Republic of Colombia

Libertad y Orden

MINISTRY OF HEALTH AND SOCIAL PROTECTION

RESOLUTION NUMBER 2492/2022

(DECEMBER 13TH, 2021)

Whereby articles 2, 3, 16, 25, 32, 37 and 40 of Resolution 810/2021 are amended, which provides the technical regulations on the requirements on nutritional and front-of-package labeling that packaged and packed foods for human consumption must met.

THE MINISTER OF HEALTH AND SOCIAL PROTECTION

In exercise of its legal powers, particularly those conferred as per Articles 267 of Act 09/1979, Sections 4, 7 and 30 10 of Article 2 of Decree-Act 4107/2011, in compliance with article 5 of Act 2120/2021, and

WHEREAS

Article 5° of statutory Act 1751/2015 on the fundamental right to health, provides as obligations of the State those of *"(b) Formulate and implement health policies aimed at ensuring the effective enjoyment of the right in equal treatment and opportunities for the whole population, ensuring the harmonic coordination of the actions of all the agents of the System; (c) To formulate and implement policies aimed at the promotion of health, prevention and care of diseases and rehabilitation of its sequelae, through collective and individual actions*".

By means of Resolution 810 of June 16/2021, the Ministry of Health and Social Protection established the technical regulation on the nutritional and front labeling requirements that must be met by packaged foods for human consumption and defined the shape, color, size, maximum values, location, legend, proportions, and dimensions that the front warning labeling must contain for packaged foods for human consumption.

Article 2 of Resolution 810/2021 establishes the field of application of the regulation, as well as its exceptions: Article 1 determines the definitions used in the subject of nutritional and front labeling; Article 16 establishes on the other hand, establishes the parameters for nutritional claims and Article 25 on the parameters for health claims. Article 32 establishes the technical parameters of shape, color, size, location, maximum values of the front warning labeling and finally, Article 37 establishes the terms for exhaustion and use of stickers.

That, on July 30th, 2021, Act 2120 was enacted, the purpose of which relates to the adoption of effective measures to promote healthy food environments and prevent the emergence of non-communicable diseases, through access to clear, truthful, timely, visible, suitable, and sufficient information on food components with the purpose of promoting healthy habits.

(Hereunder, the header below is found throughout the whole document) **RESOLUTION NUMBER 2492 OF DECEMBER 13TH//2022**
Continuity of the Resolution "Whereby articles 2, 3, 16, 25, 32, 37 and 40 of Resolution 810/2021 are amended, which provides the technical regulations on the requirements on nutritional and front labeling that packaged and packed foods for human consumption must met"

That, the first two paragraphs of article 5 of Act 2120/2021, provides for that:

"(…) All edible or drinkable products classified according to the level of processing with excessive amounts of critical nutrients established by the Ministry of Health and Social Protection must implement a front label with a warning seal, which must be of high preventive impact, clear, visible, legible, easily identified and understood by consumers, with unequivocal messages that warn the consumer of the excessive contents of critical nutrients.

The National Government, headed by the Ministry of Health and Social Protection, will regulate the technical parameters of this labeling, defining the shape, content, figure, proportion, symbols, texts, maximum values, colors, size, and location on the packaging of the products that must contain it, based on the best scientific evidence available and free of conflict of interest. For this purpose, it may consider the scientific evidence provided by the World Health Organization (WHO) (…)".

That, in accordance with the provisions of paragraphs 2 and 3 of article 5 of Act 2120/2021, the criteria applicable to nutrition facts or health claims on the label of the products that must adopt the warning labels must be regulated, excepting from the front warning labeling, the typical or artisanal and minimally processed edible or drinkable products in accordance with the classification issued by the Ministry of Health and Social Protection.

That, in compliance with the provisions of Act 2120/2021, this Ministry developed the technical study in 2022, regarding the maximum values or nutrient profiles for front warning labeling, concluding that the "Nutrient Profile Model" of the Pan American Health Organization (PAHO), meets the requirements defined in the standard, in terms of the level of processing and the scientific evidence found in the literature.

In this regard, it is necessary to modify table 17 of article 32 of Resolution 810/2021 and, consequently, to add to article 3 of Resolution 810/2021 the definitions of unprocessed food, typical or artisanal food and beverages, processed food product, minimally processed food, and ultra-processed food product.

Likewise, in order to comply with the provisions of Article 5 of Act 2120/2021, the Ministry of Health and Social Protection signed Contract 113/2022, with the University of Antioquia, whose object entailed: "*To assess the best available evidence to establish the shapes, color, size, legends and location of the front labeling for processed products in Colombia*", agency that carried out a systematic review of the literature.

That, as a result of the execution of the aforementioned contract, the University of Antioquia hereby recommends amending Article 32 of Resolution 810/2021, concluding that the best scientific evidence free of conflict of interest for front labeling is as follows:

> *"shape/form: octagonal; color; black; edge; white; located in the upper third of the main display panel; warning text: "HIGH IN" critical nutrients; the text of the regulatory body: "Ministry of Health"; and insufficient evidence was found on the characteristics of proportion, size and symbols".*

That, according to the Ex-post Regulatory Impact Analysis (RIA) for front-of-package warning labeling, wherein new scientific evidence free of conflict of interest was reviewed, it was found that the best evidence for the shape is octagonal, black color, white edge, with the word HIGH, with the PAHO

Nutrient Profile Model and with restrictions on nutrition or health claims when the product has a warning label. In this regard, the results suggest that articles 2, 3, 16 and 25, in its sections 25.4 and 25.5 (on restrictions to nutritional facts or health claims), 32, 37 and 40 of Resolution 810 /2021 should be amended.

That, in this context, the regulatory proposal was published and submitted for national consultation from August 1st to 31st, 2022, and international consultation from September 27th to November 27th, 2022.

That, during the consultation period, comments were received regarding the technical inability (hygroscopicity of raw meat) to include the number of portions per package in variable weight products and that this exception is already provided for in the current legal metrology regulations, namely, in Resolution 32209/2020 of the Superintendency of Industry and Commerce, reason why the relevant adjustment is made.

That, considering the remarks made in the national consultation by the National Institute of Food and Drug Surveillance (INVIMA), it is necessary to unify section e) *fruits, vegetables, grains, eggs, fishery products, meats and edible meat products that are found in their natural state*, with section k) *Unprocessed foods*, of Article 2 of this resolution, because they belong to the same class of products and, consequently, section e) of paragraph 1 and 2 of Article 2 will be repealed and section k) will be included.

That, in compliance with Decrees 210/2003, 1471/2014, 1595/2015 and 1468/2020, this Ministry requested prior concept to the Ministry of Commerce, Industry and Tourism. To this end, such portfolio, through the Directorate of Regulation, by means of file number 1-2022-028262, indicated: "*the issuance of prior concept by this Directorate is not applicable. Therefore, it is appropriate to submit a request for international notification to the World Trade Organization (WTO)"*.

That the technical regulation adopted by this resolution was notified to the WTO by means of signature of document number G/TBT/N/COL/246/Rev.1 of September 27/2022.

That with respect to the draft resolution, the advocacy concept of the jurisdiction was issued, in accordance with the provisions of Article 7 of Act 1340/2009 regulated by Decree 1074/2015, wherein the Superintendent Delegate for the Protection of the Jurisdiction of the Superintendency of Industry and Commerce, by means of file number 22-367713 dated September 30th, 2022, recommends the following:

> "*1. To extend the deadlines foreseen in the paragraphs contained in article 40 of the Draft in such a way that it is sufficient and duly justified based on the realities of the market and the observations of interested third parties; 2. Remove from paragraphs 1 and 2 of Article 1 of the Draft the "culinary ingredients"; 3. Refrain from using the same symbol used to warn about the content of critical nutrients to warn about the content of sweeteners in a packaged or packed food for human consumption until it does not have information regarding the types of sweeteners that exist in the market and their relation with the benefits or detriments to health; 4. In the case of the label whose legend or descriptor is "Contains Sweetener", design a different and particular symbol for the case, in order to avoid limiting free economic competition or impacting in a negative way and without due justification some agents in the market with respect to others*."

That, in view of the remarks made by the Superintendency of Industry and Commerce, the contents of the second recommendation will be accepted, while suggestions found in recommendations 1, 3 and 4 cannot be accepted, considering that the period of 6 months, counted after the publication of the act, is enough time for the producers, marketers and importers to adapt the labeling of their products, even more so when since August 2021, and in accordance with the provisions of Act 2120 of the same year, the obligation to review aspects of nutritional information and front warning labeling had been generated. Additionally, it is noteworthy that the evidence provided by the expert's research and *Ex-post Analysis* suggests that caloric and non-caloric sweeteners have an impact on health and that the most appropriate form of warning is the octagonal one.

That, in accordance with section 2 of Article 1 of Act 962/2005, amended by Article 39 of Decree Act 019/2012 and Article 3 of Decree 2106/2019, this Ministry requested the opinion of the Administrative Department of Public Service, who issued an opinion under file number 20225010371971, as follows.

> "*Hereby informs that this does not include the adoption of a new procedure, nor the structural modification of existing procedures, and in this regard does not require the positive concept referred to in section 2 of article 1 of Act 962/2005, as amended by article 3 of Decree Act 019/2012 and article 3 of Decree Act 2106/2019*."

That, in accordance with the foregoing, in order to comply with Article 5 of Act 2120/2021, based on scientific evidence free of conflict of interest, it is necessary to amend Articles 2°, 3°, 16, 25, 32 and 37 of Resolution 810/2021 and therefore repeal the provisions of Article 40, in order to establish consistent periods of transition, to comply with the amendments provided in this act and to specify the effective dates of the rules that currently regulate the matter.

That in accordance with the above, it is necessary to establish a technical regulation that guarantees the sanitary requirements to be met by packaged foods for human consumption, as a necessary measure to provide consumers with clear and understandable nutritional information, in order to promote balanced and healthy nutrition and to protect human health and prevent possible damage to human health.

In light of the foregoing,

IT IS HEREBY RESOLVED AS FOLLOWS:

Article 1. Article 2° of Resolution 810/2021 is hereby amended and rendered as follows.

> **"Article 2**. ***Scope of application****. The provisions set forth in this resolution apply to all packaged foods for human consumption and processed and ultra-processed packaged or packaged food products, national and imported food products marketed in the national territory*.

2.1. *The following foods are exempted from the application of nutrition labeling:*

a) Infant formula for children from 0 to 6 months of age.
b) Infant formula for children between 6 and 12 months of age.
c) Special infant formula.
d) Food for Special Medical Purposes (APMES from its name in Spanish, FSMP).
e) Single-ingredient products and containing no additional additives.
f) Foods with packaging of natural origin materials.
g) Herbal and fruit infusions, tea, decaffeinated tea, instant or soluble tea, or tea extract; or decaffeinated tea extract and decaffeinated coffee, instant o soluble coffee, or coffee extract; or decaffeinated coffee extract, which do not contain added ingredients.
h) Bulk foods.
i) Food used as raw material for industry and secondary ingredients that are not sold directly to the consumer.
j) Spices or vegetable seasonings, which have not been added with salt/sodium or additives containing sodium, fats and/or sugars.
k) Unprocessed foods
l) Minimally processed foods
m) Typical or artisanal food and beverages

2.2*. The following foods are exempted from the application of front warning labeling:*

a) Infant formula for children from 0 to 6 months of age.
b) Infant formula for children between 6 and 12 months of age.
c) Special infant formula.

d) Food for Special Medical Purposes (APMES from its name in Spanish, FSMP).
e) Single-ingredient products and containing no additional additives.
f) Iodized and fluoride salt, and salt substitutes.
g) Foods with packaging of natural origin materials.
h) Herbal and fruit infusions, tea, decaffeinated tea, instant or soluble tea, or tea extract; or decaffeinated tea extract and decaffeinated coffee, instant to soluble coffee, or coffee extract; or decaffeinated coffee extract, which do not contain added ingredients.
i) Bulk foods.
j) Food used as raw material for industry and secondary ingredients that are not sold directly to the consumer.
k) Packaged foods with no added salt/sodium, fats and/or sugars
l) *Hydrating-energy drinks for sportsmen and women.*
m) *Unprocessed foods.*
n) *Minimally processed foods*
o) *Typical or artisanal food and beverages*

The manufacturer wishing to make nutrient, nutritional or health claims for the previously excluded foods shall comply with the provisions of this technical regulation.

***Paragraph 1**. Packaged raw meat to which food products, seasonings or additives containing salt or sodium have been added, must only declare the sodium content and if this exceeds the limit established in Article 32 of this administrative act; must label the front sodium warning seal. The nutritional table must cover at least 15% of the area where it is located.*

***Paragraph 2**. For variable weight products, the inclusion of servings per package in the nutritional table and on the main display side of the package does not apply.*

Article 2. Let Article 3 of Resolution 810/2021 be amended, which shall be rendered as follows*:*

***"Article 3**. **Definitions**. For the application of this resolution, the following definitions are adopted:*

***3.1 Essential fatty acids**: nutrients that are required and cannot be synthesized by the human organism, so they must be supplied in the diet. The essential fatty acids are linoleic and alpha-linolenic, as well as EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid), which, due to their very low conversion rate, must be supplied in the diet.*

***3.2 Minimally processed foods**: unprocessed foods that have been subjected to cleaning, removal of inedible or undesirable parts, drying, grinding, fractioning, roasting, blanching, pasteurization, cooling: freezing, vacuum packing or non-alcoholic fermentation. Minimally processed foods also include combinations of two or more foods that are unprocessed or minimally processed and may have added vitamins and minerals to restore the original micronutrient content or for public health purposes. These foods shall not have added salt/sodium, fats or sugars or additives containing them, including, but not limited to; fresh, split, dried, refrigerated, or frozen fruits; vegetables, grains, and legumes, dried, refrigerated, or frozen; nuts; edible meat products, refrigerated or frozen; fish products, refrigerated or frozen; eggs and milk.*

***3.3 Typical or artisanal food and beverages**: packaged foods that comply with the following requirements: (i) produced from non-industrialized traditional practices, (ii) that appertain to the cultural tradition of the regions of the country and (iii) gradually complying with the safety conditions in keeping with the provisions of articles 3 and 7 of Act 2254/2022, or the one that amends or supersedes it.*

***3.4 Unprocessed foods**: foods produced directly from plants or animals that are not subjected to any physical or chemical modification from the moment they are extracted from nature until their culinary preparation or consumption. They may also be referred to as fresh or natural foods.*

***3.5 Total available printing area**: total label area minus back seals.*

***3.6 Total sugars**: monosaccharide and disaccharide type carbohydrates naturally existing in or*

added to foods.

3.7 Added sugars: *These are added sugars, including sugars that are added during food processing or packaged as such, and include sugars such as monosaccharides and disaccharides, those contained in syrups and those naturally contained in honey and fruit or vegetable juice concentrates. They do not include intrinsic sugars found in milk, fruits and vegetables and sugars that are non-glycemic carbohydrates.*

3.8 Total carbohydrates*: all mono-, di-, oligo- and polysaccharides, including polyalcohol and fiber found in the food.*

3.9 Available or glycemic carbohydrates: *total carbohydrate content of the food minus the content of dietary fiber, polyalcohols and non-glycemic carbohydrates.*

3.10 Non-available or non-glycemic carbohydrate: *carbohydrates that have several chemical shapes, and although digested, do not provide glucose for cellular metabolism. They must demonstrate a glycemic index lower than 15, corresponding to the lowest value existing in a glycemic carbohydrate (fructose).*

3.11 Cholesterol*: sterol-like substance found in fats of animal origin.*

3.12 Nutrient function claim*: are statements of properties that describe the physiological role of the nutrient in the growth, development, and normal functions of the organism.*

3.13 Nutrient claims*: standardized list or ranking of the nutrient content in a foodstuff.*

3.14 Property claims of other functions*: relate to specific beneficial effects of the consumption of foods and their components (non-nutritive nutrients) on physiological functions and biological activities, but do not include nutrient function claims. Such claims relate to a positive contribution to health or a health-related condition, or to the improvement of a function, or to the modification or preservation of health.*

3.15 Health Claim Statement*: any representation that states, suggests, or implies that there is a relationship between a food or a constituent/component of such food, and health.*

3.16 Nutritional claims*: any representation that asserts, suggests, or implies that a product contains particular nutritional properties, including, but not limited to, its energy value and protein, fat, carbohydrate, and dietary fiber content, as well as its vitamin and mineral content. The mention of substances in the list of ingredients, or the name or trademark of the packaged food, or the mention of nutrients as a mandatory part of nutrition labelling, or the quantitative or qualitative claim of certain nutrients or ingredients on the label, shall not constitute a nutrition claim.*

3.17 Disease Risk Reduction Property Claims*: are claims related to the consumption of a food or a component of a food in the context of a total diet, which may assist in the reduction of the risk of a disease or health-related condition. Risk reduction means significantly altering a major risk factor or factors recognized as being involved in the development of a chronic disease or adverse health-related condition.*

3.18 Total diet*: usual diet of an individual or population.*

3.19 Sweeteners*: any substance other than added and/or free sugars that bestows a sweet flavor.*

3.20 Variable weight packaging*: packages wherein the contents are individually measured, packaged, labeled and each package has a different weight and/or volume.*

3.21 Packaging made of natural materials*: element designed to contain a food that includes, but is not limited to plantain leaves, bijao leaves, corn leaves, calabash tree husk.*

3.22 Dietary fiber: edible carbohydrates that are neither digested nor absorbed in the small intestine of humans*. Dietary fiber consists of one or more of the following carbohydrates: edible carbohydrates naturally found in foods in the form wherein they are consumed, carbohydrates extracted from food raw materials by physical, enzymatic, or chemical means, and synthetic*

carbohydrates.

3.23 Insoluble fiber*: is the fraction of dietary fiber that does not dissolve in water*

3.24 Soluble fiber: *the fraction of dietary fiber that dissolves in water.*

3.25 Infant formula for children from 0 to 6 months of age*: product in liquid or powder form intended for the feeding of children from 0 to 6 months of age, used when prescribed by a health professional, which alone, covers the nutritional needs of the child, as the main liquid source of nutrition until the introduction of complementary feeding for cases wherein breastfeeding is not possible.*

3.26 Infant formula for children between 6 and 12 months of age*: product in liquid or powder form, specially manufactured according to the nutritional needs of children between 6 and 12 months of age, used when prescribed by a health professional, in conjunction with complementary feeding.*

3.27 Special Infant Formula*: product in liquid or powder form whose composition has been modified to address certain physiological disorders or conditions during the first months of life and even after the introduction of complementary feeding.*

3.28 Voluntary nutrient fortification*: the process whereby food manufacturers decide to add specific essential nutrients to certain foods or food categories.*

3.29 Total fat*: sum of saturated fat, monounsaturated fat, polyunsaturated fat and includes trans fats.*

3.30 Fats or lipids*: substances insoluble in water and soluble in organic solvents, consisting especially of fatty acid esters. This term includes triglycerides, phospholipids, glycolipids, waxes, and sterols.*

3.31 Saturated fat or saturated fatty acids*: those that do not have double bonds in their hydrocarbon chain.*

3.32 Monounsaturated fats or monounsaturated fatty acids*: those having a double bond in its hydrocarbon chain. For labeling or tagging purposes, monounsaturated fat shall be understood as that which has a double bond in its Cis.*

3.33 Polyunsaturated fats or polyunsaturated fatty acids*: those having two or more double bonds in its hydrocarbon chain. For labeling or tagging purposes, polyunsaturated fat shall be understood as that which presents double bonds in its Cis.*

3.34 Trans-isomer or trans-fat or trans fatty acids*: all geometric isomers of monounsaturated and polyunsaturated fatty acids having, in the trans configuration, one or more non-conjugated carbon-carbon double bonds. For labeling or labeling purposes, trans fat shall be understood as the sum of all monounsaturated and polyunsaturated isomers in trans configuration that meet the above description.*

3.35 Glycemic index*: is defined as the incremental area under the blood glucose response curve from a 50 g serving of carbohydrate from a test food, expressed as a percentage of the response to the same amount of carbohydrate from a standard food (white bread or glucose) consumed by the same subject. This value is only considered valid when it is determined directly following the official protocol established by the FAO/WHO Panel of Experts, as it is a biological test susceptible to different factors.*

3.36 Syrups*: viscous liquids consisting of a solution of sugars in water or in fruit juices or a mixture of these, with or without aromatic agents and authorized additives.*

3.37 Household food measurement: *are utensils or shapes commonly used by the consumer to measure food, including, but not limited to: cup, glass, slice unit, tablespoon, teaspoon.*

3.38 Minerals: *inorganic substances necessary for physiological processes and which are not a*

source of energy.

***3.39 Nutrient**: any chemical substance usually consumed as a component of a food which is necessary for growth, development and/or maintenance of health, or the deficiency of which will cause characteristic chemical or physiological changes to take place.*

***3.40 Essential nutrient**: nutrient that is not synthesized by the organism or is synthesized in insufficient quantities and that must be consumed to ensure growth, development and/or preservation of health.*

***3.41 Serving**: is the amount of a food usually consumed on one sitting by persons over 4 years of age and adults or by children over 4 years of age and under 4 years of age, which must be stated on the label and is expressed using common household measures appropriate for that food.*

***3.42 Prebiotics**: substrates that are selectively utilized by host microorganisms that provide a health benefit to the host microorganisms.*

***3.43 Probiotics**: microorganisms: live organisms which, when administered in appropriate amounts, provide a health benefit to the host.*

***3.44 Processed food products**: food products manufactured with technological processes, subjected to transformation processes, and may have two or more ingredients added, such as salt, sugar, fats, or others. They have two or more ingredients or additives and more than 50% of the ingredients are unprocessed or minimally processed foods.*

***3.45 Ultra-processed food products**: food products made with technological processes, subjected to transformation processes to which salt, sugar, fats or other ingredients are added. They have more than 5 ingredients and/or additives and less than 50% of the ingredients are unprocessed or minimally processed foods. Its ingredients include but are not limited to: casein, whey, protein hydrolysate, soy protein isolate, hydrogenated, partially hydrogenated or interesterified fats, modified starches.*

***3.46 Single ingredient product**: packaged food wherein the list of ingredients contains only one ingredient, including, but not limited to, packaged water, coffee, coffee beans ground, sugar, olive oil.*

***3.47 Reconstituted product**: the one which by its nature of consumption must be reconstituted in some edible solvent either to obtain a solid, semi-solid or liquid product, ready to be consumed.*

***3.48 Protein: polymers of L-alpha amino acids linked by peptide bonds**: Proteins are called simple when they are made up only of amino acids and compound when they include other substances such as lipids, carbohydrates, minerals, inter alia.*

***3.49 Glycemic response**: the degree of change or gradient in blood glucose content following consumption of a test carbohydrate in a beverage or food, in relation to a standard such as glucose.*

***3.50 Nutritional labeling**: any description contained on a food label or tag intended to inform the consumer about the nutrient content, nutritional properties, and health properties of a food.*

***3.51 Warning labeling or front labeling**: information system located on the main display face, which shows in a truthful, clear, fast, and simple way, when a packaged product has excessive contents of nutrients of public health concern (sugars, saturated fat, trans fat, sodium) and the presence of sweeteners.*

***3.52 Positive seal**: a seal of approval stating that the food contains low levels of nutrients of public health concern (added sugars, saturated fat, and sodium) and that no sweeteners are used in the formulation.*

***3.53 Symbiotics**: is understood as the combination of prebiotic substances with probiotic cultures that are found in the same food.*

***3.54 Main mealtime**: in the framework of daily food planning, it refers to the periods wherein food*

is distributed in greater proportions: breakfast, lunch, and dinner.

***3.55 Nutrient Reference Values (NRVs) or Reference value**: are a set of numerical values that are based on scientific data for the purposes of nutrition labeling and relevant nutritional claims. These two types of NRVs comprise:*

a. ***Nutrient Reference Values - Requirements (NRV-R):** are those that refer to NRVs based on nutrient levels associated with nutrient requirements.*
b. ***Nutrient reference values - non-communicable diseases (NRV NCD):** are those that refer to NRVs based on nutrient levels associated with reduced risk of diet-related noncommunicable diseases, excluding diseases or disorders caused by nutrient deficiencies.*

***3.56 Vitamins**: organic substances essential for the maintenance of health, growth, and normal body functioning. They are required in small quantities and are not a source of energy.*

Article 3. Article 16 of Resolution 810/2021 is hereby amended to be rendered as follows:

"*Article 16. General Requirements.* All food stuffs that make use of nutritional claims must comply with the following requirements:

16.***1 General Requirements***:

16.1. The only nutrition claims allowed shall be those made on the basis of the daily reference values established in these technical regulations, and to the fatty acids set forth in Articles 19.1 and 19.2 from the same technical regulation.

16.2 The font size of terms or descriptors used for nutrition claims shall not exceed more twice the size of the letters used in the name of the food.

16.3 When a product has one or more front warning labels, it cannot bear nutritional claims.

***Paragraph**. The nutrition claims that had already been approved by the Specialized Food and Beverage Chamber of the Invima, will remain in force for this technical regulation. Additionally, if another claim is required for a nutrient that does not have a reference value, the manufacturer must request it to the Specialized Food and Beverage Chamber of the Invima*."

Article 4. Article 25 of Resolution 810/2021 is hereby amended to be rendered as follows:

***Article 25**. **Prohibitions on health claims.** The following claims are prohibited:*

25.1 *Health claims should not suggest that the food by itself is enough for the daily diet, nor should they suggest that a balanced diet based on common foods does not provide all nutrients in sufficient quantities.*

25.2 *Health claims should not promote the excessive consumption of any food, nor be contrary to the good eating habits established in the Guías Alimentarias Basadas en Alimentos (Food-Based Dietary Guidelines) for the Colombian population.*

25.3 *Health claims should not raise doubts about the safety and quality of similar foods.*

25.4 *When a product has 1 or more front warning labels, it may not make health claims.*

25.5 *It is not allowed to quantify the degree of risk reduction of disease caused by metabolic factors attributable to NCDs.*

25.6 *Health claims should not imply any healing, medicinal or therapeutic properties at all.*

25.7 *The term "healthy" or any term derived therefrom, such as "health", "wholesome", "healthily", "wholesomeness", "good health", "sanitary condition", may not be used in the labeling or tagging of a food stuff to describe it as "healthy" or render it in such a way as to imply that the food itself communicates "health".*

25.8 *The terms "whole meal", "balanced nutrition", "complete nutrition" or equivalents, whereby it may be assumed that a meal by itself is sufficient for daily nutrition, shall not be used.*

Article 5. Article 32 of Resolution 810/2021 is hereby amended to be rendered as follows:

"Article 32. Front warning labeling*: When salt/sodium, sugars, fats, or sweeteners have been added to a processed or ultra-processed packaged food product and their content is equal to or exceeds the value established in table 17, it shall label the nutritional characteristics related to the added nutrient.*

Table No. 17 Nutrient content limits for the implementation of warning labels

Nutrient	Solid (100 g) - semi-solids	Liquid (100 mL)
Sodium	>= 1mg/kcal and/or >= 300 mg/100g packaged raw meats to which salt/sodium has been added, the limit is 300 mg/100g	>= 1mg/kcal Non-alcoholic beverages without energy intake: ≥ 40 mg sodium per 100 ml
Sugars	>= 10% of the total energy from free sugars	>= 10% of the total energy from free sugars
Saturated fat	>= 10% of the total energy from Saturated fat	>= 10% of the total energy from Saturated fat
Trans fats	>= 1% of the total energy from Trans fats	>= 1% of the total energy from Trans fats
Sweeteners	Any quantity of sweeteners	Any quantity of sweeteners

32.1 *For the application of the aforementioned table, the following rules must be considered:*

a) For the purposes of this article, a food shall be understood to be solid or liquid according to the unit of measurement used in the claim of the net content of the food, namely, it shall be solid if its net content is expressed in mass units according to the international system of units, or liquid if its net content is expressed in volume units according to the international system of units. In the case of packaged foods that are consumed reconstituted shall be understood as solid or liquid, depending on whether the product is ready to eat, according to the reconstitution instructions defined by the manufacturer. These instructions may include cooking.

b) Shall be understood as packaged or packed foods to which salt/sodium has been added those foods to which any salt or sodium-containing additive or any ingredient containing added sodium salts has been used as an ingredient or additive during the manufacturing process.

c) Packaged or packed foods with added sugars shall be understood as those that meet the definition of added sugars, as defined in Resolution 3803/2016, or the one that amends it or supersedes it.

d) Packaged or packed foodstuffs to which fats have been added are those to which vegetable or animal fats used as ingredients, partially hydrogenated vegetable oils (vegetable shortening, vegetable cream or margarine) and ingredients containing added fats that have been used as an ingredient during the manufacturing process.

e) Processed or ultra-processed packaged products to which sweeteners have been added shall be understood to be those that during the manufacturing process sweeteners or ingredients containing added sweeteners have been used as an ingredient or additive.

32.2 To calculate the percentages established in table 17, the following procedure shall be followed:

- ***a. Sodium****: Regarding sodium, two calculations must be performed. If either of the two results is higher than the stated amount, the sodium warning label must be applied. 1. First calculation: if it is a solid food or beverage with calories, take any amount of food, it can be 100 g or ml, or the serving, and divide the declared sodium content, by the number of kcal, claimed in the same amount, if this ratio is equal to or greater than 1, the sodium warning label must be applied. 2. Second calculation: The sodium content must be calculated in 100 g or mL and if this is equal to or exceeds 300 mg, the sodium warning label must be applied. Now, for non-energy or no-calorie beverages, the content must be calculated in 100 mL and if this exceeds or is equal to 40 mg, the front sodium warning label must be applied.*
- ***b. Sugars***: the free sugars existing in food must be identified, as provided for in Resolution 3803/2016 or in the one that amends it or supersedes it. Once identified, in any amount of food, the quantity of free sugars in grams must be multiplied by the sugar conversion factor (4 kcal/g). This result is divided by the total kcal of the same amount of food and multiplied by 100. Finally, this result is compared with the percentage established in table 17, and if it is equal to or greater than 10%, the sugar warning label must be applied. Additionally, to calculate the free sugars from the added sugars, the calculation must start from the added sugars and add the sugars contained in fruit and/or vegetable juices.
- ***c. Saturated fats***: The quantity of saturated fat in grams should be multiplied by the fat conversion factor (9 kcal/g) for any quantity of food. This result is divided by the total kcal of the same quantity of food and multiplied by 100. Finally, the result is compared with the percentage provided in Table 17, and if it is equal to or greater than 10%, the front saturated fat warning label must be applied.
- ***d. Trans fats:*** *The quantity of trans fat in grams should be multiplied by the fat conversion factor (9 kcal/g) in any quantity of food. This result is divided by the total kcal of the same quantity of food and multiplied by 100. Finally, this result is compared with the percentage provided in Table 17, and if it is equal to or greater than 1%, the front saturated fat warning label must be applied.*

32.3 **Shape of the front warning seal**: The way to highlight the nutritional characteristics indicated in the first paragraph of this article shall be by including stamps on the label, which shall entail an octagonal symbol with a black background and white border, and inside the text "HIGH IN", followed by: "SATURATED FATS" or “TRANS FATS” "SODIUM" or "SUGARS" or with the text “CONTAINS SWEETENERS” individually or with 2 or 3 or 4 or 5 labels (as appropriate). The letters in the text of the labels must be capital letters and white in color, ARIAL BOLD font. In addition, in the same symbol, the word "MINSALUD" must be written in white letters, according to image 6 of this article

IMAGE 6. Shape of the front warning seal

Paragraph*: No other front labeling format or type of warning seal shape may be used, nor may the text, typeface, diagram, or drawing be changed, regardless of whether or not it carries front warning labeling. Likewise, the shape of the front warning labeling cannot be used to include seals with a different text that refers to other nutrients or any component of the packaged products other than those that are the object of this regulation (salt/sodium, sugars, fats, sweeteners).*

32.4 Warning seal dimensions and location*:* The referenced symbol(s) shall be located on the third upper right side of the front face (or main display face) of the product label. In case of cylindrical and conical containers, the seals must be placed on the upper front third. The dimensions of the referenced symbol(s) shall be determined according to the area of the main display face of the label, according to the following table:

Table 18. Warning seal dimensions

Area of the main label face (cm^2)	High and wide seal
< 30 cm^2	Label on secondary packaging and, if not available, a QR code or a web page where it can be consulted must be included.
>= 30 cm^2 to < 35 cm^2	1.7 x 1.7 cm
>= 35 cm^2 to < 40 cm^2	1.8 x 1.8 cm
>= 40 cm^2 to < 50 cm^2	2.0 x 2.0 cm
>= 50 cm^2 to < 60 cm^2	2.2 x 2.2 cm
>= 60 cm^2 to < 80 cm^2	2.5 x 2.5 cm
>= 80 cm^2 to < 100 cm^2	2.8 x 2.8 cm
>= 100 cm^2 to < 125 cm^2	3.1 x 3.1 cm
>= 125 cm^2 to < 150 cm^2	3.4 x 3.4 cm
>= 150 cm^2 to < 200 cm^2	3.9 x 3.9 cm
>= 200 cm^2 to < 250 cm^2	4.4 x 4.4 cm
>= 250 cm^2 to < 300 cm^2	4.8 x 4.8 cm
> 300 cm^2	5% of the size of the main face

32.4.1 *When more than one symbol with the descriptor "HIGH IN" is to be labeled, they should be arranged side by side or one below the other, considering the forms described in item f) of article 32.3.*

32.4.2 *For products that must bear two (2) or more seals, the area of the main face available for seals (ADS) shall be determined as follows:*

a. *For surfaces with an area of the main face of the containers greater than or equal to 30 cm^2 and less than or equal to 300 cm^2, the ADS must be considered 65% of the result resulting from the specifications of "calculation of the area of the main face of the containers".*
b. *For surfaces with an area of the main face of the containers greater than 300 cm^2, according to table 18, must use a single octagonal seal size of 3.9 cm x 3.9 cm*.

32.4.3 *The symbol(s) shall be conspicuously, indelibly, and easily readable under normal circumstances of purchase and use. Under no circumstances may they be covered totally or partially.*

32.3 Warning seal proportions*: All elements (text and icons) must be centered on the y-axis of the black square. Below are the proportions. The letter "x" represents the unit of proportion on which the seal icon is built*

32.3.1 *Sodium. The letter "x" represents the unit of proportion on which the seal icon is built*.

32.3.2 *Saturated fats. The letter "x" represents the unit of proportion whereupon the seal icon is built.*

32.3.2 *Trans fats. The letter "x" represents the unit of proportion whereupon the seal icon is built*.

32.3.4 *Sugars. The letter "x" represents the unit of proportion whereupon the seal icon is built.*

32.3.5 *Sweeteners. The letter "x" represents the unit of proportion whereupon the seal icon is built.*

32.3.6 Ways of distribution

a. Option 1

b. Option 2

b. Option 3

b. Option 4

Paragraph*. Stickers may also be used on the label in an indelible manner, provided that they meet the requirements of characteristics, size and location defined in administrative act. The sticker must be securely affixed by means of adhesion, printing, sewing, embossing, silk-screen printing, heat sealing, or other similar means, in such a way as to ensure that it does not become detached from the product under normal conditions of use, preservation, storage, transport and remains affixed until*

the time of marketing and shelf life.

Article 6. Article 37 of Resolution 810/2021 is hereby amended and rendered as follows:

"Article 37. ***Authorization for label stock-outs and use of stickers and complementary label.*** *For the depletion of labels, the use of stickers and complementary label, the following standards must be followed:*

37.1. *The holders of the registration, license, sanitary notification of packaged food and beverages, who have already implemented the front warning labeling (circular seal) and nutritional labeling, and those who continue to comply with the provisions of resolution 333/2011, may file a request for depletion of labels only once before the INVIMA until February 28th, 2023; the deadline for running out of stock will be defined by the INVIMA, without exceeding the term provided for in paragraph 2 of Article 8 of this administrative act*."

37.2. *Those responsible for packed or packaged foods may use stickers on the label, as established in article 32 and with regard to front warning labeling, as long as the stickers comply exactly with the provisions contained in this technical regulation. This alternative shall not require prior authorization by Invima*.

37.3. *For imported products, provided that they have the CIS Sanitary Inspection Certificate issued by Invima, the use of a label or complementary label containing the information required in this resolution will be allowed, which must be attached on a visible place and its adjustment may be made before, during or after the nationalization process and prior to its commercialization.*

37.4 *As for national products, the use of a label or complementary label containing only the nutritional information required in this resolution, which must be attached in a visible place, will be allowed until December 15th, 2023, without authorization from INVIMA or until June 15th, 2024, at the latest, when authorized by INVIMA.*

Article 7. Article 40 of Resolution 810/2021 is hereby amended and rendered as follows:

"Article 40. Transitory nature. The implementation of the technical requirements for nutrition and front-of-package labeling will follow the following rules:

40.1 *The amending provisions provided in this administrative act, as well as the other requirements described in the technical regulation on nutritional and front-of-package labeling, shall be implemented within six (6) months following the date of publication of this act in the Official Gazette, period wherein the holders of registrations, licenses and sanitary notifications, producers, importers and marketers of packaged foods for human consumption and the other sectors bound to comply with the provisions herein, shall adapt their processes and products in accordance with the conditions established in the technical regulation*.

40.2 *Manufacturers who wish to adjust the nutritional and front-of-package warning labeling on the labels before the six (6) months provided for in the previous paragraph, may do so in full compliance with the requirements of this administrative act.*

40.3 *As of June 15th, 2024, as published in the Official Gazette, packaged, and packaged foods that do not comply with the nutritional and front-of-package warning labeling set forth in the technical regulation must be recalled from the market by the producer or marketer, regardless of the date of manufacture, marketing, or packaging of the food*.

40.4 *For returnable packaging, a period of 5 years will be granted, counted from the date of publication of this administrative act in the Official Gazette, to comply with the conditions set forth in the technical regulation. However, since June 16th, 2023, the front warning seal must be placed on the lid for returnable packages that cannot be labeled on the front side, or with a*

sticker on the secondary package.

40.5 Entrepreneurs must comply with the requirements set forth in the technical regulations on nutritional labeling and front warning labels, within the time provided in the regulations to be issued, in compliance with Article 7 of Act 2254/2022.

Article 8. *Validity and repeals.* This administrative act shall enter into force from the date of its publication in the *Diario Oficial* (Official Gazette), amends articles 2, 3, 16, 32, 37, and 40 of Resolution 810/2021, and repeals Article 3 of Resolution 4135/1976, Resolution 333/2011, section 5.2, and Article 6 of Resolution 2508 /2012 once the deadline of six months set forth in the prior article is expired.

BE PUBLISHED, NOTIFIED AND ENFORCED

Issued in Bogotá, DC, on the day December 13th, 2022

(Signed)
DIANA CAROLINA CORCHO MEJIA
Minister of Health and Social Protection

Approved by:

Vice Minister of Public Health and Service Provision (Signed)
Director of Promotion and Prevention (Signed)
Legal Director (Signed)