and easy to read on normal circumstances of purchase and use. In no case may they be covered totally or partially.

Paragraph IV: When it is appropriate to label more than one symbol with the descriptor "EXCESS", these must be arranged next to each other as specified in Annex A.

Paragraph V: When a product is excessive in one or more nutrients or contains sweeteners in accordance with the provisions of the FIFTH and SIXTH ARTICLES, no declaration of nutritional properties or any health or health claims.

Paragraph VI: Products containing at least one "EXCESS" symbol It must also include it in all advertising, sponsorship and promotion of the same. Paragraph VII: The graphic characteristics of the nutritional descriptors will be those following (Figure 2):

Figure 2. Elements of the descriptor: (1) Octagonal base that contains the message; (2) White margin with black border; (3) White margin with black trim border on background; (4) Main message describer; (5) Signature of the Ministry of Health.



Paragraph VIII: When a product has more than one main display panel, the EFAN must be applied on each of the main exhibition panels following the provisions of the FIFTH, SIXTH and SEVENTH ARTICLES.

ARTICLE EIGHTH: Transitional provisions. From the date of put into force of this resolution, a grace period of eighteen months in order to integrate the EFAN into the original design of the packaging or container of the product.

Paragraph: Within the framework of those eighteen months of grace, labeling will be permitted provisional complementary label or sticker type, in order not to hinder the marketing of the products. whose manufacturers have already printed (the packaging or labeling) to date. This deadline applies equally to imported items. that come from countries that do not have this type of regulation. will be awarded a period of six months from the entry into force of this resolution for the design and placement of this temporary complementary label or decal.

ARTICLE NINTH: The sanctions corresponding to this resolution, will be those provided for in Law No. 42-01 General Health, relating to the non-compliance with the provisions of the health authority. Also, as for provided in Law No. 358-05 General Protection of the Rights of the Consumer or User, within the framework of matters related to the right to information and what is provided for in other complementary legislations, as well as the right common.

ARTICLE TEN: MISPAS will implement through the Program of Nutrition education strategies for the population for the interpretation of the EFAN in relationship with health benefits.

ARTICLE ELEVEN: You are instructed to send a full copy of this document. resolution, to the following: Ministry of Industry, Commerce and MSMEs (MICM), National Institute for the Protection of Consumer Rights (PROCONSUMIDOR), Dominican Institute for Quality (INDOCAL) and Management General of Medicines, Food and Health Products (DIGEMAPS).

ARTICLE TWELVE: The Office of Access to Information is instructed Information publish the content of this document on the institutional web portal resolution.

GIVEN, SIGNED AND SEALED, In the city of Santo Domingo de Guzmán, District Nacional, capital of the Dominican Republic, on () days of month of the year two thousand twenty-four (2024).

Dr. Víctor Elías Atallah Lajam Minister of Public Health and Social Assistance

Annex. Glossary.

For the purposes of applying this resolution it will be understood as:

Free sugars: monosaccharides and disaccharides, plus sugars that are naturally present in honey, syrups, musts. juices and fruit juices vegetables, fruit or vegetable juice concentrates, powdered fruits, which have been added to foods and non-alcoholic beverages by the manufacturer.

Nutrition claim: any representation that states, suggests, presupposes or implies that a food has nutritional properties individuals.

Health or health claims: any representation that declares, suggests or implies that there is a relationship between a food, or a constituent of said food, and health benefits.

Sweeteners: substances other than sugars. that impart a flavor sweet to the products. These can be caloric and non-caloric.

Caloric sweeteners: substances other than sugars, which impart a sweet flavor to the products and provide energy. This criterion also includes polyalcohols, the isomers and epimers of low-fat monosaccharides and disaccharides calories and those sweetening additives that may fulfill another function technological in the final product, even when they were declared in the list of ingredients with that other function.

Non-caloric sweeteners: any natural or artificial substance used to sweeten and does not provide energy.

Primary container or packaging: the container or packaging in direct contact with the product.

Secondary container or packaging: the container or packaging that contains one or more primary packaging along with any protective material required.

Front Front Nutritional Warning Labeling (EFAN): information system simplified, located in the main display area of the packaging that warns of truthful, clear, fast and simple way about content that exceeds the levels maximums of critical nutrients and ingredients.

Trans fats: that have at least one carbon-carbon double bond in trans configuration, regardless of whether it is produced industrially or comes from ruminants.

Panel or main display face: area of the container where the name and trademark of the product in its most relevant form and prominent, visible to the consumer before he takes the product from its place of deployment at the point of sale.

Sponsorship: any form of contribution to any act, activity, natural person or legal, public or private, with the purpose, effect or possible effect of promoting directly or indirectly a product or the consumption of a product.

Advertising and promotion: all forms of communication, recommendation, message or commercial action with the purpose, effect or possible effect of promoting directly or indirectly, a product, or the brand related to the product, or consumption of a product, or to increase the recognition, attraction or consumption of a product.

Sodium: is a chemical element that exists naturally in foods associated with other molecular residues or atoms as an ionic bond forming chemical salts. One gram of table salt contains 400 mg of sodium (1g of sodium is equivalent to 2.5 g of table salt).

Annex 2 Examples of Front-of Pack Labels in U.S. Products in the Dominican Market





















Attachments:

No Attachments.